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President and CEO

May 21, 2025

The Honorable Andrew Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable Abigail Slater
Assistant Attorney General
U.S. Department of Justice, Antitrust Division
950 Pennsylvania Avenue, NW
Washington, DC 20530

**Re: Requests for Public Comment Regarding Reducing Anti-Competitive
Regulatory Barriers; Docket Nos. FTC-2025-0088-0001 (Apr. 14, 2024) and
ATR-2025-0001 (Mar. 27, 2025)**

Dear Chairman Ferguson and Assistant Attorney General Slater:

The Federation of American Hospitals (FAH or we) appreciates this opportunity to submit comments to the Federal Trade Commission (FTC) and Department of Justice, Antitrust Division (together, the Agencies) on the *Requests for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers*, Docket Nos. FTC-2025-0088-0001 (Apr. 14, 2024) and ATR-2025-0001 (Mar. 27, 2025).

The FAH is the national representative of more than 1,000 tax-paying hospitals throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in urban, suburban, and rural areas across 46 States, Washington, DC, and Puerto Rico. Our members include teaching, acute, rehabilitation, behavioral health, and long-term care hospitals, which together provide a wide range of critical inpatient, ambulatory, post-acute, emergency, children's, and cancer services to patients across the country.

We respectfully offer our perspectives on various federal and state laws and regulations that harm competition in the healthcare sector. These are:

- The Noncompete Rule¹ adopted by the FTC under the previous Administration, which—

¹ 16 C.F.R. Part 910.

to the extent it survives judicial review—would impose significant distortions in hospital competition resulting from the disparate treatment of nonprofit and taxpaying hospitals.

- The eligibility rules for the 340B Drug Pricing Program,² which grant substantial savings for outpatient drugs to nonprofit or public hospitals that qualify as safety-net hospitals under clear, objective criteria, but which deny those savings to tax-paying hospitals that satisfy the same criteria.
- The growing patchwork of state laws and regulations that require state-level reporting for transactions in the healthcare sector,³ insofar as they burden interstate commerce with onerous requirements that exceed and, in some cases, undermine those required by the federal Hart-Scott-Rodino Act.
- The anticompetitive effects of a flawed independent dispute resolution (IDR) process, that is meant to fairly and appropriately resolve payer-provider disputes regarding certain out-of-network payments for healthcare services. This IDR process must be improved to incentivize health insurance payers to negotiate in good faith and meet the requirements of the IDR process in order to achieve the vision of the *No Surprises Act* (NSA), which we supported upon enactment in December 2020.

We also offer our thoughts on the narrowly tailored restrictions that Congress has justifiably imposed on physician-owned hospitals. These restrictions serve an important role in ***promoting competition*** by preventing physicians from engaging in unfair business practices like “cherry-picking” the healthiest patients or “cream-skimming” the most profitable patients, to ensure that full-service community hospitals are able to compete fairly. These restrictions are important because physicians hold a position of sacred trust with their patients and act as critical gatekeepers between patients and hospitals.

We appreciate the opportunity to submit these comments and applaud this Administration’s commitment to eliminating anticompetitive laws and regulations. We believe these efforts will prove invaluable in promoting free and fair markets, reducing waste, and growing the American economy for the benefit of all Americans.

A. Noncompete Rule

As the Agencies know, on April 23, 2024, the FTC voted along party lines to adopt a sweeping, retroactive ban on employee noncompetes (the Noncompete Rule).⁴ That same day,

² 42 U.S.C. § 256(b).

³ See, e.g., Cal. Health & Safety Code §§ 127500 *et seq.*; Cal. Code Regs. tit. 22, §§ 97431 *et seq.*; Colo. Rev. Stat. §§ 6-19.101 *et seq.*; Conn. Gen. Stat. § 19a-486i; Haw. Rev. Stat. §§ 323D-71 *et seq.*; 740 Ill. Comp. Stat. 10/7.2a; Ind. Code § 25-1-8.5; Mass. Gen. Laws ch. 6D, § 13; 958 Mass. Code Regs. §§ 7.00 *et seq.*; Minn. Stat. §§ 145D.01 *et seq.*; N.M. Stat. §§ 59A-63-2 *et seq.*; Nev. Rev. Stat. §§ 598A.290 *et seq.*; Nev. Rev. Stat. §§ 439A.126; NY Pub. Health L. §§ 4550 *et seq.*; Ore. Rev. Stat. §§ 415.501 *et seq.*; R.I. Gen. Laws §§ 23-17.14 *et seq.*; Vt. Stat. Ann. tit. 18, §§ 9405c *et seq.*; Wash. Rev. Code. §§ 19.390.010 *et seq.*

⁴ Pursuant to Instruction 2 of the FTC’s Request, the Noncompete Rule was codified at 16 C.F.R. Part 910. Its effective date was originally set for September 4, 2024, but before the Rule could take effect it was set aside by Order of the U.S. District Court for the Northern District of Texas. That Order is currently on appeal. The Noncompete Rule satisfies the definition of a “significant regulatory action,” insofar as it purports to retroactively

the Noncompete Rule was challenged in the U.S. District Court for the Northern District of Texas and, on August 20, 2024, that court vacated the Noncompete Rule on the grounds that it is both an unlawful assertion of FTC authority and unreasonably broad.⁵ That Order is currently on appeal to the Fifth Circuit, where proceedings have been stayed while the FTC determines whether and how to proceed.

The current FTC should not spend another penny of taxpayer money in defense of the Noncompete Rule. Instead, the FTC should formally rescind the Noncompete Rule as an overreach into an area of longstanding state regulation and expertise. As now-Chair Ferguson and Commissioner Holyoak noted in their respective dissents against the Noncompete Rule⁶—and as two federal courts have subsequently agreed⁷—the Noncompete Rule oversteps the powers delegated to the FTC by Congress and therefore is both unconstitutional and contrary to law.

Beyond this jurisdictional defect, the Noncompete Rule also is based on a deeply flawed empirical record. As the FAH explained in its rulemaking comments,⁸ the economic literature consistently finds that *all else equal, employees earn more money when they have noncompete agreements*.⁹ The evidence speaks for itself and is especially strong in the medical profession. *Primary care physicians who have noncompetes make 14% more per hour, experience faster earnings growth early in their careers, and enjoy higher lifetime earnings than physicians who do not*.¹⁰ These empirical findings are backed by a strong, intuitive explanation, which is

invalidate some tens of millions of otherwise-lawful, contractual, property interests.

⁵ *Ryan, LLC v. FTC*, 746 F. Supp. 3d 369 (N.D. Tex. 2024) (appeal pending).

⁶ See Dissenting Statement of Commissioner Andrew N. Ferguson, *In the Matter of the Non-Compete Clause Rule*, Matter No. P201200 (June 28, 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-noncompete-dissent.pdf; Dissenting Statement of Commissioner Melissa Holyoak, *In the Matter of the Non-Compete Clause Rule*, Matter No. P201200 (June 28, 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/2024-6-28-commissioner-holyoak-nc.pdf.

⁷ *Ryan, LLC v. FTC*, 746 F. Supp. 3d 369 (N.D. Tex. 2024) (appeal pending); see also *Properties of the Villages, Inc. v. FTC*, 2024 WL 3870380 (M.D. Fla. Aug. 15, 2024) (appeal pending) (finding the Noncompete Rule to be unlawful as to the named plaintiff, citing the major-questions doctrine).

⁸ See Comments of Federation of American Hospitals (“FAH Noncompete Comment Letter”), RIN: 3084-AB74 (Apr. 19, 2023), at 8-12, available at https://downloads.regulations.gov/FTC-2023-0007-21034/attachment_2.pdf. The FAH incorporates these earlier comments into this letter by reference.

⁹ See, e.g., Natarajan Balasubramanian et al., *Employment Restrictions on Resource Transferability and Value Appropriation from Employees*, subsequently published as 45 STRAT. MGMT. J. 2519, 2525 (2023), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3814403 (“[E]very study of NCA use—including studies of the average worker and of physicians and executives—finds that NCAs themselves are associated with higher earnings . . .”); Evan Starr et al., *Noncompete Agreements in the U.S. Labor Force*, 64 J. L. AND ECON. 53, 58 & n.9 (2021) (after applying both “basic” and “advanced” controls, finding that workers with noncompetes earn 11.5% or 6.8%, respectively, more than workers do without them); Donna Rothstein and Evan Starr, *Mobility Restrictions, Bargaining, and Wages: Evidence from the National Longitudinal Survey of Youth 1997* (2021), at 14, <https://ssrn.com/abstract=3974897> (after applying no controls, “basic” controls, and “advanced” controls, finding that workers with noncompetes earn 24.7%, 12.7%, or 5.0%, respectively, more than workers do without them); Liyan Shi, *Optimal Regulation of Noncompete Contracts*, 91 ECONOMETRICA 425, 449 (2023) (“an executive with a noncompete clause is associated with a starting wage that is 13% (or \$130K in 2010 prices) higher than one who is free to move”); Omesh Kini et al., *CEO Noncompete Agreements, Job Risk, and Compensation*, 34 REV. FIN. STUD. 4701, 4732 (2021).

¹⁰ See Kurt Lavetti et al., *The Impacts of Restricting Mobility of Skilled Service Workers: Evidence from*

that noncompetes promote continuity and integration of care by allowing medical practices to: increase investments in physician patient relationships; protect hospitals' recruitment investments, especially in rural areas where there are workforce shortages; encourage hospitals to make investments in training their employees; and encourage sharing of proprietary information within hospitals. This creates a true “win-win” that promotes competition and benefits all stakeholders.

However, putting aside these jurisdictional and empirical defects, the Noncompete Rule also should be rescinded pursuant to Executive Order 14267,¹¹ on the grounds that it is anticompetitive. The purported basis for the Noncompete Rule is Section 5 of the Federal Trade Commission Act, which applies to entities that are “organized to carry on business for its own profit or that of its members.”¹² This statutory limitation means that, in the healthcare industry, the Noncompete Rule would only apply to the 24% of U.S. community hospitals that are owned by tax-paying organizations. The FTC does not have the authority to regulate the 58% that are owned by nonprofits, nor to the 18% that are owned by State or local governments.¹³ The Noncompete Rule would thus impose different rules of “fairness” for different competitors, which often compete in the same labor markets, based solely on their tax status. This is inequitable and anticompetitive on its face. There is a reason that not a single State in the country considers an employer's tax status as a factor in determining the legality of a noncompete.

