IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

325 7th Street, N.W., 9th Floor
Washington, D.C. 20004

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

CENTERS FOR MEDICARE & MEDICAID SERVICES,

7500 Security Boulevard
Baltimore, MD 21244;

UNITED STATES DEPARTMENT OF THE TREASURY,

1500 Pennsylvania Ave., N.W.
Washington, D.C. 20220;

INTERNAL REVENUE SERVICE,

1111 Constitution Ave., N.W.
Washington, D.C. 20224;

UNITED STATES DEPARTMENT OF LABOR,

200 Constitution Ave., N.W.
Washington, D.C. 20210;

Case No. _____

EMPLOYEE BENEFITS SECURITY ADMINISTRATION,

200 Constitution Ave., N.W.
Washington, D.C. 20210;

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

JANET YELLEN, in her official capacity as Secretary of the Department of Treasury,

1500 Pennsylvania Ave., N.W.
Washington, D.C. 20220;

CHARLES P. RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,

1111 Constitution Ave., N.W.
Washington, D.C. 20224;

DOUGLAS O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement,

1111 Constitution Ave., N.W.
Washington, D.C. 20224;

MARTIN J. WALSH, in his official capacity as Secretary of the Department of Labor,

200 Constitution Ave., N.W.
Washington, D.C. 20210; and

ALI KHAWAR, in his official capacity as Acting Assistant Secretary for the Employee Benefits Security Administration,

200 Constitution Ave NW, Suite N-5677
Washington, D.C. 20210

Defendants.

COMPLAINT

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GLOSSARY

Term	Definition
ACA	Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010)
CBO	Congressional Budget Office
CMS	Centers for Medicare & Medicaid Services
EBSA	Employee Benefits Security Administration
FTC	Federal Trade Commission
HHS	U.S. Department of Health and Human Services
IRS	Internal Revenue Service
PBM	Pharmacy benefit manager
PCMA	Pharmaceutical Care Management Association
Proposed Rule	84 Fed. Reg. 65464 (Nov. 27, 2019)
Transparency Rule	85 Fed. Reg. 72158 (Nov. 12, 2020)

Plaintiff Pharmaceutical Care Management Association, for its complaint against Defendants the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF THE TREASURY; INTERNAL REVENUE SERVICE; UNITED STATES DEPARTMENT OF LABOR; EMPLOYEE BENEFITS SECURITY ADMINISTRATION; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; JANET YELLEN, in her official capacity as Secretary of the Department of Treasury; CHARLES P. RETTIG, in his official capacity as Commissioner of the Internal Revenue Service; DOUGLAS O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement; MARTIN J. WALSH, in his official capacity as Secretary of the Department of Labor; and ALI KHAWAR, in his official capacity as Acting Assistant Secretary for the Employee Benefits Security Administration, alleges, by and through its attorneys, as follows:

INTRODUCTION

1. In November 2020, in the final days of the Trump Administration, the Department of Health and Human Services ("HHS")—under the leadership of Secretary Alex Azar, a former pharmaceutical executive and lobbyist—rushed out a pair of procedurally irregular final rules that destroy the primary (and arguably only) marketplace constraint on rising prescription drug prices: the ability of pharmacy benefit managers ("PBM"), the principal entities tasked with reducing drug costs for health plans and their enrollees, to privately negotiate price concessions from drug manufacturers. Although cloaked in the language of noble-sounding ideals such as transparency and lowering the nominal "list" prices for prescription drugs, key parts of these two rules serve mainly to drive *up* the total drug price ultimately borne by health plans, taxpayers,

and consumers by advantaging drug manufacturers in negotiations over price concessions. This is because problematic portions of each rule force public disclosure of the terms of PBMs' confidential negotiations with drug manufacturers, opening the door for manufacturers to tacitly collude with each other to increase drug prices.

2. Plaintiff Pharmaceutical Care Management Association ("PCMA"), the national trade association representing PBMs, brought a separate lawsuit in this Court challenging the first of these twin regulations, the so-called "Rebate Rule," *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666 (Nov. 30, 2020). *See PCMA v. HHS*, No. 1:21-cv-95 (D.D.C. filed Jan. 12, 2021). The Rebate Rule undercut private negotiations in the context of federally subsidized Medicare Part D prescription drug plans by mandating that the price concessions manufacturers offer to PBMs under those plans be applied at the point of sale—*e.g.*, the pharmacy counter—thus allowing drug manufacturers to reverse-engineer their competitors' prices. After other agencies, private-sector actuarial studies, and HHS's own actuaries revealed the damaging consequences of disclosing this proprietary information—an increase in net drug prices, Medicare Part D enrollee premiums, and federal spending—PCMA led the charge against the Rebate Rule. In response to PCMA's complaint, which is currently pending in this Court before Judge Bates, HHS immediately offered to stipulate to a one-year suspension of the Rebate Rule while it reviews the rule. *See* Order, *PCMA*, No. 1:21-cv-95 (D.D.C. Mar. 15, 2021), ECF No. 27.

3. This lawsuit challenges parts of the second of HHS's pair of regulations targeting PBMs' negotiations with drug manufacturers: the "Transparency Rule," *Transparency in Coverage*, 85 Fed. Reg. 72158, 72158 (Nov. 12, 2020). This time taking up the mantle of transparency, HHS—joined by the Departments of the Treasury ("Treasury") and Labor

("DOL") (collectively, the "Departments")—again seeks to force PBMs to publicly reveal the proprietary terms of drug pricing negotiations with drug manufacturers. The Rule requires most group health plans (both insured and self-insured) and health insurance issuers offering health insurance coverage in the individual and group markets to make two types of disclosures, only one of which PCMA challenges here.

4. The first disclosure, which PCMA does *not* challenge, requires health plans and health insurance issuers to disclose cost-sharing information to individual enrollees upon request through an internet-based self-service tool, so that consumers can estimate how much they will pay out of pocket when purchasing prescription drugs through their health plans. PCMA is not challenging this requirement because it strongly supports the Departments' stated goal of bringing meaningful and actionable transparency to health care purchasers and consumers. Even before the Rule was proposed, PBMs were at the forefront of health care price transparency, informing enrollees about their coverage for specific drugs and their expected out-of-pocket costs for prescriptions, often through online tools. As the Departments recognized, "more than 90 percent of plans, issuers, and [third-party administrators] currently provide some form of internet-based self-service tool to their consumers." *Transparency Rule*, 85 Fed. Reg. at 72256. PCMA thus "support[ed] the Departments' intention that plans provide access to their enrollees through an internet-based self-service tool." PCMA Comment Letter at 2 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19236.

5. The second disclosure requirement is where the Rule goes astray and violates the law. It requires plans and issuers to reveal, not to individual consumers, but to the public at large, sensitive data about prescription drug prices—including the "historical net prices" paid after deducting drug manufacturer price concessions—through a machine-readable file, a large

data set in a format understandable only to computers. Though these requirements were adopted with the purported purpose of helping consumers make informed decisions about which health plans to purchase and how much they should expect to spend out of pocket under those plans, in reality they offer no meaningful transparency to the consumers they supposedly benefit. Instead, they require plans and issuers to disclose proprietary, highly confidential information that is of no practical use to consumers, in a format (machine-readable files, which are designed to be automatically read and processed by *computers*, not human beings) that no consumer could possibly understand. And they do so without any input from the industry or public at large, because the Departments never bothered to propose the historical net price disclosure requirement (or anything like it) in the notice of proposed rulemaking.

