IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA *in his official capacity as Secretary of HHS*, U.S. DEPARTMENT OF LABOR, JULIE A. SU *in her official capacity as Acting Secretary of Labor*, U.S. DEPARTMENT OF THE TREASURY, *and* JANET YELLEN *in her official capacity as Secretary of the Treasury*, Defendants.	Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. "'To make fully informed decisions about their health care, patients must know the price and quality of a good or service in advance.'" 85 Fed. Reg. 72158, 72160 (Nov. 12, 2020). Yet "'patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care.'" *Id.* "The lack of this information is widely understood to be one of the root problems causing dysfunction within America's health care system." *Id.*

2. Congress acted to remedy this longstanding problem by ensuring public access to clear, upfront information about the price of health care. Congress mandated that health plans and health insurance issuers "make available to the public, accurate and timely disclosure of" certain "information." 42 U.S.C. §18031(e)(3); *see also* 42 U.S.C. §300gg-15a. This information includes both statutorily required information and "[o]ther information as determined appropriate by the Secretary" of Health and Human Services. *Id.*

3. To fulfill this statutory mandate, the Defendant Agencies (the U.S. Departments of Health & Human Services, Labor, and the Treasury) undertook a lengthy notice-and-comment process to determine what information health plans should be required to disclose. At the end of this process, Defendants concluded that "transparency in health coverage requirements will strengthen America's health care system by giving health care consumers, researchers, regulators, lawmakers, health innovators, and other health care stakeholders the information they need to make, or assist others in making informed decisions about health care purchases." 85 Fed. Reg. at 72160. To remedy the well-documented problems resulting from a lack of transparency, Defendants promulgated comprehensive regulations requiring healthcare plans and issuers to disclose to the public (among other things) prescription drug prices, and to do so by January 1, 2022.

4. But, after being sued by industry groups challenging the final regulations, Defendants indefinitely suspended enforcement of several core aspects of these crucial price transparency rules. Worse, they did so by posting online FAQs, rather than following the required notice-and-comment procedures that must precede any substantive changes to an existing regulation.

5. The public has a right to the important information that is subject to disclosure under the final rules, but because of Defendants' unlawful amendment of those rules, plans and issuers are ignoring their legal obligation to report it. Defendants' non-enforcement policies reflect unlawful substantive changes to existing regulations that were not promulgated in accordance with the APA's procedures for modifying a regulation. Those policies are unlawful and must be set aside.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction under 5 U.S.C. §553 and 28 U.S.C. §§1331, 2201(a), 2202.

7. Venue is proper because plaintiff Foundation for Government Accountability resides in this district. 28 U.S.C. §1391(e)(1).

PARTIES

8. Plaintiff Foundation for Government Accountability (FGA) is a non-partisan, non-profit organization that helps millions achieve the American

dream by improving welfare, work, health care, and election integrity policy in the states and in Washington, D.C. FGA seeks to obtain and disseminate health care pricing information to fulfill its mission of reducing the costs of health care for all Americans. FGA resides in Naples, Florida.

9. Defendant U.S. Department of Health and Human Services is an agency of the federal government.

10. Defendant Xavier Becerra is sued in his official capacity as Secretary of Health and Human Services.

11. Defendant U.S. Department of Labor is an agency of the federal government.

12. Defendant Julie A. Su is sued in her official capacity as Acting Secretary of Labor.

13. Defendant U.S. Department of the Treasury is an agency of the federal government.

14. Defendant Janet Yellen is sued in her official capacity as Secretary of the Treasury.

15. Plaintiff refers to Defendants collectively as "the Agencies."

16. Defendants both individually and collectively are responsible for interpreting and enforcing Section 1311(e) of the Affordable Care Act, 42 U.S.C. §18031(e), and the Transparency in Coverage Rule, 45 C.F.R.

§147.212, and for promulgating and implementing the challenged Non-Enforcement Policies discussed below.