Tellingly, the uneven playing field caused by the Noncompete Rule cannot be described as an unintended consequence. It was fully known and intended. The rulemaking notice discussed the problem of the FTC's limited authority over nonprofits in some detail, only to conclude that “even if true, arguments that for-profit and other covered entities could suffer competitive harm ... would not change the Commission's finding.”¹⁴ Reasoning by analogy, the rulemaking notice rationalized that “the Commission would not refrain from seeking to enjoin unlawful price fixing by a for-profit within its jurisdiction because entities outside its jurisdiction under the FTC Act would not be subject to the same FTC action.”¹⁵ But this puts the cart before the horse. Price-fixing is universally understood to be anticompetitive in all its forms, which is why courts hold price-fixing to be unlawful *per se*. Reasonably tailored noncompetes, by contrast, are often procompetitive—such as when they enable medical practices to invest in patient relationships and thereby pay physicians more money—or, at a minimum, are not “unfair.” This, of course, is why the great majority of state legislatures and courts *allow*, and indeed, enforce them. In other words, in the case of price-fixing, the harm to competition is caused by the price-fixers, who may or may not fall within the FTC's limited jurisdiction. But in

Physicians, 55 J. HUM. RES. 1025 (2020); see also FAH Noncompete Comment Letter, *supra* note 8, at 8-12 (detailing these empirical findings and explaining why they make sense in healthcare).

¹¹ Executive Order 14267, *Reducing Anti-Competitive Regulatory Barriers* (Apr. 9, 2025).

¹² 15 U.S.C. §§ 44-45.

¹³ American Hosp. Ass'n, *Fast Facts on U.S. Hospitals, 2025* (2025), available at <https://www.aha.org/system/files/media/file/2025/01/Fast-Facts-on-US-Hospitals-2025.pdf>.

¹⁴ Non-Compete Clause Rule, 89 Fed. Reg. 38,342, at 38,450 (May 7, 2024).

¹⁵ *Id.* at 38,449.

the case of the Noncompete Rule, *the harm to competition is caused by the Noncompete Rule itself*, precisely *because* the FTC is an agency with limited jurisdiction.

B. Eligibility Rules for the 340B Drug Discount Program

Turning next to a federal statute, the FAH submits that the eligibility rules for participation in the so-called “340B” Drug Discount Program¹⁶ are overly narrow and anticompetitive in effect. Created in 1992, the 340B Program requires drug manufacturers that participate in Medicaid to offer discounts on certain outpatient drugs to hospitals that participate in the Program. To qualify for participation, a hospital must satisfy two criteria, which for purposes of this letter we will call the “DSH Payment Requirement” and the “Nonprofit/State Requirement.” First, the DSH Payment Requirement provides that hospitals must receive a Medicare Disproportionate Share Hospital (DSH) payment adjustment of at least 11.75% or, in the case of rural referral centers or sole community hospitals, at least 8%.¹⁷ Second, the Nonprofit/State Requirement provides that hospitals must either be (i) “owned or operated by a unit of State or local government,” (ii) “a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government,” or (iii) “a private non-profit hospital which has a contract with a State or local government to provide healthcare services to low income individuals who are not entitled to benefits under [Medicaid or Medicare].”¹⁸

The FAH has no objection to the DSH Payment Requirement, which is a bright-line, objective test to measure how much of a hospital’s patients qualify for need-based social assistance. The Nonprofit/State Requirement, however, is arbitrary, discriminatory, and anticompetitive. The Agencies should advocate for Congress to amend the statute to open the eligibility rules to *all* hospitals that satisfy the objective, nondiscriminatory requirements of the DSH Payment Requirement.¹⁹

The 340B Program’s discriminatory effects harm competition in multiple ways. Most fundamentally, they distort the marketplace by conferring a substantial cost savings advantage in favor of nonprofit and public hospitals. This pricing disparity creates an uneven playing field and a significant barrier to entry into the already-challenging business of operating safety-net hospitals. This is especially the case in low-income service areas where there is an incumbent nonprofit or public hospital because tax-paying hospitals find themselves at a government-imposed cost disadvantage against such incumbents. When a non-profit hospital seeks to affiliate with a larger system, tax paying acquirers are often unable to compete for these opportunities because the non-profit knows that it will be ineligible 340B pricing if it becomes part of a tax-paying system.

¹⁶ 42 U.S.C. § 256b(a)(4)(L).

¹⁷ The DSH Payment Requirement does not apply to “critical access hospitals.” But critical access hospitals must separately satisfy the Nonprofit/State Requirement to qualify for participation in 340B. *See* 42 U.S.C. § 256b(a)(4)(N).

¹⁸ 42 U.S.C. § 256b(a)(4)(L).

¹⁹ At a minimum, the Agencies should advocate for “grandfathering” any hospitals that qualify for participation in the 340B Program but subsequently cease to meet the Nonprofit/State Requirement due to conversion to for-profit, tax-paying status or being acquired by a for-profit, tax-paying hospital.

These perverse results undermine the whole point of the 340B Program, which is to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”²⁰ To serve this laudable goal, the DSH Payment Requirement ensures that the savings made possible by the 340B Program are only available to hospitals that provide an essential, safety-net function for their communities. The Nonprofit/State Requirement, however, does nothing to serve the policy goals of the 340B Program. All the Nonprofit/State Requirement does is *exclude* bona fide safety-net hospitals for participation if they happen to pay taxes. Why put a hole in a safety net?

Advocates for the Nonprofit/State Requirement might argue that nonprofit and public hospitals provide a greater rate of uncompensated care than their for-profit counterparts. But the data do not support this argument. In fact, Medicare cost-report data suggest that the nonprofit and public hospitals that participate in the 340B Program actually provide a *lower rate* of uncompensated care to patients than non-participating hospitals provide.²¹

If the goal of the 340B Program is to stretch federal dollars to reach more patients and provide more services, then the Program should be available to all hospitals that satisfy the DSH Payment Requirement, regardless of whether they happen to pay taxes. If anything, eliminating the Nonprofit/State Requirement to allow tax-paying hospitals to compete on a level playing field will *generate* additional tax dollars, in the form of increased output and tax revenue from these tax-paying competitors.

C. State “Mini-HSR Acts” for Healthcare Transactions

Next, we turn to the States. In recent years, at least fifteen States have enacted State-level premerger notification requirements for certain transactions in the healthcare industry.²² Because these laws and regulations overlap in large part with the federal Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the HSR Act),²³ we will refer to them as State “mini-HSR Acts.”

The FAH respects the sovereign rights of States to regulate transactions that affect the health and well-being of their residents. But we caution that this already-byzantine patchwork of State mini-HSR Acts is growing in number and complexity, and it threatens to pose an undue burden on the vast majority of mergers, acquisitions, and affiliations that are either procompetitive (*e.g.*, by enabling efficiencies, synergies, and/or economies of scale) or harmless. Some States’ mini-HSR Acts *themselves* impose anticompetitive distortions on the marketplace

²⁰ *PhRMA v. U.S. Department of Health & Human Services*, 138 F. Supp. 3d 31, 34 (D.D.C. 2015) (quoting H.R. Rep. No. 102-384, pt. 2, at 12 (1992)).

²¹ Avalere Health, *OPPS Medicare Part B Payment Impact Analysis*, 11 (Mar. 2021), available at https://assets.fah.org/uploads/2021/04/20210326_OPPTS_Analysis_for_FAH.pdf.

²² See, e.g., Cal. Health & Safety Code §§ 127500 *et seq.*; Cal. Code Regs. tit. 22, §§ 97431 *et seq.*; Colo. Rev. Stat. §§ 6-19.101 *et seq.*; Conn. Gen. Stat. § 19a-486i; Haw. Rev. Stat. §§ 323D-71 *et seq.*; 740 Ill. Comp. Stat. 10/7.2a; Ind. Code § 25-1-8.5; Mass. Gen. Laws ch. 6D, § 13; 958 Mass. Code Regs. §§ 7.00 *et seq.*; Minn. Stat. §§ 145D.01 *et seq.*; N.M. Stat. §§ 59A-63-2 *et seq.*; Nev. Rev. Stat. §§ 598A.290 *et seq.*; Nev. Rev. Stat. §§ 439A.126; NY Pub. Health L. §§ 4550 *et seq.*; Ore. Rev. Stat. §§ 415.501 *et seq.*; R.I. Gen. Laws §§ 23-17.14 *et seq.*; Vt. Stat. Ann. tit. 18, §§ 9405c *et seq.*; Wash. Rev. Code. §§ 19.390.010 *et seq.*

²³ 15 U.S.C. § 18a.

by applying different standards on healthcare transactions involving in-state nonprofits than they apply for healthcare transactions involving tax-paying or nonprofits from outside the State.²⁴ The FAH thus offers four principles that should guide the Agencies’ analysis and advocacy with respect to any further mini-HSR Acts that States may consider in the future, whether for healthcare transactions or otherwise.²⁵

First, overlapping federal and state premerger laws can consume an inordinate amount of time and effort out of merging parties—especially given the newly expanded rules under the HSR Act.²⁶ As the Agencies know, in their final months in office, the FTC under the previous Administration voted to dramatically expand the information, documents, and level of detail required for HSR filings. For instance, HSR filings now require parties to submit narrative statements identifying any known or planned competitive overlaps or supply relationships between them, various lists of top-ten customers, two categories of ordinary-course business documents, a statement about the rationale for the transaction, and detailed information about certain prior transactions the parties may have made over the prior five years.²⁷ To be clear, the FAH respects the Agencies’ view that the new HSR rules are, to borrow Chairman Ferguson’s description, an “improvement over the status quo”²⁸ in terms of making the HSR form more effective for the Agencies in screening for mergers that may be anticompetitive. But the Agencies should understand that the new HSR rules pose a material burden on business.