6. The historical net price disclosure requirement achieves none of the Departments' objectives, while simultaneously crippling one of the few proven methods of lowering prescription drug prices: negotiated manufacturer price concessions. Prescription drug prices in individual and group health insurance markets and a variety of federal programs are set through private negotiations between drug manufacturers and PBMs on behalf of their plan and issuer clients, among others (including pharmacies and wholesalers), based on discounts and rebates from the nominal "list" prices at which manufacturers sell drugs. Health plans and health insurance issuers hire PBMs to administer their drug benefits and negotiate price concessions from pharmacies and manufacturers. Manufacturers, in turn, pay these price concessions to PBMs, lowering the net price of their drugs, in order to enhance the treatment of their drugs on plan formularies, the tiered list of drugs covered by the plan. In general, PBMs pass these negotiated price concessions on to their health plan and health insurance issuer clients, who in turn use these cost savings to lower premiums and cost-sharing for their enrollees.

7. This entire system depends on PBMs' ability to effectively negotiate price concessions from drug manufacturers. And that ability, in turn, depends on PBMs' ability to conduct meaningful private negotiations, maintaining the details of their contracts with drug manufacturers as trade secrets that are not publicly available, including to other drug manufacturers. The Transparency Rule upends this long-standing and highly effective dynamic. By forcing plans and issuers to disclose historical net prices, the Rule undermines PBMs' bargaining power, only making it *harder* for them to save costs for health plans, issuers, and ultimately, the consumer. This, of course, is the exact opposite of the Departments' stated purpose—and commenters would have told them that, but the Departments failed to even propose the disclosure requirement regarding historical net prices in the notice of proposed rulemaking, as foundational principles of administrative law require. As a result, the public was deprived of the opportunity to provide meaningful comments on this part of the Rule.

8. While driving up drug prices, the requirement to disclose historical net prices offers consumers no actionable information because net prescription drug prices are not charged to consumers and never appear on a bill. Consumers pay monthly premiums, which are disclosed to them before they sign up for their health coverage, plus out-of-pocket costs that are either a fixed dollar amount or a percentage of the price charged at the pharmacy counter *before applying manufacturer price concessions*. Disclosing net prices calculated *after* applying price concessions thus does nothing to help consumers choose among health plans or anticipate their individual costs, and indeed will likely only confuse them. And no individual consumer can make heads or tails of a machine-readable file, so consumers cannot use the machine-readable file to actually improve their knowledge about their healthcare costs. Instead, the most likely audience for this information is drug manufacturers, who will analyze the information about their

competitors' prices to gain an unfair advantage in negotiations with PBMs, driving up costs for consumers.

9. This deeply flawed requirement cannot stand. The Departments' failure to seek public input on the historical net price disclosure requirement is reason enough to set aside this part of the Rule. But that is only the half of it. The Departments lack authority to mandate the public disclosure of historical net prices in the first place. Their statutory authority to require disclosures runs only to consumer-facing information that is relevant to the enrollee's rights or benefits under a plan, including information about plan benefit coverage and the plan or issuer's overall viability. 42 U.S.C. § 18031(e)(3)(A)(i)-(viii). Such information helps a consumer select among different health plans. Information about historical net prices in a machine-readable format, by contrast, is competitively sensitive information that is not consumer-facing and cannot meaningfully be used by consumers to make informed healthcare choices. The Departments thus have no business—at least, no business authorized by Congress—requiring their disclosure.

10. The historical net price disclosure requirement is arbitrary and capricious in numerous other respects. Rather than achieving its intended purpose of lowering drug costs, the Rule will only harm the vast majority of enrollees by undermining PBMs' ability to negotiate price concessions from manufacturers, a process that currently saves these enrollees money in the form of lower cost-sharing and premiums. The Rule will also critically undermine HHS's publicly stated goal of promoting value-based arrangements to reward healthcare providers with incentive payments based on the quality of care provided. The disclosure of historical net prices will send the wrong market signal, leading purchasers of individual and group health insurance coverage to focus on the unit prices of drugs purchased by their issuers and PBMs, rather than on the value of the mix of drugs covered and dispensed. Moreover, the Departments entirely failed

even to consider less burdensome alternatives (as they are required to do), such as limiting disclosure to less recent, and therefore less competitively sensitive, data. And the Departments never attempt to reconcile their newfound belief that forced disclosure of sensitive drug pricing data could stop or decrease the cost of drugs with previous agency actions that correctly recognized that disclosing such information would *increase* costs.

11. The requirement that plans and issuers use machine-readable files to disclose this data also exceeds the Departments' authority. The provision of the Patient Protection and Affordable Care Act ("ACA") on which the Departments rely requires that plans disclose certain information "in plain language" "to the public," yet simple common sense makes clear that machine-readable files designed for computer processing are not understandable to the public. 42 U.S.C. § 18031(e)(3)(A), (B). This is also why the challenged portions of the Rule will not further its transparency goals; a consumer cannot make use of the data in order to attend to her everyday healthcare needs.

12. For all of these reasons, the Transparency Rule's historical net price disclosure and machine-readable file requirements must be vacated as unlawful, *ultra vires*, procedurally improper, arbitrary and capricious, and contrary to the Administrative Procedure Act ("APA").

PARTIES

13. Plaintiff PCMA is a non-profit § 501(c)(6) corporation duly organized under the laws of the State of Delaware, with its principal place of business in Washington, D.C. PCMA is the national trade association representing America's PBMs, which administer prescription drug plans for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the health insurance marketplaces.

14. PBMs are the only entities in the supply chain whose mission is to lower drug costs for health plans, health insurance issuers, and ultimately, consumers. Plans and issuers engage PBMs to maximize the value of prescription drug benefits by negotiating price concessions from drug manufacturers and pharmacies, in addition to providing numerous other services. PBMs also lower costs in other ways, such as by encouraging the use of generics, developing formularies, and helping patients with adherence to the prescribed plan of care. Two 2020 studies estimated that PBMs helped beneficiaries and payers save on average $962 per beneficiary per year in prescription drug costs, equaling more than $1 trillion over the ensuing decade. Visante, Inc., *The Return on Investment (ROI) on PBM Services* (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf; Visante, Inc., *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers* (Feb. 2020), https://www.pcmanet.org/wp-content/uploads/2020/02/Pharmacy-Benefit-Managers-Generating-Savings-for-Plan-Sponsors-and-Consumers-2020-1.pdf. PBMs would not serve 270 million beneficiaries through all types of health plans if they did not bring down costs.

15. PCMA's members include the following PBMs: Abarca Health, CerpassRx, CVS Caremark, Envolve Pharmacy Solutions, Express Scripts, Humana Pharmacy Solutions, IngenioRx, Integrated Prescription Management, Magellan Rx Management, Maxor Plus, MedImpact Healthcare Systems, OptumRx, PerformRx, Prime Therapeutics, ProAct, RxSense, Serve You Rx, and WellDyneRx (collectively, the "members"). PCMA's members each administer prescription drug benefits on behalf of health plans and their enrollees, including enrollees who reside or purchase pharmaceuticals in Washington, D.C.