BACKGROUND

I. Federal Agencies Must Comply with the Administrative Procedure Act in Promulgating and Amending Regulations.

17. The APA requires an agency action be set aside if it is issued "without observance of procedure required by law." 5 U.S.C. §706(2)(D). Parties injured by such a federal agency action may seek judicial review. *See id.* §§702, 704.

18. The APA requires that all "'legislative rules'"—those that have the "'force and effect of law'"—be promulgated through notice-and-comment procedures that give the public an opportunity for input, and require the agency to consider those comments in crafting its final action. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

19. Once 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. The APA requires agencies to "use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Id.* at 101. "'[A]n agency issuing a legislative rule is itself bound by the rule until that rule is amended or revoked' and 'may not alter [such a rule] without notice and comment.'" *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017).

20. Notice and comment protects affected parties from unannounced and unjustified changes in agency rules and ensures agencies make decisions based on complete, comprehensive information and data. *See Hewitt v. Comm'r of IRS*, 21 F.4th 1336, 1343 (11th Cir. 2021).

II. Congress Mandates Transparency in Health Coverage.

21. Finding the actual price of health care can be extremely difficult and confusing. "[P]rices of health care services [are] not readily available," and it is "difficult for consumers to obtain price estimates in advance for health care services," in part because of "a complex billing structure resulting in bills from multiple providers, … the lack of public disclosure of rates negotiated between providers and third-party payers," 84 Fed. Reg. 65464, at 65466 (Nov. 27, 2019), and the wide variation of "[p]rices for the same or similar services and treatments … both among regions, among facilities within a region, and even within a facility, based on the payer." Brian Blase, Ph.D., *Transparent Prices Will Help Consumers and Employers Reduce Health Spending* at 2, Tex. Pub. Pol'y Found. (Sept. 27, 2019), perma.cc/7ZGD-SHYE.

22. This lack of transparency harms patients. "Increased enrollment in [high deductible health plans] and the shift to coinsurance across plan and benefit designs means that [patients] have a vested interest in learning the costs of care prior to paying for items or services, as they are responsible for paying out-of-pocket expenditures, which are directly dependent on the

negotiated or contractual price." 85 Fed. Reg. at 72161. But "[w]hen [patients] seek care, they do not typically know whether they could have received the same service from another provider at lower prices." *Id.* at 72160. Instead, third parties "negotiate prices on the [patient's] behalf and reimburse costs directly to health care providers, concealing the actual price from the [patient] at the point of care." *Id.* Patients often learn the price "only after services are rendered" when they receive a bill or explanation of benefits. *Id.*

23. This lack of transparency severely distorts the health care market, resulting in waste and inefficiency across this massive sector of the economy. Without clear information about prices, patients cannot "shop for health care items and services … efficiently." *Id.* at 72161. And "market forces cannot drive competition" and "demand for lower prices" either. *Id.* "This lack of competition in many health care markets is demonstrated by significant, unexplained variations in prices for procedures, even within a single region." *Id.* But "research show[s] how price transparency leads to lower and more uniform pricing in health care markets." *Id.* at 72162.

24. Lack of price transparency harms patients in other ways as well. It undermines the ability of "researchers, regulators, lawmakers, patient and consumer advocates, and businesses that provide [patient] support tools and services" to assist patients in "mak[ing] informed health care decisions." *Id.* at 72161. "For instance, with pricing information researchers could better assess

the cost-effectiveness of various treatments; state regulators could better review issuers' proposed rate increases; patient advocates could better help guide patients through care plans; employers could adopt incentives for consumers to choose more cost-effective care; and entrepreneurs could develop tools that help doctors better engage with patients." *Id.*

25. Lack of transparency also exacerbates the problem of surprise billing. *See id.* "[T]he disclosure of pricing directly to consumers could help mitigate some unexpected health care costs" and "allow stakeholders to develop better tools to help patients avoid surprises and improve oversight of health insurance issuers, plans, and providers." *Id.*

