IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

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| CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA and TYLER AREA CHAMBER OF COMMERCE,<br><br>*Plaintiffs*,<br><br>v.<br><br>UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF LABOR, EMPLOYEE BENEFITS SECURITY ADMINISTRATION, DEPARTMENT OF THE TREASURY, INTERNAL REVENUE SERVICE, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES,<br><br>*Defendants*. | ) | Civil Action No. 6:21-cv-309 |

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs Chamber of Commerce of the United States of America ("U.S. Chamber") and Tyler Area Chamber of Commerce ("Tyler Chamber") (collectively, "Plaintiffs"), bring this action for declaratory and injunctive relief against the Department of Health and Human Services, the Centers for Medicare & Medicaid Services, the Department of Labor, the Employee Benefits Security Administration, the Department of the Treasury, the Internal Revenue Service, and the current heads of those agencies in their official capacities (collectively, "Defendants"), alleging as follows:

## INTRODUCTION

1. This action under the Administrative Procedure Act ("APA") challenges part of a final rule issued by Defendants, entitled "Transparency in Coverage," 85 Fed. Reg. 72,158 (Nov. 12, 2020) (the "Rule").

2. Plaintiffs and their members believe that health care should be affordable and accessible. To that end, Plaintiffs and their members have long supported efforts to provide consumers with meaningful tools and data for making informed health care decisions. For example, many health insurance companies have developed tools to provide consumers with individualized information regarding cost-sharing and expected out-of-pocket costs for products and services, including prescription drugs. These innovative tools, which are constantly being upgraded with new technology and improved in response to customer feedback, supply patients and

employers with useful information about treatment options and the cost of health care.

3. The Rule, in part, seeks to achieve these important efforts and objectives. In this action, Plaintiffs do not challenge all aspects of the Rule. Rather, Plaintiffs challenge specific provisions of the Rule that are not consumer-focused and that are in fact counterproductive, wasteful, and unlawful. These provisions of the Rule threaten to reduce competition, and ultimately raise costs to consumers, by revealing confidential, commercially sensitive information that competitors currently do not share with each other. The required public disclosure of that closely guarded information runs afoul of long-established protections against the forced disclosure of confidential commercial information, including trade secrets, and is detrimental to the business community as a whole. By Defendants' own estimates, compliance with the challenged provisions of the Rule will cost billions of dollars in just the first year of implementation, and hundreds of millions of dollars annually every year thereafter.

4. As finalized, the Rule has two main sections. The first section, labeled "required disclosures to participants, beneficiaries, or enrollees," requires insurers, including employers who maintain self-insured health plans, to provide certain "cost-sharing information" to individuals upon request via a website or in paper form. 85 Fed. Reg. at 72,306; *see id.* at 72,158 (requiring insurers to disclose, upon request, "an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider"). The second section, labeled "requirements for

public disclosure," requires insurers to post on a website a host of internal pricing data in three "machine-readable files" (*i.e.*, data files), including an "In-network Rate File," an "Allowed Amount File," and a "Prescription Drug File." *Id.* at 72,221, 72,308. This action challenges aspects of the second section of the Rule and does not challenge the first section.

5. The Rule defines "machine-readable file" as "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.* at 72,306 (emphasis added). This definition makes no reference to readability *by human beings*.

6. Nor is the content of the files readily understandable by the average consumer. The In-network Rate File provisions of the rule require disclosure of "applicable rates" for all items and services covered by a plan in-network, except prescription drugs. The "applicable rate" for a particular item or service may include one or more of three data points: the "negotiated rate"; the "derived amount"; and the "underlying fee schedule rate." The negotiated rate is the rate that an insurer contractually agreed to pay for the covered item or service. The "derived amount" is a number that reflects the price that the insurer assigned the item or service "for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of [45 C.F.R.] § 153.710(c)." *Id.* at 72,305. The "underlying fee schedule rate" is a number that reflects the rate for the item or service that the insurer used as a mathematical input to calculate an individual's cost-

sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount. *Id.* at 72,305–08.

7. The Allowed Amount File provisions of the rule are the out-of-network counterpart to the In-network Rate File provisions. The Allowed Amount File provisions require disclosure of billed charges and "out-of-network allowed amounts," meaning the maximum amount that an insurer will pay for a covered item or service, furnished by an out-of-network provider. *Id.* at 72,308–09. Although "covered items or services" may include prescription drugs, the vast majority of prescription drug transactions are in-network.

8. The Prescription Drug File provisions of the rule require disclosure of not only the "negotiated rates" that insurers contractually agreed to pay for covered prescription drugs, but also, for each such drug, a more complex and novel data point that the Rule calls "historical net price." *Id.* at 72,309. The Rule defines "historical net price" as "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.* at 72,305.

9. The three machine-readable files, including the Prescription Drug File, must be updated on a monthly basis. *Id.* at 72,243–44. The "historical net price" is computed for a 90-day period beginning 180 days before the date a particular Prescription Drug File is published. *Id.* at 72,237.

