UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 2:23-cv-207-JLB-KCD

DEFENDANTS' COMBINED MOTION TO DISMISS (OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT) AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiff alleges that a series of "Frequently Asked Questions" (FAQ) responses posted on Defendants' websites violated the notice-and-comment requirements of the Administrative Procedure Act (APA). Ultimately, Plaintiff wants this Court to order the Executive Branch to enforce the Executive Branch's own health care price-transparency rules more aggressively. Plaintiff's only claim lacks merit, because these FAQ responses are "general statements of policy," and thus subject to an explicit textual exemption from the APA's notice-and-comment requirements. 5 U.S.C. § 553(b)(A). Primarily, that is because they "do not have the force and effect of law and are not meant to bind the public in any way[.]" Ex. 2, FAQs Part 49, at 1.

But the Court need not (and should not) reach the merits. Plaintiff—the Foundation for Government Accountability (FGA)—is not a health care provider, health insurer, pharmaceutical company, or pharmacy. Plaintiff is not a doctor, nurse, nurse practitioner, pharmacist, or physician's assistant. Plaintiff is not a patient. Plaintiff does not buy, sell, use, prescribe, or market prescription drugs. Plaintiff is not even an association of which any of the above are members. Instead, Plaintiff is an advocacy organization, which describes itself as "a non-profit, multi-state think tank that promotes public policy solutions to create opportunities for every American to experience the American Dream." Ex. 1, Mar. 2023 Press Release. Plaintiff thus filed this suit not to remedy some concrete, particularized, and individualized injury, but instead, in its own words, "to force the Biden administration to follow the law[.]" *Id.*

Of course, the Supreme Court "has repeatedly held that an asserted right to have the Government act in accordance with law is not sufficient, standing alone, to confer jurisdiction on a federal court." *Allen v. Wright*, 468 U.S. 737, 754 (1984). And those principles are especially well-settled where, as here, Plaintiff asks the judiciary to micromanage the Executive Branch's discretion not to bring certain types of enforcement actions. In short, "the Executive Branch's traditional discretion over whether to take enforcement actions against violators of federal law" means "that the federal courts are not the proper forum to resolve this dispute," *United States v. Texas*, 143 S. Ct. 1964, 1975 (2023), and that Plaintiff lacks Article III standing.

Even setting aside standing, "an agency's decision not to take enforcement action" is also presumptively "immune from judicial review under § 701(a)(2)" of the APA, *Heckler v. Chaney*, 470 U.S. 821, 832 (1985), and there is no statutory constraint that would overcome that presumption here. And the serial updates to agency FAQ responses that Plaintiff challenges here likewise do not qualify as "final agency action" reviewable under the APA. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).

Plaintiff's complaint should thus be dismissed, either for lack of subject-matter jurisdiction or for failure to state a claim upon which relief can be granted. Plaintiff's motion for summary judgment should then be denied as moot.

BACKGROUND

The Patient Protection and Affordable Care Act, signed into law by President Obama in March 2010, Pub. L. No. 111-148, generally "requires health plans" to "make available to the public, accurate and timely disclosure of" certain categories of

information, 42 U.S.C. § 18031(e)(3)(A)(i)-(vii), as well as any "[o]ther information as determined appropriate by the Secretary," *id.* § 18031(e)(3)(A)(viii). A related provision, 42 U.S.C. § 300gg-15a, extends those requirements to a wider set of plans.

Almost a decade later, President Trump issued Executive Order 13877, *Improving Price & Quality Transparency in American Healthcare to Put Patients First*, 84 Fed. Reg. 30849 (June 24, 2019). Among other things, the Executive Order directed relevant agencies to solicit public "comment on a proposal to require healthcare providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care." 84 Fed. Reg. at 30850. Shortly thereafter, HHS, the Department of the Treasury, and the Department of Labor ("Defendants") jointly initiated that rulemaking, which ultimately resulted in publication of the Transparency in Coverage Rule (or "TiC Rule"). 85 Fed. Reg. 72158 (Nov. 12, 2020).

The Rule has two primary sections. The first concerns "required disclosures to participants, beneficiaries, or enrollees," and requires plans and issuers to provide certain "cost-sharing information" to specified individuals upon request. 45 C.F.R. § 147.211. The second section, about "requirements for public disclosure"—the portion of the Rule that Plaintiff is concerned about here—requires plans and issuers to publicly disclose certain data about costs relating to covered items and services. *Id.* § 147.212. The Rule generally requires such data to be publicly disclosed in three "machine-readable" files, including, as relevant here, a "prescription drug" file, which

must report certain drug-pricing information in "dollar amounts." 45 C.F.R. §§ 147.210, 147.212(b)(1)(iii). All these requirements remain in effect today.

Generally, with respect to health insurance issuers, "[t]he states have primary enforcement authority with respect to" these requirements—not the federal government. 45 C.F.R. § 150.101(b)(2); *see* 42 U.S.C. § 300gg-22(a). But if a state fails to enforce these provisions adequately, HHS may also impose "a civil money penalty" for non-compliance on a health plan or issuer in that state. 42 U.S.C. § 300gg-22(b)(2); *see* 45 C.F.R. Part 150.

Shortly after the Rule was finalized, Congress enacted the No Surprises Act as part of the Consolidated Appropriations Act of 2021 ("CAA"), which imposed significant new transparency requirements on plans and issuers. *See* 42 U.S.C. § 300gg-120. By requiring disclosure of extensive information every year about prescription drug and health care spending, these later-enacted requirements further changed the regulatory landscape, raising concerns about potentially duplicative and overlapping reporting requirements for prescription drugs. Litigation ensued, in federal courts in Texas and the District of Columbia.[1]

To "answer questions from stakeholders to help people understand the law and promote compliance," on August 20, 2021, Defendants jointly issued a set of FAQ responses on this subject. Ex. 2 at 1. Q1 asked: "Will the Departments enforce the machine-readable file provisions in the TiC Final Rules?" *Id.* The answer: "Yes,

[1] *See* Compl., *Chamber of Com. of the U.S. v. HHS*, No. 6:21-cv-00309 (E.D. Tex. Aug. 10, 2021); Compl., *Pharm. Care Mgmt. Ass'n v. HHS*, No. 1:21-cv-2161 (D.D.C. Aug. 12, 2021).

subject to two exceptions, plans and issuers must make public machine-readable files disclosing in-network rates and out-of-network allowed amounts and billed charges." *Id.* The exceptions were directly responsive to "concern[s] about potentially duplicative and overlapping reporting requirements for prescription drugs" in the aftermath of the CAA. *Id.* at 2. That is, "[i]n response to the later statutory enactment and stakeholder concerns, as an exercise of enforcement discretion," Defendants announced their intent to "defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish machine-readable files related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate." *Id.* Defendants also cautioned explicitly, however, that despite this partial, temporary, and non-binding exercise of enforcement discretion, the legal obligations imposed by the ACA, the CAA, and the TiC rule were unchanged: "The contents of" the FAQ responses themselves "do not have the force and effect of law and are not meant to bind the public in any way," and are instead "intended only to provide clarity to the public regarding existing requirements under the law." *Id.* at 1.

Subsequent FAQ responses further clarified Defendants' enforcement priorities. On April 19, 2022, Defendants confirmed that they did not intend to bring enforcement actions regarding disclosure requirements for which compliance, it turned out, might not be possible. *See* Ex. 3, FAQs Part 53, at 2 (acknowledging that under certain "alternative reimbursement arrangements" that are "not uncommon," it "may not be possible" to provide some of the information required by the TiC Rule).

And on August 19, 2022, Defendants reiterated that they intended to "defer enforcement of the requirement that plans and issuers publish a machine-readable file related to prescription drugs while the Departments consider, through notice-and-comment rulemaking, whether this requirement remains appropriate." Ex. 4, FAQs Part 55, at 26. As of the date of this filing, although Defendants have not yet published a notice of proposed rulemaking to that effect, it remains their intent to do so.

Plaintiff moved for summary judgment on June 19, 2023. ECF No. 33 ("Pl.'s MSJ"). Defendants now move to dismiss (or, in the alternative, for summary judgment), and oppose Plaintiff's motion.

DEFENDANTS' STATEMENT OF MATERIAL FACTS[2]

1. The Transparency in Coverage Rule does not impose or alter any regulatory obligations on Plaintiff. *See* 85 Fed. Reg. at 72158.

2. The FAQ responses that are challenged in Plaintiff's complaint do not impose or alter any regulatory obligations on Plaintiff. *See* Ex. 2 at 1.

3. On the day that it filed this lawsuit, Plaintiff issued a statement (attributed to FGA's President and CEO) that identified the purpose of this litigation as a generalized desire in ensuring that the government follows the law: "FGA is taking the fight for transparency to federal court to force the Biden administration to follow the law, without exception and without delay." Ex. 1.

[2] Defendants agree with Plaintiff that statements of material fact are not strictly "necessary for the resolution of this case" under the APA, but likewise are including one here (as well as a response to Plaintiff's statement) "for completeness and to ensure compliance with the Court's scheduling order." Pl.'s MSJ at 3 n.*.

4. That same press release also included a statement (attributed to the "FGA legal director"), which advanced an interest in advocating for the interests of consumers, none of whom are parties to this lawsuit: "Since they won't implement the rule on their own as the law requires, we're asking the federal court to order them to, delivering the transparency consumers deserve." Ex. 1.

5. The FAQ responses that are challenged in Plaintiff's complaint are not binding on the government, on regulated parties, or on Plaintiff. *See* Ex. 2 at 1 ("The contents of this document do not have the force and effect of law and are not meant to bind the public in any way[.]").

RESPONSE TO PLAINTIFF'S STATEMENT OF MATERIAL FACTS

1. Undisputed.

2. Undisputed.

3. Undisputed.

4. Undisputed.

5. Undisputed.

6. Undisputed.

7. Undisputed that "[t]he Foundation for Government Accountability (FGA) is a non-partisan, non-profit organization" that describes its mission as to "help[] millions achieve the American dream by improving welfare, work, healthcare, and election integrity policy in the states and in Washington, D.C."

8. Immaterial, but undisputed.

9. Immaterial, but undisputed.

10. Disputed. According to Plaintiff, it filed this lawsuit in order "to give *consumers* full pricing information for medications," and to "force the Biden administration to follow the law." Ex. 1 (emphasis added).

11. Disputed. *See* 45 C.F.R. § 147.212(b) (requiring disclosure).

12. Immaterial, but undisputed.

ARGUMENT

Apparently, Plaintiff "often advocates for more transparency in healthcare pricing." Pl.'s MSJ at 14-15. It is free to do so before the political branches, but there is no basis—either in Article III of the Constitution, or in the APA—to obtain an order from a federal court seeking more aggressive enforcement by the Executive Branch of the Executive Branch's own rules. This case should thus be dismissed either (1) for lack of Article III standing, (2) because of the Executive Branch's presumptively unreviewable discretion not to bring enforcement actions, *Heckler*, 470 U.S. at 821, or (3) because Plaintiff does not challenge any "final agency action" under the APA. In the alternative, if the Court does reach the merits, these FAQ responses are "general statements of policy," 5 U.S.C. § 553(b)(A), and thus did not have to go through notice-and-comment rulemaking before their publication on agency websites. Either at the threshold or on the merits, this case should thus be dismissed in its entirety.

I. Plaintiff lacks Article III standing.

a. Standing is "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). A plaintiff who seeks to establish standing "must have (1) suffered an injury in fact,

(2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "The party invoking federal jurisdiction bears the burden of establishing these elements," which "are not mere pleading requirements but rather an indispensable part of the plaintiff's case[.]" *Lujan*, 504 U.S. at 561.

Recently, the Supreme Court "has 'also stressed that the alleged injury must be legally and judicially cognizable.'" *Texas*, 143 S. Ct. at 1970 (quoting *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). "That 'requires, among other things,' that the 'dispute is traditionally thought to be capable of resolution through the judicial process'—in other words, that the asserted injury is traditionally redressable in federal court." *Id.* "In adhering to that core principle, the Court has examined 'history and tradition,' among other things, as 'a meaningful guide to the types of cases that Article III empowers federal courts to consider.'" *Id.* (quoting *Sprint Commc'ns Co., L.P. v. APCC Servs., Inc.*, 554 U.S. 269, 274 (2008)). As a result, a lawsuit "may not proceed" in federal court where the "plaintiff has not suffered any physical, monetary, or cognizable intangible harm traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2206 (2021).

To be sure, when the plaintiff is a regulated party, "there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Lujan*, 504 U.S. at 561-62. "When, however, as in this case, a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is

needed." *Id.* at 562. For example, as relevant here, "a citizen lacks standing to contest the policies of the" Executive Branch—in particular, policies of enforcement discretion—"when he himself is neither prosecuted nor threatened with prosecution" under the challenged enforcement policy. *Texas*, 143 S. Ct. at 1968 (quoting *Linda R. S. v. Richard D.*, 410 U.S. 614, 619 (1973)).

b. Although it was Plaintiff's burden to demonstrate Article III standing, *Lujan*, 504 U.S. at 561, it has made no effort to identify any injury "traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion*, 141 S. Ct. at 2206. To the contrary, there is a well-established tradition against allowing challenges to Executive Branch nonenforcement policies like these.

In *Linda R. S. v. Richard D.*, 410 U.S. 614 (1973), the Supreme Court held that "a citizen lacks standing to contest the policies of the prosecuting authority when he himself is neither prosecuted nor threatened with prosecution." *Id.* at 619. There, a mother sued a district attorney who had failed to prosecute the father of her child for not paying child support. *Id.* at 616-19. The prosecutor had adopted a policy against prosecuting "fathers of illegitimate children," and the mother challenged the policy as a denial of equal protection. *Id.* at 616. The Court held that she lacked standing, explaining that, "in American jurisprudence at least, a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another." *Id.* at 619.

The Supreme Court reaffirmed this tradition just last month. In *United States v. Texas*, Texas and Louisiana sued the Department of Homeland Security (DHS),

seeking to have the courts vacate DHS's new immigration enforcement policy guidelines as inconsistent with the Immigration and Nationality Act, asserting that the statute "require[s] the Department to arrest *more* criminal noncitizens pending their removal." 143 S. Ct. at 1968. The Supreme Court rejected that challenge to the enforcement guidelines for lack of Article III standing. *Id.* at 1976. In doing so, it reiterated the conclusion of *Linda R. S.*, that in American jurisprudence, a party "lacks a judicially cognizable interest in the prosecution . . . of another." *Id.* at 1970. The Court pointed to the lack of historical precedent for allowing such suits, and noted the importance of "history and tradition" in determining the types of cases an Article III court can entertain. *Id.* at 1970-73.

These principles reflect both Article II and Article III constraints. Article II vests the executive power in the President and directs him to take care that the laws are faithfully executed. U.S. Const. art. II, § 1, cl. 1; art. II, § 3. Decisions about "how to prioritize and how aggressively to pursue legal actions against defendants who violate the law" thus fall "within the discretion of the Executive Branch, not within the purview of private plaintiffs (and their attorneys)." *TransUnion*, 141 S. Ct. at 2207. Under Article III, meanwhile, federal courts sit to protect against "the exertion of unauthorized administrative power," *Stark v. Wickard*, 321 U.S. 288, 310 (1944)—not to *compel* agencies to *exert* coercive power against third parties not before the court.

These principles decide this case. Just as in *Texas*, Plaintiff's claim here implicates Article II's assignment to the Executive Branch, not the judiciary, of the "authority to decide 'how to prioritize and how aggressively to pursue legal actions

against defendants who violate the law.'" 143 S. Ct. at 1971 (quoting *TransUnion*, 141 S. Ct. at 2207). Likewise, just as in *Texas*, the Executive Branch here has identified narrow circumstances where it (at least for now) "elects not to" pursue enforcement action, and thus "does not exercise coercive power over an individual's liberty or property" or "infringe upon interests that courts often are called upon to protect." *Id.*

Plaintiff objects that the Executive Branch is declining to enforce disclosure requirements that are "important to FGA's research and advocacy efforts." Pl.'s MSJ at 14. But Plaintiff has "no judicially cognizable interest in procuring enforcement" of federal law against third parties. *Sure-Tan, Inc. v. NLRB*, 467 U.S. 883, 897 (1984). Plaintiff cannot evade that rule by arguing that the Executive's enforcement policies indirectly affect it. Enforcement policies routinely have indirect effects on others—consider, say, crime victims—but those effects are not judicially cognizable. The mother in *Linda R. S.*, for example, plainly had "an interest in the support of her child." 410 U.S. at 619. Even so, she lacked standing to "contest the policies of the prosecuting authority" because she was "neither prosecuted nor threatened with prosecution." *Id.* Likewise, the Court in *Texas* acknowledged that "federal policies frequently generate indirect effects on state revenues or state spending," but those indirect effects could not "overcome[] the fundamental Article III problem with th[at] lawsuit" brought by two states. 143 S. Ct. at 1972 n.3.