As an illustration, consider a hypothetical transaction where Hospital System A, headquartered in Texas, seeks to acquire Hospital System B, headquartered in Florida, in an HSR-reportable transaction. Under the new HSR rules, Hospital Systems A and B would have to submit extensive information about the transaction, their respective business operations, and the extent to which they compete or supply one another with goods, services, or intellectual property. They would also have to submit voluminous documents about the transaction, as well as certain ordinary-course business plans or reports from the past twelve months. All told, in addition to paying a filing fee of up to \$2,390,000 and observing a 30-day waiting period before closing, an HSR filing would now require Hospital Systems A and B to spend an estimated 105

²⁴ See, e.g., Colo. Rev. Stat. § 6-19.203(1) (“A [nonprofit-to-nonprofit] transaction that will not result in a material change in the charitable purposes to which the assets of the hospital have been dedicated, and will not result in a termination of the attorney general’s jurisdiction over those assets caused by a transfer of a material amount of those assets outside the state of Colorado, shall proceed without further review.”); R.I. Gen. Laws § 23-17.14-8(a) (“The department of health shall review all proposed conversions involving a hospital in which one or more of the transacting parties involves a for-profit corporation.”); Vt. Stat. Ann. tit. 18, §§ 9420(d)(1) (“Other than subsection (q) of this section and subdivision (2) of this subsection, this section shall not apply to conversions in which the party receiving assets of a nonprofit hospital is a nonprofit corporation.”).

²⁵ In April, the State of Washington became the first state to adopt a version of the Uniform Antitrust Pre-Merger Notification Act, which will require state-level premerger reporting for certain Hart-Scott-Rodino-reportable transactions that have a nexus to Washington State, regardless of industry. See S.B. 5122 (2025 session, effective July 27, 2025). Our comments apply with equal force to healthcare-specific premerger reporting laws as they do to general premerger reporting laws such as the Uniform Antitrust Premerger Notification Act.

²⁶ 15 U.S.C. § 18a.

²⁷ See generally Premerger Notification; Reporting and Waiting Period Requirements, 89 Fed. Reg. 89,216 (Nov. 12, 2024).

²⁸ Concurring Statement of Commissioner Andrew N. Ferguson, *In the Matter of Amendments to the Premerger Notification and Report Form and Instructions, and the Hart-Scott-Rodino Rule*, Matter No. P239300, 2 (Oct. 10, 2024) available at https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-final-hsr-rule-statement.pdf.

hours apiece on paperwork—up from the estimated 37 hours that were required just one year ago.²⁹ These are resources that the parties cannot use for making investments in, or lowering the cost of, care to better compete in the marketplace.

Now suppose that Hospital Systems A and B each own small, rural hospitals in California.³⁰ In this case, in addition to all the costs and burdens that are already required under the new HSR rules, the parties would also be required to make a “notice of a material change transaction” in California. This California notice would require the parties to submit a copy of their federal HSR filing.³¹ But the California notice would also require, among many, many other things: extensive information and documentation about the parties’ organizations, operations, and licenses; extensive information and documentation about the transaction; a narrative description of the transaction’s goals, terms, and potential impacts on the public, on workers, and on competition; a college-admissions-style narrative about “why the transaction is necessary or desirable;” financial data and records about the parties going back three years; information about other transactions the parties may have made going back ten years; data about the “age, gender, race, ethnicity, preferred language spoken, disability status, and payor category” of the patients that the parties serve; a statement on whether the transaction might impact “specialized services for LGBTQ+ populations;” a list of the “primary languages used” by the parties when providing services; and, finally, an open-ended request for “any analysis and/or documents supporting” any of these narrative responses.³²

After receiving all of this information, the California Office of Health Care Affordability would have 60 days to decide whether to conduct a more detailed “Cost and Market Impact Review,” which can take up to 120 days to complete.³³ Only then, after potentially half-a-year of process and paperwork, the matter would go to the California Attorney General to make an actual law-enforcement decision. All told, the State of California could easily require the parties to spend thousands of hours and millions of dollars on a state notification, above and beyond the hundreds of hours and millions of dollars that are already required for their HSR filings.

The second principle the Agencies should keep in mind is that, while States can, of course, regulate transactions that take place within their own borders, principles of federalism require that individual States must not unduly burden interstate commerce. As the Supreme Court has explained:

²⁹ Until the recent changes to the HSR form, the FTC estimated the preparation of HSR filings to take approximately 37 hours on average. *See* 88 Fed. Reg. 3413, 3414 (Jan. 19, 2023); 88 Fed. Reg. 42,178, 42,208 (June 29, 2023). The FTC has estimated that the recent changes will add an average of approximately 68 hours for each filing, representing a total estimated burden of 105 hours for each side. *See* 89 Fed. Reg. 89,216, 89,334 (Nov. 12, 2024). Respectfully, the FAH considers these numbers to be low.

³⁰ For example, the California mini-HSR Act would be triggered by Hospital System A owning a \$25 million hospital in San Diego and Hospital System B owning a \$10 million hospital in Crescent City, some 850 miles away.

³¹ Cal. Code Regs. tit. 22, § 97438(c)(1).

³² *See generally* Cal. Code Regs. tit. 22, § 97438(b).

³³ *See* Cal. Code Regs. tit. 22, § 97440 (providing 60 days for Office to decide whether to conduct a review); *id.* § 97442 (providing 90 days from that decision date, extendable by an additional 30 days, to complete that review).

Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State. And, specifically, the Commerce Clause dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another.³⁴

On this basis, the Supreme Court has invalidated an Illinois securities law that required certain tender offers to be registered with the Illinois Secretary of State at least 20 days prior to closing.³⁵ Notably, that law only applied to tender offers that had a meaningful connection to Illinois.³⁶ Still, the Supreme Court had little difficulty determining that the tender-offer law violated the dormant Commerce Clause two separate ways: by “directly regulat[ing] transactions which take place across state lines,” and by imposing “a substantial burden on interstate commerce which outweighs its putative local benefits.”³⁷

For all the same reasons, State mini-HSR Acts raise serious concerns of extraterritoriality and unduly burdening interstate commerce. Consider again the hypothetical transaction between Hospital Systems A and B. To the extent the State of California requires a Texas corporation to spend millions of dollars and observe months of delays before it can acquire a Florida corporation, California is imposing a far greater burden on interstate commerce than the registration requirement and waiting period that Illinois was forbidden from imposing on tender offers. Indeed, the California “notice of a material change” system comes very close to what the Supreme Court has described as “the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the states under the Articles of Confederation,”³⁸—precisely the situation the Commerce Clause was written into the Constitution to prevent.

Third, as more and more States adopt their own unique laws for reporting healthcare transactions, risks arise of conflicting legal obligations. Consider again Hospital Systems A and B but, this time, suppose that the parties own hospital assets in California, Oregon, and Washington State. In that case, the parties will now be subject to four different premerger notification regimes, each with its own unique waiting period: 30 days under the HSR Act,³⁹ 90 days in California (at a minimum, assuming no protracted Cost and Market Impact Review),⁴⁰ 180 days in Oregon,⁴¹ and 60 days in Washington.⁴² This is untenable. Under the dormant Commerce Clause, “the practical effect of [a State] statute must be evaluated not only by

³⁴ *Healy v. The Beer Institute*, 491 U.S. 324, 336-37 (1989).

³⁵ *Edgar v. MITE Corp.*, 457 U.S. 624 (1982).

³⁶ For example, the Illinois law would have applied when the corporation at issue had 10% of its shares held by Illinois citizens, or when two of the following three conditions were met: the corporation was headquartered in Illinois, was incorporated in Illinois, or had 10% of its capital and surplus in Illinois. *Id.* at 627.

³⁷ *Id.* at 641-46.

³⁸ *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

³⁹ See 15 U.S.C. § 18a(b)(1)(B).

⁴⁰ Cal. Code Regs. tit. 22, §§ 97435(a).

⁴¹ Ore. Rev. Stat. § 415.501(4).

⁴² Wash. Rev. Code. § 19.390.030

considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, by many or every, State adopted similar legislation.”⁴³ And as more and more States adopt their own esoteric rules for reporting healthcare transactions, conflicts like these will only compound.

Notably, in Washington State, the parties are required to submit their HSR filings to the State Attorney General at least 60 days before closing.⁴⁴ This is a nice idea, in that it avoids duplicative efforts as between the HSR filing and the State filing. But in practice, the State of Washington has effectively converted the 30-day HSR waiting period authorized by Congress into a 60-day waiting period, usurping the legislative balance that Congress struck in crafting the HSR Act. The difference is more than just a matter of days on a calendar. For example, to the extent that Washington State’s 60-day waiting period causes parties to file their HSR filings earlier in the process than they otherwise would (*e.g.*, by filing HSR on the basis of a preliminary letter of intent, rather than waiting until the definitive agreement is signed), the result is that the HSR filing will provide the federal Agencies with *less detail* about the transaction’s terms and *fewer business documents* from which to ascertain the transaction’s competitive effects.⁴⁵ The result is to deprive the federal Agencies of information they would otherwise have received to help them evaluate the transaction, undermining the will of Congress as reflected in the HSR Act.

Finally, States that enact mini-HSR Acts should strive to provide the business community with the same clarity of purchase and transparency of process that the Agencies today provide with the federal *Merger Guidelines*. While the FAH may not agree with every aspect of the revised *Merger Guidelines*,⁴⁶ the *Guidelines* at least provide the business community with a transparent statement of how the Agencies analyze mergers and acquisitions. The States that have adopted mini-HSR Acts, however, have done no such thing. Instead, reviews of transactions under State mini-HSR Acts are, at best, opaque and, at worst, biased against tax-paying or out-of-state interests. The ultimate result is not the promotion of competition but rather the undermining of competition, by chilling investments, innovation, and risk-taking in favor of protecting and entrenching the already-established incumbents.

For all of these reasons, the Agencies should view the rise of State mini-HSR Acts with skepticism. To the extent that States continue to adopt such laws, the Agencies should advocate for efficiency and harmonization among the States, especially with respect to transactions that cross state lines. For instance, if a State wants to be notified about certain types of transactions,

⁴³ *Healy v. The Beer Institute*, 491 U.S. 324, 337 (1989).

⁴⁴ Wash. Rev. Code. § 19.390.060.

⁴⁵ Another potential complication comes from timing. For federal purposes, HSR clearance expires one year after the expiration of the federal waiting period. See 16 C.F.R. § 803.7(a). Therefore, if the federal Agencies cleared a transaction during the initial thirty-day waiting period only for Washington State to investigate the transaction for 396 days (or longer) before the parties could close, then for federal purposes the parties would be required to file HSR once, pay a filing fee, and then, after a year, *refile* their HSR filing to the federal Agencies, submit a new HSR filing fee, and observe a new federal waiting period.