10. According to the Rule, authority to require the disclosure of these machine-readable files is derived from 42 U.S.C. § 18031(e)(3)(A). Under 42 U.S.C. § 18031(e)(3)(B), however, disclosures pursuant to § 18031(e)(3)(A) must be made in "plain language." The machine-readable-file requirement forces plans, including self-funded plans, to disclose vast amounts of highly technical pricing data in a "digital representation" designed to be readable by a computer, instead of plain language designed to be accessible to individual patients and consumers. Because that complicated, unwieldy format cannot be reconciled with Congress's command that disclosures be made in plain language, the machine-readable-file requirements violate the law and must be set aside.

11. Moreover, the original, proposed version of the Rule, 84 Fed. Reg. 65,464 (Nov. 27, 2019) ("Proposed Rule"), did not include any "historical net price" requirement. In fact, the term "historical net price" does not even appear anywhere in the Proposed Rule. Interested parties therefore lacked meaningful notice and opportunity to comment on this improper, unanticipated, and burdensome new requirement. Defendants thus violated the Administrative Procedure Act by imposing this new requirement without providing notice and an opportunity to comment.

12. The requirement that Plaintiff U.S. Chamber, and the members of both Plaintiffs that are subject to the Rule, calculate and publicly disclose the "historical net price" of prescription drugs in a massive, unwieldy spreadsheet does not serve the stated goal of enhancing affordability and meaningful consumer transparency in

health care. At the same time, the requirement forces the improper disclosure of confidential, commercially sensitive information, deprives businesses of the opportunity to gain a competitive advantage from their proprietary information, saddles private parties with billions of dollars in compliance costs, and will only serve to drive up (not down) the costs that patients and plans will pay for health care. This belated addition to the Rule is improper, insufficiently reasoned, and exceeds Defendants' statutory authority. For those additional and independently sufficient reasons, the "historical net price" requirement likewise must be set aside.

## PARTIES AND STANDING

13. Plaintiff Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 members, including members in the Eastern District of Texas, and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. Among other things, the U.S. Chamber works with federal and state governments to improve our nation's health care system by achieving meaningful transparency, promoting consumer choice, and supporting reforms that yield greater value to patients and employers. The U.S. Chamber is a 501(c)(6) nonprofit organization headquartered in Washington, D.C.

14. The U.S. Chamber has standing to bring this suit because it will be directly impacted by the Rule's requirements, as the U.S. Chamber is a self-insured employer that is directly subject to the Rule and therefore is required to comply with

the Rule. The U.S. Chamber will incur substantial costs in order to comply with the Rule's burdensome and unlawful "machine-readable file" requirements, including the "historical net price" requirement. In addition, the U.S. Chamber has associational standing because its members will be directly and adversely affected by the Rule and thus would have standing to sue in their own right; because the interests the U.S. Chamber seeks to protect are germane to its policy aims; and because neither the claims asserted nor the relief requested requires an individual member to participate in this suit. Along with the U.S. Chamber members that are directly subject to the Rule (and therefore will incur substantial costs in order to comply with the Rule's requirements), many other U.S. Chamber members, and the U.S. Chamber itself, will be harmed by the Rule because it will drive up their health care costs, divert resources from more pressing health care needs, and make it more difficult for them to operate their businesses or organizations. The Rule will also harm the U.S. Chamber and its members by requiring the disclosure of competitively sensitive proprietary information.

15. The Tyler Area Chamber of Commerce of Tyler, Texas, is the region's largest business organization. It represents approximately 1,800 members, including members in the Eastern District of Texas. The Tyler Chamber works with federal and state governments to improve the health care system in the region and improve the quality of life for all of its citizens. The Tyler Chamber is a 501(c)(6) nonprofit organization located in Tyler, Texas.

16. Plaintiff Tyler Chamber has standing to bring this suit because its members will be directly and adversely affected by the Rule and thus would have standing to sue in their own right; because the interests the Tyler Chamber seeks to protect are germane to its policy aims; and because neither the claims asserted nor the relief requested requires an individual member to participate in this suit. Along with the Tyler Chamber members that are directly subject to the Rule, many other Tyler Chamber members, and the Tyler Chamber itself, will be harmed by the Rule because it will drive up their health care costs, divert resources from more pressing health care needs, and make it more difficult for them to operate their businesses or organizations. The Rule will also harm the Tyler Chamber and its members by requiring the disclosure of competitively sensitive proprietary information.

17. Defendant Department of Health and Human Services ("HHS") is an executive department of the United States headquartered in Washington, D.C. and is subject to the APA. *See* 5 U.S.C. § 551(1).

18. Defendant Centers for Medicare & Medicaid Services ("CMS") is an agency within HHS and is subject to the APA. *See* 5 U.S.C. § 551(1).