The same logic applies here. Plaintiff's desire to force the government to compel third parties to publish additional information about drug pricing that may be helpful in its advocacy efforts is (at best) the sort of "indirect effect[]" from "federal policies"

that the Supreme Court has rejected as insufficient to challenge a policy of Executive Branch enforcement discretion. Indeed, Plaintiff's improved-issue-advocacy theory is far less direct than the financial and familial interests at stake in *Linda R. S.* (child support payments) or the sovereign interests at stake in *Texas* (state spending to support undocumented immigrants). The Supreme Court has been vigilant in preventing this sort of workaround. *See, e.g.*, *Texas*, 143 S. Ct. at 1973 ("If the Court green-lighted this suit, we could anticipate complaints in future years about alleged Executive Branch under-enforcement of any similarly worded laws[.]").

c. Plaintiff also lacks Article III standing for more conventional reasons, which apply even outside the unique context of a lawsuit seeking to micromanage the Executive Branch's enforcement discretion. Although Plaintiff's standing theory is never spelled out explicitly, it appears to rely on the following chain of hypothesized causal inferences: (1) because of the challenged FAQ responses, "[h]ealth insurance issuers and group plans are failing to disclose the prescription drug information required by the TiC Rule," Pl.'s MSJ at 19; (2) if the Court vacated those FAQ responses, issuers and plans *would* disclose that information; (3) Plaintiff would then "use the information to advance its mission" more successfully, *id.* at 16.

This theory impermissibly relies on a "speculative chain of possibilities," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013), about the "independent action[s] of some third party not before the court," *Lujan*, 504 U.S. at 560 (quoting *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41-42 (1976)). For starters, Plaintiff has not even

established that regulated parties are actually "failing to disclose the prescription drug information required by the TiC Rule." Pl.'s MSJ at 19. Plaintiff's only citation for that proposition is to two (possibly outdated) third-party websites, both of which acknowledge the legal obligations imposed by the Transparency in Coverage Rule, and neither of which supports Plaintiff's characterization as "openly touting their refusal to abide by the terms of the TiC Rule." *Id.* For example, UnitedHealth reports that "[c]ompliance with the laws and regulations applicable to our business is a fundamental commitment of UnitedHealth Group," and that it "intend[s] to comply with the requirements of the new rules." *Transparency in Coverage Rule*, UnitedHealth, https://perma.cc/7P4M-4GJC. Plaintiff offers no evidence about what any other third parties are doing, nor the extent to which those decisions have been affected (if at all) by the challenged FAQ responses.[3]

In any case, even if some third parties are currently violating the legal obligations imposed by the Transparency in Coverage Rule—which Defendants acknowledge is a possibility, albeit one unsupported by the record—Plaintiff offers no evidence that granting the relief requested here would change that. Defendants have already expressed their intent not to bring enforcement actions regarding certain features of the Transparency in Coverage Rule, at least pending further rulemaking.

[3] Plaintiff's only other citation is to Premera's website, which appears to have last been updated more than a year ago but, in any event, is also inconsistent with Plaintiff's characterization. *See Transparency in Coverage Rule*, Premera (June 9, 2022), https://perma.cc/W2FK-E76U ("Implementation efforts are underway, and we have a company-wide, cross-functional team working as part of an implementation project to ensure we are in compliance with all aspects of the rule as required on insured business.").

A court order vacating the FAQ responses would not change that intent—after all, Plaintiff has not requested (and there would be no legal basis for) an order requiring Defendants to bring specific enforcement actions. So even if the FAQ responses were stricken from the internet, it is not at all clear that any plans and issuers—who are not before the Court, and who (at least on Plaintiff's telling) are already violating the law—would alter their behavior.

This uncertainty is further compounded by the fact that "states have primary enforcement authority with respect to" many of these requirements, 45 C.F.R. § 150.101(b)(2), and those states (who are not parties to this lawsuit) are not obligated to adopt the same enforcement priorities as the federal government. The Supreme Court has been "reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment." *Clapper*, 568 U.S. at 413. This Court should be reluctant, too.[4]

Certain features of Plaintiff's challenge make this uncertainty even more stark. One of the FAQ responses addresses a practical "problem" that "stakeholders" brought "to the Departments' attention" only "[a]fter the TiC Final Rules were issued"—namely, that there are "alternative reimbursement arrangements" that are "not uncommon" "for which reporting a current and accurate dollar amount for items

[4] To be sure, the FAQ responses generally "encourage[] states" as the "primary enforcers" of these requirements "to take a similar enforcement approach" as the federal government. *See, e.g.*, Ex. 2 at 2. But to put it mildly, states do not always do what the federal government "encourages" them to do, *id.*, and Plaintiff has offered no evidence at all about the enforcement practices of the states, let alone how they might respond to vacatur of these FAQ responses.

and services . . . before the item or service is provided or rendered may not be possible." Ex. 3 at 2. Obviously, if reporting that information is impossible, then regulated parties are not going to report it—with or without a public statement of enforcement discretion from the government. And for obvious reasons, the Executive Branch is extraordinarily unlikely to pursue enforcement action for failure to do the impossible.

Finally, even if the Court were willing to speculate that the chain of inferences above would play out in exactly the way that Plaintiff predicts, the assumption that Plaintiff's advocacy efforts would be more successful with the benefit of more granular price information—including, for example, publication of information in "machine-readable files," 85 Fed. Reg. at 72158—is even more speculative. The vague mission of the "Foundation for Government Accountability"—that is, to "promote[] public policy solutions to create opportunities for every American to experience the American Dream," Ex. 1—has only a highly indirect and purely theoretical connection to the information at stake here.

d. At times, Plaintiff's filings (at least arguably) adopt the jargon of informational standing. But that cannot save the complaint from dismissal, because "[a]n asserted informational injury that causes no adverse effects cannot satisfy Article III," *TransUnion*, 141 S. Ct. at 2214, and for all the reasons above, Plaintiff has not demonstrated any judicially cognizable adverse effects. The Court need go no further to reject any theory of informational standing, to the extent Plaintiff asserts it.

Even if this doctrine applied here, Plaintiff cannot satisfy its requirements. To demonstrate a sufficiently particularized informational injury, courts have required a

plaintiff to show that "(1) it has been deprived of information that, on its interpretation, a *statute* requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm *Congress* sought to prevent by requiring disclosure." *Elec. Priv. Info. Ctr. v. Dep't of Commerce*, 928 F.3d 95, 103 (D.C. Cir. 2019) (*EPIC*) (quoting *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016)) (emphases added); *see also Elec. Priv. Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 378 (D.C. Cir. 2017) (same); *accord Trichell v. Midland Credit Mgmt., Inc.*, 964 F.3d 990, 1004 (11th Cir. 2020) (to establish standing a plaintiff must at a minimum demonstrate a "substantive entitlement to receive information" under a relevant statute) (cited favorably in *TransUnion*, 141 S. Ct. at 2205, 2214).

Here, no "statute requires the government or a third party to disclose" the information that Plaintiff seeks. *EPIC*, 928 F.3d at 103. The source of the legal obligation is an administrative rule, as Plaintiff repeatedly acknowledges. *See, e.g.*, Pl.'s MSJ at 19 (arguing that third parties are "failing to disclose the prescription drug information required by the TiC Rule," citing no statute); *see also id.* at 13 ("required by the TiC rule"), *id.* at 21 (same), *id.* at 23 (same).

That makes all the difference. After all, although "Congress's creation of a statutory prohibition or obligation . . . does not relieve courts of their responsibility to independently decide whether a plaintiff has suffered a concrete harm under Article III," it is still the case that "[c]ourts must afford due respect to *Congress's* decision to impose a statutory prohibition or obligation on a defendant[.]" *TransUnion*, 141 S. Ct.

at 2204-05 (emphasis added). That "respect" for Congress is the source of the (otherwise counterintuitive) notion that an informational injury can sometimes suffice under Article III, at least when a court is faced with "public-disclosure or sunshine laws that entitle all members of the public to certain information." *TransUnion*, 141 S. Ct. at 2214. But here, the statute authorizes *the Executive Branch* to decide what (if any) "[o]ther information as determined appropriate by the Secretary" must be disclosed. 42 U.S.C. § 18031(e)(3)(A)(ix). As a result, enforcement of those obligations "falls within the discretion of the Executive Branch, not within the purview of private plaintiffs (and their attorneys)." *TransUnion*, 141 S. Ct. at 2207.

e. Plaintiff's remaining standing-related arguments can be disposed of quickly. First, in a filing-day press-release, Plaintiff expressed its desire "to force the Biden administration to follow the law[.]" Ex. 1. But "Article III grants federal courts the power to redress harms that defendants cause plaintiffs, not a freewheeling power to hold defendants accountable for legal infractions." *TransUnion*, 141 S. Ct. at 2205.

Second, Plaintiff's chief legal officer separately advanced an interest in advocating for the interests of consumers, who are neither parties to this lawsuit nor members of Plaintiff: "Since [the Executive Branch] won't implement the rule on their own as the law requires, we're asking the federal court to order them to, delivering the transparency *consumers* deserve." Ex. 1 (emphasis added). But "a party cannot ordinarily rest his claim to relief on the legal rights or interests of third parties." *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2117 (2020), *abrogated in part on other grounds*

by Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022). There is nothing extraordinary about this lawsuit that would warrant a departure from that rule.

* * *

For all these reasons, "the federal courts are not the proper forum to resolve this dispute," *Texas*, 143 S. Ct. at 1975, which should be dismissed for lack of standing.

II. Defendants' authority to adopt policies of non-enforcement discretion is committed to agency discretion by law.[5]

In addition to showing Article III standing, under the APA, "before any review at all may be had, a party must first clear the hurdle of § 701(a)." *Chaney*, 470 U.S. at 828. 5 U.S.C. § 701(a)(2) provides that APA review is unavailable to challenge "agency action" that is "committed to agency discretion by law." Section 701(a)(2) applies to various types of agency decisions that "traditionally" have been regarded as unsuitable for judicial review. *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993). The textbook example is an agency's decision to issue a discretionary policy of non-enforcement.

Heckler v. Chaney is particularly instructive. There, the Supreme Court considered a challenge to the decision of the Food and Drug Administration (FDA) not to enforce the Federal Food, Drug, and Cosmetic Act against the "unapproved use of approved drugs" for capital punishment. *Chaney*, 470 U.S. at 824. The FDA had reasoned that it lacked jurisdiction to bring such enforcement actions and that, even if it had jurisdiction, the agency would exercise its "inherent" enforcement discretion to

[5] Under Eleventh Circuit precedent, the question of "[w]hether an agency action is reviewable under § 701(a)(2) is a matter of subject matter jurisdiction." *Animal Legal Def. Fund v. USDA*, 789 F.3d 1206, 1214 (11th Cir. 2015).

decline to do so. *Id.* The Supreme Court refused to subject the agency's decision to APA review. *Id.* at 831.

The Court observed that "an agency's decision not to prosecute or enforce, whether through civil or criminal process," is "generally committed to an agency's absolute discretion" and "unsuitab[le] for judicial review." *Chaney*, 470 U.S. at 831. It explained that a decision not to enforce "often involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," including "whether agency resources are best spent on this violation or another" and whether enforcement in a particular scenario "best fits the agency's overall policies." *Id.* The Court noted, in addition, that when an agency declines to enforce, it "generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id.* at 832. And it recognized that an administrative agency's enforcement discretion "shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch." *Id.*

Accordingly, the Court concluded that, absent a statute "circumscribing an agency's power to discriminate among issues or cases it will pursue," the agency's "exercise of enforcement power" is "committed to agency discretion by law." *Id.* at 833, 835. The Eleventh Circuit has repeatedly reaffirmed this understanding of *Chaney*. *See, e.g.*, *Fla. Defs. of Env't v. U.S. Forest Serv.*, No. 20-12046, 2021 WL 4944806, at *1 (11th Cir. Oct. 25, 2021) ("[T]he refusal to take enforcement action is

traditionally committed to agency discretion by law."); *Conservancy of Sw. Fla. v. U.S. Fish & Wildlife Serv.*, 677 F.3d 1073, 1084 (11th Cir. 2012) ("[A]n agency's decision not to take enforcement action is committed to its discretion."). Analogous enforcement discretion is routinely exercised within the Department of Justice, both within and between presidential administrations, and separation-of-powers considerations underscore why it has never been considered amenable to APA review. *See United States v. Armstrong*, 517 U.S. 456, 464 (1996) ("Attorneys retain broad discretion to enforce the Nation's criminal laws."); *see also, e.g.*, Dep't of Justice, *Guidance Regarding Marijuana Enforcement* (Aug. 29, 2013), https://perma.cc/8Y6M-6D53.

These principles are independently fatal to Plaintiff's complaint, which explicitly seeks to challenge the Executive Branch's "non-enforcement policies." Compl. ¶ 5. Here, just as in *Chaney*, the government has not "exercise[d] its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." 470 U.S. at 832. Instead, it has chosen a path of (partial, temporary, and non-binding) lenience. That "decision not to prosecute or enforce" is "committed to an agency's absolute discretion" and "unsuitab[le] for judicial review." *Id.* at 831.

"Of course," if Congress had meaningfully "circumscribe[d] agency discretion," then the agency would not be "free simply to disregard statutory responsibilities" in the name of enforcement discretion. *Lincoln*, 508 U.S. at 193; *accord Chaney*, 470 U.S. at 833-34. But here, there is no such statutory constraint. Just the opposite: the statutory language *reinforces* the discretion of the Executive Branch to require (or not

require) disclosure of "[o]ther information *as determined appropriate by the Secretary*." 42 U.S.C. § 18031(e)(3)(A)(ix) (emphasis added). "[T]he statute's permissive language makes it all the more apparent that the decision at issue is committed to agency discretion." *Conservancy of Sw. Fla.*, 677 F.3d at 1084.

Accordingly, even if Plaintiff had Article III standing, this case should still be dismissed for lack of subject-matter jurisdiction, because the relevant agency decisions are all "committed to agency discretion by law." 5 U.S.C. § 701(a)(2).

III. Plaintiff fails to challenge any final agency action.[6]

Under the APA, judicial review is available only to challenge "final agency action." 5 U.S.C. § 704. There are two elements: "First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016) (quoting *Bennett*, 520 U.S. at 177-78). The FAQ responses at issue here fail both requirements.

As for the first final-agency-action requirement, Plaintiff has at most identified various actions that are "of a merely tentative or interlocutory nature." *Hawkes*, 578 U.S. at 597 (quoting *Bennett*, 520 U.S. at 177-78). The challenged FAQ responses were always intended to be temporary, while Defendants "consider[], through notice-and-

[6] The Eleventh Circuit has stated that the APA's final-agency-action requirement is a matter of subject-matter jurisdiction. *See, e.g.*, *Nat'l Parks Conservation Ass'n v. Norton*, 324 F.3d 1229, 1236 (11th Cir. 2003); *accord LabMD, Inc. v. FTC*, 776 F.3d 1275, 1280 (11th Cir. 2015).

comment rulemaking, whether" these disclosure "requirement[s] remain[] appropriate." Ex. 2 at 2. And although they have not yet proposed or finalized a new rule on this subject, doing so remains Defendants' intent. It is that rule that will eventually represent "the consummation of the agency's decisionmaking process" on this issue, *Hawkes*, 578 U.S. at 597—not these FAQ responses.

Plaintiff's failure to satisfy the second final-agency-action requirement—that is, to identify an agency action "by which rights or obligations have been determined, or from which legal consequences will flow," *id.*—is even clearer. The FAQ responses state that they are "intended only to provide clarity to the public regarding existing requirements under the law," they "do not have the force and effect of law," and they "are not meant to bind the public in any way." Ex. 2 at 1. Rather than create or alter new legal obligations, these documents "answer questions from stakeholders to help people understand the law and promote compliance." *Id.* But they do not actually change the legal obligations to which regulated parties are subject—those remain set forth in the relevant statutory provisions, 42 U.S.C. § 18031(e)(3); *id.* § 300gg-15a, and in the Transparency in Coverage rule, 85 Fed. Reg. at 72158. None of those legal obligations was altered by Defendants' announcement of its (partial, temporary, and non-binding) intent not to bring certain specific types of enforcement actions—just as marijuana's legality under federal law is unchanged by guidance adjusting the Executive Branch's enforcement posture,[7] and immigration law is unaltered by

[7] *See, e.g.*, Dep't of Justice, *Guidance Regarding Marijuana Enforcement* (Aug. 29, 2013), https://perma.cc/8Y6M-6D53, at 4 ("As with the Department's previous statements on this subject,

changes to the immigration enforcement priorities that happen in every new administration.[8] The FAQ responses themselves make this clear. *See, e.g.*, Ex. 2 at 1 (before discussing enforcement discretion, summarizing what the "TiC Final Rules require").

IV. Plaintiff's notice-and-comment claim is meritless.

For the reasons above, the Court need not (and should not) reach the merits of Plaintiff's only claim. If the Court were to reach the merits, however, the FAQ responses did not need to go through notice and comment before they were posted on agency websites. That is because they qualify as "general statements of policy," 5 U.S.C. § 553(b)(A), and are thus explicitly exempt from notice-and-comment requirements under the plain text of the APA.

a. At the outset, two threshold matters regarding the appropriate legal standard warrant correction and clarification. First, Plaintiff's merits arguments proceed from the assumption that "[o]nce an agency has enacted a policy through notice-and-comment rulemaking, it cannot change that policy without following the same procedures used to enact it." Compl. ¶ 19; *see also* Pl.'s MSJ at 18-19. Although that used to be the law (at least, in the D.C. Circuit), it isn't anymore.

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this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law.").

[8] *See, e.g.*, *Arizona v. Biden*, 40 F.4th 375, 381-82 (6th Cir. 2022) (Sutton, C.J.) (describing this historical practice in concluding that challenge to immigration enforcement priorities was unlikely to succeed on the merits due to lack of Article III standing, lack of final agency action, and because the relevant decisions were committed to agency discretion by law under *Heckler v. Chaney*).