16. Each of PCMA's members has Article III standing because they will incur development, data storage, and reporting costs in order to disclose information in the machine-readable file format required by the Transparency Rule. Although the Rule directs plans and issuers, rather than PBMs, to disclose information, much of that information, including historical net prices, is uniquely in the possession of PBMs, not plans and issuers. The Departments thus recognize that plans and issuers will need to "rely on written agreements with other parties, such as PBMs, to obtain the necessary data to comply with the disclosure requirements." 85 Fed. Reg. at 72208. For that reason, the Rule specifies that a plan or issuer "may satisfy the [disclosure] requirements . . . by entering into a written agreement under which another party (such as a PBM or other third-party) provides the information required." *Id.* Many of the plans and issuers served by PCMA's members accordingly have required, or are likely to require in the near future, PCMA's members to enter into written agreements that require PCMA's members to provide information required by the Rule.

17. Moreover, portions of the Rule require disclosure of confidential, proprietary information, including historical net prices. By requiring public disclosure of this information, the Rule will drastically undercut PCMA's members' bargaining power in negotiating drug prices with manufacturers and reduce their ability to lower the cost of prescription drugs.

18. These injuries are directly and immediately traceable to the challenged parts of the Rule and would be remedied by a judgment vacating these parts of the Rule.

19. PCMA has associational standing to bring this lawsuit on behalf of its members because at least one of its members has Article III standing, the interests that PCMA seeks to protect are germane to its organizational purpose of promoting PBMs and the proven tools they

utilize to lower prescription drug prices, and neither the claims asserted nor the relief requested in this lawsuit requires the participation of individual PCMA members.

20. Defendants are the federal agencies that jointly promulgated the Transparency Rule and the agency officials responsible for promulgating the Rule.

21. Defendant HHS is an executive department of the United States federal government that is headquartered in Washington, D.C.

22. Defendant Centers for Medicare & Medicaid Services ("CMS") is an administrative agency within HHS that is headquartered in Baltimore, Maryland. CMS is responsible for administering multiple federal health programs and the federally facilitated marketplace for health plans, and for regulating group health plans and health insurance issuers providing coverage outside of the federally facilitated marketplaces.

23. Defendant Treasury is an executive department of the United States federal government that is headquartered in Washington, D.C.

24. Defendant Internal Revenue Service ("IRS") is an administrative agency within the Department of the Treasury that is headquartered in Washington, D.C. The IRS is responsible for administering tax aspects of health coverage laws.

25. Defendant DOL is an executive department of the United States federal government that is headquartered in Washington, D.C.

26. Defendant Employee Benefits Security Administration ("EBSA") is an administrative agency within the Department of Labor that is headquartered in Washington, D.C. EBSA is responsible for administering employment-based health coverage laws.

27. HHS, Treasury, and DOL (collectively, the "Departments") jointly promulgated the Transparency Rule challenged in this lawsuit through CMS, the IRS, and EBSA, respectively.

28. Defendant Xavier Becerra is Secretary of Health and Human Services. The Secretary is a signatory to the Transparency Rule. He is sued in his official capacity.

29. Defendant Chiquita Brooks-LaSure is Administrator of CMS. The Administrator is a signatory to the Transparency Rule. She is sued in her official capacity.

30. Defendant Janet Yellen is Secretary of the Treasury. The Secretary oversees the Assistant Secretary of the Treasury for Tax Policy, which is a signatory to the Transparency Rule but is currently vacant. Secretary Yellen is sued in her official capacity.

31. Defendant Charles P. Rettig is Commissioner of the Internal Revenue Service. He is sued in his official capacity.

32. Defendant Douglas O'Donnell is Deputy Commissioner for Services and Enforcement, a division within the IRS. The Deputy Commissioner for Services and Enforcement is a signatory to the Transparency Rule. He is sued in his official capacity.

33. Defendant Martin J. Walsh is Secretary of Labor. He is sued in his official capacity.

34. Defendant Ali Khawar is Acting Assistant Secretary for EBSA. The Assistant Secretary is a signatory to the Transparency Rule. He is sued in his official capacity.

JURISDICTION AND VENUE

35. This action arises under the ACA and the APA. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331. The Court is authorized to issue the nonmonetary relief sought herein pursuant to the APA, 5 U.S.C. §§ 702, 705, 706.

36. Venue is proper in this Court under 28 U.S.C. § 1391(e)(l) because this is an

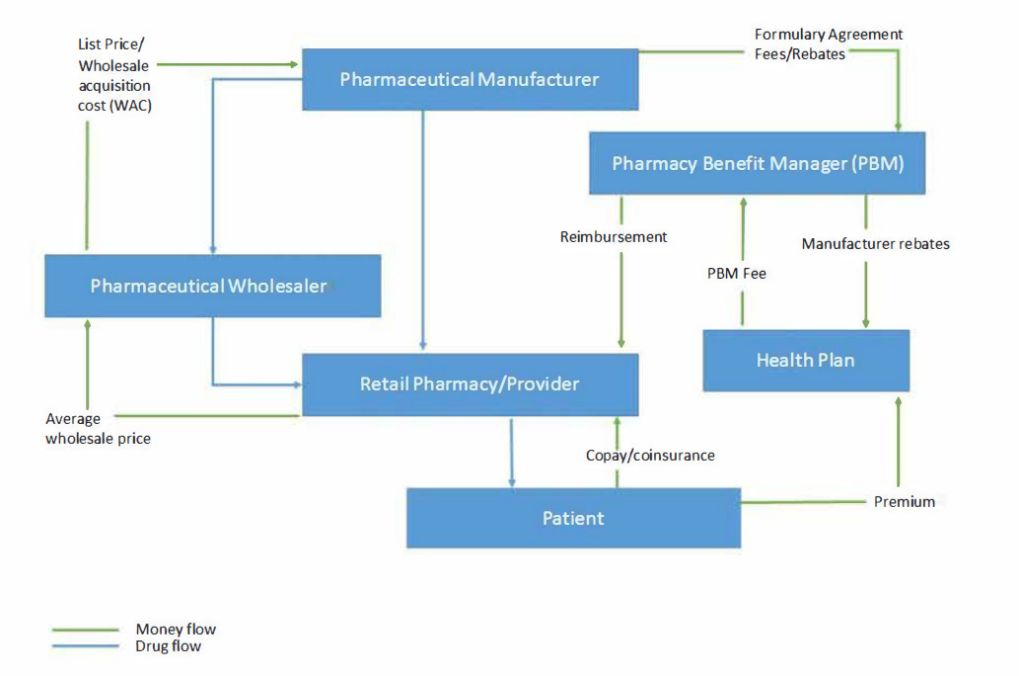
action against agencies of the United States and several officers of the United States. Defendants HHS, Treasury, IRS, DOL, and EBSA reside in this judicial district; Defendant CMS resides in this judicial district for purposes of this litigation, *see* 28 U.S.C. § 1391(c)(2); Defendants Becerra, Brooks-LaSure, Yellen, Rettig, O'Donnell, Walsh, and Khawar perform their official duties in this judicial district; a substantial part of the events or omissions giving rise to this action occurred in this judicial district; Plaintiff resides in this judicial district; and no real property is involved in the action.

FACTUAL ALLEGATIONS

I. LEGAL AND FACTUAL BACKGROUND

A. Prescription Drug Prices Are Set Through Negotiations Between Drug Manufacturers, Wholesalers, Pharmacies, Health Plans And Health Insurance Issuers, And Pharmacy Benefit Managers

37. Prescription drug prices in the private insurance market and a variety of federal programs are set through negotiations between drug manufacturers, wholesalers, pharmacies, PBMs, and health plans and health insurance issuers based on price concessions from the nominal "list" prices at which manufacturers sell drugs to wholesalers and other larger purchasers. Plans and issuers hire PBMs to administer their drug plans and negotiate price concessions from pharmacies and manufacturers.