19. Defendant Department of the Treasury ("Treasury") is an executive department of the United States headquartered in Washington, D.C. and is subject to the APA. *See* 5 U.S.C. § 551(1).

20. Defendant Internal Revenue Service ("IRS") is an agency within Treasury and is subject to the APA. *See* 5 U.S.C. § 551(1).

21. Defendant Department of Labor ("DOL") is an executive department of the United States headquartered in Washington, D.C. and is subject to the APA. *See* 5 U.S.C. § 551(1).

22. Defendant Employee Benefits Security Administration ("EBSA") is an agency within DOL and is subject to the APA. *See* 5 U.S.C. § 551(1).

23. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is sued in his official capacity as head of HHS.

24. Defendant Chiquita Brooks-LaSure is Administrator of CMS. Administrator Brooks-LaSure is sued in her official capacity as head of CMS.

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

26. Defendant Charles P. Rettig is the Commissioner of the IRS. Commissioner Rettig is sued in his official capacity as head of the IRS.

27. Defendant Douglas O'Donnell is Deputy Commissioner for Services and Enforcement, a division within the IRS. Deputy Commissioner O'Donnell is sued in his official capacity.

28. Defendant Martin J. Walsh is the Secretary of Labor. Secretary Walsh is sued in his official capacity as head of DOL.

29. Defendant Ali Khawar is the Acting Assistant Secretary for EBSA. Acting Assistant Secretary Khawar is sued in his official capacity as acting head of EBSA.

## JURISDICTION AND VENUE

30. The Court has jurisdiction to adjudicate this action under 28 U.S.C. § 1331 and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*.

31. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States, at least one Plaintiff resides in this district, and no real property is involved in this action.

32. Plaintiffs are entitled to the requested declaratory and injunctive relief under the APA, 5 U.S.C. §§ 701–06, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02.

## BACKGROUND

33. In promulgating the Rule, Defendants purported to rely on two sources of statutory authority: section 1311(e)(3) of the Patient Protection and Affordable Care Act ("PPACA"), 42 U.S.C. § 18031(e)(3), which sets forth various disclosure requirements for health plans offered on health insurance Exchanges established under the PPACA; and section 2715A of the Public Health Service Act, 42 U.S.C. § 300gg-15a, which extends those disclosure requirements to a wider set of plans, including off-Exchange plans.

34. Section 1311(e)(3) of the PPACA, titled "Transparency in Coverage," addresses transparency in health insurance coverage and imposes certain reporting and disclosure requirements on health plans seeking certification as plans that may be offered on a health insurance Exchange. 42 U.S.C. § 18031(e)(3).

35. Under section 1311(e)(3)(A), plans must submit to the Exchange, the Secretary of HHS, and the State insurance commissioner, and must make available to the public, eight types of information specified by Congress: (i) claims payment policies and practices; (ii) periodic financial disclosures; (iii) data on enrollment; (iv) data on disenrollment; (v) data on the number of claims that are denied; (vi) data on rating practices; (vii) information on cost-sharing and payments with respect to any out-of-network coverage; and (viii) information on enrollee and participant rights. *Id.* § 18031(e)(3)(A)(i)–(viii).

36. Following those eight specific provisions, section 1311(e)(3)(A) includes as romanette (ix) a residual provision requiring plans to submit and disclose "[o]ther information as determined appropriate by the Secretary." *Id.* § 18031(e)(3)(A)(ix).

37. Per section 1311(e)(3)(B), any information required to be submitted under subparagraph (A), including romanette (ix), must be provided in "plain language." 42 U.S.C. § 18031(e)(3)(B). The term "plain language" is defined as "language that the intended audience, including individuals with limited English proficiency, can readily understand and use because that language is concise, well-organized, and follows other best practices of plain language writing." *Id.*

38. In addition to subparagraph (A)'s requirements to publicly disclose certain information, section 1311(e)(3) includes in subparagraph (C) a requirement to disclose certain enrollee-specific cost-sharing information upon request by an enrollee. Plans must, upon request, "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[.]" *Id.* § 18031(e)(3)(C).

39. Section 2715A of the Public Health Service Act requires group health plans and health insurance issuers offering group or individual coverage to "comply with the provisions of section 1311(e)(3) of [the PPACA]," except that a plan or coverage not offered through an Exchange need only submit the information required "to the Secretary and the State insurance commissioner, and make such information available to the public," rather than also having to submit the information to the Exchange. 42 U.S.C. § 300gg-15a.

40. On June 24, 2019, President Trump issued Executive Order 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First." 84 Fed. Reg. 30,849. Among other directives, that order instructed the Secretaries of HHS, the Treasury, and Labor to issue an advance notice of proposed rulemaking, "consistent with applicable law," soliciting comment on a proposal to require health care 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.