In the D.C. Circuit, it used to be "that an agency must use the APA's notice-and-comment procedures when it wishes to issue a new interpretation of a regulation that deviates significantly from one the agency has previously adopted." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 95 (2015) (summarizing *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579 (D.C. Cir. 1997)). When confronted with the question of whether that principle "is consistent with the APA," however, the Supreme Court held "that it is not." *Id.* The D.C. Circuit's prior approach "improperly impose[d] on agencies an obligation beyond the 'maximum procedural requirements' specified in the APA" itself. *Id.* at 100 (quoting *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978)).

Accordingly, much of the pre-*Perez* D.C. Circuit law that Plaintiff relies upon here—which predates the Supreme Court's rejection of the D.C. Circuit's maximalist approach to notice-and-comment rulemaking—can be disregarded. Instead, the Court should consider only whether the FAQ responses fit within the definition of "general statements of policy," 5 U.S.C. § 553(b)(A), as that statutory term of art has been interpreted by the Supreme Court and the Eleventh Circuit. *See infra* at 26-28. And it makes no difference to that analysis whether (and to what extent) the FAQ responses depart from the Transparency in Coverage rule itself—which did go through notice and comment, but which is not before the Court.

Second, Plaintiff's motion makes another, related category error: Plaintiff argues at length that the FAQ responses are *not* "interpretive rules," but rather are "legislative rules" that "must go through notice and comment." Pl.'s MSJ at 18-21.

But the APA exempts from notice-and-comment all "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). In other words, if the challenged FAQ responses are "general statements of policy," *id.*—as Defendants argue, *infra*—then it does not matter that they do not *also* qualify under the distinct exception for "interpretive rules." Defendants have never argued (and do not now argue) that the FAQ responses are interpretive rules. So, once again, most of Plaintiff's arguments (and most of Plaintiff's authority) can be set aside—Plaintiff's filing simply does not address the key merits question.

b. With that out of the way, the central merits question here is whether the challenged FAQ responses qualify as "general statements of policy." 5 U.S.C. § 553(b). The APA itself offers no definition of that phrase, which once led an Eleventh Circuit panel to lament that "analyzing a rule within the general statement of policy exception is akin to wandering lost in the Serbonian Bog." *Jean v. Nelson*, 711 F.2d 1455, 1480 (11th Cir. 1983), *on reh'g en banc*, 727 F.2d 957 (11th Cir. 1984) (vacating as moot), *aff'd on other grounds*, 472 U.S. 846 (1985).

In the intervening decades, however, both the Supreme Court and the Eleventh Circuit have provided more guidance. According to the Supreme Court, the APA's "general statements of policy" exception covers "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln*, 508 U.S. at 197 (citations omitted). And the Eleventh Circuit has stated that, "[g]enerally, whether a particular agency proceeding announces a rule or a general policy statement depends upon whether the agency

action establishes a binding norm." *Nat'l Mining Ass'n v. Sec'y of Lab.*, 589 F.3d 1368, 1371 (11th Cir. 2009). To make that judgment, the Eleventh Circuit has identified three factors: "(1) the agency's expressed intentions as reflected by its characterization of the statement, (2) whether the statement was published in the Federal Register or the Code of Federal Regulations, and (3) whether the action has binding effects on private parties." *Id.*

Here, making things easy, all three factors point in the same direction. First, as for "the agency's expressed intentions as reflected by its characterization of the statement," *id.*, the FAQs make crystal clear what they are (and what they are not): "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way . . . . This document is intended only to provide clarity to the public regarding existing requirements under the law." Ex. 2 at 1; *see id.* ("[T]hese FAQs answer questions from stakeholders to help people understand the law and promote compliance."). The agency has thus unquestionably characterized these documents not as a "binding norm," but rather as statements of policy, designed to provide helpful guidance to regulated parties.

Second, as for "whether the statement was published in the Federal Register or the Code of Federal Regulations," *Nat'l Mining*, 589 F.3d at 1371, it was not—the FAQ responses were published only on Defendants' websites, which is again consistent with their role as informal agency policy statements exempt from notice and comment.

As for the third (and arguably most important) factor—"whether the action has binding effects on private parties," *id.*—once again, it plainly does not. As Defendants

explained on the first page of the FAQ responses, they are "intended only to provide clarity to the public regarding existing requirements under the law," they "do not have the force and effect of law," and they "are not meant to bind the public in any way." Ex. 2 at 1. Indeed, they are not even binding on the agency itself, which expressly reserved the right to "revisit" these policies "in the future." Ex. 3 at 2.

Plaintiff asserts that the FAQ responses "indefinitely suspend[] the obligation to provide prescription-drug price information under the TiC Rule." Pl.'s MSJ at 19. That is incorrect. The Rule remains in full effect. *See* 45 C.F.R. § 147.212(b). All that the FAQ responses do is "advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power," *Lincoln*, 508 U.S. at 197—in particular, how Defendants intend (at least for now) to exercise their enforcement discretion. *See, e.g.*, Ex. 2 at 1 (before discussing enforcement discretion, summarizing what the "TiC Final Rules require"). That is a hallmark of a statement of policy, rather than a binding norm with the "force and effect of law." *Perez*, 575 U.S. at 96.

V. Plaintiff's requested relief is overbroad.

For the reasons above, Plaintiff is not entitled to any relief. Even so, the scope of relief requested in Plaintiff's motion is overbroad. On top of its requests for declaratory relief and to "set[] aside" the FAQ responses,[9] Plaintiff also separately

[9] Although the Eleventh Circuit has stated that "vacatur . . . is the ordinary APA remedy," *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Engineers*, 781 F.3d 1271, 1290 (11th Cir. 2015), nothing in the APA authorizes such relief to extend beyond the parties to a case, *see, e.g.*, *Texas*, 143 S. Ct. at 1981 (Gorsuch, J., concurring) ("If the Congress that unanimously passed the APA in 1946 meant to overthrow the 'bedrock practice of case-by-case judgments with respect to the parties in each case' and vest courts with a 'new and far-reaching' remedial power, it surely chose an obscure way to do it.") (quoting *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C. J., concurring)).

requests "a permanent injunction barring the Agencies from implementing" them. Pl.'s MSJ at 23. For two reasons, that request should be denied, even if Plaintiff were to prevail on every other issue.

First, Plaintiff has not carried its burden to show entitlement to a permanent injunction, which is always "an act of equitable discretion by the district court," *eBay Inc. v. MercExchange*, LLC, 547 U.S. 388, 391 (2006)—even if the plaintiff has otherwise prevailed on the merits. Plaintiff's arguments about irreparable harm (Pl.'s MSJ at 23-24) simply restate its theory of Article III injury. But as discussed above, Plaintiff has suffered no legally cognizable harm at all, *see supra* at 10-19—let alone harm that is irreparable, for which the burden is even higher. *See, e.g.*, *Tex. All. for Retired Ams. v. Hughs*, 976 F.3d 564, 568 n.1 (5th Cir. 2020) (contrasting the "showing of standing that a plaintiff must show to overcome a motion to dismiss" with the higher burden necessary to support injunctive relief). And as for the public interest and the balance of the equities, Plaintiff states only that "[t]here is 'no public interest in the perpetuation of unlawful agency action.'" Pl.'s MSJ at 25 (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)). For the reasons above, Defendants' actions were lawful. But regardless, injunctive relief requires more—success on the merits is not enough. *See, e.g.*, *Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1097 (11th Cir. 2004) ("success on the merits" is only one of four factors). Accordingly, Plaintiff has not carried its burden to show entitlement to an injunction.

Second, Plaintiff's remedial theory is inconsistent with its merits theory. Plaintiff argues that Defendants failed to observe certain procedures required by the

APA before publishing FAQ responses on the internet. But even if that were correct, it would not mean that the agency *couldn't* announce the challenged enforcement policies—it would (at most) mean that Defendants had to go through notice and comment (or show good cause to skip notice and comment, *see* 5 U.S.C. § 553(b)(B)) before doing so. While Plaintiff leaves unclear what, exactly, it means by an injunction that would "permanently" prevent Defendants from "implementing" the policy reflected in the FAQs, such an injunction (depending on how it is worded) could forever deprive the agencies of their enforcement discretion on this issue. There is no basis for that result, which is inconsistent with Plaintiff's own theory and with basic principles of equity, under which "injunctive relief must be tailored to fit the nature and extent of the established violation," *Gibson v. Firestone*, 741 F.2d 1268, 1273 (11th Cir. 1984)—to say nothing of its deep tension with the principle that, under Article II of the Constitution, the power to "take care that the laws be faithfully executed" is "entrusted to the executive branch—and only to the executive branch." *Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 459 (D.C. Cir. 2001) (citing U.S. Const. art. II, § 3).

CONCLUSION

Plaintiff's complaint should be dismissed in its entirety, either for lack of subject-matter jurisdiction or for failure to state a claim upon which relief can be granted. Plaintiff's motion for summary judgment should then be denied as moot. In the alternative, the Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion for summary judgment.

Dated: July 28, 2023

Respectfully submitted,

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 2:23-cv-207-JLB-KCD

Exhibit 1

Press Release from the Foundation for Government Accountability (March 23, 2023)

FOR IMMEDIATE RELEASE
March 23, 2023

Contact: Adam Gibbs
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FGA v. HHS: The Fight for Transparent Drug Pricing

The Foundation for Government Accountability launches federal lawsuit to require the Biden administration to enforce drug price transparency rule.

Naples, FL—Today, the Foundation for Government Accountability (FGA) filed a federal lawsuit against the U.S. Departments of Health and Human Services (HHS), Labor, and Treasury for lack of enforcement of a drug price transparency rule which requires group health plans and health insurers to publish prescription drug prices to give consumers full pricing information for medications.

The Trump administration announced the Transparency in Coverage effort in 2019. The rule was finalized in 2020 and the drug price transparency provision was set to take effect on January 1, 2022. But before the rule could take effect, the Biden administration used an FAQ guidance document to block enforcement of the rule.

> "Two years of inaction on drug price transparency is enough. FGA is taking the fight for transparency to federal court to force the Biden administration to follow the law, without exception and without delay," **said Tarren Bragdon, President and CEO of FGA.** "Patients have a fundamental right to control their own health care decisions and that includes budgeting for medical expenses and prescriptions. Without full pricing information, families are left with higher costs and lower confidence in our health care system."
>
> **"**The American people deserve to make informed choices with all cards face up. The Biden administration has made that impossible by putting the needs of Big Pharma before the needs of patients," **added Tarren Bragdon.** "FGA is fighting for transparency that puts people first."

The Biden administration's refusal to enforce this rule effectively repeals the price transparency consumers were excepting to help lower medical expenses. Instead, more than 1,200 prescription drugs saw their prices increase faster than inflation between 2021 and 2022.

> "Refusing to enforce a rule on the books without following the formal process of withdrawing the rule is a violation of federal law. FGA is taking this fight directly to the federal court to order the implementation and enforcement of this drug price transparency rule," **said Stewart Whitson, FGA legal director**. "There are no excuses left for the Biden administration: Either they are for transparency or against. Since they won't implement the rule on their own as the law requires, we're asking the federal court to order them to, delivering the transparency consumers deserve."

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The Foundation for Government Accountability (FGA) is a non-profit, multi-state think tank that promotes public policy solutions to create opportunities for every American to experience the American Dream. To learn more, visit TheFGA.org.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
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THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

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Exhibit 2

Frequently Asked Questions – Part 49 (August 20, 2021)

FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 49

August 20, 2021

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA) and certain provisions of title I (the No Surprises Act) and title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (the CAA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Transparency in Coverage Machine-Readable Files

The Transparency in Coverage Final Rules (the TiC Final Rules) require non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets to disclose on a public website information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files.[1] The machine-readable file requirements of the TiC Final Rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q1: Will the Departments enforce the machine-readable file provisions in the TiC Final Rules?

Yes, subject to two exceptions, plans and issuers must make public machine-readable files disclosing in-network rates and out-of-network allowed amounts and billed charges. Under the first exception, as an exercise of enforcement discretion, the Departments will defer enforcement of the TiC Final Rules' requirement that plans and issuers publish machine-readable files relating to prescription drug pricing pending further rulemaking, as described below.[2] Under the second

[1] 85 FR 72158 (Nov. 12, 2020).
[2] 26 CFR 54.9815-2715A3(b)(1)(iii); 29 CFR 2590.715-2715A3(b)(1)(iii); and 45 CFR 147.211(b)(1)(iii).

exception, as an exercise of enforcement discretion, the Department will defer enforcement of the TiC Final Rules' requirement to publish the remaining machine-readable files until July 1, 2022, as described in Q2.

After the Departments finalized the TiC Final Rules, Congress enacted the CAA, which imposes important new transparency requirements on plans and issuers, including prescription drug reporting requirements under section 204 of division BB of the CAA. These requirements significantly changed the regulatory landscape since the TiC Final Rules were adopted. Moreover, stakeholders have expressed concern about potentially duplicative and overlapping reporting requirements for prescription drugs. For example, under the TiC Final Rules, plans and issuers must publicly post pricing information for all covered prescription drugs by January 1, 2022. Under section 204 of the No Surprises Act, however, plans and issuers must also report some of the same prescription drug pricing information to the Departments by December 27, 2021.

In response to the later statutory enactment and stakeholder concerns, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish machine-readable file related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Q2: Are plans and issuers required to make public the machine-readable files for in-network rates and out-of-network allowed amounts and billed charges for plan years (in the individual market, policy years) beginning on or after January 1, 2022?

The Departments recognize the number of CAA provisions plans and issuers are required to implement by January 1, 2022 and the considerable time and effort required to make the machine-readable files available in the form and manner required in the TiC Final Rules[3] at the same time. Therefore, with respect to plan or policy years beginning on or after January 1, 2022, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement to make public the machine-readable files for in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022.

On July 1, 2022, the Departments intend to begin enforcing the requirement that plans and issuers publicly disclose information related to in-network rates and out-of-network allowed amounts and billed charges for plan years (in the individual market, policy years) beginning on or after January 1, 2022. For 2022 plan years and policy years beginning subsequent to July 1, 2022, plans and issuers should thus post the machine-readable files in the month in which the plan year (in the individual market, policy year) begins, consistent with the applicability provision of the TiC Final Rules. HHS encourages states that are primary enforcers of this

[3] 26 CFR 54.9815-2715A3; 29 CFR 2590.715-2715A3; and 45 CFR 147.212.

requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Price Comparison Tools

The TiC Final Rules require plans and issuers to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request.[4] This information must be available for plan years (in the individual market, policy years) beginning on or after January 1, 2023, with respect to the 500 items and services identified by the Departments in Table 1 in the preamble to the TiC Final Rules,[5] and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024.[6]

Internal Revenue Code (Code) section 9819, Employee Retirement Income Security Act (ERISA) section 719, and Public Health Service (PHS) Act section 2799A-4, as added by section 114 of division BB of the CAA, require plans and issuers to offer price comparison guidance by telephone and make available on the plan's or issuer's website a "price comparison tool" that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider. This requirement is applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q3: How do the different regulatory and statutory requirements for the self-service price comparison tools under the TiC Final Rules and the CAA interact?

The TiC Final Rules created a comprehensive set of requirements for plan and issuer disclosure of estimated cost-sharing information through an online tool, and in paper form, upon request. These requirements for the disclosure of cost-sharing information would allow a participant, beneficiary, or enrollee to request cost-sharing information for a discrete covered item or service by billing code or descriptive term, according to the participant's, beneficiary's, or enrollee's request. Further, the TiC Final Rules require a plan or issuer to provide cost-sharing information for a covered item or service in connection with an in-network provider or providers, or an out-of-network allowed amount for a covered item or service provided by an out-of-network provider, according to the participant's, beneficiary's, or enrollee's request, permitting the individual to specify the information necessary for the plan or issuer to provide meaningful cost-sharing liability information.

Because the price comparison methods required by the CAA are largely duplicative of the internet-based self-service tool component of the TiC Final Rules, the Departments intend to propose rulemaking and seek public comment regarding, among other issues, whether

[4] 26 CFR 54.9815-2715A2(b); 29 CFR 2590.715-2715A2(b); and 45 CFR 147.211(b).
[5] 85 FR 72158; 72182 (Nov. 12, 2020).
[6] 26 CFR 54.9815-2715A2(c)(1); 29 CFR 2590.715-2715A2(c)(1); and 45 CFR 147.211(c)(1).

compliance with the internet-based self-service tool requirements of the TiC Final Rules satisfies the analogous requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A-4. These provisions, however, add a requirement that was not imposed under the TiC Final Rules: that price information also must be provided over the telephone upon request. Therefore, the Departments intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form, as described in the TiC Final Rules, must also be provided over the telephone upon request.

Additionally, because plans and issuers have already been expecting to implement the first phase (500 items and services) of the internet-based self-service tool of the TiC Final Rules for plan years (in the individual market, policy years) beginning on or after January 1, 2023 and have been working towards that applicability date, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement that a plan or issuer make available a price comparison tool (by internet website, in paper form, or telephone) before plan years (in the individual market, policy years) beginning on or after January 1, 2023, aligning the enforcement date of Code section 9819, ERISA section 719, and PHS Act section 2799A-4 with the TiC Final Rules requirements. Until that time, the Departments will focus on compliance assistance. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach. However, the Departments encourage plans and issuers with existing tools or programs to continue to make those tools or programs accessible. Plans and issuers are encouraged to work toward updating the standards of these tools and programs to meet the minimum requirements in the TiC Final Rules by the regulatory applicability date.