26. Lack of transparent pricing also contributes to medical debt and hardship for consumers. Millions of Americans owe medical debt to hospitals and other health care providers. *See* LeBoutillier, *Know Before You Go: CMS Should Use Hospital Price Transparency Rule Enforcement to Encourage Consumer-Driven Health Care for Cost Containment* at 7, J. of Health Care Fin. (2023). Patients may incur ruinous debts and face litigation to enforce those debts without knowing the cost of the services they received before they were provided or, indeed, whether the debts fairly reflect the costs of services rendered. "The medical debt impact on public health policy manifests as decreased utilization, potential decreased access to care, negative health outcomes, and increased poverty." *Id.* at 8. "Price transparency is one piece of

a comprehensive strategy to protect consumers against medical debt and adverse public health outcomes by helping consumers understand their [medical] bills and shop for services to avoid high-cost care." *Id.*

27. Efforts by states and private groups to increase transparency often proved insufficient in the absence of uniform rules, thus warranting federal intervention. "[S]tate transparency requirements are generally not applicable to self-insured group health plans, which cover approximately 58.7 percent of private-sector workers." 85 Fed. Reg. at 72162-63. In addition, "millions of insured Americans … do not have access to any type of health care pricing tool," and "many price transparency tools on the market only offer wide-range estimates or average estimates of pricing that use historical claims data … [which] may not accurately reflect an individual's plan design and benefits … to allow the consumer to meaningfully predict costs." *Id.* at 72163. These "existing price transparency tools [are] often … difficult for users to navigate," because it is "difficult to compare one plan against another, understand the scope of services covered and their costs, and interpret the terminology plans and issuers use." *Id.*

28. Congress acted to provide the public more information about the cost of healthcare in the Affordable Care Act of 2010. In particular, Section 1311 of the Act requires "transparency in coverage" from health plans. *See* 42 U.S.C. §18031.

29. Section 1311(e)(3) mandates that health plans on insurance exchanges "make available to the public, accurate and timely disclosure of" certain "information." *Id.* §18031(e)(3). This requirement to "make such information available to the public" also extends to "group health plan[s] and … health insurance issuer[s] offering group or individual health insurance coverage" that are not on an exchange. 42 U.S.C. §300gg-15a. This information includes "[c]laims payment policies and practices," "[d]ata on rating practices," and "[i]nformation on cost-sharing and payments with respect to any out-of-network coverage." 42 U.S.C. §18031(e)(3). A health plan must also make available "[o]ther information as determined appropriate by the Secretary." *Id.*

30. Section 1311 includes several specific provisions meant to achieve its goal of public access to information about the cost of health care. It requires disclosures to be "submitted … in plain language." *Id.* Congress defined "plain language" to mean "language that the intended audience, including individuals with limited English proficiency, can readily understand and use." *Id.* Congress required the Secretaries of HHS and Labor to "jointly develop and issue guidance on best practices of plain language writing." *Id.*

31. Section 1311(e)(3) also requires "health plans … to permit individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a

specific item or service by a participating provider in a timely manner upon the request of the individual." *Id.* "At a minimum, such information shall be made available to such individual through an Internet website and such other means for individuals without access to the Internet." *Id.*

III. The Agencies Implement Section 1311's Public Access Requirements through the Transparency in Coverage Rule.

32. Nine years after Section 1311's passage, the President concluded that "[o]paque pricing structures [were] benefit[ing] powerful special interest groups, such as large hospital systems and insurance companies, but … [were] leav[ing] patients and taxpayers worse off than would a more transparent system." Executive Order 13877, 84 Fed. Reg. 30849, 30849 (June 24, 2019). To empower patients to "make fully informed decisions about their healthcare," as promised in Section 1311(e)(3), the President directed HHS to issue regulations "requir[ing] 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." *Id.* at 30850.