41. If Defendants had issued an advance notice of proposed rulemaking as directed by the Executive Order, that would have given stakeholders time to provide input on how best to achieve the goals of the Executive Order. But Defendants did

not do so. Nor did Defendants focus their proposal, as contemplated by the Executive Order, on helping patients predict their "out-of-pocket costs" before they receive care.

42. Instead, on November 27, 2019, Defendants skipped the advance notice step altogether and released a proposed rule of far greater breadth, complexity, and impact. 84 Fed. Reg. at 65,464. Defendants issued a 60-page proposed rule seeking to impose a host of detailed new disclosure requirements on plans and issuers. Defendants asserted that the "overarching goal" of the Proposed Rule was to "support a market-driven health care system by giving consumers the information they need to make informed decisions about their health care and health care purchases." *Id.*

43. Although the Proposed Rule differed in important respects from the final Rule, the Proposed Rule was like the final Rule in that it had two main components. The first component required group health plans and health insurance issuers to disclose a variety of "cost-sharing information" upon request to participants, beneficiaries, and enrollees. The required disclosures included not only a bottom-line estimate of an individual's cost-sharing liability for all covered items or services, but several other "content elements" that, according to the Proposed Rule, "generally reflect the same information that is included in an [Explanation of Benefits] after health care services are provided." 84 Fed. Reg. at 65,471. One of these elements was the negotiated rate between plans and providers for covered items and services (including prescription drugs), which the Proposed Rule described as "generally … an essential input" for calculating cost-sharing liability. *Id.*

44. This cost-sharing component of the Proposed Rule was predicated on the enrollee-specific cost-sharing transparency provision in section 1311(e)(3)(C) of the PPACA. 84 Fed. Reg. at 65,470.

45. The second main component of the Proposed Rule required plans and issuers to assemble and publicly disclose information in two regularly updated "machine-readable files": a Negotiated Rate File, containing in-network rates negotiated with providers for covered items and services, 84 Fed. Reg. at 65,479; and an Allowed Amounts File, containing "historical out-of-network allowed amounts" for covered items and services, *id*. at 65,480. The term "out-of-network allowed amounts" was defined as "the maximum amount a group health plan or health insurance issuer would pay for a covered item or service furnished by an out-of-network provider." *Id*. at 65,521. The Proposed Rule asserted that negotiated rates and out-of-network allowed amounts "directly determine[]" deductible requirements, coinsurance requirements, and maximum out-of-pocket limits, and can thus help consumers choose the coverage that best meets their needs. *Id.* at 65,477.

46. The Proposed Rule predicated the authority to mandate disclosure of the Allowed Amounts File on section 1311(e)(3)(A)(vii) of the PPACA, and it appeared to claim authority to mandate the disclosure of both files under the residual provision in romanette (ix) of section 1311(e)(3)(A). *See* 84 Fed. Reg. at 65,477.

47. The Proposed Rule set forth a tight deadline for implementing the detailed requirements of both of the two main components of the rule. According to

the Proposed Rule, the requirements would apply for plan years that began on or after one year after the effective date of the final Rule. *Id.* at 65,523.

48. Nothing in the Proposed Rule required, or even addressed the possibility of requiring, disclosure of "historical net price" data for prescription drugs (or any other items or services) in the machine-readable files.

49. For purposes of the *cost-sharing component* of the Proposed Rule, although Defendants sought comment regarding "whether a rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs," 84 Fed. Reg. at 65,472, Defendants made no mention of "net price" or "historical net price." Moreover, Defendants gave no hint that a disclosure requirement for "a rate other than the negotiated rate"—whether the undiscounted price, a "net price," or a "historical net price" —might be added to *the machine-readable file component* of the rule. Likewise, while Defendants solicited comment on "whether and how to account for any and all rebates, discounts, and dispensing fees *to ensure individuals have access to meaningful cost-sharing liability estimates* for prescription drugs," *id.* (emphasis added), this solicitation was clearly directed at the cost-sharing component of the Proposed Rule.

50. Against this backdrop, the final Rule surprisingly added a "historical net price" requirement that had appeared nowhere in the Proposed Rule. Defendants did not add this requirement to the consumer cost-sharing tool set forth in the final Rule. Instead, they added the requirement to a new, publicly-disclosed "Prescription Drug File." The final Rule made this change for purposes, and with effects, that have

nothing to do with individuals' "access to meaningful cost-sharing liability estimates." *See* 85 Fed. Reg. at 72,236–38.

51. As an element of the Prescription Drug File, the "historical net price" requirement is predicated solely on the residual provision in section 1311(e)(3)(A)(ix) of the PPACA, not on the cost-sharing transparency provision in section 1311(e)(3)(C). *See* 85 Fed. Reg. at 72,159.

52. Unlike the disclosures required in section 1311(e)(3)(A)(i)–(viii), "historical net price" comprises complex, commercially sensitive pricing information. This kind of data is entitled to legal protections against disclosure as proprietary business information and trade secrets. In addition, compelled disclosure of such data may affect health care market dynamics in ways that benefit neither businesses nor patients, such as by inhibiting private parties from competing on price in confidential negotiations.