Transparency in Plan or Insurance Identification Cards

Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A–1(e), as added by section 107 of division BB of the CAA, require plans and issuers to include in clear writing, on any physical or electronic plan or insurance identification (ID) card issued to participants, beneficiaries, or enrollees, any applicable deductibles, any applicable out-of-pocket maximum limitations, and a telephone number and website address for individuals to seek consumer assistance. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q4: Will the Departments be issuing regulations addressing the ID card requirements prior to the effective date?

No. However, the Departments do intend to engage in future rulemaking addressing implementation of the ID card requirements, including how plans and issuers offering complex plan and coverage designs should represent information on an ID card. Pending future rulemaking, plans and issuers are expected to implement the ID card requirements using a good faith, reasonable interpretation of the statute.

Plans and issuers may design various, but reasonable, methods to comply with the law. When analyzing a plan's or issuer's efforts to comply with the ID card requirements, the Departments

will consider whether the plan's or issuer's provision of information on ID cards is reasonably designed and implemented to provide the required information to all participants, beneficiaries, and enrollees entitled to access it on their ID cards. More specifically, the Departments will consider each of the specific data elements included on relevant ID cards; whether any data element required, but not included on the face of an ID card, is made available through information that is provided on the ID card, as well as the mode by which any information absent from the card is made available; the date by which a plan or issuer makes required information available on relevant ID cards; and, for QHP issuers that offer plans through an Exchange, whether the ID card complies with applicable accessibility standards for people with disabilities and people with limited English proficiency under 45 CFR Part 92 and 45 CFR 155.205(c).

As an example, pending any implementing rulemaking, the Departments would not deem a plan or issuer to be out of compliance with ID card requirements where a plan or issuer includes on any physical or electronic ID card issued to participants, beneficiaries, or enrollees the following: the applicable major medical deductible and applicable out-of-pocket maximum, as well as a telephone number and website address for individuals to seek consumer assistance and access additional applicable deductibles and maximum out-of-pocket limits. Additional deductibles and out-of-pocket maximum limits could also be provided on a website that is accessed through a Quick Response code (commonly referred to as a QR code) on the participant's, beneficiary's, or enrollee's ID card or through a hyperlink in the case of a digital ID card.

Good Faith Estimate

PHS Act section 2799B–6, as added by section 112 of division BB of the CAA, requires providers and facilities, upon an individual's scheduling of items or services, or upon request, to inquire if the individual is enrolled in a health plan or health insurance coverage, and to provide a notification of the good faith estimate of the expected charges for furnishing the scheduled item or service and any items or services reasonably expected to be provided in conjunction with those items and services, including those provided by another provider or facility, with the expected billing and diagnostic codes for these items and services. If the individual is enrolled in a health plan or coverage (and is seeking to have a claim for the item or service submitted to the plan or coverage), the provider must provide this notification to the individual's plan or coverage. In the case that the individual is not enrolled in a health plan or coverage or does not seek to have a claim for the item or service submitted to the plan or coverage, the provider must provide this notification to the individual. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q5: Will HHS be issuing regulations addressing the Good Faith Estimate requirement prior to the statutory effective date?

HHS intends to issue regulations implementing good faith estimate requirements for individuals not enrolled in a health plan or coverage or who are not seeking to have a claim for the scheduled items or services submitted to the plan or coverage prior to the statutory effective date.

However, given the complexities of developing the technical infrastructure for transmission of the necessary data from providers and facilities to plans and issuers, HHS recognizes that

compliance with this section related to individuals who are enrolled in a health plan or coverage and are seeking to have a claim for the scheduled items or services submitted to the plan or coverage is likely not possible by January 1, 2022. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. HHS is of the view that insured consumers have existing recourse to challenge out-of-pocket costs through the internal claims and appeals and external review process described under existing law and regulations,[7] and are therefore not in the same position as uninsured consumers or consumers not seeking to submit a claim to their plan or coverage would be without enforcement by the CAA's statutory deadline. However, HHS will investigate whether additional interim solutions for insured consumers are feasible. HHS encourages states that are primary enforcers of this requirement with regard to providers and facilities to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach. HHS notes that any rulemaking to fully implement the requirements of PHS Act section 2799B–6 will include a prospective applicability date that gives providers and facilities a reasonable amount of time to comply with any new requirements.

Advanced Explanation of Benefits

Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A-1(f), as added by section 111 of division BB of the CAA, require plans and issuers, upon receiving a "good faith estimate" regarding an item or service as described in PHS Act section 2799B-6, to send a participant, beneficiary, or enrollee (through mail or electronic means, as requested by the participant, beneficiary, or enrollee) an Advanced Explanation of Benefits notification in clear and understandable language. The notification must include: (1) the network status of the provider or facility; (2) the contracted rate for the item or service, or if the provider or facility is not a participating provider or facility, a description of how the individual can obtain information on providers and facilities that are participating; (3) the good faith estimate received from the provider; (4) a good faith estimate of the amount the plan or coverage is responsible for paying, and the amount of any cost-sharing for which the individual would be responsible for paying with respect to the good faith estimate received from the provider; and (5) disclaimers indicating whether coverage is subject to any medical management techniques. The notice also must indicate that the information provided is only an estimate based on the items and services reasonably expected to be provided at the time of scheduling (or requesting) the item or service and is subject to change and any other information or disclaimer the plan or coverage determines appropriate that is consistent with information and disclaimers required under this section of the statute. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q6: Will the Departments be issuing regulations addressing the Advanced Explanation of Benefits prior to the effective date of January 1, 2022?

[7] *See* PHS Act section 2719; 26 CFR 54.9815–2719; 29 CFR 2590.715-2719; 45 CFR 147.136; 29 CFR 2560.503-1.

No. The Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers, starting January 1, 2022, the good faith estimates required under PHS Act section 2799B-6, which plans and issuers must then include in the Advanced Explanation of Benefits. Stakeholders have requested that the Departments delay the applicability date of this provision until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with this section is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an Advanced Explanation of Benefits. However, HHS will investigate whether interim solutions are feasible for insured consumers. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Prohibition on Gag Clauses on Price and Quality Data

Code section 9824, ERISA section 724, and PHS Act section 2799A-9, as added by section 201 of division BB of the CAA, prohibit plans and issuers from entering into an agreement with a provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict the plan or issuer from: (1) providing provider-specific cost or quality of care information or data to referring providers, the plan sponsor, participants, beneficiaries, or enrollees, or individuals eligible to become participants, beneficiaries, or enrollees of the plan or coverage; (2) electronically accessing de-identified claims and encounter data for each participant, beneficiary, or enrollee; and (3) sharing such information, consistent with applicable privacy regulations. In addition, plans and issuers must annually submit to the Departments an attestation of compliance with these requirements. These provisions are effective December 27, 2020 (the date of enactment of the CAA).

Q7: Will the Departments be issuing regulations addressing the prohibition on gag clauses?

No. The statutory language of section 201 of division BB of the CAA is self-implementing, and the Departments do not expect to issue regulations on gag clauses at this time. Until any further guidance is issued, plans and issuers are expected to implement the requirements prohibiting gag clauses using a good faith, reasonable interpretation of the statute. However, the Departments intend to issue implementation guidance to explain how plans and issuers should submit their attestations of compliance and anticipate beginning to collect attestations starting in 2022.

Protecting Patients and Improving the Accuracy of Provider Directory Information

Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A-5(a) and (b), as added by section 116 of division BB of the CAA, establish standards related to provider directories that are intended to protect participants, beneficiaries, and enrollees with

benefits under a plan or coverage from surprise billing. These provisions generally require plans and issuers to establish a process to update and verify the accuracy of provider directory information and to establish a protocol for responding to requests by telephone and electronic communication from a participant, beneficiary, or enrollee about a provider's network participation status. If a participant, beneficiary, or enrollee is furnished an item or service by a nonparticipating provider or nonparticipating facility, and the individual was provided inaccurate information by the plan or issuer under the required provider directory or response protocol that stated that the provider or facility was a participating provider or participating facility, the plan or issuer cannot impose a cost-sharing amount that is greater than the cost-sharing amount that would be imposed for items and services furnished by a participating provider or participating facility and must count cost-sharing amounts toward any in-network deductible or in-network out-of-pocket maximum. These provisions are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Code section 9820(c), ERISA section 720(c), and PHS Act section 2799A-5(c), as added by section 116 of division BB of the CAA, require plans and issuers to make certain disclosures regarding balance billing protections to participants, beneficiaries, and enrollees that are similar to disclosure requirements applicable to providers and facilities under PHS Act section 2799B-3, as implemented in 45 CFR 149.430. In general, plans and issuers must make publicly available, post on a public website of the plan or issuer, and include on each Explanation of Benefits for an item or service with respect to which the requirements under Code section 9816, ERISA section 716, and PHS Act section 2799A-1 apply, information on: (1) the requirements under those sections, as applicable; (2) the requirements and prohibitions applied under PHS Act sections 2799B-1 and 2799B-2; (3) other applicable state laws on out-of-network balance billing; and (4) contacting appropriate state and federal agencies if an individual believes the provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q8: Will the Departments be issuing regulations addressing the provider directory requirements prior to January 1, 2022?

No. The Departments intend to undertake notice and comment rulemaking to implement the provider directory requirements, but rulemaking will not be issued until after January 1, 2022. Until further rulemaking is issued, plans and issuers are expected to implement these provisions using a good faith, reasonable interpretation of the statute. Pending any implementing rulemaking, the Departments will not deem a plan or issuer to be out of compliance with provider directory requirements as long as the plan or issuer imposes only a cost-sharing amount that is not greater than the cost-sharing amount that would be imposed for items and services furnished by a participating provider, and counts those cost-sharing amounts toward any deductible or out-of-pocket maximum, in a case when a participant, beneficiary, or enrollee receives items and services from a nonparticipating provider and the individual was provided inaccurate information by the plan or issuer under a provider directory or response protocol that stated that the provider or facility was a participating provider or participating facility.

Q9: Will the Departments be issuing regulations addressing the balance billing disclosure requirements applicable to plans and issuers prior to the effective date of the requirements?

No. As stated in the preamble to the Requirements Related to Surprise Billing; Part 1 (July 2021 Interim Final Rules), the Departments may address the balance billing requirements in more detail in future guidance or notice and comment rulemaking. Until further guidance or rulemaking is issued, plans and issuers are expected to implement these requirements using a good faith, reasonable interpretation of the statute. The Departments will take into account the statutory applicability date and the timeframe for implementation when determining good faith compliance with the law.[8]

To reduce burdens and facilitate compliance with these disclosure requirements, the Departments issued a model disclosure notice that may be used to satisfy the disclosure requirements regarding the balance billing protections.[9] As the Departments stated in the July 2021 Interim Final Rules, the Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of Code section 9820(c), ERISA section 720(c), and PHS Act section 2799A-5(c), if all other applicable requirements are met.[10]

Continuity of Care

Code section 9818, ERISA section 718, and PHS Act sections 2799A-3 and 2799B-8, as added by section 113 of division BB of the CAA, establish continuity of care protections that apply in the case of an individual with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer. These protections ensure continuity of care in instances when terminations of certain contractual relationships result in changes in provider or facility network status. These provisions are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q10: Will the Departments be issuing regulations addressing the continuity of care requirements prior to January 1, 2022?

No. The Departments intend to undertake notice and comment rulemaking to implement the continuity of care requirements, but do not expect to do so until after January 1, 2022. The Departments note that any rulemaking to implement these provisions will include a prospective applicability date that provides plans, issuers, providers, and facilities with a reasonable amount of time to comply with any new requirements. Until rulemaking to fully implement these provisions is adopted and applicable, plans, issuers, providers, and facilities are expected to implement the requirements using a good faith, reasonable interpretation of the statute.

[8] 86 FR 36872, 36877 (July 13, 2021).
[9] The model disclosure notice is available at https://www.cms.gov/httpswwwcmsgovregulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10780.
[10] 86 FR at 36877.

Grandfathered Health Plans

Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans.[11] For example, grandfathered health plans are subject neither to the requirement to cover certain preventive services without cost sharing under section 2713 of the PHS Act, nor to the annual limitation on cost sharing set forth under section 2707(b) of the PHS Act. If a plan or coverage were to lose its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements.

Q11: Are grandfathered health plans generally subject to the requirements under the CAA?

Yes. The CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of division BB of the CAA amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protection provisions of division BB of the CAA, including those related to choice of health care professional, apply to grandfathered health plans.

Reporting on Pharmacy Benefits and Drug Costs

Code section 9825, ERISA section 725, and PHS Act section 2799A-10, as added by section 204 of division BB of the CAA, include certain reporting requirements for plans and issuers. These reporting requirements primarily relate to prescription drug expenditures, requiring that plans and issuers submit relevant information to the Departments. This information includes general information regarding the plan or coverage, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered. Plans and issuers must also report the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.

Additionally, plans and issuers must report, among other things, total spending by the plan or coverage broken down by the type of costs, including hospital costs and provider and clinical service costs, for primary care and specialty care separately; spending on prescription drugs by the plan or coverage as well as by participants, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable. Plans and issuers must report the impact on premiums of rebates, fees, and any other remuneration paid by drug

[11] For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that the Affordable Care Act added or amended and that were incorporated into the Code and ERISA, visit https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf.

manufacturers to the plan or coverage or its administrators or service providers with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year. Finally, plans and issuers must report any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration.

Finally, these provisions require the Departments to issue biannual public reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the impact of prescription costs on premium rates, aggregated in such a way that no drug or plan specific information will be made public. In addition, these reports must not include any confidential or trade secret information submitted to the Departments.

Q12: How do the Departments intend to implement the reporting requirements for plans and issuers to submit information to the Departments related to pharmacy benefits and drug costs?

The Departments intend to issue regulations that will address the pharmacy benefit and drug cost reporting requirements. However, the Departments recognize the significant operational challenges that plans and issuers may encounter in complying with these reporting requirements by the statutory deadlines set forth in the statute. The Departments anticipate that plans and issuers may also need additional time to modify contractual agreements to enable disclosure and transfer of the required data between various entities; to develop internal processes and procedures; and to identify, compile, prepare, and validate the required data. Accordingly, the Departments will defer enforcement of the requirement to report the specified information by the first deadline for reporting on December 27, 2021 or the second deadline for reporting on June 1, 2022, pending the issuance of regulations or further guidance. Until regulations or further guidance is issued, the Departments strongly encourage plans and issuers to start working to ensure that they are in a position to be able to begin reporting the required information with respect to 2020 and 2021 data by December 27, 2022. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach, and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 2:23-cv-207-JLB-KCD

Exhibit 3

Frequently Asked Questions – Part 53 (April 19, 2022)

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 53

April 19, 2022

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Transparency in Coverage Machine-Readable Files

The Transparency in Coverage Final Rules (the TiC Final Rules) require non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets to disclose, on a public website, information regarding in-network rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files.[1] The machine-readable file requirements of the TiC Final Rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The Departments previously announced that they will defer enforcement of the requirements related to machine-readable files disclosing in-network and out-of-network data until July 1, 2022.[2] The Departments also previously announced that they will defer enforcement of the requirement that plans and issuers publish a machine-readable file related to prescription drugs while they consider, through notice-and-comment rulemaking, whether this requirement remains appropriate.[3]

The TiC Final Rules require plans and issuers to publish all applicable rates, which may include one or more of the following: negotiated rates, underlying fee schedule rates, or derived amounts for all covered items and services in the In-network Rate File. The Departments specify in the preamble to the TiC Final Rules that the In-network Rate File requirement applies to plans and issuers regardless of the type of payment model or models under which they provide coverage.[4] If the plan or issuer does not use negotiated rates for reimbursement of items and services, the plan or issuer must report derived amounts, to the extent those amounts already are calculated in the normal course of business. The TiC Final Rules do not require plans or issuers to develop a new methodology for providing derived amounts. If the plan or issuer uses underlying fee schedule rates for calculating cost sharing, the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rates or derived amounts.

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[1] 26 CFR 54.9815-2715A3; 29 CFR 2590.715-2715A3; and 45 CFR 147.212; 85 FR 72158 (Nov. 12, 2020).

[2] *See* FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, Q 2, available at: https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.

[3] *See id.* at Q 1.

[4] 85 FR at 72226.

Notably, the TiC Final Rules require that these rates be reflected in the In-network Rate File as dollar amounts. While there are many alternative reimbursement arrangements that do not have a dollar amount associated with particular items and services before the item or service is provided or rendered, a dollar amount can still be determined in some instances under these models. Accordingly, in the preamble to the TiC Final Rules, the Departments provide a list of alternative reimbursement arrangements and summarize general reporting expectations for these models, while acknowledging that this list is not exhaustive, as there may be other alternative reimbursement or contracting arrangements in use.[5] Specifically, the Departments summarize the general reporting expectations for several alternative reimbursement arrangements, including bundled payment arrangements and capitation arrangements (including sole capitation arrangements and partial capitation arrangements), reference-based pricing without a defined network, reference-based pricing with a defined network, and value-based purchasing. For example, the preamble clarifies that for payment arrangements under which adjustments are made after care is provided, the plan or issuer should disclose the base negotiated rate before adjustments are applied.[6]

After the TiC Final Rules were issued, stakeholders have utilized GitHub and other forums to raise to the Departments' attention alternative reimbursement arrangements for which reporting a current and accurate dollar amount for items and services in the In-network Rate File before the item or service is provided or rendered may not be possible. Specifically, stakeholders have asked the Departments how to report dollar amounts for negotiated rates that result from certain "percentage-of-billed charges" contract arrangements, under which a dollar amount can be determined only retrospectively because the agreement between the plan or issuer and the in-network provider states that the plan or issuer will pay a fixed percentage of the billed charges. It is the Departments' understanding that these types of arrangements are not uncommon for certain types of items or services (such as low-volume procedures or high-cost, outlier inpatient care) and that plans and issuers may enter into these arrangements, in part, because the arrangements include limitations on a provider's ability to charge amounts for furnished items and services that significantly vary from an established rate schedule (such as a hospital's chargemaster)—though the rates reflected in such a schedule may not necessarily be the amounts charged. Thus, plans and issuers may be able to estimate the potential range of rates in advance, but they cannot determine accurate dollar amounts until a claim is made.