Baylor Scott & White Health Comment Letter on Rebate Rule at 9 (July 16, 2018), https://www.regulations.gov/document?D=CMS-2018-0075-2999.

38. In a typical transaction, a wholesaler acquires a drug from the manufacturer at the list price, possibly with a discount negotiated between the wholesaler and the manufacturer. The wholesaler then sells the drug to the pharmacy at a rate negotiated between the wholesaler and the pharmacy.

39. At the point of sale—*e.g.*, at the pharmacy counter—the pharmacy dispenses the drug to plan enrollees under a contract between the pharmacy and the PBM, usually at a rate negotiated in advance. Payment to the pharmacy for the drug is then shared between the enrollee and the PBM, which reimburses the pharmacy according to the terms of the contract between the PBM and the pharmacy. Plans then reimburse the PBM at a rate negotiated between the plan and the PBM.

40. The enrollee's out-of-pocket payment at the point of sale is determined by the terms of his or her plan. While terms vary from plan to plan, this payment often includes 100%

of the rate owed by the plan, up to a set deductible, then when the deductible is met, a fixed dollar amount copayment or coinsurance equal to a percentage of the rate owed by the plan. Deductibles, copayments, and coinsurance help control drug spending by ensuring that enrollees bear some of the cost of their medication and are incentivized to make cost-effective decisions between competing treatment options. These cost-sharing payments also offset plan spending, leading to savings that plans and issuers can use to lower premiums.

41. In addition to negotiating prices with pharmacies, PBMs also negotiate price concessions from manufacturers. Manufacturers typically pay price concessions to PBMs retrospectively—*i.e.*, in the form of rebates after the point of sale, rather than, *e.g.*, at the pharmacy counter—and PBMs then pass rebates on to plans and issuers. Manufacturers pay these price concessions to PBMs, lowering the net price of their drugs, to enhance the treatment of their drugs on plan formularies, the tiered list of drugs covered by the plan. PBM-negotiated retrospective drug rebates are the most proven and practical method to obtain pricing concessions from drug manufacturers.

42. As part of their services in administering drug plans, PBMs typically handle the negotiations with manufacturers, make payments to pharmacies, and collect manufacturer price concessions. Plans and issuers reimburse PBMs for the drug, and the PBMs pass manufacturer price concessions on to the plan. PBMs may be compensated in part based on their ability to lower drug prices, such as by being allowed by the plan to retain a portion of the price concessions negotiated on behalf of the plan as part of their service fee. Or plans and issuers may choose instead to pay PBMs solely in the form of service fees calculated on a per-claim or per-enrollee basis. In general, however, PBMs pass through to plans and issuers the vast majority of negotiated price concessions—ranging from, for example, 90.8% of rebates in the

commercial context, to 99.6% in the Medicare context—and plans and issuers then use the price concessions to lower enrollees' and their own health spending. *See*, *e.g.*, Pew Charitable Trusts, *The Prescription Drug Landscape, Explored* at 40 (Mar. 2019), https://bit.ly/3777Ocg; Government Accountability Office, *MEDICARE PART D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* (July 2019), https://www.gao.gov/assets/710/700259.pdf; *see also Transparency Rule*, 85 Fed. Reg. at 72233-34 (noting that "PBMs passed through . . . 91 percent [of manufacturer rebates] in 2016").

43. The total price paid by the plan or issuer after accounting for all price concessions is referred to in the Transparency Rule as the "**net price**." Because manufacturer price concessions are typically paid *after* the point of sale and are not accounted for in calculating the enrollee's deductible, copayment, or coinsurance, the net price for a drug does not directly determine and often will not correlate with the enrollee's out-of-pocket cost for the drug.

B. Confidentiality Is Essential To The Functioning Of The Prescription Drug Market

44. The prescription drug pricing system depends on PBMs' ability to effectively negotiate price concessions from manufacturers. PBMs' success in negotiations in turn depends critically on their ability to negotiate confidentially, maintaining the details of their manufacturer contracts as trade secrets that are not available to other drug manufacturers or otherwise disclosed to the public.

45. PBMs preserve confidentiality by ensuring that the terms of any particular price concession are not publicly disclosed or discernible to third parties, including the pharmacy at the point of sale. Confidentiality, in turn, allows PBMs to bargain from a position of strength to reduce drug prices. The price-concession system depends on the exercise of bargaining power by PBMs acting on behalf of plans and issuers to counteract the pricing power of manufacturers.

46. By contrast, public disclosure of sensitive pricing information negotiated between PBMs would make it harder to negotiate and thus to save costs for plans and issuers. Generally, when a competitor's best offer is known, discounts offered by other manufacturers will decrease, so as to not exceed the discount offered by the competitor, thus establishing a pricing floor. And because for some medical conditions there are relatively few treatments available, a seller can gain the upper hand and increase its margins with only a few data points. In effect, the public availability of pricing information allows tacit collusion between manufacturers, who will not be willing to offer prices below their competitors. Without the leverage afforded by the existing system of confidential contracts with manufacturers, the ability of PBMs to extract price concessions from manufacturers would be significantly weakened, and the total net cost paid by health plans and issuers and their enrollees would therefore increase.

47. Common sense, historical evidence, and expert opinion all point to the harmful effects of revealing this sensitive information on PBM bargaining power. Leading academic economists are clear on this issue: Tacit collusion is real, and the availability of final net cost information leads to *higher* net costs overall. Testimonies of Drs. Fiona Scott Morton and Craig Garthwaite to the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (Mar. 7, 2019), https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1976.

48. This consensus view—that government-enforced information sharing will raise costs by reducing PBMs' ability to negotiate deeper discounts on drug prices—is also the considered opinion of several federal agencies with expertise in market analysis. These agencies include: (1) the Congressional Budget Office ("CBO"), a "strictly nonpartisan" office that produces "independent analyses of budgetary and economic issues to support the Congressional

budget process," CBO, *Introduction to CBO*, https://www.cbo.gov/about/overview; (2) the Federal Trade Commission ("FTC"), which independently enforces federal antitrust laws; and (3) CMS—one of the agencies through which the Transparency Rule was promulgated.

49. The CBO, in a landmark paper on the advantages and disadvantages of price transparency in healthcare, recognized that "[t]he markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices." CBO, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals*, at 4 (June 5, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf ("CBO Transparency Study"). In "highly concentrated" markets like the prescription drug market, "where only a small number of firms operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them." *Id.* Hence, "reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers." *Id.*

50. The FTC shares the CBO's view of the negative effect of disclosure of drug prices. Based on "extensive . . . experience with PBMs," the FTC has explained that "[i]f pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors . . . then tacit collusion among manufacturers is more feasible," so that government-mandated disclosures "may lead to higher prices for . . . pharmaceuticals." FTC, *Letter to Assemblyman Aghazarian* at 3, 9 (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf ("FTC Letter"). Rules requiring such disclosure thus "may have the unintended

consequences of limiting competition, thus increasing the cost of pharmaceuticals" by "mak[ing] it more difficult for PBMs to generate cost savings (including rebates)," and thus "result in an increase in health insurance premiums and reduced availability of insurance coverage for pharmaceuticals." *Id.* at 2.