53. The "historical net price" requirement also has a far more significant economic impact than the requirements enumerated in (i)–(viii), both because of the costs of compliance and because of its interference with private business practices.

54. During the notice-and-comment process, commenters raised concerns that Defendants' tight deadline for creating the machine-readable files was unrealistic. Defendants not only refused to extend the deadline, but piled even more burdens on regulated parties by adding the "historical net price" requirement to the machine-readable files, without taking into account the extra time needed to implement that unexpected addition to the Rule. *See* 85 Fed. Reg. at 72,253.

## FIRST CAUSE OF ACTION

### The "Machine-Readable Files" Requirement Exceeds Defendants' Statutory Authority in Violation of the Administrative Procedure Act

55. Plaintiffs reassert and incorporate by reference all preceding allegations.

56. The APA, 5 U.S.C. § 706(2)(C), directs a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations[.]"

57. The requirement to publicly disclose information in three "machine-readable files" exceeds Defendants' statutory authority, jurisdiction, and limitations under the PPACA (including as extended by PHS Act Section 2715A).

58. The asserted source of statutory authority for the "machine-readable files" requirement is section 1311(e)(3)(A) of the PPACA. Specifically, the In-network Rate File and the Prescription Drug File are predicated on section 1311(e)(3)(A)(ix), which authorizes the HHS Secretary to mandate the disclosure of "[o]ther information as deemed appropriate by the Secretary," 42 U.S.C. § 18031(e)(3)(A)(ix). The Allowed Amount File is predicated on section 1311(e)(3)(A)(vii), which requires disclosure of "[i]nformation on . . . payments with respect to any out-of-network coverage." *See* 85 Fed. Reg. at 72,159 (internal quotation marks omitted).

59. Because the "machine-readable file" portion of the Rule is predicated on subparagraph (A) of section 1311(e)(3), it must comply with the "plain language" requirement codified in subparagraph (B) of section 1311(e)(3). 42 U.S.C. § 18031(e)(3)(B). Subparagraph (B) provides that disclosures pursuant to

subparagraph (A) "shall be provided in plain language," meaning "language that the intended audience, including individuals with limited English proficiency, can readily understand and use because that language is concise, well-organized, and follows other best practices of plain language writing."

60. By definition, a "machine-readable file" is designed not for understanding and use by ordinary people, but to be "imported or read *by a computer system* for further processing *without human intervention*." 85 Fed. Reg. at 72,306 (emphasis added).

61. The In-network Rate File, Allowed Amount File, and Prescription Drug File each require the disclosure of an overwhelming array of complicated internal pricing data, accompanied by technical jargon, in a massive, unwieldy "machine-readable file"—which the Rule itself acknowledges "may not be easy for an average consumer to navigate," 85 Fed. Reg. at 72,234.

62. That is the opposite of a simple, plain-language disclosure requirement. Congress did not intend to authorize, and did not authorize, Defendants to require the disclosure of information that is not capable of being readily understood and used by average consumers. Still less did Congress authorize Defendants to require the disclosure of information in a format, and by a mechanism, that is inconsistent with that requirement.

63. Although Defendants apparently contemplate that technical information will be "translated into consumer-friendly tools by third-party application developers," 85 Fed. Reg. at 72,225, the very fact that the information

requires "translat[ion]" by third parties with specialized expertise makes clear that it is not already in "plain language" that the public can "readily understand and use."

64. Under the "major questions" doctrine, moreover, Congress must speak clearly before it will be found to have delegated decisions of major economic and political significance to an administrative agency. Even Defendants acknowledge that the Rule is "likely to result in an annual effect on the economy of $100 million or more" and will impose direct costs and burdens on nearly 2,000 health insurance issuers and third-party administrators (TPAs), as well as all 50 states (to say nothing of the many thousands of self-insured plans that insure tens of millions of Americans and remain directly subject to the Rule even if they hire TPAs or others to help them comply with it). 85 Fed. Reg. at 72,269, 72,294. In reality, the cost and burden of the Rule will be far greater. As Defendants' Regulatory Impact Analysis indicates, the cost of complying with the machine-readable files requirement is estimated to be more than $3.5 billion in the first year of implementation and hundreds of millions of dollars *annually* thereafter. *See id.* at 72,285, 72,288, 72,290.

65. For these reasons, the portion of the Rule requiring publication of the three machine-readable files should be held unlawful and set aside.

## SECOND CAUSE OF ACTION

### The "Historical Net Price" Requirement Exceeds Defendants' Statutory Authority in Violation of the Administrative Procedure Act

66. Plaintiffs reassert and incorporate by reference all preceding allegations.

67. The APA, 5 U.S.C. § 706(2)(C), directs a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction authority, or limitations[.]"