To address these situations, the Departments are providing an enforcement safe harbor for satisfying the reporting requirements for plans and issuers that use alternative reimbursement arrangements that do not permit the plans and issuers to derive with accuracy specific dollar amounts contracted for covered items and services in advance of the provision of that item or service, or that otherwise cannot disclose specific dollar amounts according to the schema as provided in the Departments' technical implementation guidance through GitHub. This safe harbor is further described in Q1 and Q2 of these FAQs Part 53.

The Departments will monitor the implementation of the machine-readable files requirements and may revisit this safe harbor in the future, including when access to underlying fee schedules becomes more widely available in connection with the development of pathways for providers to transmit expected charges to plans and issuers in support of the development of advanced explanations of benefits as required under Internal Revenue Code section 9816(f), the Employee

[5] *Id.* at 72158, 72226.

[6] *Id.* at 72228.

Retirement Income Security Act section 716(f), and the Public Health Service Act section 2799A-1(f), as added by Section 111 of title I (the No Surprises Act) of division BB of the Consolidated Appropriations Act, 2021.[7] HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not regard a state as failing to substantially enforce this requirement if it takes such an approach.

This safe harbor will not apply to a particular alternative reimbursement arrangement if the Departments determine that the particular arrangement can sufficiently disclose a dollar amount. The Departments encourage the continued utilization of GitHub to submit suggestions on ways the schema should support alternative reimbursement arrangements.

Q1: In the In-network Rate File, how can plans and issuers report applicable rates for specific items or services provided under "percentage-of-billed-charges" contracts if an exact dollar amount cannot be determined for those items or services prospectively?

For contractual arrangements under which a plan or issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated, plans and issuers may report a percentage number, in lieu of a dollar amount. For example, if a negotiated arrangement for a particular item or service provides for reimbursement for 70 percent of billed charges, and the plan or issuer is unable to ascertain the dollar amount that will be billed for the item or service in advance, the Departments will permit the plan or issuer to report the in-network rate using the applicable percentage of 70.

Documentation specific to the format requirements for percentage-of-billed-charges arrangements can be found here: https://github.com/CMSgov/price-transparency-guide/tree/master/schemas/in-network-rates#negotiated-price-object.

Q2: In the In-network Rate File, how can plans and issuers report applicable in-network rates for items and services provided under alternative reimbursement arrangements that are not supported by the schema or require additional context to be understood?

In situations in which alternative reimbursement arrangements are not supported by the schema, or in instances where the contractual arrangement requires the submission of additional information to describe the nature of the negotiated rate, plans and issuers may disclose in an open text field a description of the formula, variables, methodology, or other information necessary to understand the arrangement. The open text field may be utilized for reporting only if the schema—as provided in the Departments' technical implementation guidance through GitHub—does not otherwise support the arrangement.

Documentation specific to use of the open text field can be found here: https://github.com/CMSgov/price-transparency-guide/tree/master/schemas/in-network-rates#negotiated-price-object.

[7] Pub. L. No. 116-260 (2020).

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 2:23-cv-207-JLB-KCD

Exhibit 4

Frequently Asked Questions – Part 55 (August 19, 2022)

FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 55

August 19, 2022

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act and title I (the No Surprises Act)[1] of Division BB of the Consolidated Appropriations Act, 2021. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

The No Surprises Act

Sections 102 and 103 of the No Surprises Act added section 9816 to the Internal Revenue Code (Code), section 716 to the Employee Retirement Income Security Act (ERISA), and section 2799A-1 to the Public Health Service Act (PHS Act). Section 104 of the No Surprises Act added sections 2799B-1 and 2799B-2 to the PHS Act. Section 105 of the No Surprises Act added section 9817 to the Code, section 717 to ERISA, and sections 2799A-2 and 2799B-5 to the PHS Act. These provisions provide protections against surprise medical bills for out-of-network emergency services; out-of-network non-emergency services provided with respect to a visit to a participating health care facility; and out-of-network air ambulance services.

Sections 102 and 104 of the No Surprises Act added section 9820(c) to the Code, section 720(c) to ERISA, and sections 2799A-5(c) and 2799B-3 to the PHS Act, generally requiring group health plans, health insurance issuers offering group or individual health insurance coverage, and health care providers and health care facilities to make certain disclosures regarding balance billing protections to the public and to individual participants, beneficiaries, and enrollees.

The Departments issued interim final rules in July 2021 to implement certain of these provisions (July 2021 interim final rules).[2] The July 2021 interim final rules generally prohibit balance billing and limit cost sharing for out-of-network services subject to the surprise billing provisions of the No Surprises Act. Under the No Surprises Act and its implementing regulations, cost-sharing amounts for out-of-network emergency services and applicable non-emergency items and services must be calculated based on the recognized amount, which is:

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[1] The No Surprises Act was enacted as title I of Division BB of the Consolidated Appropriations Act, 2021. Pub. L. 116-260, 134 Stat. 1182 (2020).

[2] 86 FR 36872 (July 13, 2021). The July 2021 interim final rules are generally applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The HHS-only regulations that apply to health care providers, facilities, and providers of air ambulance services are generally applicable with respect to items and services furnished during plan years (in the individual market, policy years) beginning on January 1, 2022.

(1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act (SSA);

(2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or

(3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the qualifying payment amount (QPA).

Cost-sharing amounts for out-of-network air ambulance services must be calculated using the lesser of the billed charge or the QPA.

The QPA is generally the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished, increased for inflation.[3] The median contracted rate is determined with respect to all plans of the plan sponsor (or, if applicable, administering entity) or all coverage offered by the issuer that are offered in the same insurance market. The July 2021 interim final rules establish the methodology for calculating the QPA, including when a plan or issuer lacks sufficient information to calculate a median of contracted rates with participating providers, facilities, or providers of air ambulance services.

Applicability to No-Network and Closed Network Plans

Q1: Do the balance billing prohibitions of the No Surprises Act apply to nonparticipating providers, emergency facilities, and providers of air ambulance services when providing emergency services, certain non-emergency services, or air ambulance services to a participant, beneficiary, or enrollee who is covered under a group health plan or group or individual health insurance coverage that does not have a network of providers, such as a plan that utilizes reference-based pricing?

Yes, with respect to emergency services and air ambulance services. The balance billing prohibitions in sections 2799B-1 and 2799B-5 of the PHS Act, implemented at 45 CFR 149.410 and 149.440, apply to nonparticipating emergency facilities, nonparticipating providers, and nonparticipating providers of air ambulance services, with respect to any participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is furnished emergency services or air ambulance services (for which benefits are provided under the plan or coverage). A nonparticipating provider is any physician or other health care provider that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

[3] *See* Rev. Proc. 2022-11, 2022-3 IRB 449, available at https://www.irs.gov/pub/irs-drop/rp-22-11.pdf. *See also* Notice 2022-11, 2022-14 IRB 939, available at https://www.irs.gov/pub/irs-drop/n-22-11.pdf.

A nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to post-stabilization emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively. These definitions[4] and the protections afforded to participants, beneficiaries, or enrollees related to emergency services and air ambulance services are not dependent on whether the group health plan or group or individual health insurance coverage has a network of providers.

In contrast, the provisions that prohibit balance billing for non-emergency services apply only to services provided by a nonparticipating provider with respect to a visit to a participating health care facility. A participating health care facility is any health care facility[5] that has a contractual relationship directly or indirectly with a plan or issuer setting forth the terms and conditions upon which the relevant item or service is furnished to the participant, beneficiary, or enrollee under the plan or coverage.[6] Therefore, as stated in the preamble to the July 2021 interim final rules, the prohibitions on balance billing for non-emergency services provided by nonparticipating providers with respect to a visit to certain participating facilities would never be triggered if a plan or coverage does not have a network of participating facilities.[7]

Q2: Do the surprise billing provisions of the No Surprises Act apply to a group health plan or group or individual health insurance coverage that does not have a network of providers, such as a plan that utilizes reference-based pricing?

Yes, with respect to emergency services and air ambulance services. The provisions that limit cost sharing for out-of-network emergency services apply if a plan or issuer provides or covers any benefits for emergency services and the services are provided by a nonparticipating provider or nonparticipating emergency facility. Similarly, the provisions that limit cost sharing for out-of-network air ambulance services apply if a plan or issuer provides or covers any benefits for air ambulance services and those services are provided by a nonparticipating provider of air ambulance services. As stated in Q1, the definitions of nonparticipating provider or nonparticipating emergency facility and the protections afforded to participants, beneficiaries, or

[4] The implementing regulations define "nonparticipating provider" and "nonparticipating emergency facility" but do not include a separate definition of "nonparticipating provider of air ambulance services." The regulations define "provider of air ambulance services" to mean an entity that is licensed under applicable state and Federal law to provide air ambulance services. 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30. Similar to the definition of "nonparticipating provider," the Departments consider a provider of air ambulance services to be a nonparticipating provider of air ambulance services if the provider of air ambulance services does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of air ambulance services under the plan or coverage, respectively.

[5] Under the July 2021 interim final rules, a health care facility is defined, in the context of non-emergency services, as one of the following: (1) a hospital (as defined in section 1861(e) of the SSA), (2) a hospital outpatient department, (3) a critical access hospital (as defined in section 1861(mm)(1) of the SSA), and (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the SSA.

[6] 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.

[7] 86 FR 36872, 36904 (July 13, 2021).

enrollees related to emergency services and air ambulance services are not dependent on whether the group health plan or group or individual health insurance coverage has a network of providers.[8]

In contrast, as also noted in Q1, the provisions that limit cost sharing for non-emergency services apply only to services provided by a nonparticipating provider with respect to a visit to a participating health care facility. Therefore, as stated in the preamble to the July 2021 interim final rules, the provisions that limit cost sharing for non-emergency services provided by nonparticipating providers with respect to a visit to certain participating facilities would never be triggered if a plan or coverage does not have a network of participating facilities.[9]

Q3: How must a group health plan or group or individual health insurance coverage that does not have a network of providers calculate cost sharing for out-of-network items and services that are subject to the surprise billing provisions of the No Surprises Act?

In general, for emergency services furnished by a nonparticipating provider or a nonparticipating emergency facility, and for non-emergency services furnished by nonparticipating providers with respect to a visit to a participating health care facility, cost sharing is calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for the services, as defined by the statute and in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.

If an All-Payer Model Agreement or specified state law applies, the plan or issuer must calculate cost sharing for out-of-network services that are subject to the No Surprises Act (other than out-of-network air ambulance services) based on the amount determined by the All-Payer Model Agreement or specified state law.

If an All-Payer Model Agreement or specified state law does not apply (including for all out-of-network air ambulance services subject to the No Surprises Act), cost sharing is determined based on the lesser of the billed charge or the QPA.

The July 2021 interim final rules establish the methodology for calculating the QPA, including when a plan or issuer lacks sufficient information to calculate a median contracted rate. If a plan or issuer does not have sufficient information to calculate a median contracted rate—including because the plan or issuer does not have a network of participating providers for the item or service involved—the plan or issuer must calculate the QPA using an eligible database, in accordance with the regulations.[10]

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[8] *See* Q4 regarding the calculation of the out-of-network rate for out-of-network items and services that are subject to the surprise billing provisions of the No Surprises Act.

[9] *Id*.

[10] 26 CFR 54.9816-6T(c)(3), 29 CFR 2590.716-6(c)(3), and 45 CFR 149.140(c)(3). Note that when a plan or issuer has sufficient information to calculate the median of its contracted rates, but payments under its contractual agreements are not on a fee-for-service basis (such as bundled or capitation payments), the plan or issuer is required under the July 2021 interim final rules to calculate the QPA using underlying fee schedule rates or derived amounts. The regulations do not permit a plan or issuer to use underlying fee schedules or derived amounts to calculate the QPA in any other circumstance.

Example: Person X is enrolled in a group health plan that does not have a network of providers or facilities. Under the terms of the plan, the plan pays a reference-based amount, based on a fee schedule, for items and services covered under the plan. Participants and beneficiaries generally are responsible for the difference between the provider's or facility's billed charge and the payment amount set under the plan. The plan applies a deductible, after which the plan does not impose cost sharing for covered services. Person X has satisfied the deductible for the current plan year. Person X is taken to a hospital emergency room for emergency services, and the facility sends the plan a bill for $1,200 for CPT code 99282. There is no All-Payer Model Agreement or specified state law that is applicable with respect to the plan. Under the plan's terms, the plan would pay a reference-based amount of $800 for CPT code 99282 after the deductible is satisfied.

Conclusion: Under the No Surprises Act, the emergency facility is prohibited from billing Person X for an amount that exceeds Person X's cost-sharing requirement. Person X's cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by the nonparticipating emergency facility was equal to the recognized amount for the services. Since neither an All-Payer Model Agreement nor a specified state law applies, the plan must calculate the recognized amount using the QPA. Because the plan does not have a network from which to calculate median contracted rates, the QPA is calculated using an eligible database. Using an eligible database, the plan determines the applicable QPA is $900. Because Person X's deductible has been satisfied and the plan does not impose other cost-sharing requirements for emergency services, Person X owes no cost sharing and cannot be billed or held liable for the $400 difference between the amount billed by the facility ($1,200) and the plan's reference-based amount ($800).

Q4: How must a group health plan or group or individual health insurance coverage that does not have a network of providers calculate the out-of-network rate for out-of-network items and services that are subject to the surprise billing provisions of the No Surprises Act?

If an All-Payer Model Agreement or specified state law applies, the plan or issuer must calculate the out-of-network rate for out-of-network services that are subject to the No Surprises Act based on the amount determined by the All-Payer Model Agreement or specified state law, consistent with the definition of "out-of-network rate" set forth in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.

If an All-Payer Model Agreement or specified state law does not apply, the out-of-network rate is the amount the nonparticipating provider, emergency facility, or provider of air ambulance services and the plan or issuer agree upon as the amount of payment for the item or service (including if the amount agreed upon is the initial payment sent by the plan or issuer or is agreed upon through negotiations with respect to such item or service). However, if the parties enter into the Federal independent dispute resolution (IDR) process and do not agree upon a payment amount before the date on which the certified IDR entity makes a determination with respect to such item or service, then the amount determined by the certified IDR entity is the out-of-

network rate. As a result, a plan or coverage that utilizes a reference-based pricing structure (or a similar network design) and does not have a network of providers may be required to make a total payment that is different than the plan's or issuer's reference-based amount for items and services that are subject to the surprise billing provisions of the No Surprises Act.

Q5: How do the maximum-out-of-pocket requirements of section 2707(b) of the PHS Act apply to items and services subject to the No Surprises Act for a non-grandfathered large group market plan, or self-insured group health plan, that does not have a network of providers?

In October 2014, the Departments issued FAQs Part XXI, which provide guidance on the maximum-out-of-pocket (MOOP) requirements under section 2707(b) of the PHS Act. The FAQs state that the Departments would not consider a non-grandfathered large group market plan or self-insured group health plan that utilizes reference-based pricing (or a similar network design) as failing to comply with the MOOP requirements of section 2707(b) of the PHS Act if the plan treats providers that accept the reference amount as the only in-network providers for purposes of section 2707(b) of the PHS Act, as long as the plan or issuer uses a reasonable method to ensure that it offers adequate access to quality providers at the reference-based price.[11] FAQs Part XXI set forth the specific factors the Departments will consider when evaluating whether such a plan is using a reasonable method. One of those factors is the type of service. Those FAQs state that a plan or issuer that uses reference-based pricing and treats providers that accept the reference amount as the only in-network providers for purposes of the MOOP requirements should apply only to those services for which the period between identification of the need for care and provision of the care is long enough for consumers to make an informed choice of provider. Those FAQs also state that limiting or excluding out-of-pocket spending from counting toward the MOOP with respect to providers that do not accept the reference-based price would not be considered reasonable with respect to emergency services.[12]

Note that the term "emergency services" was previously defined under section 2719A of the PHS Act and its implementing regulations, and that provision was sunset and recodified by the No Surprises Act. "Emergency services" are now defined in 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and 45 CFR 149.110(c)(2) to include certain items and services furnished after

[11] The Departments previously stated that if a plan includes a network of providers, the plan may, but is not required to, count an individual's out-of-pocket spending for out-of-network items and services toward the plan's annual out-of-pocket maximum. *See* FAQs about Affordable Care Act Implementation (Part XVIII) and Mental Health Parity Implementation, Q4 (Jan. 9, 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xviii.pdf and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html; and FAQs about Affordable Care Act Implementation (Part XIX), Q2 (May 2, 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xix.pdf and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

[12] *See* FAQs about Affordable Care Act Implementation (Part XXI) (Oct. 10, 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxi.pdf and https://www.cms.gov/sites/default/files/repo-new/61/Reference_Pricing_FAQ_10.10.14.pdf. As stated in FAQs Part XXI, compliance with section 2707(b) of the PHS Act is not determinative of compliance with any other provision of law, including section 2713 of the PHS Act (relating to coverage of preventive services). This also applies to sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, or sections 2799A-1 and 2799A-2 of the PHS Act (relating to surprise billing protections).

the patient is stabilized. Additionally, post-stabilization services are excluded from the definition of "emergency services" under the No Surprises Act if all conditions under 45 CFR 149.410(b) are met.[13] The new definition of "emergency services" reflects that, when patients receive these post-stabilization services, they may not have an opportunity in the time between identification of the need for care and provision of the care to seek a participating provider (and be protected from out-of-network cost sharing and balance billing). Therefore, consistent with the Departments' prior guidance in FAQs Part XXI, limiting or excluding out-of-pocket spending from counting toward the MOOP with respect to providers that do not accept the reference-based price would not be considered reasonable with respect to post-stabilization services that are included in the definition of "emergency services."