⁴⁶ See Comments of Federation of American Hospitals, RIN: FTC-2023-0043 (July 19, 2023), available at https://downloads.regulations.gov/FTC-2023-0043-1531/attachment_2.pdf.

then a reasonable balance might be a law that only applies to transactions that have a clear connection to a state, that allows parties to comply by submitting a copy of their federal HSR filing, that guarantees that any HSR filings so submitted will be subject to confidentiality protections that are no less than those provided under federal law,⁴⁷ that requires no more than 30 days' notice to the state, and that applies even-handedly to all industry participants as opposed to discriminating against tax-paying or out-of-state providers.

D. Enforce the *No Surprises Act* Independent Dispute Resolution Process

Hospitals fully support the surprise billing patient protections under the NSA. We urge the Administration, however, to enforce health insurer compliance with the NSA, including the IDR process which establishes a mechanism intended to resolve insurer-provider disputes over payment for certain out-of-network services. Appropriate incentives must be implemented to ensure that health insurers: provide greater payment transparency; meaningfully participate in the IDR 30-day open negotiation process; timely, appropriately, and efficiently pay out-of-network amounts and any related IDR awards; and are subject to enforcement for noncompliance.

Without appropriate incentives for health insurers, the NSA's IDR process is broken, ineffective, and anticompetitive for hospitals vis-à-vis health insurers. Insurers' ability to bypass the requirements for the NSA IDR process presents an anticompetitive dynamic in hospital and other provider negotiations with insurers because insurers can threaten to bar provider participation in their networks knowing the provider would then be subject to the broken and anticompetitive IDR dispute resolution for out-of-network claims. We urge the Agencies to support adoption by the Department of Health and Human Services of a proposed rule containing provisions intended to establish an IDR process, with appropriate incentives, for health insurers, as envisioned by the NSA when enacted in December 2020. Attached is the FAH comment letter on that proposed rule.

E. The Ban on Physician-Owned Hospitals Should be Preserved

We also write to apprise the Agencies about the importance of the current law that generally bans physician self-referrals to physician-owned hospitals, while restricting the expansion of existing (and grandfathered) physician-owned hospitals. By way of background, Congress first passed the physician self-referral law (or so-called "Stark Law")⁴⁸ 36 years ago, prohibiting physicians from referring Medicare patients to entities with which the physicians have a financial relationship, subject to certain exceptions.⁴⁹ In 2003, responding to Government Accountability Office concerns about physician-owned hospitals "cherry-picking" healthier and wealthier patients, Congress imposed an 18-month ban on referrals to new physician-owned specialty hospitals.⁵⁰ In 2005, Congress extended through August 2006 an administrative rule

⁴⁷ See generally 15 U.S.C. § 18a(h) (exempting HSR filings from FOIA and providing that "no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding [or] to either body of Congress").

⁴⁸ 42 U.S.C. § 1395nn.

⁴⁹ *Id.* § 1395nn(a).

⁵⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

that suspended the admission of new physician-owned specialty hospitals into the Medicare program.⁵¹ Then, in 2010, Congress amended two of the Stark Law exceptions—the “rural provider”⁵² and “whole hospital”⁵³ exceptions—to bar the expansion of partly or wholly physician-owned hospitals except in cases of a demonstrated community need.⁵⁴ At the same time, Congress also limited the creation of new physician-owned hospitals to ones that forgo Medicare and Medicaid reimbursement.⁵⁵

Today, federal law protects patients from the conflicts of interest and unfair business practices that are pervasive in physician-owned hospitals and under physician self-referral schemes, ensuring that full-service hospitals can compete fairly. These laws reflect the serious concerns about the anticompetitive impacts of physician-owned hospitals and physician self-referrals that have been expressed over the years by federal agencies,⁵⁶ the U.S. Chamber of

⁵¹ Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4.

⁵² 42 U.S.C. § 1395nn(d)(2). Centers for Medicare & Medicaid Services (CMS) explains that to use the rural provider exception, “an entity must furnish substantially all of the designated health services that it furnishes to residents of a rural area ... To satisfy the requirements of the rural provider exception, the designated health services must be furnished in a rural area and, in the case where the entity is a hospital, the hospital must meet the requirements of [42 U.S.C. § 1395nn(i)(3)(E)] no later than September 23, 2011.” Ctr. Medicare & Medicaid Serv., *Physician-Owned Hospitals* (updated Apr. 25, 2025), <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/physician-owned-hospitals>.

⁵³ 42 U.S.C. § 1395nn(d)(3). CMS explains that to satisfy the conditions of the whole hospital exception, “the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of [42 U.S.C. § 1395nn(i)(3)(E)] no later than September 23, 2011.” Ctr. Medicare & Medicaid Serv., *supra* note 52. Moreover, “a physician could refer Medicare or Medicaid patients to a hospital in which he or she had a financial interest” under this exception “if (1) the referring physician was authorized to perform services at that hospital and (2) the physician’s financial interest was in the *whole* hospital as opposed to a specific department or subdivision.” Cristie M. Cole, *Physician-Owned Hospitals and Self-Referral*, 15 AMA J. ETHICS, 150-155, 151 (2013), available at <https://journalofethics.ama-assn.org/article/physician-owned-hospitals-and-self-referral/2013-02>.

⁵⁴ 42 U.S.C. § 1395nn(i)(3).

⁵⁵ *Id.*

⁵⁶ U.S. Gen. Acct. Off., GAO-03-683R, *Specialty hospitals: information on national market share, physician ownership, and patients served* (2003), available at <http://www.gao.gov/new.items/d03683r.pdf>. Cole cites the GAO report to explain that many physician-owned hospitals “specialize in specific services, such as cardiac or orthopedic surgery, and many of their patients are referred from general hospitals by the POH’s physician-investors. As such, the ‘whole hospital exception’ allowed the growth of an industry that profited from the very type of self-referral scheme it was clearly intended to prevent.” Cole, *supra* note 53. See also U.S. Dept. Health & Human Serv., Off. Inspector Gen., *Physician Owned Specialty Hospitals’ Ability to Manage Medical Emergencies* (2008), available at <https://www.oig.hhs.gov/oei/reports/oei-02-06-00310.pdf> (reporting that physician-owned hospitals provide limited or no emergency services, relying instead on publicly funded 911 services when their patients need emergency care).

Commerce,⁵⁷ the Medicare Payment Advisory Commission,⁵⁸ and independent researchers.⁵⁹ For example, a 2023 research report measured the performance of non-physician-owned, full-service community hospitals against that of physician-owned hospitals.⁶⁰ Among other findings, the data showed that physician-owned hospitals “cherry-pick” patients by avoiding Medicaid beneficiaries and uninsured patients; treat fewer medically complex cases; enjoy patient care margins 15 times those of full service community hospitals; provide fewer emergency services; and are penalized the maximum amount by CMS for unnecessary readmissions at five times the rate of community hospitals.⁶¹

Conflicts of interest are inherent in physician-owned hospital arrangements, given that physicians hold a position of trust over their patients. Moreover, by “cherry-picking” the healthiest patients and “cream-skimming” (e.g., providing a limited range of highly profitable specialty services, without providing the full range of less-profitable, necessary services), physician-owned hospitals put the most vulnerable patients at risk by undermining the financial viability of full-service, community hospitals in rural and low-income areas. If the law were changed to allow physician-owned hospitals to displace community hospitals, patients would lose access to essential services like obstetrics and 24/7 emergency care that are typically only available in full-service hospitals.⁶²

As it currently stands, the law is narrowly tailored to prohibit the physician self-referral practices that are antithetical to competition, but allows for the growth of physician-owned hospitals in circumstances where there is a demonstrated community need.⁶³ In fact, since 2010, CMS has granted certain exception requests to expand physician-owned hospitals’ facility

⁵⁷ See e.g., *Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care: Hearing Before the H. Comm. on Energy and Commerce* (2023) (statement of Katie Mahoney and Bradley J. Watts, Vice Presidents, U.S. Chamber of Commerce). “One legal protection that currently helps combat unnecessary cost increases is a safeguard against certain self-referral practices. When the most profitable patient cases are referred to hospitals where physicians have a financial interest, ‘cherry-picking’ occurs. While this referral practice increases profits for these physician-owned hospitals, such cherry-picking also has the negative impact of leaving the more complicated and poorly reimbursed cases to be treated by neighboring community hospitals.” *Id.*

⁵⁸ Medicare Payment Advisory Comm’n, *Report to the Congress: Physician-Owned Specialty Hospitals*, at vii (2005), available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar05_SpecHospitals.pdf (finding that physician-owned specialty hospitals “do not have lower costs for Medicare patients than community hospitals,” “treat patients who are generally less severe cases (and hence expected to be relatively more profitable than the average),” “concentrate on particular diagnosis-related groups . . . some of which are relatively more profitable,” and “have lower shares of Medicaid patients than community hospitals”).

⁵⁹ See, e.g., Al Dobson, et al., *Select Financial, Operating and Patient Characteristics of Physician Owned Hospitals Compared to Non-Physician Owned Hospitals* (2023), available at <https://www.aha.org/system/files/media/file/2023/03/2023-Fact-Sheet-20230323-with-Appendix-and-Charts-POH-vs-Non-POH-Only.pdf>.

⁶⁰ *Id.*

⁶¹ *Id.* at 2-3.

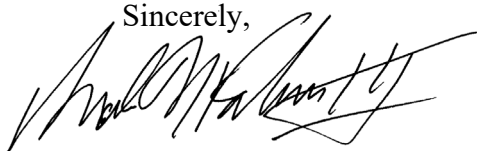
⁶² See U.S. Dept. Health & Human Serv. *supra* note 56, at 12 (“Two-thirds of physician-owned specialty hospitals use 9-1-1 as part of their emergency response procedures,” and “34 percent of [specialty] hospitals use 9-1-1 to obtain medical assistance to stabilize patients, a practice that may violate Medicare requirements”).

⁶³ 42 U.S.C. § 1395nn(i)(3).

capacity where warranted.⁶⁴ In effect now for 15 years, the system is working as Congress intended to protect patients, communities, and competition.