51. CMS has expressed the same concerns about forced information sharing. In discussing Medicare Part D—a government-subsidized prescription drug program modeled on the commercial health insurance market—CMS has stated that "releas[ing] commercially or financially sensitive data to the public" about confidential negotiations would undermine plan "sponsors' ability," through PBMs, "to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers." *Medicare Program; Medicare Part D Claims Data*, 73 Fed. Reg. 30664, 30668 (May 28, 2008). Accordingly, CMS recognized the strong "need to protect th[is] sensitive data." *Id.*

C. The Affordable Care Act's Disclosure Provisions Preserve The Confidentiality Of Price-Concession Negotiations

52. Congress left the system of confidential, manufacturer drug price concessions intact when it enacted the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010). The ACA creates state health insurance Exchanges that serve as a marketplace for consumers to shop for and purchase health insurance coverage. *See* Vanessa C. Forsberg, Cong. Research Serv., R44065, *Overview of Health Insurance Exchanges* (Apr. 29, 2021), https://crsreports.congress.gov/product/pdf/R/R44065. Under the ACA, group health plans and health insurance issuers may offer private health insurance plans on an Exchange if they are certified as a qualified health plan under the statute. *See id.*; 42 U.S.C. § 18021 (defining "qualified health plan").

53. Health plans and health insurance issuers that seek certification must comply with, among other things, the "[t]ransparency in coverage" requirement that is codified at 42 U.S.C. § 18031(e). A separate provision of the ACA extends this requirement to nearly all "group health plan[s]" and "health insurance issuer[s] offering group or individual health insurance coverage," including plans that are not offered through an Exchange. *Id.* § 300gg-15a (citing *id*. § 18031(e)(3)).

54. Together, these provisions specify eight discrete categories of information that plans and issuers must disclose to the public, to certain federal and state government officials, and—for plans offered through an Exchange—to the Exchange. 42 U.S.C. §§ 18031(e), 300gg-15a. They also authorize the HHS Secretary to require certain additional disclosures.

55. Section 18031(e)(3)(A) outlines the required disclosures. It provides:

> The Exchange shall require health plans seeking certification as qualified health plans to submit to the Exchange, the Secretary, the State insurance commissioner, and make available to the public, accurate and timely disclosure of the following information:
>
> (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.
>
> (viii) Information on enrollee and participant rights under this title.
>
> (ix) Other information as determined appropriate by the Secretary.

42 U.S.C. § 18031(e)(3)(A)(i)-(ix).

56. The eight disclosure items enumerated by Section 18031(e)(3)(A)(i)-(viii) are mandatory. They identify categories of information that plans and issuers are always required to provide. Each category comprises consumer-facing information relevant to enrollee's rights or benefits under a plan, including: (1) "plan benefit coverage information (what is covered under a plan, how the plan is rated, the number of claims that are denied, how to receive benefits, whether and how out-of-network services are covered)"; (2) "information on the overall health" or viability "of the issuer" or plan ("enrollment, disenrollment, financial disclosures"); and (3) "enrollee rights." CVS Health Comment Letter at 4 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19008.

57. In addition to these mandatory disclosure items, the residual clause of Section 18031(e)(3)(A) requires plans and issuers to disclose "[o]ther information as determined appropriate by the Secretary." 42 U.S.C. § 18031(e)(3)(A)(ix). But nothing in the statute suggests that Congress intended to authorize the HHS Secretary to require disclosure of confidential, proprietary pricing information such as historical net prices. None of the eight mandatory disclosure categories require disclosure of that type of information. Nor do net prices relate to a consumer's rights or benefits because that information speaks to the plan's financial burden, not the enrollee's.

58. Section 18031(e)(3)(B) further specifies the format of the required disclosure. It provides that "[t]he information required to be submitted under subparagraph (A) shall be provided in plain language. The term 'plain language' means 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." 42 U.S.C. § 18031(e)(3)(B). The statute thus requires health plans to provide the disclosed information in a way that the public can readily understand.

59. Consistent with Congress's directive, prior to the Transparency Rule, HHS had never exercised its authority under Section 18031(e) to require public disclosure of proprietary pricing information such as historical net prices. Instead, it required only disclosure of the eight categories of information specifically enumerated by Congress. *See* 45 C.F.R. § 156.220(a); *see also Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans*, 77 Fed. Reg. 18310, 18417 (Mar. 27, 2012) (noting that "HHS intends that the reporting obligations established in [45 C.F.R. § 156.220] will be aligned with the [statutory] transparency reporting standards").

II. THE TRANSPARENCY RULE

60. The challenged parts of the Transparency Rule upend the established practice of confidential price-concession negotiations, and thus undermine PBMs' efforts to drive down drug prices, by requiring that health plans and health insurance issuers, through their PBMs, disclose proprietary pricing information in a machine-readable file format that will be unintelligible to ordinary consumers and that fails to provide any actionable information to consumers. The Departments imposed these requirements in the waning days of the Trump Administration without notice and opportunity to comment on key aspects of the proposal that were included for the first time in the final Rule, and despite objections from commenters that the requirements would exceed the Departments' statutory authority and would mislead and confuse consumers.

A. The Departments Issue A Notice Of Proposed Rulemaking That Requires Health Plans And Health Insurance Issuers To Disclose In-Network Rates And Out-Of-Network Allowed Amounts Through A Machine-Readable File, But Not Historical Net Prices

61. The Transparency Rule was a direct response to an Executive Order demanding that agencies start the rulemaking process for a rule that would force the disclosure of information about out-of-pocket costs to consumers. In June 2019, President Trump issued an Executive Order that directed the Departments—HHS, Treasury, and DOL—to "issue an advance notice of proposed rulemaking" that would require healthcare providers, insurance issuers, and 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." Exec. Order 13877 § 3(b), 84 Fed. Reg. 30849, 30850 (June 24, 2019).

62. The Departments responded by issuing a notice of proposed rulemaking in November 2019 with regard to the Transparency Rule. *See Transparency in Coverage*, 84 Fed. Reg. 65464 (Nov. 27, 2019) ("Proposed Rule"). The Departments even sped up the process, skipping past the advance notice of proposed rulemaking stage—the step ordered by the President—and proceeding straight to a notice of proposed rulemaking, to "more quickly address" the issue raised in the Executive Order. *Id.* at 65465.

63. The Departments proposed to exercise the HHS Secretary's authority under the ACA's "[t]ransparency in coverage" requirements, 42 U.S.C. §§ 18031(e)(3)(A), 300gg-15a, to impose on most group health plans and health insurance issuers offering health insurance coverage in the individual and group markets two new sets of disclosures—a "self-service-tool requirement" and a "machine-readable file requirement"—with respect to all aspects of health coverage, including prescription drug coverage.

64. The proposed **self-service-tool requirement** would require plans and issuers to disclose cost-sharing information to the plan's enrollees upon request through an internet-based self-service tool. The purpose of this disclosure is to allow plan beneficiaries and enrollees to obtain an estimate of their potential cost-sharing liability for covered items and services, including prescription drugs, that they might receive from a particular health care provider. *Proposed Rule*, 84 Fed. Reg. at 65470. PCMA is not challenging the Rule's self-service-tool requirement, and generally "support[ed] the Departments' intention that plans provide access to their enrollees through an internet-based self-service tool." PCMA Comment Letter at 2 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19236. That was "no surprise," because plans and PBMs support "meaningful and actionable transparency," and already provide the public with tools to help consumers access helpful information about prescription drug prices. *Id.* at 1-3.