Q6: Do the surprise billing provisions of the No Surprises Act apply in the case of a group health plan or group or individual health insurance coverage that generally does not provide out-of-network coverage?

Yes. The No Surprises Act's protections regarding emergency services, non-emergency services furnished by a nonparticipating provider with respect to a visit to a participating facility, and air ambulance services apply if those services are otherwise covered under the plan or coverage, even if the plan or coverage otherwise does not provide coverage for out-of-network items or services.

Note that, under section 9816(a) of the Code, section 716(a) of ERISA, and section 2799A-1(a) of the PHS Act, if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, including on an out-of-network basis, in accordance with the No Surprises Act and its implementing regulations.[14] Similarly, under section 9816(b) of the Code, section 716(b) of ERISA, section 2799A-1(b) of the PHS Act, if a plan or issuer provides or covers benefits with respect to non-emergency items and services, the plan or issuer must cover the items and services furnished to a participant, beneficiary, or enrollee of the plan or coverage by a nonparticipating provider with respect to a visit at a participating health care facility in accordance with requirements set forth in 26 CFR 54.9816-5T(c), 29 CFR 2590.716-5(c), and 45 CFR 149.120(c) related to cost sharing, payment amounts, and procedural requirements related to billing disputes. Finally, under section 9817(a) of the Code, section 717(a) of ERISA, and section 2799A-2(a) of the PHS Act, if a plan or issuer provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with requirements set forth in 26 CFR 54.9817-1T(b), 29 CFR 2590.717-1(b), and 45 CFR 149.130(b) related to cost sharing, payment amounts, and procedural requirements related

[13] Under 45 CFR 149.410(b), post-stabilization services are emergency services unless all of the following conditions are met: (1) the attending emergency physician or treating provider determines that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition; (2) the provider or facility furnishing such additional items and services satisfies the notice and consent criteria of 45 CFR 149.420(c) through (g); (3) the participant, beneficiary, or enrollee (or their authorized representative) is in a condition to receive notice and provide consent; and (4) the provider or facility satisfies any additional requirements or prohibitions under state law.

[14] *See* 26 CFR 54.9816-4T, 29 CFR 2590.716-4, and 45 CFR 149.110.

to billing disputes.[15] These requirements may result in a plan or coverage providing benefits for out-of-network items and services subject to the surprise billing provisions, even if the plan or coverage otherwise would not provide coverage for these items or services on an out-of-network basis.

Applicability to Air Ambulance Services

Q7: If a plan or issuer covers air ambulance services only for emergencies, is the plan or issuer required under the No Surprises Act to cover non-emergent air ambulance services (such as non-emergent inter-facility transports) provided by a nonparticipating provider of air ambulance services?

No. Under 26 CFR 54.9817-1T, 29 CFR 2590.717-1, and 45 CFR 149.130, if a plan or issuer provides or covers any benefits for air ambulance services, the plan or issuer must cover "such services" from a nonparticipating provider of air ambulance services in accordance with the implementing regulations. The Departments in this instance interpret "such services" to mean air ambulance services the plan or issuer provides or covers, as opposed to all air ambulance services. Therefore, if non-emergent air ambulance services are not covered under the terms of a plan or coverage, neither the No Surprises Act[16] nor its implementing regulations require the plan or issuer to cover those services or limit the amount a participant, beneficiary, or enrollee may be charged for those services.[17]

Q8: Do the protections against surprise medical bills in the No Surprises Act apply to air ambulance services furnished by a nonparticipating provider of air ambulance services when the point of pick-up is in a jurisdiction outside of the United States?

Yes. The requirements in 26 CFR 54.9817-1T, 29 CFR 2590.717-1, and 45 CFR 149.130 and 45 CFR 149.440 prohibiting surprise medical bills for air ambulance services apply to air ambulance services (for which benefits are available under the plan or coverage) furnished by a nonparticipating provider of air ambulance services that is licensed under applicable state and federal law to provide air ambulance services, and that therefore meets the definition of a provider of air ambulance services set forth in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30, even if the point of pick-up is in a jurisdiction outside of the United States.

Q9: How should a plan or issuer identify the geographic region used to calculate the QPA for air ambulance services when the point of pick-up is outside of the United States?

Under 26 CFR 54.9816-6T(a)(7)(ii), 29 CFR 2590.716-6(a)(7)(ii), and 45 CFR 149.140(a)(7)(ii), the geographic region in which air ambulance services are furnished is based on the point of pick-up, which is defined under 42 CFR 414.605 as the location of the individual at the time the

[15] *See* Q7 for further detail about the coverage requirements applicable to air ambulance services.
[16] Section 9817 of the Code, section 717 of ERISA, and section 2799A-2 of the PHS Act.
[17] In contrast, and as noted in Q6, if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover all emergency services, as defined in the No Surprises Act and its implementing regulations. 26 CFR 54.9816-4T, 29 CFR 2590.716-4, and 45 CFR 149.110.

individual is placed on board the ambulance. For air ambulance services, a "geographic region" generally is defined as one region consisting of all metropolitan statistical areas (MSAs) in the state, and one region consisting of all other portions of the state, determined based on the point of pick-up.[18]

If a plan or issuer does not have sufficient information, as defined under 26 CFR 54.9816-6T(a)(15), 29 CFR 2590.716-6(a)(15), and 45 CFR 149.140(a)(15), to calculate the median contracted rate based on this primary definition, the "geographic region" is one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division, determined based on the point of pick-up. In cases in which a plan or issuer does not have sufficient information using its own contracted rates to calculate the median contracted rate using either definition, the plan or issuer must determine the QPA using the same definitions of "geographic region" based on data from an eligible database, pursuant to 26 CFR 54.9816-6T(c)(3), 29 CFR 2590.716-6(c)(3), and 45 CFR 149.140(c)(3).

The Departments recognize that the July 2021 interim final rules do not currently provide for geographic regions outside of the United States. Therefore, the methodology for calculating the QPA for air ambulance services, either based on a plan's or issuer's contracted rates or using an eligible database, does not currently account for air ambulance services that are subject to the surprise billing protections of the No Surprises Act when the point of pick-up is outside of the United States.

In future rulemaking, the Departments intend to address the geographic region to be used to calculate the QPA for air ambulance services when the point of pick-up is in a jurisdiction outside of the United States. Until that rulemaking is finalized and effective, plans and issuers are expected to use a reasonable method to determine which geographic region under the interim final regulations applies for purposes of calculating the QPA for air ambulance services for which the point of pick-up is outside of the United States. For example, the Departments will consider a plan or issuer to have used a reasonable method if the plan or issuer identifies the relevant geographic region based on the border point of entry to the United States following patient pick-up.[19]

> *Example:* A nonparticipating provider of air ambulance services is dispatched from Florida to pick up an individual experiencing a medical emergency in the Bahamas, and transports the individual back to a hospital in the United States, entering the United States through the Miami-Fort Lauderdale-West Palm Beach MSA. The nonparticipating provider of air ambulance services submits a claim to the individual's plan or issuer for the services. The plan or issuer determines that the air ambulance services are a covered benefit under the terms of the individual's coverage. The plan or issuer could reasonably

[18] The Departments consulted with the National Association of Insurance Commissioners, as required by the No Surprises Act, to establish the geographic regions to be used in the methodology for calculating the QPA set forth in the July 2021 interim final rules.

[19] This method is generally consistent with the approach used in Medicare for air ambulance transports from areas outside of the United States to the United States for covered claims. *See* Medicare Claims Payment Manual, Chapter 15, Section 20.1.5D (Rev. 11365, 04-28-22), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c15.pdf.

calculate the QPA for the air ambulance services using the geographic region that corresponds to the United States border point of entry, which in this case would be the region consisting of all MSAs in Florida, provided the plan or issuer has sufficient information to calculate a median contracted rate for that region.

Applicability to Emergency Services Furnished in a Behavioral Health Crisis Facility

The surprise billing protections set forth in the No Surprises Act and its implementing regulations apply to emergency services[20] (with respect to an emergency medical condition) that are furnished with respect to a visit to a hospital emergency department (defined to include a hospital outpatient department that provides emergency services) or an independent freestanding emergency department,[21] including ancillary services routinely available to the emergency department to evaluate that emergency medical condition, as well as pre- and post-stabilization services (regardless of the department of the hospital in which the services are furnished). The term "emergency medical condition" means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in section 1867(e)(1)(A)(i)-(iii) of the SSA, as added by the Emergency Medical Treatment and Labor Act (EMTALA), referring to placing the health of the individual (or, with respect to a pregnant person, the health of the person or their unborn child) in serious jeopardy, serious impairment to bodily functions, and serious dysfunction of any bodily organ or part.

Under the July 2021 interim final rules, as noted above, the term "emergency department of a hospital" includes a hospital outpatient department that provides emergency services. The July 2021 interim final rules also define "independent freestanding emergency department" to mean a health care facility (not limited to those described in the definition of "health care facility" in the July 2021 interim final rules) that provides emergency services, and is geographically separate and distinct from a hospital and separately licensed as such by a state.[22] The preamble to the July 2021 interim final rules states that the definition of "independent freestanding emergency department" is intended to include any health care facility that is geographically separate and

[20] For the definition of emergency services, see 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and 45 CFR 149.110(c)(2).
[21] For the definitions of emergency department of a hospital and independent freestanding emergency department, see 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.
[22] 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.

distinct from a hospital, and licensed by a state to provide emergency services (as defined in the July 2021 interim final rules), with respect to an emergency medical condition.[23]

Q10: How do the surprise billing provisions of the No Surprises Act and its implementing regulations apply to emergency services furnished with respect to a visit to a behavioral health crisis facility?

The July 2021 interim final rules made clear that the definition of emergency medical condition includes mental health conditions and substance use disorders that satisfy that definition.[24] The Departments recognize that individuals experiencing behavioral health emergencies may be served most effectively in settings outside of hospital emergency departments and that states, localities, and health care systems are actively exploring alternatives to hospital-based care to respond to behavioral health emergencies, including through services provided in specialized facilities that are staffed by behavioral health providers trained to provide crisis services.

To the extent that services provided in response to a behavioral health crisis meet the definition of "emergency services," and are provided with respect to a visit to a facility that meets the definition of an "emergency department of a hospital" or an "independent freestanding emergency department," as those terms are defined under the July 2021 interim final rules, these services are subject to the surprise billing protections in the No Surprises Act and its implementing regulations applicable to emergency services.[25] This is true regardless of whether the license issued to the facility uses the term "hospital emergency department" or "independent freestanding emergency department" and regardless of whether the license issued to the facility uses the term "emergency services" to describe the services the facility is licensed to provide. For example, if under state licensure laws, a facility that provides behavioral health crisis response services is permitted to provide emergency services as described in 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and 45 CFR 149.110(c)(2), and is geographically separate and distinct from a hospital, then such a facility would fall within the definition of "independent freestanding emergency department" under the July 2021 interim final regulations, and the surprise billing protections would apply with respect to emergency services provided with respect to a visit to the facility.

General Disclosure for Protections Against Balance Billing

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, as added by the No Surprises Act, require plans and issuers to make certain disclosures regarding balance billing protections to participants, beneficiaries, and enrollees that are similar to disclosure requirements applicable to providers and facilities under section 2799B-3 of the PHS Act, as implemented in 45 CFR 149.430.

[23] 86 FR 36872, 36879 (Jul. 13, 2021).
[24] 26 CFR 54.9816–4T(c)(1), 29 CFR 2590.716–4(c)(1), and 45 CFR 149.110(c)(1).
[25] In addition, to the extent that a medical screening examination and stabilizing treatment provided in response to a behavioral health crisis meet the definition of "emergency services," and are provided in an outpatient department of a hospital, these services are also subject to the surprise billing protections applicable to emergency services.

In general, plans and issuers must make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information on:

(1) the requirements under those sections, as applicable;

(2) the requirements and prohibitions applied under sections 2799B-1 and 2799B-2 of the PHS Act (relating to the prohibitions against balance billing for emergency and non-emergency services in certain circumstances);

(3) other applicable state laws on out-of-network balance billing; and

(4) contacting appropriate state and Federal agencies if an individual believes the provider or facility has violated the prohibition against balance billing.

These disclosure requirements are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

To reduce burden and facilitate compliance with these disclosure requirements, the Departments issued a model disclosure notice that may be used to satisfy the disclosure requirements regarding balance billing protections.[26] The Departments consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, if all other applicable requirements are met.

Q11: May a group health plan that does not have its own website satisfy the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, with respect to posting the required information on a public website of the plan, if the plan's service provider posts the required information on its public website on behalf of the group health plan?

Yes. If a group health plan does not have a website, the plan may satisfy the requirements to post on its public website the information required by section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, by entering into a written agreement under which a plan's health insurance issuer or third-party administrator (TPA), as applicable, posts the information on its public website where information is normally made available to participants, beneficiaries, and enrollees, on the plan's behalf. To the extent a health insurance issuer or TPA posts the required information on its public website on behalf of a plan, the plan satisfies the requirements with respect to posting the information on the plan's public website if the health insurance issuer or TPA makes the information available in the required manner. The Departments note this guidance applies in instances in which the plan sponsor (for example, an

[26] *See* Q13, which explains which versions of the standard notice and consent form and model disclosure notice providers, facilities, plans, and issuers may use.

employer) may maintain a public website, but the group health plan sponsored by the employer does not.

Notwithstanding the preceding paragraph, if a plan enters into a written agreement under which a health insurance issuer or TPA agrees to post the required information on its public website on behalf of the plan, and the health insurance issuer or TPA fails to do so, the plan violates the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act.

Q12: Are plans and issuers required under section 9820(c)(1)(B) of the Code, section 720(c)(1)(B) of ERISA, and section 2799A-5(c)(1)(B) of the PHS Act to provide information on all state laws regarding balance billing?

No. The statute requires plans and issuers to provide information only on "applicable" state laws regarding out-of-network balance billing. The Departments will consider a plan or issuer to be in compliance with the requirements in section 9820(c)(1)(B) of the Code, section 720(c)(1)(B) of ERISA, and section 2799A-5(c)(1)(B) of the PHS Act if the plan's or issuer's disclosure includes information on state laws applicable to balance billing that apply with respect to participants, beneficiaries, and enrollees in such coverage.

The Departments do not expect a plan or issuer to provide information on state laws that do not apply to a particular participant, beneficiary, or enrollee that is enrolled in the plan or coverage. The Departments note that many state laws regarding balance billing and other surprise billing protections such as limits on cost sharing do not apply with respect to participants, beneficiaries, and enrollees who are enrolled in coverage provided by a self-insured group health plan or out-of-state issuer.

The Departments note that, prior to the enactment of the No Surprises Act, some states adopted laws that apply to providers and facilities within the state with respect to participants, beneficiaries, and enrollees who are enrolled in coverage over which the state does not have jurisdiction, such as coverage provided by a self-insured ERISA plan (that did not or could not voluntarily opt in to the state law) or by an out-of-state health insurance issuer. These state laws do not establish requirements that apply to self-insured group health plans or, generally, coverage provided by out-of-state health insurance issuers. The Departments will not consider a plan or out-of-state issuer to violate the requirements in section 9820(c)(1)(B) of the Code, section 720(c)(1)(B) of ERISA, and section 2799A-5(c)(1)(B) of the PHS Act if the plan's or issuer's disclosure does not include information on state laws that would not apply to claims arising under the relevant plan or policy regarding out-of-network balance billing. However, if a self-insured plan has voluntarily opted into a state law that provides such protections, the plan is required to disclose information on any such state law.

Standard Notice and Consent Form and Model Disclosure Notice Regarding Patient Protections Against Balance Billing

Section 2799B-2 of the PHS Act, as implemented in 45 CFR 149.410 and 149.420, allows nonparticipating providers and facilities to seek consent from an individual to waive the

individual's balance billing and cost-sharing protections in certain situations. In order to seek that consent, the nonparticipating provider or facility must provide written notice to participants, beneficiaries, or enrollees in accordance with guidance issued by HHS, and in the form and manner specified in guidance. HHS issued standard notice and consent documents that nonparticipating providers and facilities must use in order to meet the requirements of the notice and consent exception. HHS considers use of these documents in accordance with their accompanying instructions to be good faith compliance with the notice and consent requirements of section 2799B-2(d) of the PHS Act, provided that all other requirements are met. To the extent a state develops notice and consent documents that otherwise meet the statutory and regulatory requirements under section 2799B-2(d) of the PHS Act and 45 CFR 149.410 and 149.420, the state-developed documents will meet the Secretary of HHS's specifications regarding the form and manner of the notice and consent documents.