The FAH appreciates this opportunity to submit these comments. If you have any questions, or if we can assist the Agencies as they consider the Requests, please contact me or any member of my staff at (202) 624-1500.

Sincerely,



⁶⁴ See, e.g., Ctr. Medicare & Medicaid Serv., *Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition*, FR Doc. 2016-26117 (Oct. 28, 2016), available at <https://www.federalregister.gov/documents/2016/10/28/2016-26117/medicare-program-approval-of-request-for-an-exception-to-the-prohibition-on-expansion-of-facility>; Ctr. Medicare & Medicaid Serv., *Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition*, FR Doc. 2019-01927, (Feb. 9, 2019), available at <https://www.federalregister.gov/documents/2019/02/11/2019-01927/medicare-program-approval-of-request-for-an-exception-to-the-prohibition-on-expansion-of-facility>; Ctr. Medicare & Medicaid Serv., *Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition*, FR Doc. 2021-05095, (Mar. 11, 2021), available at <https://www.federalregister.gov/documents/2021/03/11/2021-05095/medicare-program-approval-for-an-exception-to-the-prohibition-on-expansion-of-facility-capacity>; Ctr. Medicare & Medicaid Serv., *Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition*, FR Doc. 2021-05095, (Dec. 20, 2022), available at <https://www.federalregister.gov/documents/2022/12/20/2022-27566/medicare-program-approval-of-request-for-an-exception-to-the-prohibition-on-expansion-of-facility>.



Charles N. Kahn III
President and CEO

December 22, 2023

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 Julie A. Su
Acting Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Federal Independent Dispute Resolution Operations; CMS-9897-P; 88 Fed. Reg. 75,744 (November 3, 2023).

Dear Secretaries Becerra and Yellen and Acting Secretary Su:

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 proposed rules, Federal Independent Resolution Operations, published in the Federal Register (88 Fed. Reg. 75,744) on November 3, 2023. The FAH and its members strongly support the *No Surprises Act* (NSA), 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.

Following the implementation of the NSA in 2022, the FAH has received reports of plan and issuer regular and systemic practices that go against the spirit and letter of the NSA and the Departments’ regulations, leaving providers and facilities without baseline information, including the amount of the qualifying payment amount (QPA), the methodological basis for the initial payment of the non-contracted claim, the identity of the plan or issuer responsible for payment, and the applicable regulatory framework for payment disputes with the plan or issuer. The profound information asymmetry between providers and facilities on the one hand and plans and issuers on the other impedes the efficient resolution of disputes and is contrary to the NSA’s design. And, where providers and facilities are nonetheless successful in initiating and prevailing in the Federal independent dispute resolution (IDR) process, the provider or facility often experiences that the plan or issuer simply fails to pay. Against this backdrop, the FAH appreciates and supports the Departments’ attention to the flow of information in the Proposed Rule and urges the Departments to likewise consider measures to address the serious problem of non-compliance by plans and issuers.

Use of CARCs and RARCs
(Parts II.B and II.H, 45 CFR § 149.100)

Improving the adequacy, usefulness, and consistency of information provided on remittance advices for out-of-network claims is a matter of critical importance, and the FAH strongly supports the Departments’ proposed addition of 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR § 149.100, applicable beginning on the effective date of the final rules. FAH members report receiving remittance advices from plans and issuers that do not provide basic and essential information or report information in inconsistent ways that require burdensome manual evaluation of remittance advices. The required use of claim adjustment reason codes (CARCs) and remittance advice remarks codes (RARCs) will assist in improving the information flow from plans and issuers to non-contracted providers and facilities in a clear and standardized fashion.

With respect to the implementation timeframe for CARCs and RARCs, the FAH strongly supports prompt implementation with the effective date of the Final Rule, as proposed. Any burden associated with operationalizing the use of CARCs and RARCs does not provide a basis for a prolonged implementation timeframe when providers are not currently receiving the baseline information necessary to understand a plan’s or issuer’s adjudication of an out-of-network claim (including the QPA for each item or service) or to even determine the identity of the payer with certainty.

Although the FAH strongly supports the mandatory use of CARCs and RARCs consistent with the proposed rules, the FAH requests that the Departments closely review and refine the existing RARCs and consider developing new CARCs and RARCs that are more specific and tailored, including RARCs that could be used to provide the information required to be shared about the QPA. A current RARC merely reports that “cost sharing was calculated based on the qualifying payment amount, in accordance with the No Surprises Act.” This information does not actually give the provider or facility the requisite clarity with respect to the actual QPA determined by the plan or issuer, but plans and issuers have used this RARC code in lieu of the disclosures required under 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d). The development of RARCs that provide information required to be disclosed about the QPA would significantly aid efficient communication regarding claims. To the extent that there are information elements that cannot be shared through the use of an existing CARC or RARC, however, the Departments should clarify that the use of CARCs or RARCs does not suffice for compliance with the requirements under 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d).

Information to be Shared About the QPA
(Part II.C, 45 CFR § 149.140(d))

(1) Improving Transparency Regarding the QPA

As noted in the Proposed Rule, the implementation of the NSA has been significantly hampered by inadequate information exchange regarding the QPA. Providers and facilities receive remittance advices that simply fail to clearly disclose the QPA, in violation of existing 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1). And, when providers and facilities promptly request the additional QPA information specified in subsection (d)(2), either the information is not provided at all, or it is not provided in a timely fashion as would be required for the provider or facility to understand what the QPA actually represents. The lack of transparency around the QPA and related information is a significant detriment to the efficient resolution of payment disputes, and it serves no purpose but to increase the provider and facility costs associated with providing out-of-network emergency services to plans’ and issuers’ members and enrollees.

The FAH supports the proposed amendment to the beginning of subsection (d) as it will confirm that information must be disclosed whether the recognized amount is the QPA or the billed amount. As discussed below in connection with bundled payment arrangements (Parts II.A and E), some plans and issuers have failed to disclose the QPA, claiming that the recognized amount is based on the billed amount for one of a number of items and services and then improperly treating that payment for a line item as a bundled payment for all of the items and services. The proposed revisions will make clear that a plan or issuer cannot avoid disclosure of the QPA through such tactics.

The FAH, however, strongly urges the Departments to take more decisive action with respect to the disclosure of information relating to the QPA—including the QPA itself. With the Transparency in Coverage Final Rule, 85 Fed. Reg. 72,158 (Nov. 12, 2020), the Departments have already taken significant steps to promote transparency around plans’ and issuers’ out-of-

network allowed amounts.¹ ***The FAH urges the Departments to modernize the Transparency in Coverage rules to account for the intervening passage of the NSA by requiring public disclosure of the QPA for each item and service in each geographic region where the plan or issuer is not subject to a specified state law for that item or service.*** Because the QPA for established items and services are generally calculated based on the median contracted rate on January 31, 2019, and only change based on the CPI-U, plans and issuers should already have internal QPA data that can be used consistently and uniformly in the adjudication of claims under the NSA. And once the QPA information is loaded, annual updates based on the CPI-U would be relatively simple to implement. Therefore, the expansion of the public machine-readable file to include QPA information would impose only a marginal additional burden on plans and issuers, while providing patients, providers, and facilities with critical information that will aid in assessing the plan's or issuer's initial payment on a claim subject to the NSA.

In addition, the FAH continues to urge the Departments to expand the range of QPA-related information that plans and issuers are required to disclose with the initial payment or notice of denial of payment. In comments on the Departments July 13, 2021, Interim Final Rule, the FAH urged the Departments to significantly expand the range of information that is shared with facilities and providers in the normal course.² ***After observing the implementation of the NSA and the profound information asymmetry between plans and issuers on the one hand and providers and facilities on the other, the FAH continues to urge the Departments to incorporate the data elements in subsection (d)(2) into subsection (d)(1) so that this important information regarding the QPA is automatically provided with the initial payment or notice of denial.***

FAH members report that when providers and facilities have requested the additional information specified in subsection (d)(2), plans and issuers generally have not responded with the requested information in a timely manner (if at all). As a result, the requested information cannot aid meaningful negotiations or inform the decision to initiate IDR, undermining the purpose of the regulatory requirement. Because the information specified in subsection (d)(2) is either necessary to the plan's or issuer's calculation of the QPA or not applicable to a particular item's or service's QPA, the provision of the information specified in subsection (d)(2) should be minimally burdensome to the plan or issuer.

In the alternative, if the information set forth in subsection (d)(2) continues to be provided only upon request, the FAH strongly urges the Department to clarify that "in a timely manner" means within fifteen business days of a request and to establish transparency and accountability around plans' and issuers' compliance with this requirement. The FAH recommends a 15-day timeframe for providing this information because this would allow a provider or facility that promptly requests the information to evaluate it before deciding whether to initiate open negotiations. The later in the process that information is provided, the less likely it is to have a meaningful impact. Along these lines, the FAH recommends that the Federal IDR portal be revised to collect information on this QPA-related information. The initiating party's open negotiation notice and notice of IDR initiation should have optional files that the party can

¹ 26 CFR § 54.9815-2715A3; 29 CFR § 2590.715-2715A3; 45 CFR § 147.212.

² Available at: <https://www.fah.org/wp-content/uploads/2021/09/FAH-Comments-Surprise-Billing-Part-One-FINAL.pdf> (Attachment A).

use to indicate whether a request was made, whether the requested information was provided timely, and the information that was provided. A certified IDR entity should have insight into a plan's or issuer's failure (or refusal) to provide the information under subsection (d)(2) when assessing the QPA and the parties' respective offers.

In addition to the information described in subsection (d), the FAH continues to believe that plans and issuers should provide additional methodological details concerning the calculation of the QPA with each initial payment or notice of denial. In particular, the FAH recommends adding disclosure requirements for the following 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, as well as this same information for up to five alternative reasonably related service codes designated by the provider or facility;
- (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.

Compiling and sharing this information with providers and facilities with claims payment would not be unduly burdensome because plans and issuers are already required to consider the foregoing information in order to accurately determine the QPA and this information would not generally change over time.

(2) **Disclosure of Plan or Issuer Contact Information in Advance of the Federal IDR Registry**

The FAH generally supports the revisions to subsection (d)(1)(iv) and (v) concerning the statement on open negotiations and the Federal IDR process. The FAH, however, recommends that proposed subsection (d)(1)(v) be revised to: (1) require disclosure of an agent with authority to act on behalf of the plan or issuer in open negotiations, along with contact information for such agent; (2) be immediately effective, acknowledging that the requirement to provide a registration number would be inapplicable for disclosures made prior to the applicable date for registration; and (3) require disclosure of the data elements set forth in proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 if the plan or issuer is not registered more than 30 days after the establishment of the Federal IDR registry.