65. The proposed **machine-readable file requirement** would require plans to disclose—to the public at large, not just to individual enrollees—large volumes of pricing data regarding covered health care transactions, including prescription drug purchases, through a file format intelligible only to computers and not ordinary consumers. *Proposed Rule*, 84 Fed. Reg. at 65477. As originally proposed, health plans and issuers would have been required to produce two machine-readable files: one concerning in-network provider negotiated rates, and one concerning out-of-network allowed amounts. *Id.*

66. The "**Negotiated Rate File**" would require plans and issuers to disclose the "amount a plan or issuer, or a third party . . . on behalf of a plan or issuer, has contractually agreed to pay an in-network provider for a covered item or service pursuant to the terms of an agreement between the provider and the plan, issuer, or third party on behalf of a plan or issuer."

Proposed Rule, 84 Fed. Reg. at 65472, 65479. In the prescription drug context—where PBMs negotiate with pharmacies to determine the price of most prescription drugs at the point of sale—the Negotiated Rate File would cover the vast majority of drug sales.

67. The out-of-network "**Allowed Amount File**" would require plans and issuers to disclose "the maximum amount a plan or issuer would pay for a covered item or service furnished by an out-of-network provider." *Proposed Rule*, 84 Fed. Reg. at 65473, 65479-80. Under this requirement, plans would have to "detail each discrete out-of-network allowed amount the plan calculated in connection with a covered item or service" during the 90-day time period that begins 180 days prior to the publication of the machine-readable file. *Id.* at 65480. Because few prescription drug transactions are out of network, the Allowed Amount File would have less relevance in the prescription drug context.

68. The Departments proposed that plans and issuers would be required to provide this information through machine-readable files posted on the internet. A machine-readable file is a file, such as a spreadsheet, that contains tabular data in a way that can be easily processed and exchanged by machines. *See* U.S. General Services Administration, *A Primer on Machine Readability for Online Documents and Data* (Sept. 24, 2012), https://www.data.gov/developers/blog/primer-machine-readability-online-documents-and-data. The Proposed Rule defined "machine-readable file" to mean "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." *Proposed Rule*, 84 Fed. Reg. at 65481. The Departments specified that machine-readable files would need to use a non-proprietary format so that any computer system could import and read the file disclosed by plans and issuers. *Id.* For example, a JSON (JavaScript Object Notation), XML (eXtensible Markup Language), or CSV

(Comma Separated Values) file is a machine-readable file; a PDF (Portable Document Format) file is not. *Id.*

69. The Departments presented the Proposed Rule as a solution to "health care spending." *Proposed Rule*, 84 Fed. Reg. at 65477. According to the Departments, the public availability of negotiated rates and out-of-network allowed costs would "empower consumers to make informed decisions about their health care" by giving consumers the ability to compare plans' "pricing information" and "effectively shop for items and services." *Id.* at 65477, 65464. The Departments acknowledged that "due to the complexity of our health care system and the data that drives plan and issuer payments for health care services," data about negotiated rates and allowed amounts "is unlikely to be usable by the average consumer." *Id.* at 65478. But the Departments predicted that requiring the public disclosure of such information would "encourage innovation" by third parties who could "help consumers understand" the information. *Id.* In turn, the Departments stated based on "[g]eneral economic theory" that "markets work best when there is price competition," public disclosure of negotiated rates and allowed amounts would create "downward pressure on health care pricing" and thus lower drug prices. *Id.* at 65477-78. The Departments also aimed to "reduce surprises in relation to consumers' out-of-pocket costs for health care services." *Id.* at 65465.

70. As originally proposed, the machine-readable file requirement was limited to *two* machine-readable files—the "Negotiated Rate File" and the "Allowed Amount File." The Proposed Rule *did not* propose disclosing an entirely separate category of drug pricing information—historical net prices—that would ultimately end up in the final Rule.

71. The closest the Proposed Rule came to addressing net prices was a general request for "comment regarding whether a rate other than the negotiated rate, such as the undiscounted

price, should be required to be disclosed for prescription drugs, and 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." 84 Fed. Reg. at 65472. Although the request raised questions about the possibility of accounting for "rebates," it never mentioned net prices or suggested that disclosing historical net prices would be an appropriate or effective way to account for rebates and other price concessions. To the contrary, the request was directly tied to the goal of "ensur[ing] [that] individuals have access to meaningful cost-sharing liability estimates for prescription drugs," *id.*—a goal not furthered by the disclosure of historical net prices because net prices do not determine an enrollee's cost-sharing obligations. Further, the request occurred only in the context of discussing the internet-based self-service tool—*not* the machine-readable files, where the new historical net price disclosure requirement was ultimately added (in addition to negotiated rates). *See id*. at 65472-73 (asking whether and how to disclose such information "when the consumer searches for cost-sharing information" on the internet-based tool).

72. The Proposed Rule thus provided no notice that the Departments might consider requiring plans and issuers to disclose confidential, proprietary information regarding historical net price, let alone through a machine-readable file format targeted only at third parties rather than consumers.

73. Under the Proposed Rule, the obligation to make publicly available the two machine-readable files would apply "for plan years beginning on or after" "1 year after [the] effective date of the final rule." *Proposed Rule*, 84 Fed. Reg. at 65516, 65520, 65522.

B. Commenters Raise Concerns About The Proposed Disclosure Requirements, But Do Not Anticipate Or Comment On The Possibility That The Final Rule Might Add A Requirement To Publicly Disclose Historical Net Prices

74. The Departments received more than 25,000 comment letters in response to the Proposed Rule. *Transparency Rule*, 85 Fed. Reg. at 72167. Commenters challenged multiple aspects of the proposed disclosure requirements, including the use of machine-readable files, and cautioned the Departments at a high level of generality against requiring the disclosure of proprietary information. But the comments also made clear that commenters did *not* understand the Departments to be contemplating disclosure of net price information—historical or otherwise—as evidenced by commenters' virtual silence on the topic.

75. Commenters explained that the proposed machine-readable file requirement was incompatible with the requirements of the ACA's transparency in coverage provision and would undermine the goal of providing actionable transparency to consumers. To ensure that disclosures pursuant to that provision serve the needs of consumers, the ACA requires plans to disclose required information in "plain language" that members of the public can understand. 42 U.S.C. § 18031(e)(3)(B). Commenters explained, however, that a "machine-readable file does not consist of 'language that the intended audience . . . can readily understand and use'" because machine-readable file formats "are not accessible or understandable to typical consumers." Fed'n of Am. Hosp. Comment Letter at 3-4 (Jan. 29, 2020) (omission in original) (quoting 42 U.S.C. § 18031(e)(3)(B)), https://www.regulations.gov/comment/CMS-2019-0163-19259. Indeed, commenters noted, the Departments had "explicitly recognize[d] that consumers will only be able to use the information" disclosed in machine-readable files if third parties independently developed "tools." UnitedHealth Group Comment Letter at 13 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-18837.

76. Commenters further warned that relying on third-party intermediaries to translate machine-readable files into information provided to consumers would risk confusing consumers rather than clarifying the healthcare marketplace. PCMA, for example, advised that "[t]hird parties who use the machine-readable files to present information to consumers are not accountable to provide accurate information to consumers and do not have the full context to provide accurate, actionable information; tools created outside of the plan's purview will only confuse enrollees." PCMA Comment Letter, *supra*, at 13-14. Other commenters cautioned that "[t]he machine-readable component of this rule . . . appear[s] more targeted at providing data to third party application (app) developers than ensuring consumers have access to meaningful, personalized data." AHIP Comment Letter at 2 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-18950.