33. To implement Section 1311, the Agencies proposed and finalized the landmark Transparency in Coverage (TiC) Rule. *See* Final Rule, 85 Fed. Reg. 72158 (Nov. 12, 2020); NPRM, 84 Fed. Reg. 65464 (Nov. 27, 2019). The Agencies issued a Notice of Proposed Rulemaking on November 27, 2019. 84 Fed. Reg. 65464. The Agencies "received over 25,000 comments in response

to the proposed rules from a range of stakeholders, including plans and issuers, health care providers, prescription drug companies, employers, state regulators, health IT companies, health care policy organizations and think tanks, and individuals." 85 Fed. Reg. at 72167. After analyzing comments over the next year, the Agencies issued the final TiC Rule on November 12, 2020, carefully responding to those comments in a document spanning 150 pages of the Federal Register. 85 Fed. Reg. 72158.

34. Section 147.212 of the final TiC Rule requires "public disclosure of 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." 45 C.F.R. §147.212(b). "A group health plan or health insurance issuer must make [this information] available on an internet website … in three machine-readable files"—an "in-network rate" file, an "out-of-network allowed amount" file, and a "prescription drug" file. A "[m]achine-readable file" is "a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost." *Id.* §147.210. All the information on these files must be provided in "dollar amounts." *Id.* §147.212(b)(1)(i)(C), 147.212(b)(1)(ii), 147.212(b)(1)(iii).

35. As relevant here, the plan or issuer's "prescription drug" file must contain "negotiated rates" and "[h]istorical net prices" of prescription drugs, with each rate and price "[r]eflected as a dollar amount." *Id.* §147.212(b)(1)(iii). A negotiated rate is "the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager." *Id.* §147.210(a)(2)(xvi). A historical net price is "the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug." *Id.* §147.210(a)(2)(xi).

36. Each machine-readable file "must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services." *Id.* §147.212(b)(2). And each reporting "group health plan or health insurance issuer must update the machine-readable files and information … monthly." *Id.* §147.212(b)(3).

37. Section 147.212 of the TiC Rule has two safe harbor provisions.

38. First, "[a] group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under … this section, provided that the plan or issuer corrects the information as soon as practicable." *Id.* §147.212(c)(4).

39. Second, "[a] group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable." *Id.* §147.212(c)(5).

40. The TiC Rule had an effective date of January 1, 2022, giving affected entities more than a year from promulgation to come into compliance. *Id.* §147.212(c)(1) ("The provisions of [the TiC Rule] apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2022."). While the Agencies initially proposed an effective date of "1 year after the finalization of th[e] rule," 84 Fed. Reg. at 65490, 65523, some commenters asked for an extension of "at least one year and up to five years." 85 Fed. Reg. at 72252-53. The Agencies carefully considered those requests for further delay but concluded that January 1, 2022 was an appropriate effective date. *See* 85 Fed. Reg. at 72252-53.

IV. Congress Enacts Additional Disclosure Requirements in the 2021 Consolidated Appropriations Act Transparency Rules.

41. After the Agencies promulgated the TiC Rule, but before it went into effect, Congress enacted additional price transparency rules in the Consolidated Appropriations Act of 2021 (CAA). *See* Pub. L. No. 116-260, Division BB, §204 (codified at 42 U.S.C. §300gg-120).

42. These new rules require group health plans and insurance issuers offering group or individual insurance coverage to submit to the Agencies additional, complementary information about prescription drugs. This information includes the 50 most frequently dispensed and 50 most costly drugs, total spending on health care services broken down by type of costs (*i.e.*, hospital costs, provider costs, drug costs, etc.), and average monthly premiums. *See id.* These disclosure requirements did not displace those in Section 1311 and the TiC Rule but required the disclosure of even more information.