At present, proposed subsection (d)(1)(v) does not include any requirement to identify the entity that has authority to negotiate (and settle) on behalf of the plan or issuer. In the time period between the effective date of the Final Rule and the establishment of a process for initiating open negotiations through the Federal IDR portal, providers and facilities will depend on plans' and issuers' disclosures to obtain the information necessary to initiate and then participate in meaningful open negotiations. Thus, the current requirement to provide appropriate contact information for initiating open negotiations should, at a minimum, remain in place for this interim period. ***In addition, the FAH strongly recommends that this disclosure be specific to an agent with authority to act (including settle) on behalf of the plan or issuer.*** At present, providers and facilities report that some plans and issuers provide contact information for an individual or entity that purports to engage in negotiations but ultimately lacks the authority to bind the plan or issuer to a settlement. This practice results in disputes that unnecessarily go to IDR for resolution and could have been settled with meaningful participation by the plan or issuer. The FAH also requests that the Department retain the requirement to provide information on the agent with the disclosures under subsection (d) after open negotiations migrate to the portal. Once the portal for open negotiations is operational, the process would still be aided by early and clear communication identifying the agent that is authorized to engage in open negotiations on behalf of the plan or issuer.

The FAH also requests that proposed subsection (d)(1)(v) be revised to be immediately effective. The plan or issuer should be capable of providing the legal business name of the group health plan (if any) or issuer and the legal business name of the plan sponsor (if applicable) upon the effective date of the Final Rule. During any period of time where the plan or issuer is not yet registered under section 149.530, there would be no obligation to provide a registration number under the plain language of subsection (d)(1)(v), so this provision does not warrant a later effective date.

The FAH is also concerned that providers and facilities will be left in the dark regarding critical plan and issuer information even after establishment of the Federal IDR registry because a plan or issuer that fails to register would not be obligated to report most of the data that is intended to be accessible through the registry. Therefore, the FAH requests that the Departments expand subsection (d)(1)(v) to specify that, if a plan or issuer is not registered more than 30 days after the establishment of the Federal IDR registry, the plan or issuer must provide each data element specified in proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530. This addition would further incentivize prompt registration by plans and issuers and ensure that providers and facilities are not penalized should a plan or issuer fail to register.

(3) Enforcement and Applicability

Finally, in light of the significant problems reported by providers and facilities with respect to information disclosures with the initial payment or notice of denial, the FAH urges the Department to take action to ensure that a plans' or issuers' delays or deficiencies do not prejudice providers or facilities in the dispute resolution process. For example, the FAH recommends the creation of a process by which a provider could obtain a case-by-case extension of deadlines based on the plan's or issuer's failure to disclose the information required under subsection (d).

Federal IDR Process Registration of Group Health Plans, Health Insurance Issuers, and Federal Employees Health Benefits Carriers (Parts II.F. & II.G, 45 CFR § 149.530)

The FAH strongly supports proposed 26 CFR 54.9816–9, 29 CFR 2590.716–9, and 45 CFR 149.530 and the prompt establishment of a publicly accessible Federal IDR registry. As noted in the Proposed Rule, providers and facilities are “often missing or cannot locate key information needed for open negotiation and the Federal IDR process despite the disclosure requirements” under the implementing regulations.³ Providers and facilities have confronted missing or contradictory information regarding the identity of the plan or issuer responsible for payment of the out-of-network claim and cannot reliably determine whether the plan or issuer is subject to a specified state law or the contact information for the person or office responsible for open negotiations. A public Federal IDR registry that serves as a single source of truth on these threshold facts would be a significant and critical measure to ameliorate providers’ and facilities’ lack of information regarding non-contracted plans and issuers.

Registration Requirement. The FAH urges the Departments to finalize the registration requirement as proposed. The proposed registration deadline in subsection (b)(1) provides a 30-business-day registration period for existing plans and issuers, which is not unduly burdensome in light of the straightforward nature of the information called for in subsection (b)(2). Any plan or issuer must have this basic information promptly available as part of its normal operations and in order to be able to handle out-of-network claims in compliance with the NSA. As such, the burden associated with registering would not impose an excessive burden on plans and issuers.

Along similar lines, the FAH supports finalization of the registration requirement for all plans and issuers without regard to whether or not the plan or issuer has received any open negotiation notices. Universal registration is necessary to ensure that providers and facilities do not encounter unnecessary difficulty accessing the information necessary to initiate open negotiation and engage in the Federal IDR process. In fact, registration information may be of particularly significant importance in situations involving smaller plans or issuers that are relatively inexperienced with the Federal IDR process as their systems and processes may be less sophisticated and claims may fall within the wrong workflow. Universal registration provides additional assurance that the provider or facility will always have access to certain threshold information about the plan or issuer.

Public Availability. In order to maximize the effectiveness of the Federal IDR registry, the FAH requests that the Departments make it publicly available. Broad access to the registry will ensure that each provider and facility has a reliable source through which it can confirm basic plan and issuer information. And, the simple information disclosed in the registry does not include trade secrets, private information, or other data that should be insulated from public disclosure. In short, public availability would create an informational safety net of significant value and would create minimal (if any) risks.

Membership ID Cards. In Part II.G. of the Proposed Rule, the Departments note that they are considering, under their general rulemaking authority to establish the Federal IDR

³ 88 Fed. Reg. at 75,804.

process, requiring certain NSA-related disclosures on plan or insurance cards. *The FAH strongly supports improving the information disclosed on member ID cards so that the provider or facility has basic information relating to the plan or issuer and the NSA before any bill is submitted for out-of-network care.* The types of information described in the proposed rule—applicability of State or Federal surprise billing protections, coverage type, and regulatory authority—would be significant for providers, and the FAH would support such proposals. But the FAH recommends that the Departments consider requiring each plan or issuer to instead include the applicable registration number assigned under proposed 26 CFR § 54.9816–9, 29 CFR § 2590.716–9, and 45 CFR 149.530. As long as the Federal IDR registry is publicly available, by displaying the registration number on the ID card, a plan or issuer could effectively and efficiently provide patients, providers, and facilities with key NSA-related information in a minimum of space.

Enforcement. Finally, with respect to enforcement of the registration requirement, the FAH supports the Departments’ use of their investigative and referral authority, including HHS’s authority under 45 CFR 149.150 and 45 CFR Part 150, to promote compliance and the accuracy of the registry. In addition, the FAH recommends that, if a plan or issuer fails to register through the Federal IDR registry by the time an offer is due in IDR, the plan’s or issuer’s offer should not be considered received in the same way that an offer is not considered received if a party fails to pay the certified IDR entity fee.⁴ Moreover, a plan or issuer should be bound by its IDR registration information in IDR and should not be permitted to take an inconsistent positions with respect to eligibility for IDR during the course of the Federal IDR process.

Open Negotiation and Initiation of the Federal IDR Process **(Part II.D., 45 CFR § 149.510(b))**

(1) Initiation of Open Negotiations

The FAH appreciates the Departments’ recognition that excessive disputes regarding receipt of the open negotiation notice burdens the Federal IDR process and contributes to the significant backlog of disputes at IDR. The FAH likewise supports the Departments’ proposal to move the exchange of open negotiation notices to the Federal IDR portal as a pragmatic measure to reduce these disputes and promote efficiencies. This proposal will be particularly useful once the Federal IDR registry is operational because there will then be transparency on two critical fronts—basic information about the plan and issuer and documentation of the initiation of open negotiations.

In implementing this proposal, the FAH urges the Departments to ensure that the portal allows the provider or facility initiating open negotiations to select “not provided” or “unknown” for plan- or issuer-specific information that the plan or issuer has failed to provide. For example, in many cases the plan or issuer fails to provide the QPA with the initial payment or notice of denial of payment, such that an initiating provider cannot supply the QPA information. It appears from proposed subsection (b)(1)(ii)(6) that the Departments contemplate that a provider or facility can properly initiate open negotiations even if it has not received the QPA from the plan or issuer, but it is important to ensure that this is accounted for when this

⁴ Proposed 26 CFR 54.9816–8(d)(1)(ii), 29 CFR 2590.716–8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii).

component of the portal is operationalized. At present, FAH members report problems when initiating the IDR process without QPA information, including burdensome requests from the certified IDR entity for the provider or facility to provide QPA information when the plan or issuer has failed to disclose it. It is the FAH's hope that a portal-based open negotiation notice exchange and the response notice will provide a backstop for adequate information exchange, as long as the open negotiation initiation notice form on the portal permits initiation by a party that has not received required information.

(2) **Meaningful Participation in Open Negotiation and the Response Notice**

The FAH strongly supports initiatives designed to ensure that both parties actively participate in open negotiations and to promote the effectiveness of open negotiations. Such active participation should include the exchange of threshold information and positions and should be undertaken in good faith through agents with settlement authority. Consistent with the reports of certified IDR entities described in the Proposed Rule, FAH members confirm that plans and issuers wait until the selection of the certified IDR entity to raise objections to the applicability of the Federal IDR process or dispute the accuracy of basic information relating to the dispute, a practice that exemplifies the failure to participate in good faith in open negotiations, increases the number of disputes that proceed to IDR initiation, and slows down the processing of disputes at IDR. In addition, FAH members report that a number of plans and issuers have limited their participation in open negotiations to negotiation companies or other agents that lack the authority to bind the plan or issuer to a resolution of the dispute, resulting in disputes that must proceed to IDR, despite an agreement in principal between the negotiating agents.

Consistent with the foregoing discussion, *the FAH strongly supports the proposed requirement that the party receiving the open negotiation notice (generally a plan or issuer) respond with a written open negotiation response notice and supporting documents as specified in proposed subsection (b)(1)(iii)*. The threshold exchange of information that would necessarily occur by virtue of the response notice requirement would provide an improved foundation for a meaningful open negotiation process.