77. Commenters also cautioned that health plans and issuers could not realistically build the systems and compile the information necessary to comply with the machine-readable file requirement on the timeline that the Proposed Rule set forth—*i.e.*, "1 year after [the] effective date of the final rule." *Proposed Rule*, 84 Fed. Reg. at 65516. Put simply, the "short implementation timeframe demonstrate[d] a lack of understanding of the steps necessary to successfully create and implement new systems of this magnitude." UnitedHealth Group Comment Letter, *supra*, at 25. First, plans would need to understand what operational and administrative changes would be needed to comply with the new rule's requirements. *Id.* Second, plans would need to analyze current IT systems and develop new IT systems. *Id.* Third, plans would need to develop data-collection processes that could collect "hundreds of millions of distinct data points" pulled from multiple platforms (for example, combining cost accumulator data from member databases, plan design information from product databases, and negotiated

rates from provider contracting databases). *Id.* Fourth, plans would need to examine "thousands of provider contracts" to determine what those contracts say about the disclosure of information, and renegotiate contracts that did not meet the final rule's requirements. *Id.* at 26. Finally, plans would need to create administrative support systems, conduct outreach to health care providers, train support functions, and design and test the tools needed to ensure the machine-readable files are accurate. *Id.*

78. All told, commenters explained, one year was far too short of an implementation timeline. "Half of commercial issuers anticipate[d] it would take two years or longer to make all necessary changes to initially develop the" required machine-readable files. AHIP Comment Letter, *supra*, at 40, 42. Another 18 percent expected it would take "at least 18 months." *Id.* Accordingly, commenters urged the Departments—if they proceeded with the requirement to publish machine-readable files—to change the implementation timeline so that the requirement would be effective no earlier than plan or policy years beginning three years after the rule's effective date. *Id.*; *see also* UnitedHealth Group Comment Letter, *supra*, at 26.

79. More broadly, commenters raised concerns that the Proposed Rule went too far in its efforts to achieve transparency, and would do more harm than good. PCMA, in particular, emphasized the CBO's and FTC's "warning[s]" that "too much price transparency can lead to tacit collusion—and thus higher prices." PCMA Comment Letter, *supra*, at 17. Excessive disclosures, PCMA explained, would allow drug manufacturers to gain valuable insight into the price concessions that competing manufacturers had offered, "reduc[ing] negotiation leverage" for plans and PBMs and "result[ing] in higher overall spending." *Id.* at 17-18.

80. Commenters likewise questioned the Departments' statutory authority to direct the disclosure of confidential pricing information. PCMA explained that the ACA "delineates

eight data elements . . . to be reported, as well as a ninth 'catch all' for *similar* data not otherwise covered by the preceding data fields." PCMA Comment Letter, *supra*, at 15 (citing 42 U.S.C. § 18031(e)(3)(A)). But the list of information that must be disclosed under the ACA—such as "data on enrollment, data on claims denials, and information on cost-sharing"—bears little resemblance to the types of information that the Departments were proposing to be disclosed. *Id.* PCMA warned that requiring the disclosure of "confidential pricing information" would "mov[e] well beyond the scope of the authority provided by Congress." *Id.*

81. While commenters thus raised concerns about the disclosure of proprietary information at a high level of generality, the vast majority of the 25,000 comments unsurprisingly did not mention specific concerns about the disclosure of net prices, historical or otherwise, because the Proposed Rule did not propose to require disclosure of that information. And those that mentioned those issues did so only in passing.

82. PCMA, for example, expressed its general opposition to requiring disclosure of "[a]ny information . . . beyond" the originally proposed disclosures, and briefly listed "specific net prices or price concessions" as an example, in "keeping the proprietary nature of this information in mind." PCMA Comment Letter, *supra*, at 2, 12. But these fleeting references to net prices comprised only two isolated sentences in PCMA's 18-page comment letter. That passing discussion stands in sharp contrast to the extensive discussion PCMA had devoted to the importance of keeping net prices confidential in commenting on a related HHS rule just nine months earlier. *See* PCMA Comment Letter on Rebate Rule at 6, 11, 16, 31, 33-34, 45-46, 96 (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19773; *see Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666 (Nov. 30, 2020). It also stands in contrast to the lengthy discussion of historical net

prices that PCMA later submitted after the Departments added a historical net price requirement to the final Transparency Rule. *See infra* ¶¶ 97, 112. Given PCMA's longstanding and vigorous opposition to disclosure of proprietary information about prescription drug price concessions and net prices, PCMA's near silence on the issue in commenting on the Proposed Rule is proof positive that the Proposed Rule did not provide notice of the Departments' historical net price disclosure requirement.

C. The Departments Promulgate A Final Rule That Retains The Machine-Readable File Requirement And Adds A New Requirement Forcing Public Disclosure Of Historical Net Prices

83. Despite commenters' objections, the Department proceeded with the rulemaking. On November 12, 2020, less than a week after President Trump's defeat in the November election became apparent, HHS issued a final rule—the Transparency Rule. *Transparency in Coverage*, 85 Fed. Reg. 72158, 72158 (Nov. 12, 2020). The final Rule preserved the central features of the Proposed Rule but added an additional machine-readable file requirement that requires plans and issuers to disclose confidential, proprietary information about historical net prices.

84. The Departments carried forward the Proposed Rule's requirement that health plans disclose cost-sharing information to a plan beneficiary or enrollee upon request through an internet-based self-service tool. *Transparency Rule*, 85 Fed. Reg. at 72158. The Departments also carried forward the requirement that health plans disclose to the public in-network provider negotiated rates and historical out-of-network allowed amounts through a machine-readable file. *Id.* The Departments noted that making this information public was designed to reduce "surprise billing," *i.e.*, when consumers are "surprised by the price of a health care item or service when they receive the bill after receiving care." *Id.* at 72161.

85. But the Departments strayed from the Proposed Rule by requiring the public disclosure of a new, third category of information: historical net prices. The Departments identified the historical net price disclosure as an "additional" requirement that the Departments were "also adopt[ing]" on top of the previously proposed requirements—not a mere "modificatio[n]" of a previously proposed requirement, like some other, more minor changes adopted. *Transparency Rule*, 85 Fed. Reg. at 72220-21. Indeed, the Transparency Rule had to "add" a definition for the "new" term "historic[al] net price" because that concept was admittedly "not included in the proposed regulations." *Id.* at 72178. With the Trump Administration already on its way out the door, however, the Departments rushed this new requirement out without providing a new notice-and-comment period—or, for that matter, *any* opportunity—for commenters to weigh in on the requirement.