V. The Agencies Adopt Multiple Non-Enforcement Policies Without Notice and Comment.

43. On August 10, 2021, shortly before the TiC Rule was scheduled to go into force, industry groups sued the Agencies, arguing that Section 147.212 of the TiC Rule violated the APA. *See Chamber of Com. v. HHS*, 6:21-cv-309, Doc. 1 (E.D. Tex.). Specifically, they challenged the requirement to report the historical net prices of prescription drugs and to do so in machine-readable files, arguing that these requirements would be too costly to implement.

44. On August 20, 2021, the Agencies jointly issued FAQ Part 49. *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021), perma.cc/YLW4-VVTF. The first question asked, "Will the Departments enforce the machine-readable file provisions in the TiC Final Rules?" *Id.* at 1. The Agencies explained, "Yes, subject to two exceptions." *Id.* "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." *Id.* (citing 45 C.F.R. §147.211(b)(1)(iii)). Despite the unambiguous effective date of January 1, 2022, in the Final Rules, *see* 45 C.F.R. §147.212(c)(1), the Agencies declared they would "defer enforcement … until July 1, 2022." *Aug. 2021 FAQs*, *supra* at 2.

45. The Agencies justified this extension based on "stakeholders … expressed concern about potentially duplicative and overlapping reporting requirements for prescription drugs" under the CAA and TiC Rule, *id.*, even though the two rules require disclosure of different information.

46. The August 2021 FAQs also announced an indefinite pause on enforcement of the requirement to report prescription drug prices in machine-readable files. It explained that "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 [sic] related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate." *Id.* The FAQs encouraged states to "to take a similar enforcement approach," and assured states the Agencies would "not determine that a state is failing to substantially enforce this requirement if it takes such an approach." *Id.* Since then, the Agencies have not initiated notice and comment rulemaking to amend or repeal Section 147.212's requirement to publish prescription drug prices in "machine-readable files" beginning on January 1, 2022.

47. Four days after the Agencies published these Non-Enforcement Policies in this FAQ, on August 25, 2021, the industry groups who had sued to challenge Section 147.212 of the TiC rule voluntarily dismissed their lawsuit against the Agencies. *See Chamber of Com.*, 6:21-cv-309, Doc. 12.

48. Three months later, the Agencies issued an interim final rule addressing disclosure requirements under the CAA. 86 Fed. Reg. 66662 (Nov. 23, 2021). This interim final rule did not address the disclosure requirements of the ACA or the TiC Rule. *See id.*

49. The following year, the Agencies issued an April 2022 FAQ that created yet another "enforcement safe harbor for satisfying the reporting requirements" in the TiC Rule. *FAQs about Affordable Care Act*

Implementation Part 53 (Apr. 19, 2022), perma.cc/HB78-WZHD. This time the Agencies suspended enforcement of the requirement to report prices in dollar amounts in two situations. First, a plan or insurance issuer did not have to report dollar amounts when it encountered difficulty "deriv[ing] with accuracy specific dollar amounts contracted for covered items and services in advance of the provision of that item or service." *Id.* Second, the Agencies also excused compliance where health plans found it difficult to "disclose specific dollar amounts according to the schema as provided in the Departments' technical implementation guidance." *Id.*

50. The Agencies stated that this safe harbor would continue indefinitely unless and until the Agencies decided to "revisit this safe harbor in the future." *Id.* As of this filing, the Agencies have not revisited this safe harbor.

51. On August 19, 2022, the Agencies issued yet another FAQ reiterating that they had "defer[ed] enforcement of the requirement that plans and issuers publish a machine-readable file related to prescription drugs." *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* at 26 (Aug. 19, 2022), perma.cc/U2KG-FBW4. As of this filing, the Agencies continue to not enforce this unambiguous requirement of the TiC Rule.