68. The "historical net price" requirement exceeds Defendants' statutory authority, jurisdiction, and limitations under the PPACA (including as extended by PHS Act Section 2715A).

69. The sole asserted source of statutory authority for the "historical net price" requirement is the residual provision in section 1311(e)(3)(A) of the PPACA, which authorizes the Secretary of HHS to mandate the disclosure of "[o]ther information as deemed appropriate by the Secretary," 42 U.S.C. § 18031(e)(3)(A)(ix).

70. Common sense and established principles of statutory interpretation, including the canon of *ejusdem generis*, require that a general residual provision of the kind in romanette (ix) be construed to cover only items similar to those enumerated in the preceding romanettes (i) through (viii).

71. The historical net price requirement has little in common with the disclosures required by romanettes (i) through (viii). Whereas the enumerated disclosures involve comparatively simple, coverage-related information, some of which may commonly be found on a patient's Explanation of Benefits, the historical net price requirement mandates the disclosure of complex commercially sensitive pricing information that is confidential, is not publicly available, and has no relevance to a patient's cost-sharing obligations. In fact, this type of pricing information is

typically protected against disclosure as a trade secret or proprietary business information.

72. The historical net price requirement also differs dramatically from the statutorily enumerated disclosures with respect to the costs of compliance and burdens on regulated parties.

73. In enacting section 1311(e)(3)(A)(ix), Congress did not give Defendants carte blanche to impose disclosure requirements substantially unlike the requirements that Congress specifically enumerated. By including romanette (ix) only at the end of a long list of disclosure provisions, all of which call for relatively simple, generic disclosures, Congress followed established conventions of statutory interpretation that dictate a limited, contextual understanding of Defendants' authority. Nor would Congress have intended to undermine established protections for proprietary business information and trade secrets, especially without saying so.

74. That common-sense understanding of the disclosure provisions in section 1311(e)(3)(A) is reinforced by statutory context that further delineates the reach and limits of those provisions. As discussed above, in a neighboring provision, Congress required the information "required to be submitted under subparagraph (A)" to be "provided in plain language" that "the intended audience, including individuals with limited English proficiency," can "readily understand and use." 42 U.S.C. § 18031(e)(3)(B). The requirement to disclose large quantities of highly technical "historical net price" information in a "machine-readable file" is especially difficult to square with that mandate.

75. Under the "major questions" doctrine, moreover, Congress must speak clearly before it will be found to have delegated decisions of major economic and political significance to an administrative agency. Defendants' interpretation of the residual provision would vest in them vast power to require private parties to supply an unbounded array of information to the government and the public without any clear limiting principle.

76. As noted above, *see supra* ¶ 64, Defendants estimate that the cost of the machine-readable files will be more than $3.5 billion in the first year of implementation. The cost of the Prescription Drug File alone is estimated to be more than $490 million in the first year and over $100 million annually thereafter. *Id.* at 72,272.

77. The "historical net price" requirement is of major economic and political significance, both because of the high cost of compliance and because of its disruptive effects on the operation of the health care industry.

78. Congress did not authorize, let alone clearly authorize, anything like the "historical net price" requirement, which requires complex, costly, and burdensome calculations and would disclose confidential and commercially sensitive information.

79. Moreover, construing section 1311(e)(3)(A)(ix) to authorize the historical net price disclosure requirement would raise serious constitutional concerns.

80. The Takings Clause of the Fifth Amendment prohibits the government from taking "private property . . . for public use, without just compensation."

81. The Takings Clause has long been understood to protect not only tangible property, but also intangible property, including trade secrets.

82. The disclosure of historical net price information to competitors and counterparties, as mandated by the Rule, would deprive each affected entity of the opportunity to continue to obtain a competitive advantage from trade secrets.

83. Requiring the disclosure of the "historical net price" of prescription drugs would reveal proprietary business information and trade secrets, taking private property for public use without just compensation.

84. Given the traditional primacy of the States in regulating health insurance, a broader interpretation of section 1311(e)(3)(A)(ix) would also raise concerns about undermining principles of federalism.

85. Finally, interpreting section 1311(e)(3)(A)(ix) to authorize Defendants to require whatever they want—regardless of how novel and distinct from the enumerated disclosures in romanettes (i) through (viii)—would raise serious concerns under the non-delegation doctrine. Congress may not delegate to the Executive unbounded discretion, with no legislated limiting principle, to make rules binding the conduct of private parties.

86. For these reasons, the "historical net price" requirement should be held unlawful and set aside.

## THIRD CAUSE OF ACTION

### The "Historical Net Price" Requirement is not a Logical Outgrowth of the Proposed Rule

87. Plaintiffs reassert and incorporate by reference all preceding allegations.

88. The APA, 5 U.S.C. § 706(2)(D), directs a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law."

89. The APA, 5 U.S.C. § 553(b)(3), requires an agency conducting notice-and-comment rulemaking to publish in its notice of proposed rulemaking "either the terms or substance of the proposed rule or a description of the subjects and issues involved."