In order to further support meaningful open negotiations, the FAH continues to believe that subsection (b)(1) should be revised to require the parties to participate in open negotiations in good faith. Experience with the open negotiation process has shown that some plans and issuers fail to participate in open negotiations in good faith under the current rules, making the open negotiation process an exercise in futility in too many cases. As such, the FAH urges the Departments to go beyond “encourag[ing] disputing parties to negotiate in good faith during” the open negotiation period⁵ by formally adding a good faith requirement. In addition, the FAH believes that such a good faith requirement should be appropriately enforced by HHS or State regulators, and the IDR entity should consider information regarding a party's failure to negotiate in good faith when making its payment determination.

⁵ 88 Fed. Reg. at 75,764.

With respect to the content of the notices, *the FAH appreciates and strongly supports the Departments' proposal that the open negotiation notice (subsection (b)(1)(ii)(3)) and the open negotiation response notice (subsection (b)(1)(iii)(3)) each include an "attestation that the third party [submitting the notice] has the authority to act on behalf of the party it represents in the open negotiation."* As described above, FAH members report plans or issuers participating through agents that purport to have authority to act on behalf of the plan or issuer but ultimately lack the authority to bind the plan or issuer to a settlement. In these cases, the agents participating in open negotiations might reach agreement concerning the out-of-network rate, but that agreement among the agents does not resolve the dispute because the agent cannot bind the plan or issuer. As a result, disputes that should be resolved at open negotiation nonetheless proceed to a determination through the Federal IDR process at the same time that disputes are backlogged in IDR. It is the FAH's understanding that "authority to act on behalf" of a party includes the authority to bind that party to an agreement regarding the out-of-network amount such that the required attestation would end this practice, but the FAH recommends that the Departments confirm this point in the Final Rule.

In addition, the FAH recommends that the Departments expand the content requirements for both the open negotiation initiation notice and response notice exchange information regarding the parties' preferred certified IDR entities should the dispute proceed to IDR. An early exchange of this information could facilitate the prompt selection of a certified IDR entity at IDR because it would provide the party initiating IDR with the option to select the responding party's preferred certified IDR entity at initiation, thereby streamlining the process and minimizing later delays in the process.

With respect to the timing of the notice, the FAH urges the Departments to *advance the deadline for open negotiations to the tenth business days after the submission of the open negotiation notice*. A response period of ten business days would ensure that the parties have the majority of the open negotiation period to actually conduct open negotiations after the initial exchange of information through these notices. In addition, the content specified in proposed subsection (b)(1)(iii) should be readily available to the responding party such that a longer period is unnecessary.

Lastly, in order to ensure that the response notice requirement meaningfully advances the goal, the FAH recommends that the Departments expressly address the consequences and penalties for a responding party's failure to provide a response notice. For the initiating party, the written open negotiation notice is necessary to initiate the open negotiation period and ultimately access the Federal IDR process, creating inherent and necessary consequences for the initiating party if it fails to make the submission. But the Proposed Rule does not establish consequences should the responding party fail to submit a response notice. *The FAH urges the Departments to address this asymmetry by providing that the non-initiating party's offer will not be considered received if it failed to submit the required open negotiation response notice*, in the same way that a party's offer will not be considered received if the party fails to pay the certified IDR entity fee under subsection (d)(1)(ii).

(3) Initiation of the Federal IDR Process

The FAH supports the Departments’ plans to enhance the Federal IDR portal to allow the transmission of notices, including supporting documentation through the portal and to streamline the notice process. It is particularly important that, with the migration of the open negotiation notice to the Federal IDR portal, that the portal be modified to pre-populate the notice of IDR initiation so that the initiating party is not burdened with the re-entry of duplicative data. Likewise, supporting documentation that is uploaded to the portal in connection with open negotiations should also be considered supporting documentation to the notice of IDR initiation so that documents (e.g., the remittance advice) do not need to be re-uploaded at each stage of the process.

The FAH also asks the Departments to ensure that the portal allows the provider or facility initiating the IDR process to select “not provided” or “unknown” for plan- or issuer-specific information that the plan or issuer has failed to provide. As explained in connection with the notice of initiation of open negotiations, non-compliance by plans and issuers has resulted in providers and facilities proceeding to open negotiations without key information, including in particular the QPA. Finalizations of certain elements of the Proposed Rule will hopefully improve information exchange such that these situations become less common, but the option to leave the QPA field blank in the IDR initiation notice is important to ensure that a provider or facility is not be effectively barred from initiating IDR by virtue of the plan’s or issuer’s failure to disclose the QPA.

Federal IDR Process Following Initiation (Part II.E., 45 CFR § 149.510(c) et seq.)

(1) Eligibility Determinations—Reconsideration and Appeal Processes

The FAH is concerned that proposed subsection (c)(2) contemplates eligibility determinations that cannot be reconsidered or further reviewed, even where the determination is based on a clerical or factual error. In the course of eligibility reviews, it is inevitable that an item or service that is in fact a qualified IDR item or service will be mistakenly determined to be ineligible due to simple error (e.g., mistakenly failing to consider data properly submitted or a clerical error concerning the entry of deadlines). Under the NSA, only a determination of the amount of payment for a qualified item or service is a determination that is binding upon the parties and shielded from judicial review.⁶ A determination that an item or service is not a qualified item or service, on the other hand, is given no special status under the NSA. The Proposed Rule does not provide any rationale that would support treating an eligibility determination as final and unreviewable, but instead simply includes finality language in the proposed regulation without discussion. *The FAH believes that simple factual errors should be reviewable and remediable through an informal reconsideration request, an appeal to the Departments or judicial review, and urges the Departments to expressly establish a simple*

⁶ Section 102 of the NSA (adding section 9816(c)(5)(E) of the Internal Revenue Code, section 716(c)(5)(E) of ERISA, and section 2799A-1(c)(5)(E) of the Public Health Services Act).

process for obtaining such review, particularly in cases involving simple mistakes of fact or clerical errors.

(2) **Administrative Fees**

The FAH strongly urges the Departments to extend the timeframe for the initiating party's payment of the administrative fee to ten days after the date of preliminary selection of the certified IDR entity so that the initiating party has enough time to make payment by check or another preferred payment method. The Proposed Rule does not discuss the methods of payment that could be used to pay the administrative fee, but concludes that a two-day period provides "adequate time to pay the fee."⁷ The FAH is concerned that this tight proposed deadline would effectively limit the initiating party to using a credit card to pay the administrative fee, and urges the Departments to finalize a deadline that is sufficient for payment of the administrative fee by check.

With respect to the proposed administrative fee amounts, the FAH has concerns with some of the reduced administrative fee amounts and urges the Departments to distinguish between disputes that are ineligible for the Federal IDR process but are submitted to IDR in reliance on information provided by the plan or issuer on the remittance advice, in the open negotiation response notice, or otherwise and those that are erroneously submitted without such reliance. A provider or facility should be entitled to rely on disclosures by the plan or issuer relating to the eligibility of a dispute for resolution through the Federal IDR process. Where a dispute is ultimately found to be ineligible for the Federal IDR process and the provider or facility so relied on a disclosure by the plan or issuer, the plan or issuer should be required to pay 100 percent of the administrative fee (or 50 percent, in the case of a low-dollar dispute), and the provider's or facility's administrative fee should be reduced to 20 percent. If it is unduly burdensome to assess responsibility for the submission of an ineligible item or service to IDR, the FAH would alternatively support mutually reducing the parties' administrative fees to 60 percent (standard dispute) or 35 percent (low-dollar dispute) that is ineligible for the Federal IDR process. The FAH, however, opposes a policy that presumes that the submission of an ultimately ineligible dispute to the Federal IDR process is the fault of the initiating party and should produce higher fees for the initiating party.

(3) **Plan or Issuer Failure to Timely Pay the Out-of-Network Amount**

As the Departments note, the timeframe for payment between the parties after the payment determination is set by statute at 30 calendar days and cannot be extended.⁸ This deadline is clear in both the NSA and the Departments' implementing regulations, but FAH members report that plans and issuers frequently fail to make payment within this timeframe or at all, forcing the prevailing provider or facility to incur even more costs to collect appropriate payment for the qualified IDR item or service furnished to the plan's or issuer's member. *The FAH therefore urges the Departments to improve oversight, accountability, and enforcement of the obligation to pay the out-of-network amount within 30 days.* In particular, the FAH requests that the Departments require payment through the Federal IDR portal or the submission

⁷ 88 Fed. Reg. at 75,797.

⁸ 88 Fed. Reg. at 75,780.

of proof of payment through the portal so that a plan's or issuer's compliance or non-compliance with its payment obligation can be readily assessed and an appropriate investigation or enforcement action can be initiated. In addition, the FAH urges the Departments to explore their regulatory authority to impose interest on past-due payments and to use their civil monetary penalty authority to penalize non-compliance with payment obligations.

Bundled Payment Arrangements
(Parts II.A. & II.E, 45 CFR §§ 149.30, 149.510(c)(3)(ii))

The FAH is concerned with the ongoing and inappropriate use of bundled payments by out-of-network plans and issuers for claims subject to the NSA. As a threshold matter, the FAH continues to believe that bundled payment arrangements should not be imposed on non-contracted claims subject to the NSA because there is, by definition, no arrangement between the provider or facility and plan or issuer. ***Thus, the provisions of the NSA referencing the treatment of bundled payments in IDR⁹ should properly be read as requiring that the Federal IDR process address in a single determination all items and services furnished in a single episode of care and billed on a single claim form, but not as permitting the unilateral imposition of a bundled payment arrangement by a plan or issuer.*** Under the bundled payment provision of the NSA, a provider or facility should always be permitted to obtain a single determination at IDR for all items and services furnished in single episode of care and billed on a single claim form, and there should be no requirement that the provider, facility, plan, or issuer bill or pay under a single service code for all of these items or services in order to obtain such bundled payment treatment at IDR. It is inappropriate to subject these disputes to the batching rules under proposed section 149.510(c)(4). Rather, batching—and the limitations on batching—should be properly reserved for claims involving more than one episode of care (e.g., multiple patients).