52. The Agencies have thus indefinitely suspended enforcement of core aspects of the TiC Rule without notice and comment. Through informal FAQs the Agencies have disclaimed enforcement of the regulatory requirements in 45 C.F.R. §147.212 to disclose prescription drug prices in dollar amounts and machine-readable files, starting on January 1, 2022. Not only do these Non-Enforcement Policies amend the TiC Rule's January 1, 2022 effective date, but they also create new enforcement safe harbors that far exceed the TiC Rule's more limited safe harbor provisions that protect plans and issuers from liability for only good faith, inadvertent errors and omissions that are promptly corrected. *See* 45 C.F.R. §147.212(c)(4)-(5).

VI. FGA's Injury from the Non-Enforcement Policies

53. Section 1311 requires the Government and "health plans … [to] make available to the publi[c] accurate and timely disclosure of … information as determined appropriate by the Secretary [of HHS]." 42 U.S.C. §18031(e)(3); *see also id.* §300gg-15a. Under the TiC Rule, the information that must be disclosed includes "negotiated rates" and "[h]istorical net prices" for prescription drugs "[r]eflected as … dollar amount[s]." 45 C.F.R. §147.212(b)(1)(iii). Section 1311 entitles FGA, as a member of "the public," to this information. 42 U.S.C. §18031(e)(3).

54. Congress enacted Section 1311 to provide disclosure of covered information to the public to help consumers understand their options, and to

help fight skyrocketing health care prices by allowing patients to choose lower-cost, higher-value options. *See, e.g.*, 85 Fed. Reg. at 72167-68 ("Congres[s] recogni[zed] that the Secretary of HHS … would need broad flexibility to require the disclosure of information as appropriate to deliver the transparency necessary for consumers to understand their coverage options and for regulators to hold plans and issuers accountable.").

55. As part of FGA's goal of improving health care for all Americans, FGA seeks to obtain and disseminate important information and research to the public. Ensuring price transparency is a core component of FGA's research and advocacy efforts. FGA engages nationally renowned experts on price transparency and publishes research about the effects of price transparency programs. FGA also recently sued the Centers for Medicaid and Medicare Services in this Court under the FOIA statute for information on its enforcement of hospital price transparency rules. *See FGA v. CMS*, 2:22-cv-534 (M.D. Fla.).

56. FGA also seeks to advocate for policies that will benefit health care consumers and fight waste and inefficiency in the massive healthcare sector. For example, FGA advocated for a federal policy to increase access to medicine for consumers and commended legislators working to advance that policy. FGA, *FGA Applauds Senators Braun and Murkowski for Filing the Promising Pathway Act (PPA) During Senate HELP Committee Markup* (June 14, 2022),

perma.cc/BX3R-F242. FGA also endorses state-level policies designed to benefit consumers like a proposal to let patients count low-cost care toward their deductibles even if it is out of network. FGA, *Protecting Patients' Pocketbooks*, perma.cc/D9JZ-4VGW. Recently, FGA published a paper documenting the failure of hospital systems to comply with price transparency rules and urging policymakers at both the federal and state level to take action. *See* Dublois & Ingram, *How America's Hospitals Are Hiding the Cost of Health Care*, FGA (Aug. 29, 2022), perma.cc/LH68-BSG4.

57. To fulfill its mission of seeking higher quality and more affordable healthcare for every American, FGA wants to obtain, use, and disseminate, for publicly available research and advocacy, the rate and price information for prescription drugs that the Agencies are refusing to demand from plans and issuers despite the express terms of the TiC Rule. FGA would use this information for multiple purposes crucial to its mission.

58. The rate and price information would provide crucial information for FGA to use in its research and advocacy. FGA would use this information to review policy proposals and decide which proposals would best serve the interest of health care consumers. In addition to helping identify policies that would help consumers, the rate and price information would also help FGA decide how to direct advocacy resources toward proposals that would most benefit consumers. And the data would provide a crucial resource as FGA

makes its case about policy proposals to legislators and the public. For example, FGA could point to wide discrepancies in the price for identical products in the same market to make the case to policymakers and the public that more-competitive and transparent policies would create a better-functioning health care market.