90. Under well-established court precedent, this requirement means that the final rule the agency adopts must be a "logical outgrowth" of the rule proposed, such that interested parties would have had fair notice of any new requirements and an adequate opportunity to comment on them.

91. The Proposed Rule failed to provide adequate notice that the final Rule would adopt the "historical net price" requirement, thus depriving interested parties of an opportunity to comment on such a requirement.

92. In addition, the Proposed Rule failed to provide adequate notice of the costs and burdens that the "historical net price" requirement would impose (on insurers, on self-insuring employers, and on private parties generally), thus depriving

interested parties of an opportunity to comment on the significance of these burdens and costs and on alternatives that would mitigate such burdens and costs.

93. For these reasons, the "historical net price" requirement should be held unlawful and set aside.

**FOURTH CAUSE OF ACTION**

**The "Historical Net Price" Requirement is Arbitrary and Capricious**

94. Plaintiffs reassert and incorporate by reference all preceding allegations.

95. The APA, 5 U.S.C. § 706(2)(A), directs a reviewing court to "hold unlawful and set aside agency action" that is "arbitrary, capricious . . . or otherwise not in accordance with law."

96. The "historical net price" requirement is arbitrary and capricious because the Rule fails to adequately explain why that requirement is justified, and because Defendants failed to adequately take into account the factors relevant to the desirability of imposing such a requirement.

97. The Rule offers two principal justifications for the "historical net price" requirement. Neither of these justifications is sufficiently reasoned.

98. First, the Rule states that the historical net price information will make consumers "aware of situations where cost-sharing liability for a prescription drug exceeds the amount their plan or issuer ultimately paid for the prescription drug," which may in turn allow them to "make an informed decision regarding whether to utilize their plan or coverage when purchasing the prescription drug." 85 Fed. Reg.

at 72,238. The Rule fails to explain, however, why consumers would base such decisions on "the amount their plan or issuer ultimately paid" rather than on *their own* out-of-pocket costs. The Rule separately requires disclosure of an estimate of the consumer's cost-sharing liability and does not explain why it is necessary also to mandate disclosure to the public of historical net prices.

99. Second, piling inference upon inference, the Rule speculates that making historical net prices public "could expose the extent of rebates and other price concessions," which in turn "could cause a reduction in the use of rebates and other price concessions," which in turn, based on a mere "correlation" between rebates and drug manufacturer list prices, could result in lower manufacturer list prices, which in turn could result in "lower consumer costs." 85 Fed. Reg. at 72,237.

100. As the Rule acknowledges, however, rebates "may reflect discounts negotiated with drug manufacturers that *lower* drug prices for the plan or issuer." *Id.* (emphasis added). Nor do Defendants contest that, as basic economics would suggest, these lower prices enable plans and issuers to pass those savings on to consumers.

101. Elsewhere in the Rule, in fact, Defendants acknowledge that as a result of the availability of historical net price information, "drug manufacturers may seek to restructure their rebate and discount programs and could potentially cease providing rebates to plans and issuers . . . which could then result in *less* savings being passed on to consumers." 85 Fed. Reg. at 72,267 (emphasis added).

102. The "historical net price" requirement is thus unjustified, counter to logic and the evidence before the agencies, and inadequately explained.

103. That is hardly surprising, given Defendants' failure to provide notice that they were contemplating imposing the historical net price disclosure requirement. If Defendants had provided notice, commenters could have explained why such a requirement would not help consumers—and in fact likely would hurt consumers by driving up costs—while imposing significant compliance costs for no good reason.

104. Defendants also acted arbitrarily and capriciously in refusing to extend the deadline for complying with the Prescription Drug File requirement, despite their belated addition of the substantial new mandate to disclose historical net prices. The failure to consider this factor is especially glaring because historical net price information is not data that is already disclosed through, for example, Explanations of Benefits.

## FIFTH CAUSE OF ACTION

### The "Machine-Readable Files" Requirement is Arbitrary and Capricious

105. Plaintiffs reassert and incorporate by reference all preceding allegations.

106. The APA, 5 U.S.C. § 706(2)(A), directs a reviewing court to "hold unlawful and set aside agency action" that is "arbitrary, capricious . . . or otherwise not in accordance with law."