If the Departments nonetheless retain the concept of a bundled payment arrangement, the FAH respectfully urges the Departments to ***limit bundled payment arrangements to: (1) situations where the provider or facility and the plan or issuer mutually agree to bundling (e.g., the provider or facility bills on a bundled basis and the plan or issuer likewise makes a bundled payment); or (2) items and services represented by an all patients refined diagnosis related group (APR DRG) code.*** In addition, the FAH strongly urges the Departments to ensure that plans and issuers provide appropriate information regarding bundled payments by enforcing the rules at 45 CFR § 149.140(d) and adopting CARCs and RARCs specific to bundled payment under proposed § 149.100. ***Ultimately, the application of a bundled payment arrangement and the scope of bundling should be clear in the remittance advice, and the application of a bundled payment arrangement does not excuse a plan or issuer from its obligation to calculate and provide a QPA for each item or service on the claim.***

At present, some plans and issuers apply proprietary or payer-specific bundled payment arrangements that are not widely recognized on claims for items and services that were not bundled by the provider or facility, producing confusion and uncertainty. This misalignment produces situations where a provider or facility receives payment that is a small fraction of the

⁹ Section 102 of the NSA (adding section 9816(c)(3)(B) of the Internal Revenue Code, section 716(c)(3)(B) of ERISA, and section 2799A-1(c)(3)(B) of the Public Health Services Act).

QPA because the plan or issuer has paid one single item or service as a “bundled” payment at the amount billed for the single item or service and then denied and excluded the charges billed for each of the other items and services purportedly included in the bundled payment. For example, if there are three items or services reported with billed charges of \$600, \$1,000, and \$400 and the plan or issuer acknowledges \$1,200 as appropriate payment when bundling these items and services, one would expect a minimum payment of \$1,200 on the claim. But facilities and providers have seen the plan or issuer inappropriately limited total payment on the bill to the charges for the first item or service (\$600), ignoring the billed charges for the other items and services purportedly “bundled” with the first. This situation is compounded by the lack of clear information about plan or issuer bundling – it is often unclear from the remittance advice which items and services were paid, which were bundled, how the bundled payment was applied, and what the QPA is for each item and service billed.

Existing section 149.510(c)(3)(ii) and the newly proposed definition of “bundled payment arrangement” (proposed section 149.30) both fail to expressly exclude the *unilateral* imposition of bundling by a plan or issuer or to limit bundling to items and services represented by DRG or APR DRG codes. As the FAH emphasized in prior comments submitted in response to the October 7, 2021, interim final rule,¹⁰ in the absence of a direct or indirect contractual relationships with respect to the furnishing of the items or services at issue, there is no payment arrangement permitting the plan or issuer to bundle. The FAH believes that there are only two situations where bundling could be appropriate: (1) where the provider or facility and plan or issuer agree on bundling (*i.e.*, a mutual bundling arrangement); or (2) a recognized DRG or APR DRG applies to the claim. In any case, the unilateral imposition of a proprietary or payer-specific bundling arrangement should not be permitted under the NSA rules.

In addition, the FAH urges the Departments to expressly address ongoing and critical problems in the flow of information from plans and issuers to facilities and providers regarding bundled payments. The Departments’ regulations properly 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.¹¹ And likewise, under section 149.140(d)(1)(i),¹² the plan or issuer is required to provide the QPA “for each item or service involved” with each initial payment or notice of denial of payment. Despite these clear and express requirements under existing law, FAH members report receiving bundled payment without QPA information for each individual item or service billed. ***This practice is contrary to law, and the FAH urges the Departments to investigate such non-compliance and enforce the QPA requirements for bundled payments.*** Moreover, the information disclosures provided with the initial payment should provide enough information for the provider or facility to determine whether the payment amount represents a bundled payment arrangement and which items and services were bundled. ***Thus, the FAH***

¹⁰ Available at: <https://www.fah.org/wp-content/uploads/2021/12/Surprise-Billing-Part-2-IDR-Good-Faith-Estimate-External-Review-FINAL.pdf> (Attachment B).

¹¹ 26 CFR § 54.9816-6T(b)(2)(iii), 29 CFR § 2590.716-6(b)(2)(iii), 45 CFR § 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 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.”)

¹² 26 CFR § 54.9816-6T(d)(1)(i), 29 CFR § 2590.716-6(d)(1)(i).

urges the Departments to develop and require the use of CARCs and RARCs that provide specific information for bundled payments applied to non-contracted claims. These CARCs and/or RARCs should disclose the application of a bundling methodology and specifically identify each item or service that was included in such bundling.

Batching Items & Services
(Part II.E.2, 45 CFR 149.510(c)(4))

The FAH supports the broader availability of batching to help reduce the IDR backlogs that have frustrated the efficient resolution of disputes through the Federal IDR process. In particular, the FAH supports eliminating artificial limitations on batching that themselves burden the IDR process. As certified IDR entities have reported to the Departments, certified IDR entities find batched disputes more burdensome than non-batched disputes “due to the extra time and resources they must expend in verifying that the items and services are properly batched and eligible for the Federal IDR process.”¹³ In fact, the substantive payment determinations in batched disputes are able to be made “relatively efficiently,” and a “substantial portion of the time and expense related to resolving disputes is spent on . . . administrative and eligibility-related tasks.”¹⁴ *Against this backdrop, the FAH supports simple and practical batching rules that allow providers to broadly batch similar items and services while minimizing the certified IDR entity’s eligibility-related tasks for batched disputes.*

(1) Line-Item Limit

The FAH strongly opposes the application of an artificial line-item limit for batched items and services because separating items and services that could otherwise be batched and addressed in a single determination into two or more determinations will increase the burden on the system while offering few or (in some cases) virtually no efficiencies. The problems of a line-item limit are particularly evident in cases where the batched items and services involve the same episode of care, involve a single code, or were subject to a uniform payment methodology by the plan or issuer.

With respect to the batching of items and services furnished to a single patient in a single patient encounter and reported on a single claim form, as explained above, the FAH supports treating such a claim as a bundled payment dispute that is the subject of a single determination without regard for any batching rules or fees. But, if items and services furnished in a single patient encounter are instead considered batched under proposed 26 CFR § 54.9816–8(c)(4)(i)(C)(1), 29 CFR § 2590.716–8(c)(4)(i)(C)(1), and 45 CFR § 149.510(c)(4)(C)(1), any line-item limit would still be inappropriate. Carving such a case into multiple IDR determinations would result in piecemeal, inconsistent, and inefficient determinations regarding payment involving a single episode of care. A certified IDR entity addressing payment for 25 line items involved in such a single episode would necessarily need to assess a number of considerations that would likewise be relevant to a determination of the remaining items and services furnished beyond the 25 line items. And limiting the certified IDR entity’s scope of

¹³ 88 Fed. Reg. at 75,782.

¹⁴ *Id.*

review to a specified number of line items would not meaningfully narrow the considerations before the certified IDR entity in a way that could expedite the payment determination.

Likewise, a line item limit should not be applied to items and services represented by an identical or comparable code under proposed subsection (c)(4)(C)(2) or service codes belonging to the same Category I CPT code range under proposed section (c)(4)(C)(3). In both cases, the limitation that the batched services must have been furnished within the same 30-business-day period is sufficient to limit the volume of batched services, and the imposition of an additional line-item limit will perpetuate and exacerbate the existing IDR backlog and result in piecemeal determinations rather than promoting efficiencies. In fact, in some of these cases, the plan or issuer might have applied the same payment methodology to 50 or more of the same or similar items and services furnished by the same provider, confirming that the services can be efficiently batched at the election of the initiating partner. In short, existing limitations on batching preclude the presentment of “large and complicated batches”¹⁵ that might warrant a line item limit, as confirmed by the relative efficiency with which certified IDR entities make payment determinations in batched disputes, and the FAH does not support the finalization of any line item limit for the batching of items and services described in proposed subsection (c)(4)(C).

(2) **Category I CPT Code Subsections**

The FAH strongly supports the Departments proposal to permit the batching of some services billed under service codes belonging to the same Category I CPT code range and urges the Departments to expand this proposal to permit additional batching, including the batching of evaluation and management CPT codes across levels. As proposed, new subsection (c)(4)(C)(2) would appropriately enable providers to obtain payment determinations of batched items and services that might not be cost-effective to dispute individually or on a code-by-code basis.

The FAH also strongly supports policies that promote the efficient resolution of payment disputes involving emergency department evaluation and management codes (namely, CPT codes 99281-99285). Non-contracted emergency providers frequently receive low payments on out-of-network claims for evaluation and management services that are financially significant in the aggregate but are not cost-effective to dispute on an individual basis. This situation produces a condition of circularity that discourages plans and issuers from contracting with emergency providers and could even place emergency services at risk. Briefly, if it is not cost-effective to dispute individual evaluation and management codes or to dispute them in multiple batches based on the applicable evaluation and management code level, emergency providers are at risk for further erosion in payments from out-of-network plans and issuers that understand the low likelihood of a payment going to IDR. This situation further disincentivizes the out-of-network plan or issuer to negotiate for network participation at reasonable rates and even incentivizes non-renewal of contracts by other plans and issuers. The aggregate impact of these pressures may prompt emergency providers to relocate, resulting in diminished access to care in the community. It is thus of critical importance that the IDR process include the opportunity to meaningfully batch emergency department evaluation and management services.

¹⁵ 88 Fed. Reg. at 75,783.

In the Proposed Rule, the Departments seek comment on ways that emergency department providers might be permitted to batch items and services across the five evaluation and management Level 1 CPT codes “without a commensurate increase in the diversity of documentation that certified IDR entities would need to review to evaluate disputes related to different, but similar conditions.”¹⁶ It is the FAH’s understanding, however, that the variability between encounters represented by different emergency department evaluation and management codes is not significantly wider than the variability between encounters represented by the same emergency department evaluation and management code, such that the items and services represented by these codes are similar (*i.e.*, an emergency department visit for the evaluation and management of a patient, including a history, examination, and medical decision-making). The availability of batching for emergency department evaluation and management codes would be particularly useful and efficient in the many situations where non-contracted plans and issuers apply a uniform, cookie-cutter payment methodology to these claims and the provider is seeking to address, in a cost-effective manner, the routine underpayment of these evaluation and management codes. Should the Departments remain concerned that the batching of emergency department evaluation and management services across similar codes would burden the IDR process, a reasonable line-item limit on batching for these services only (*e.g.*, 50 line items per batch) could be a reasonable measure to promote efficiency and address certified IDR entity concerns.

The FAH appreciates the opportunity to submit these comments on these important issues to patients and providers. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,



¹⁶ 88 Fed. Reg. at 75,790.



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,





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,