In addition, section 2799B-3 of the PHS Act, as implemented in 45 CFR 149.430, requires certain providers and facilities to provide disclosures regarding patient protections against balance billing to participants, beneficiaries, and enrollees. In general, those providers and facilities must make publicly available, post on a public website of the provider or facility (if applicable), and provide to participants, beneficiaries, and enrollees a one-page notice in clear and understandable language containing information on:

> (1) the requirements and prohibitions applicable to such provider or facility under sections 2799B-1 and 2799B-2 of the PHS Act (relating to prohibitions on balance billing for emergency and non-emergency services in certain circumstances);
>
> (2) any applicable state requirements; and
>
> (3) contacting appropriate state and federal agencies if the individual believes the provider or facility has violated the restrictions against balance billing.

HHS issued a model disclosure notice that may be used to satisfy these disclosure requirements regarding these balance billing protections, and the parallel disclosure requirements on plans and issuers in section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, which are described in more detail in Q11 and Q12. For providers and facilities, HHS considers use of the model notice in accordance with their accompanying instructions to be good faith compliance with the disclosure requirements under section 2799B-3 of the PHS Act, as implemented in 45 CFR 149.430, provided that all other requirements are met. In addition, for plans and issuers, the Departments consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements set forth in section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, provided that all other requirements are met.

Q13: Which versions of the standard notice and consent form and model disclosure notice may providers, facilities, plans, and issuers use?

HHS previously published and obtained emergency approval from the Office of Management and Budget (OMB) for a standard notice and consent form that providers and facilities must use

when providing notice and seeking consent from individuals to waive their protections against surprise bills (unless a state develops notice and consent documents that otherwise meet the statutory and regulatory requirements under section 2799B-2(d) of the PHS Act and 45 CFR 149.410 and 149.420) and a model disclosure notice that providers, facilities, plans, and issuers may use to notify individuals of their protections against balance billing.

Based on public comments, HHS has revised these documents and obtained OMB approval for the revised versions.[27]

Providers and facilities may use either the initial version of the standard notice and consent form (Appendix II) or the revised version (Appendix IV) for items and services furnished during calendar year 2022. However, providers and facilities may use only the revised version of the standard notice and consent form (Appendix IV) for items and services furnished on or after January 1, 2023. Providers and facilities may use either the initial version of the model disclosure notice (Appendix I) or the revised version (Appendix III) for making disclosures during calendar year 2022. However, HHS will consider providers' and facilities' use of only the revised version of the model disclosure notice (Appendix III) to be good faith compliance for disclosures made on or after January 1, 2023.

Similarly, the Departments will consider plans' and issuers' use of either the initial (Appendix I) or revised (Appendix III) version of the model disclosure notice in accordance with its accompanying instructions to be good faith compliance for making disclosures with respect to plan or policy years beginning on or after January 1, 2022, and before January 1, 2023. However, the Departments will consider plans' and issuers' use of only the revised version of the model disclosure notice (Appendix IV) to be good faith compliance for disclosures with respect to plan or policy years beginning on or after January 1, 2023.

Methodology for Calculating Qualifying Payment Amounts

In general, under section 9816(a)(3)(E) of the Code, section 716(a)(3)(E) of ERISA, and section 2799A-1(a)(3)(E) of the PHS Act, for a given item or service, the QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation. The median contracted rate is determined with respect to all group health plans of the plan sponsor, or all group or individual health insurance coverage offered by the health insurance issuer in the same insurance market. The No Surprises Act and the July 2021 interim final rules establish the

[27] The initial and revised versions of the model disclosure notice and standard notice and consent form are available at https://www.cms.gov/nosurprises/policies-and-resources/overview-of-rules-fact-sheets. The information collection is approved under OMB control number 0938-1401 (CMS-10780, Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in), and currently has an expiration date of May 31, 2025.

methodology that plans and issuers must use to calculate the median of contracted rates to determine the QPA.

After the July 2021 interim final rules were issued, stakeholders brought to the Departments' attention certain contractual arrangements in which providers accept contracted rates established by plans or issuers for service codes that they are not likely to bill or that are not utilized by their specific provider specialty. Stakeholders raised concerns that the inclusion of these rates in the calculation of QPAs may artificially lower the QPA, as these providers have little incentive to negotiate fair reimbursement rates for these service codes, with some even accepting $0 as their rate for codes they do not utilize.

The No Surprises Act and its implementing regulations place the responsibility for monitoring the accuracy of plans' and issuers' QPA calculation methodologies with the Departments (and applicable state authorities) by requiring audits of plans' and issuers' QPA calculation methodologies.[28] It is not the responsibility of a provider, facility, provider of air ambulance services, or certified IDR entity to verify a QPA's accuracy, and plans and issuers are not obligated to demonstrate that a QPA was calculated in accordance with the requirements of 26 CFR 54.9816-6T(c), 29 CFR 2590.716-6(c), and 45 CFR 149.140(c) unless required to do so by an applicable regulator. Providers, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the requirements of 26 CFR 54.9816-6T, 26 CFR 54.9816-6, 29 CFR 2590.716-6, and 45 CFR 149.140 may contact the No Surprises Help Desk at 1-800-985-3059, submit a complaint at https://www.cms.gov/nosurprises/policies-and-resources/providers-submit-a-billing-complaint, or contact the applicable state authority.

Q14: Under the No Surprises Act and its implementing regulations, are plans and issuers required to calculate a median contracted rate separately for each provider specialty, if the plan's or issuer's contracted rates for service codes vary based on provider specialty (as a result of the plan's or issuer's contracting process)?

Yes. Under 26 CFR 54.9816-6T(b)(3), 29 CFR 2590.716-6(b)(3), and 45 CFR 149.140(b)(3), if a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate (and consequently the QPA) must be calculated separately for each provider specialty, as applicable. Plans and issuers are required to calculate separate median contracted rates by provider specialty both in instances where their contracting process purposefully sets different rates for different specialties and in instances where the contracting process otherwise results in different rates for different specialties.

The Departments have been informed that some plans and issuers establish contracted rates by offering most providers the same fee schedule for all covered services, and then it is up to the providers to negotiate increases to the rates for the services that they are most likely to bill. After the negotiation process, the entire fee schedule may be included in the provider contract, with contracted rate modifications made only to certain service codes based on the negotiations. For example, an anesthesiologist's contract may include rates for anesthesia services that are a result of negotiations between the plan or issuer and the provider and that are materially different from

[28] 86 FR 36872, 36899 (July 13, 2021).

the contracted rates the plan or issuer has for the same anesthesia services with other providers in specialties that do not bill for those services. Similarly, an anesthesiologist's contract may also include contracted rates for other services the anesthesiologist does not provide (for example, dermatology services) that are identical to the contracted rates the plan or issuer has with other providers in specialties who similarly do not bill for those services.[29]

To the extent contracted rates for a service code vary based on only certain provider specialty types, the plan or issuer must calculate a separate median contracted rate for each provider specialty for which the rates differ. For example, if a plan's or issuer's contracted rates for a given anesthesia service are clustered at one rate for anesthesiologists and at another rate for all other provider specialties because those providers do not provide and bill for anesthesia services, the plan or issuer must calculate one median contracted rate for the anesthesia service code for anesthesiologists, and one separate median contracted rate for the same anesthesia service code for all other provider specialties. In this example, the plan or issuer would not be expected to calculate separate median contracted rates for the anesthesia service code for each of the other specialties, such as psychiatry or cardiology, because the plan or issuer does not have contracted rates for anesthesia services that vary based on those provider specialties.

The Departments understand that some natural variation in contracted rates is likely to occur as part of the contracting process. A plan or issuer may have established contracted rates for service codes that vary across providers for reasons that are not based on provider specialty. For the purpose of identifying provider specialties for which QPAs must be separately calculated, a plan's or issuer's contracted rates for an item or service are considered to vary based on provider specialty if there is a material difference in the median contracted rates for a service code between providers of different specialties, after accounting for variables other than provider specialty. Plans and issuers whose median contracted rates for a service code are not materially different between providers of different specialties are not required to calculate median contracted rates separately for each provider specialty when determining the QPA. For this purpose, whether a material difference exists depends on all the relevant facts and circumstances.

The Departments recognize that plans and issuers (reasonably and in good faith) may have not understood the July 2021 interim final rules to require the calculation of separate median contracted rates when the plan's or issuer's contracting process unintentionally results in contracted rates that vary based on provider specialty. Accordingly, the Departments will not require a plan or issuer (to the extent not already in compliance) to calculate a QPA as described in this guidance with respect to items and services furnished prior to the date that is 90 days after publication of these FAQs. HHS encourages states to take a similar approach to enforcement and will not consider a state to be failing to substantially enforce the requirements relating to the calculation of a QPA because the state takes such an approach. The Departments will monitor plans' and issuers' compliance with the July 2021 interim final rules, as interpreted in this guidance, and are continuing to monitor contracting practices that affect the calculation of the QPA, to determine whether additional guidance is needed.

[29] The Departments have been informed that some plans and issuers enter $0 in their fee schedule for covered items and services that a provider or facility is not equipped to furnish. In the Departments' view, $0 does not represent a contracted rate in these cases. Therefore, plans and issuers should not include $0 amounts in calculating median contracted rates.

Q15: How may a self-insured group health plan calculate a QPA if it offers multiple benefit package options administered by different TPAs?

Under 26 CFR 54.9816-6T(b), 29 CFR 2590.716-6(b), and 45 CFR 149.140(b), the median contracted rate used to determine the QPA for an item or service is determined with respect to all group health plans of the plan sponsor or all coverage offered by a health insurance issuer that are offered in the same insurance market. In the case of a self-insured group health plan, an "insurance market" generally means all self-insured group health plans (other than account-based plans and plans that consist solely of excepted benefits) of the plan sponsor. However, to reduce burden on self-insured group health plans, the July 2021 interim final rules provide that sponsors of self-insured group health plans may allow their TPAs to determine the QPA on behalf of the sponsor by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by the TPA, as opposed to only those of the particular plan sponsor.

Consistent with the approach set forth in the July 2021 interim final rules, if a single self-insured group health plan offers multiple benefit package options administered by different TPAs, the plan may allow each TPA acting on behalf of the plan to calculate a median contracted rate separately for those benefit package options administered by the TPA. In other words, contracted rates would not have to be aggregated across multiple mutually-exclusive benefit package options administered by different TPAs to calculate a median contracted rate. Instead, the relevant QPA in a particular case would be the QPA specific to the particular item or service under the benefit package option elected by the participant or beneficiary.

For example, if a self-insured plan offers participants a choice of two benefit packages, Option A administered by TPA "A" and Option B administered by TPA "B," the QPA for an item or service may be calculated separately for Option A and Option B, determined with respect to all self-insured group health plans administered by the same TPA (including from other plan sponsors). In this case, if a participant is enrolled in coverage under Option A, the plan would use the QPA for Option A for claims arising under that participant's coverage, as calculated by TPA "A" for all self-insured group health plans administered by TPA "A."

Requirements for Initial Payments or Notices of Denial of Payment, Related Disclosures, and Initiation of Open Negotiation Periods and Federal IDR Process

The No Surprises Act and its implementing regulations, including the July 2021 interim final rules, a second set of interim final rules issued in October 2021 (October 2021 interim final rules),[30] and the final rules issued concurrently with these FAQs establish requirements to help ensure that billing disputes related to items and services subject to the balance billing protections in the No Surprises Act are resolved in a timely fashion. Among other requirements, these include timeframes within which a plan or issuer must make an initial payment or send a notice

[30] 86 FR 55980 (Oct. 7, 2021).

of denial of payment for items and services subject to surprise billing protections;[31] disclosures a plan or issuer must furnish to a provider, facility, or provider of air ambulance services with an initial payment or notice of denial of payment;[32] and a process for initiating an open negotiation period that must precede any initiation of the Federal IDR process.[33]

Q16: Under the No Surprises Act and its implementing regulations, when must a plan or issuer send an initial payment or notice of denial of payment to a nonparticipating provider, facility, or provider of air ambulance services for items and services subject to the surprise billing protections?

Sections 9816(a)(1)(C)(iv)(I) and 9817(a)(3)(A) of the Code, sections 716(a)(1)(C)(iv)(I) and 717(a)(3)(A) of ERISA, and sections 2799A-1(a)(1)(C)(iv)(I) and 2799A-2(a)(3)(A) of the PHS Act, as added by the No Surprises Act, require plans and issuers to send an initial payment or notice of denial of payment[34] not later than 30 calendar days after a nonparticipating provider, facility, or provider of air ambulance services submits a bill related to the items and services that fall within the scope of the surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers related to a visit to a participating facility, and air ambulance services furnished by nonparticipating providers of air ambulance services. The 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for such services, commonly known as a "clean claim."[35]

The Departments will generally enforce the applicable provisions of the No Surprises Act in conjunction with states where applicable. Providers, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the 30-calendar-day requirement to send an initial payment or notice of denial of payment may contact the No Surprises Help Desk at 1-800-985-3059 or submit a complaint at https://www.cms.gov/nosurprises/policies-and-resources/providers-submit-a-billing-complaint.

Q17: May a provider, facility, or provider of air ambulance services initiate open negotiation prior to receiving an initial payment or notice of denial of payment for items and services subject to the surprise billing protections?

No. In general, providers, facilities, and providers of air ambulance services have 30 business days from the day they receive an initial payment or a notice of denial of payment from the plan

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[31] 26 CFR 54.9816-4T(b)(3)(iv)(A), 29 CFR 2590.716-4(b)(3)(iv)(A), and 45 CFR 149.110(b)(3)(iv)(A); 26 CFR 54.9816-5T(c)(3), 29 CFR 2590.716-5(c)(3), and 45 CFR 149.120(c)(3); and 26 CFR 54.9817-1T(b)(4)(i), 29 CFR 2590.717-1(b)(4)(i), and 45 CFR 149.130(b)(4)(i).

[32] 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1).

[33] 26 CFR 54.9816-8T(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1).

[34] The Departments note that a plan or issuer must send an initial payment or notice of denial of payment directly to the provider, facility, or provider of air ambulance services, as applicable. 26 CFR 54.9816-4T(b)(3)(iv)(A), 54.9816-5T(c)(3), and 54.9817(b)(4)(i); 29 CFR 2590.716-4(b)(3)(iv)(A), 2590.716-5(c)(3), and 2590.717-1(b)(4)(i); or 45 CFR 149.110(b)(3)(iv)(A), 149.120(c)(3), and 149.130(b)(4)(i). A plan or issuer does not satisfy its obligation under the statute and regulations if the plan or issuer sends an initial payment or notice of denial of payment to a participant, beneficiary, or enrollee that was furnished items or services by a nonparticipating provider, facility, or provider of air ambulance services.

[35] 86 FR 36872, 36900 (July 13, 2021).

or issuer regarding an item or service that falls within the scope of the surprise billing provisions to initiate open negotiation with respect to that item or service. If a plan or issuer fails to send an initial payment or notice of denial of payment not later than 30 calendar days after the plan or issuer receives a bill related to such an item or service from a nonparticipating provider, facility, or provider of air ambulance services that includes the information necessary to decide a claim for payment (*i.e.*, a "clean claim"), the 30-business-day timeline to initiate open negotiations will not begin until an initial payment or notice of denial of payment is made.

Providers, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the requirements to timely make an initial payment or provide notice of denial of payment may contact the No Surprises Help Desk at 1-800-985-3059 or submit a complaint at https://www.cms.gov/nosurprises/policies-and-resources/providers-submit-a-billing-complaint. The Departments will generally enforce the applicable provisions of the No Surprises Act, in conjunction with states where applicable.

Q18: Under the No Surprises Act and its implementing regulations, what constitutes an "initial payment" or a "notice of denial of payment" to a nonparticipating provider, facility, or provider of air ambulance services for items and services that are subject to the surprise billing protections?

As stated in the preamble to the July 2021 interim final rules, the initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage, prior to the beginning of any open negotiation period or initiation of the Federal IDR process.[36] The initial payment is not required to be equivalent to the QPA (or the QPA less the individual's cost-sharing amount), but as noted in Q19, the plan or issuer must include the QPA for each item or service with the initial payment or notice of denial of payment, as well as a statement certifying that the QPA applies for the purposes of the recognized amount, among other required information.

A notice of denial of payment means, with respect to an item or service for which benefits subject to the surprise billing protections are provided or covered, a written notice from the plan or issuer to the provider, facility, or provider of air ambulance services that states that payment for the item or service will not be made by the plan or coverage and explains the reason for denial.[37] For example, a notice of denial of payment could be provided if the item or service is covered but is subject to a deductible greater than the recognized amount.

The term "notice of denial of payment" does not include a notice of benefit denial due to an "adverse benefit determination" as defined in 29 CFR 2560.503-1(m)(4), as explained in the July 2021 interim final rules. There is a significant distinction between an adverse benefit determination, which may be disputed through a plan's or issuer's claims and appeals process, and a notice of denial of payment or an initial payment that is less than the billed amount under the July 2021 interim final rules, which may be disputed through open negotiation and, after that,

[36] *Id.*
[37] 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.

through the Federal IDR process. In general, when adjudication of a claim results in a participant, beneficiary, or enrollee being personally liable for payment to a provider or facility, this determination may be an adverse benefit determination that can be disputed through a plan's or issuer's typical claims and appeals process. Conversely, when: (1) the adjudication of a claim results in a decision that does not affect the amount the participant, beneficiary, or enrollee owes; (2) the dispute involves only payment amounts due from the plan or issuer to the provider, facility, or provider of air ambulance services; and (3) the provider, facility, or provider of air ambulance services has no recourse against the participant, beneficiary, or enrollee, the decision is not an adverse benefit determination and the payment dispute may be resolved through open negotiation and, if necessary, the Federal IDR process.