107. The "machine-readable files" requirement is arbitrary and capricious because the Rule fails to adequately explain why that requirement is justified, and because Defendants failed to adequately take into account the factors relevant to the desirability of imposing such a requirement. The main rationale asserted for the Rule's disclosure requirements is to "[e]nable consumers to evaluate health care options and to make cost-conscious decisions." 85 Fed. Reg. at 72,160. Defendants claim that the disclosure requirements are "direct[ly]" related to that goal. *Id.* at 72,175. In reality, however, the connection between the machine-readable files and a user-friendly consumer shopping experience is anything but direct. The files contain mountains of raw data that, as Defendants acknowledge, "[will] likely … be difficult for the average consumer to understand and effectively use." *Id.* at 72,210. Defendants speculate that useful information may find its way to consumers indirectly, through unidentified "third parties" who will supposedly develop user-friendly tools. *Id.* at 72,238. But cost-sharing self-service tools are already widely available from health care plans and issuers, who are accountable to consumers to provide accurate information, and the first section of the Rule makes these powerful tools a universal requirement. Defendants fail to justify their assumption that the machine-readable files will meaningfully enhance consumers' ability to shop for care.

108. This shortcoming is compounded by Defendants' decision to use a skewed and defective cost-benefit analysis in considering and justifying the machine-readable files requirement. As noted above, Defendants estimated that the quantified costs of the Rule will exceed $3.5 *billion* in just the first year of

implementation. *See supra*, ¶ 64. Yet the Rule neglected to quantify more than a dozen additional costs that would have greatly increased this massive number even further, including the "[p]otential increase in health care costs if consumers confuse cost with quality and value of service," the "[p]otential increase in cyber security costs . . . to prevent data breaches," the cost "to conduct quality control reviews of the information" required to be disclosed in the machine-readable files, and the cost to "renegotiate contracts in order to remove gag clauses" that currently protect commercially sensitive pricing information from disclosure. 85 Fed. Reg. at 72,260. There is no obvious reason why (unlike the costs that Defendants *did* quantify) all of these costs are incapable of being estimated. Defendants' failure to attempt even a rough estimate of these and other potentially significant costs, coupled with the inadequate estimates that Defendants *did* prepare, is further evidence of an agency decision making process that was arbitrary and capricious.

109. Finally, Defendants acted arbitrarily and capriciously in refusing to extend the deadline for implementing the machine-readable files. The machine-readable files present a logistical and technological challenge of enormous size and complexity. Thus, it is no surprise that a "majority of commenters strongly recommended delaying the proposed applicability date" of January 1, 2022. *Id.* at 72,252. Defendants dismissed concerns about this rushed timeline out of hand, asserting that the process would be "straightforward" because the files involve "already existing data." *Id.* at 72,253. But whether the data exist—in some form, somewhere in the universe—is beside the point. Plans and issuers must develop new

systems for gathering thousands upon thousands of disparate data points (which, to the extent they are not in a plan's or issuer's possession, are likely to be particularly time-consuming and costly to obtain), processing them, and converting them into the machine-readable format. That is no "straightforward" undertaking for even the largest entities subject to the Rule—and will likely be even more problematic for smaller entities, including self-insured employers such as the U.S. Chamber.

## PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court grant them the following relief:

110. A declaratory judgment that the provisions of the Rule at issue in this lawsuit are unlawful for the reasons set forth above;

111. An order vacating and setting aside the unlawful provisions of the Rule;

112. Injunctive relief barring Defendants from enforcing the unlawful provisions of the Rule;

113. An order awarding Plaintiffs their costs, disbursements, and reasonable attorney's fees associated with this litigation pursuant to 28 U.S.C. § 2412 and other applicable authority; and

114. Such other relief as the Court deems appropriate.

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Respectfully submitted,

*/s/ Jeremiah J. Anderson*

U.S. CHAMBER
LITIGATION CENTER
Daryl Joseffer
D.C. BN: 457185
(*pro hac vice* forthcoming)
Andrew R. Varcoe
D.C. BN: 473834
(*pro hac vice* forthcoming)
1615 H Street NW
Washington, D.C. 20062
Tel: (202) 463-5337
djoseffer@uschamber.com
avarcoe@uschamber.com

*Counsel for Plaintiff*
*Chamber of Commerce of the*
*United States of America*

POTTER MINTON, PC
Michael E. Jones
SBN: 10929400
110 North College Avenue
Suite 500
Tyler, TX 75702
Tel: 903-597-8311
Fax: 903-593-0846
mikejones@potterminton.com

*Counsel for Plaintiffs*

KING & SPALDING LLP
Jeremiah J. Anderson
SBN: 24040432
1100 Louisiana Street
Suite 4100
Houston, TX 77002
Tel: (713) 751 3200
Fax: (713) 751-3290
jjanderson@kslaw.com

KING & SPALDING LLP
Jeffrey S. Bucholtz
D.C. BN: 452385
(*pro hac vice* forthcoming)
***Lead Attorney***
Nikesh Jindal
D.C. BN: 492008
(*pro hac vice* forthcoming)
Alexander Kazam
D.C. BN: 1708188
(*pro hac vice* forthcoming)
1700 Pennsylvania Avenue NW
Washington, D.C. 20006
Tel: (202) 737-0500
Fax: (202) 626-3737
jbucholtz@kslaw.com
njindal@kslaw.com
akazam@kslaw.com

*Counsel for Plaintiffs*