59. Because of the Agencies' Non-Enforcement Policies, insurers are refusing to report complete information on the prices of prescription drugs, with no fear of penalties or consequences from the Agencies. FGA has thus been unable to obtain the information it seeks and is entitled to under Section 1311.

60. An order from this Court setting aside and enjoining the Non-Enforcement Policies would ensure that FGA would be able to access the price information currently being withheld. Under the TiC Rule, insurers would be required to provide the information that FGA seeks.

61. FGA also provides commentary on policies related to transparency as part of its mission to advocate for more transparency in health care prices.

62. By changing the TiC Rule through the Non-Enforcement Policies, the Agencies deprived FGA of the opportunity to comment on the new policy.

63. An order from this Court setting aside and enjoining the Non-Enforcement Policies would ensure that FGA has an opportunity to comment on the policy change enacted by the Agencies before that policy goes into effect.

FGA would offer comments explaining the importance of the policy of transparency enacted by the TiC Rule.

CLAIMS FOR RELIEF
COUNT I
Failure to Comply with Notice and Comment Procedures
5 U.S.C. §553

64. FGA repeats and re-alleges the allegations in the foregoing paragraphs as if set forth fully herein.

65. The APA requires agencies to "use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez*, 575 U.S. at 101. "'[A]n agency issuing a legislative rule is itself bound by the rule until that rule is amended or revoked' and 'may not alter [such a rule] without notice and comment.'" *Clean Air Council*, 862 F.3d at 9.

66. The Agencies promulgated the TiC Rule's requirements to report prescription drug prices (1) in dollar amounts (2) in machine-readable files (3) by January 1, 2022, all through notice and comment. 85 Fed. Reg. at 72308-10.

67. These requirements "'impose[] new rights or duties'" and thus are legislative rules. *Iowa League of Cities v. EPA*, 711 F.3d 844, 873 (8th Cir. 2013); *see, e.g.*, *Clean Air Council*, 862 F.3d at 6-7.

68. Any change to the TiC Rule's requirement to report prescription drug prices in dollar amounts and in machine-readable files by January 1, 2022 is thus an amendment of a legislative rule requiring notice and comment. *See, e.g.*, *Clean Air Council*, 862 F.3d at 6-7.

69. The same is true of the creation of a new regulatory safe harbor; it is a legislative rule that requires notice and comment. *See, e.g.*, *Mayor & City Council of Baltimore v. Trump*, 416 F. Supp. 3d 452, 500, 509 (D. Md. 2019).

70. Through their Non-Enforcement Policies, promulgated without notice and comment, the Agencies have indefinitely extended the compliance deadline for reporting prescription drug price information in dollar amounts and in machine-readable format, contrary to the plain text of the TiC Rule requiring full compliance by January 1, 2022. 45 C.F.R. §147.212(c)(1).

71. These Non-Enforcement Policies also far exceed the TiC Rule's enumerated safe harbor provisions, which protect plans and issuers from liability for only good faith, inadvertent errors and omissions that are promptly corrected. *Id.* §147.212(c)(4)-(5).

72. Because the Non-Enforcement Policies are legislative rules that effectively amend the TiC Rule, the Agencies were required to issue them through notice and comment, not internet FAQs. The Agencies' failure to do so violates the APA.

73. The Court must therefore "hold unlawful and set aside" the Non-Enforcement Policies. 5 U.S.C. §706(2).

PRAYER FOR RELIEF

WHEREFORE, FGA ask this Court to enter judgment in its favor and to provide the following relief:

(1) An order declaring the Agencies' Non-Enforcement Policies violate the APA's notice and comment requirements;

(2) An order vacating the Non-Enforcement Policies;

(3) An order permanently enjoining the Agencies from implementing the Non-Enforcement Policies;

(4) All other relief to which FGA is entitled that the Court deems just and proper.

Dated: March 23, 2022

Respectfully Submitted,

/s/ *Michael A. Sasso*

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** Pro hac vice motions forthcoming*
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