Q19: A plan or issuer receives a claim for emergency services from a nonparticipating provider, under which the recognized amount with respect to the item or service furnished by the nonparticipating provider is the QPA. After reviewing the claim, the plan or issuer provides an initial payment with an explanation of benefits that includes only a general statement that the claim was processed according to applicable state or Federal law and directs the nonparticipating provider to a website for more information. Does this satisfy the requirements of the regulations with respect to the information to be shared with an initial payment or notice of denial of payment?

No. Under 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), in cases in which the recognized amount (or, in the case of air ambulance services, the amount on which cost sharing is based) with respect to an item or service furnished by the provider or facility is the QPA, plans and issuers are required to provide in writing, in paper or electronic form, certain information to nonparticipating providers, nonparticipating emergency facilities, and nonparticipating providers of air ambulance services regarding the QPA and how to dispute an initial payment or notice of denial of payment.

Specifically, when the recognized amount is the QPA, plans and issuers must provide the following information with an initial payment or notice of denial of payment:

> (1) the QPA for each item or service involved;
>
> (2) if the QPA is based on a downcoded service code or modifier, a statement from the plan or issuer explaining that the service code or modifier billed by the provider, facility, or provider or air ambulance services was downcoded; an explanation of why the claim was downcoded, including a description of which service codes or modifiers were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded;[38]
>
> (3) a statement to certify that the plan or issuer has determined that the QPA applies for the purposes of the recognized amount (or, in the case of air ambulance services, for

[38] These requirements related to downcoding were finalized in final rules issued concurrently with these FAQs and are applicable with respect to items or services provided or furnished on or after the date that is 60 days after the date of publication of the final rules in the Federal Register for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

> calculating the participant's, beneficiary's, or enrollee's cost sharing), and that each QPA was determined in compliance with the methodology established in the July 2021 interim final rules
>
> (4) a statement that if the provider or facility, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-business-day open negotiation period does not result in a determination, generally, the provider or facility may initiate the Federal IDR process within 4 days after the end of the open negotiation period; and
>
> (5) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.[39]

In this case, because the plan or issuer provides an explanation of benefits with only a general statement about the processing of the claim and directs the provider to a website for more information, the plan or issuer has failed to provide all the information required to be provided when making an initial payment or sending a notice of denial of payment and has therefore failed to satisfy the requirements of the July 2021 interim final rules.[40]

It is important to note that plans and issuers are not required to provide a QPA in all circumstances. For example, plans and issuers are not required to provide the QPA when the recognized amount for the item or service is calculated based on an amount determined by an All-Payer Model Agreement or under a specified state law, or when the item or service is not covered under the terms of the plan or coverage.

The Departments recognize that the requirements related to when a plan or issuer must provide a QPA, particularly in instances in which a plan or issuer has provided a recognized amount that is not the QPA, have caused confusion for some providers and facilities as to whether claims for which no QPA is provided are being properly processed by plans and issuers. Remittance Advice Remark Codes (RARCs) related to the No Surprises Act were approved and made effective as of March 1, 2022.[41] Although plans and issuers are not required to use the RARCs under the No Surprises Act and its implementing regulations, the Departments strongly encourage plans and issuers to use the RARCs, subject to state law, as these codes can facilitate communication with providers and facilities regarding how claims subject to the No Surprises Act were calculated. For example, in certain instances in which the recognized amount is not the QPA, a plan or

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[39] Certain additional information must be provided in a timely manner upon request from a nonparticipating provider, facility, or provider of air ambulance services. *See* 26 CFR 54.9816-6T(d)(2), 29 CFR 2590.716-6(d)(2), and 45 CFR 149.140(d)(2).

[40] Although plans and issuers are not required to include the requisite information on an explanation of benefits, the July 2021 interim final rules require disclosure of the information and assume that issuers and TPAs will automate the process of preparing and providing the information in a format similar to an explanation of benefits. *See* 86 FR 36872, 36933.

[41] *See* Remittance Advice Remark Codes Related to the No Surprises Act (March 1, 2022), available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA-NSA-RARC-Codes.pdf.

issuer can use RARC N867 to communicate that cost sharing was calculated based on a specified state law, in accordance with the No Surprises Act.

Q20: If a plan or issuer has failed to disclose the information it is required to provide when making an initial payment or sending a notice of denial of payment, may a provider, facility, or provider of air ambulance services initiate an open negotiation period and then proceed to the Federal IDR process?

Yes. In general, providers, facilities, and providers of air ambulance services have 30 business days from the day they receive an initial payment or a notice of denial of payment from the plan or issuer regarding an item or service to initiate open negotiation with respect to that item or service, including in cases in which information required to be provided is missing. However, a plan's or issuer's failure to satisfy the disclosure requirements in 26 CFR 54.9816-6T(d)(1) or (2), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1) or (2), and 45 CFR 149.140(d)(1) or (2) could adversely affect a provider's, facility's, or provider of air ambulance services' ability to meaningfully participate in negotiations during the open negotiation period and Federal IDR process.

In these cases, when a plan or issuer fails to comply with the disclosure requirements in 26 CFR 54.9816-6T(d)(1) or (2), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1) or (2), and 45 CFR 149.140(d)(1) or (2), providers, facilities, or providers of air ambulance services retain the right to initiate the open negotiation period within 30 business days of receiving the initial payment or notice of denial of payment. In initiating the open negotiation period, the provider, facility, or provider of air ambulance services, must provide the standard open negotiation notice[42] to the plan or issuer, as required in 26 CFR 54.9816-8T(b), 29 CFR 2590.716-8(b), and 45 CFR 149.140(b).[43, 44] After the 30-business-day open negotiation period has lapsed, the provider, facility, or provider of air ambulance services may initiate the Federal IDR process in accordance with the normal timelines.

Alternatively, in cases in which a plan or issuer fails to comply with the disclosure requirements in 26 CFR 54.9816-6T(d)(1) or (2), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1) or (2), and 45 CFR 149.140(d)(1) or (2), providers, facilities, or providers of air ambulance services may request an extension to initiate the Federal IDR process,[45] and provide applicable attestations, by emailing a request for extension due to extenuating circumstances to

[42] https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-2.pdf.

[43] Note that plans and issuers are prohibited from initiating open negotiation periods or the Federal IDR process before satisfying the requirements in 26 CFR 54.9816-6T(d)(1) and (2), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1) and (2), and 45 CFR 149.140(d)(1) and (2), as applicable.

[44] The Departments expect that a party initiating open negotiation will be able to demonstrate the steps it has taken to comply with the notice requirements. Examples of steps taken to comply with the notice requirement include emailing or otherwise submitting the standard open negotiation notice to the contact or web portal address based on information provided with the initial payment or notice of denial of payment, or any contact associated with the plan or issuer if (and only if) contact information was not included with the initial payment or notice of denial of payment.

[45] 26 CFR 54.9816-8T(g); 29 CFR 2590.716-8(g); 45 CFR 149.510(g).

FederalIDRQuestions@cms.hhs.gov, including the time period(s) for which they are seeking an extension.

Failure by either party to supply information that is required to be submitted to the certified IDR entity (for example, failure to provide the QPA) may lead to a finding by the certified IDR entity that does not take into consideration the absent information, or may lead to the certified IDR entity drawing an inference about the absent information that is adverse to that party.

Providers, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the requirements of 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), including concerns that a plan or issuer is not acting in good faith with respect to this requirement, may contact the No Surprises Help Desk at 1-800-985-3059 or submit a complaint at https://www.cms.gov/nosurprises/policies-and-resources/providers-submit-a-billing-complaint. The Departments will generally enforce the applicable provisions of the No Surprises Act, in conjunction with states where applicable.

Q21: A plan or issuer establishes an online portal for nonparticipating providers, facilities, and providers of air ambulance services to submit the information necessary to initiate the open negotiation period. However, the portal does not accept uploads of the standard open negotiation form issued by the Departments, and the plan or issuer does not otherwise accept delivery of the standard open negotiation form. Instead, the plan or issuer requires that nonparticipating providers, facilities, and providers of air ambulance services manually enter information for each claim separately in a manner prescribed by the plan or issuer through the portal before the plan or issuer will engage in any open negotiation with the nonparticipating provider. Is this permissible?

No. The October 2021 interim final rules at 26 CFR 54.9816-8T(b)(1)(ii)(B), 29 CFR 2590.716-8(b)(1)(ii)(B), and 45 CFR 149.510(b)(1)(ii)(B) state that the initiating party may initiate the open negotiation period by sending an open negotiation notice to the other party electronically (such as by email) if the following conditions are satisfied:

> (1) the initiating party has a good faith belief that the electronic method is readily accessible by the other party; and
>
> (2) the notice is provided in paper form free of charge upon request.

The Departments have developed a standard open negotiation form[46] that an initiating party must use to initiate the open negotiation period. The October 2021 interim final rules do not prohibit a plan or issuer from encouraging the use of an online portal for nonparticipating providers, facilities, and providers of air ambulance services to submit the information necessary to initiate the open negotiation period, or from seeking additional information to inform good faith open negotiations, such as through use of a supplemental open negotiation form. However, because

[46] *See* Open Negotiation Notice and Instructions, available at: https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-2.pdf.

the initiating party (in this case, a nonparticipating provider) is required to use the standard open negotiation form, the other party must accept the standard open negotiation form sent by the initiating party to the contact information provided by the non-initiating party even when the initiating party does not use the plan's or issuer's portal or supplemental form, provided that the notice was sent in a manner that complies with the delivery requirements discussed above.

The October 2021 interim final rules permit the initiating party to send the open negotiation notice to the opposing party electronically if the party sending the notice has a good faith belief that the electronic method is readily accessible to the other party. For example, if a provider sends an open negotiation notice to the email address identified by the plan or issuer with the initial payment or notice of denial of payment, this electronic delivery would satisfy the delivery requirements of the October 2021 interim final rules (so long as the provider also provides the notice in paper form free of charge upon request).[47] Conversely, if a plan or issuer is in compliance with the requirement to disclose contact information with the initial payment or notice of denial of payment,[48] a provider, facility, or provider of air ambulance services generally would not have a good faith belief that sending an open negotiation notice to a general email address (that was not identified with the initial payment or notice of denial of payment) of the plan or issuer is a readily accessible electronic method under the October 2021 interim final rules.

In the preamble to the October 2021 interim final rules, the Departments encouraged plans, issuers, providers, facilities, and providers of air ambulance services to engage in good faith open negotiations. The Departments are aware of instances in which plans and issuers are not responding to or not acknowledging receipt of the notice of initiation of open negotiation, as well as instances in which providers are failing to provide information to plans and issuers in addition to what is included on the standard notice of initiation of open negotiation form, to assist the plan or issuer in identifying the claim under dispute. The Departments are of the view that these actions may hinder a party's ability to meaningfully participate in an open negotiation. The Departments consider good faith negotiations to include a dialogue between parties; at minimum, during the open negotiation period, parties should communicate to identify the claims under dispute, the type of plan or coverage responsible for the claims, and other information to help identify whether the claims qualify for the Federal IDR process. If a plan, issuer, provider, facility, or provider of air ambulance services timely sends the notice of initiation of open negotiation, and the other party does not respond during the 30-business-day open negotiation period, the initiating party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period if the item or service is a qualified IDR item or service.[49]

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[47] 86 FR 55980, 55990 (Oct. 7, 2021).

[48] Plans and issuers are required to provide contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations. 26 CFR 54.9816-6T(d)(1)(v), 29 CFR 2590.716-6(d)(1)(v), and 45 CFR 149.140(d)(1)(v).

[49] For the definition of qualified IDR item or service, see 26 CFR 54.9816-8T(a)(2)(xii), 29 CFR 2590.716-8(a)(2)(xii), and 45 CFR 149.510(a)(2)(xii).

The Departments will continue to monitor whether and how the parties to a payment dispute interact during the open negotiation period and will consider whether additional guidance is needed.

Transparency in Coverage Machine-Readable Files

The Transparency in Coverage Final Rules (the TiC Final Rules) require non-grandfathered plans and issuers offering non-grandfathered coverage in the group and individual markets to disclose, on a public website, information regarding in-network rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in separate machine-readable files.[50]

The machine-readable file requirements of the TiC Final Rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The Departments previously announced that they will defer enforcement of the requirements related to machine-readable files disclosing in-network and out-of-network data until July 1, 2022.[51] The Departments also previously announced that they will defer enforcement of the requirement that plans and issuers publish a machine-readable file related to prescription drugs while the Departments consider, through notice-and-comment rulemaking, whether this requirement remains appropriate.[52]

Additionally, the TiC Final Rules require plans and issuers to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request.[53] This information must be available for plan years (in the individual market, policy years) beginning on or after January 1, 2023, with respect to the 500 items and services identified by the Departments in Table 1 in the preamble to the TiC Final Rules,[54] and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024.[55]

Q22: May a group health plan that does not have its own website satisfy the requirements of the TiC Final Rules with respect to posting the machine-readable files on a public website, if the plan's service provider posts the machine-readable files on its public website on behalf of the group health plan?

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[50] 26 CFR 54.9815-2715A3; 29 CFR 2590.715-2715A3; and 45 CFR 147.212; 85 FR 72158 (Nov. 12, 2020).
[51] *See* FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, Q2 (Aug. 20, 2021), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf. For 2022 plan years and policy years beginning after July 1, 2022, plans and issuers should post the machine-readable files beginning in the month in which the plan year (in the individual market, policy year) begins, consistent with the applicability provision of the TiC Final Rules.
[52] *See* id. at Q1.
[53] 26 CFR 54.9815-2715A2(b); 29 CFR 2590.715-2715A2(b); and 45 CFR 147.211(b).
[54] 85 FR 72158, 72182 (Nov. 12, 2020).
[55] 26 CFR 54.9815-2715A2(c)(1); 29 CFR 2590.715-2715A2(c)(1); and 45 CFR 147.211(c)(1).

Yes. If a group health plan does not have its own public website, nothing in the TiC Final Rules requires the plan to create its own website for the purposes of providing a link to a location where the machine-readable files are publicly available. The Departments note this guidance applies in instances in which the plan sponsor (for example, the employer) maintains a public website, but the group health plan sponsored by the employer does not.

Instead, a plan may satisfy the requirements of 26 CFR 54.9815-2715A3(b), 29 CFR 2590.715-2715A3(b), and 45 CFR 147.212(b) by entering into a written agreement under which a service provider (such as a TPA) posts the machine-readable files on its public website on behalf of the plan.

To the extent a service provider posts the required information on its public website on behalf of a plan, the plan satisfies the requirements with respect to posting the information on a public website if the service provider makes the information available in the required manner, regardless of whether the group health plan has a public website.[56] In the case of aggregated Allowed Amounts files, however, the plan must post a link to the file hosted by the service provider on the plan's own website, if the plan maintains a public website, per the requirements of 26 CFR 54.9815-2715A3(b)(4)(iii), 29 CFR 2590.715-2715A3(b)(4)(iii), and 45 CFR 147.212(b)(4)(iii).

Notwithstanding the preceding paragraph, if a plan enters into an agreement under which a service provider agrees to post the machine-readable files on its public website on behalf of the plan, and the service provider fails to do so, the plan violates the disclosure requirements of 26 CFR 54.9815-2715A3(b), 29 CFR 2590.715-2715A3(b), and 45 CFR 147.212(b).

Q23: With regard to the internet-based self-service tool as required by the TiC Final Rules, will the list of codes for the 500 items and services required in the self-service tool for plan years (in the individual market, policy years) beginning on or after January 1, 2023 be updated when an item or service code is no longer valid?

The list of 500 items and services that must be included in the first phase of implementation of the internet-based self-service tool can be found on the TiC Website at www.cms.gov/healthplan-price-transparency/resources/500-items-services. The Departments will update this list quarterly to reflect the retirement of any codes that were included in Table 1 in the preamble to the TiC Final Rules list and will provide a reasonable period of time for plans and issuers to update their internet-based self-service tools to reflect the current codes. Plans and issuers should refer to this webpage for the most up-to-date list of codes to comply with the requirements regarding the self-service tool for plan years (in the individual market, policy years) beginning on or after January 1, 2023 and prior to January 1, 2024.

[56] 26 CFR 54.9815-2715A3(b)(4)(ii); 29 CFR 2590.715-2715A3(b)(4)(ii); and 45 CFR 147.212(b)(4)(ii).

APPENDICES:

Initial forms

Appendix I: Model Disclosure Notice Regarding Patient Protections Against Surprise Billing: for use by providers and facilities under section 2799B-3 of the PHS Act for disclosures during calendar year 2022, and for use by group health plans and health insurance issuers under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act for disclosures with respect to plan years beginning on or after January 1, 2022, and before January 1, 2023

Available at: https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf (see "Version 1")

Appendix II: Standard Notice and Consent Documents Under the No Surprises Act: for use by nonparticipating providers and nonparticipating emergency facilities under section 2799B-2 of the PHS Act for items and services furnished during calendar year 2022 only

Available at: https://www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf (see "Version 1")

Revised forms

Appendix III: Model Disclosure Notice Regarding Patient Protections Against Surprise Billing: for use by providers and facilities under section 2799B-3 of the PHS Act for disclosures during calendar year 2022 and on or after January 1, 2023, and for use by group health plans and health insurance issuers under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act for disclosures with respect to plan years beginning on or after January 1, 2022

Available at: https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf (see "Version 2")

Appendix IV: Standard Notice and Consent Documents Under the No Surprises Act: for use by nonparticipating providers and nonparticipating emergency facilities under section 2799B-2 of the PHS Act for items and services furnished during calendar year 2022 and on or after January 1, 2023

Available at: https://www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf (see "Version 2")