86. The Departments defined "historical net price" to mean "the retrospective average amount a plan or 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." *Transparency Rule*, 85 Fed. Reg. at 72236. The net price metric thus reflects the price paid for a drug *after* deducting manufacturer price concessions, including price concessions negotiated by PBMs. *Id*. at 72237. Under the final Transparency Rule, plans are required to disclose historical net prices "for a 90-day period beginning 180 days before the date a particular [machine-readable file] is published." *Id.*

87. To authorize this additional disclosure, the Departments again purported to rely on 42 U.S.C. § 18031(e)(3)(A)(ix)—the ACA provision that authorizes the HHS Secretary to require the disclosure of "other information as determined appropriate." *Transparency Rule*, 85 Fed. Reg. at 72167. The Departments explained that this statute allowed the HHS Secretary "to

add additional [disclosure] items as long as those items are of similar character to the items enumerated in the statute." *Id.* The Departments took this to mean any information "useful to" consumers who are "evaluat[ing] the coverage offered by plans and issuers," or any information "useful to regulators and the public" who seek to "evaluate plans' and issuers' business practices and activity in the market." *Id*. The Departments thus read the ACA to grant the HHS Secretary "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." *Id.* at 72167-68. The Departments did not explain how the public disclosure of *historical net prices* specifically fit within these supposed limits.

88. To justify this additional disclosure, the Departments stated that disclosing information about the historical net price for prescription drugs—including "rebates and other price concessions that are included in the net price"—was necessary to "achieve the goals of the" final Rule. *Transparency Rule*, 85 Fed. Reg. at 72237. As in the Proposed Rule, the Departments reasoned that the public availability of drug pricing information—now including historical net prices—would give consumers information needed to "make informed decisions about their health care," which would in turn "spur competition in health care markets" and ultimately "slow or potentially reverse" the rising cost of health care items and services. *Id.* at 72212.

89. In response to comments that requiring the disclosure of proprietary information could undermine the negotiating power that PBMs currently use to lower drug prices in the unique context of the healthcare market, *see supra* ¶ 79, the Departments asserted that "traditional market forces that affect prices in any market, including competition between providers . . . and the increased bargaining power of consumers" supported their decision. *Id.* at

72216. The Departments "recognize[d] that provider collusion could result in increased prices," but concluded that these consequences "will be mitigated *to some extent* by the actions of state and Federal regulatory and antitrust enforcement authorities and the enforcement of current market laws and regulations." *Id.* at 72267 (emphasis added).

90. To accommodate the addition of historical net prices as a third category of information in addition to negotiated rates and out-of-network allowed amounts, the Transparency Rule instructs plans to submit and publish "*three* machine-readable files" instead of the original two. *Transparency Rule*, 85 Fed. Reg. at 72158 (emphasis added). Specifically, the Departments separated out prescription drug pricing disclosures that would have been included as part of the "Negotiated Rate File" under the Proposed Rule into a separate file, termed the "**Prescription Drug File**." *Id.* at 72221. Historical net prices are part of the new "Prescription Drug File." *Id.* The Departments further changed the name of the "Negotiated Rate File" to the "**In-Network File**" to reflect the modifications made in the final Transparency Rule. *Id.*

91. The Departments brushed off commenters' concerns that disclosing information in machine-readable files would not satisfy the ACA's requirement for "plain language" disclosures by plans to typical consumers. *Transparency Rule*, 85 Fed. Reg. at 72169. The Departments acknowledged that the "information included in the machine-readable files may not be easy for an average consumer to navigate" on their own, and admitted that for the information to "ultimately benefit consumers," it would need to be "aggregate[d], standardize[d], and interpret[ed]." *Id.* at 72234, 72241. In the Departments' view, unregulated third parties could do that job: "application developers will be able to access the data" for themselves, and then incorporate that data into "internet-based tools and mobile applications that will present

information to laypersons in easy-to-understand, plain language." *Id.* at 72169. That prospect, the Departments explained, satisfied the plain language requirement because the "application developers" comprised part of the "intended audience for the information" and because those developers could use the machine-readable files to convey information in a format that is "accessible or understandable to the typical consumer." *Id.*

92. Finally, the Departments retained the implementation timeline for plans and issuers to publish machine-readable files: The relevant provisions regarding "requirements for public disclosure" of machine-readable files would "apply for plan years beginning on or after January 1, 2022." *Transparency Rule*, 85 Fed. Reg. at 72304; *see also id.* at 72252. The Departments acknowledged that the "majority of commenters strongly recommended delaying the proposed applicability date for the . . . machine-readable file requirements of the rules for at least one year and up to five years from publication of the final rules," *id.* at 72252, but the Departments expressed their "view that developing the machine-readable files should be straightforward for most plans and issuers" because the "development activities needed to establish the machine-readable files involve gathering, formatting, and making publicly available already existing data that plans and issuers use in their everyday operations," *id.* at 72253.

93. The Transparency Rule took effect on January 1, 2021. *See* 85 Fed. Reg. at 72158. The machine-readable file requirement is set to take effect on January 1, 2022. *Id.* at 72305.

94. The format for the machine-readable file is still being developed by the Departments, and plans and issuers are not yet required to start producing data, so no completed machine-readable file is publicly available. However, CMS has published preliminary "[i]mplementation [e]xamples" of the machine-readable files that will be required under the Transparency Rule. CMS, *Transparency in Coverage Technical Implementation Guide*, https://github.com/CMSgov/price-transparency-guide. The example Prescription Drug File, s*ee* CMS, *price-transparency-guide* (last visited August 9, 2021), https://github.com/CMSgov/price-transparency-guide/blob/master/examples/prescription-drugs/prescription-drugs.json, is reproduced below, and attached as Exhibit A.

```
{
  "reporting_entity_name": "medicare",
  "reporting_entity_type": "medicare",
  "plan_name": "medicare",
  "plan_id_type": "HIOS",
  "plan_id": "12345XX9876543",
  "plan_market_type": "individual",
  "last_updated_on": "2020-08-27",
  "drugs": [{
    "drug_name": "Simvastatin",
    "drug_type": "generic",
    "ndc": "16729-004",

    "prices": [{
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      "historical_net_reporting_period": "2020-08-28",
      "negotiated_rate": 0.1,
      "administrative_fee": 0.02,
      "dispensing_fee": 2,
      "transaction_fee": 0.005,
      "tin": "11-1111111",
      "service_code": "01",
      "npi": [ 2222222222, 33333333333, 4444444444, 555555555 ],

      "pharmacies":[{
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        "pharmacy_ids": [ 1111111, 22222222, 3333333, 4444444 ]
      },{
        "pharmacy_id_type": "ncpdp chain code",
        "pharmacy_ids": [ 1111111, 22222222, 3333333, 4444444 ]
      },{
        "pharmacy_id_type": "npi",
        "pharmacy_ids": [ 111111111, 2222222222, 333333333, 444444444 ]
      }]
    },{
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      "transaction_fee": 0.005,
      "tin": "22-2222222",
      "service_code": "05",
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        "pharmacy_id_type": "npi",
        "pharmacy_ids": [ 111111111, 2222222222, 333333333, 444444444 ]
      }]

    }]
  }]
}
```

95. The above example shows information related to just *one* drug, including *two* individualized price entries and the pharmacies for which the price applies. The machine-readable files that plans and issuers ultimately submit under Section 18031(e)(3)(A) would cover prices for *tens of thousands* of drugs, at *hundreds* of pharmacies each, and thus will be orders of magnitude larger and more complex than CMS's singular machine-readable file prototype.

D. After The Rule Is Published, CMS Issues An Information Collection Request As Required By The Paperwork Reduction Act

96. The public's first opportunity to say anything about the Transparency Rule's historical net price requirement came more than a month *after* the Rule was adopted. On December 30, 2020, CMS published an Information Collection Request, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. §§ 3501-3520, seeking input on the "burden," "necessity," "utility," or "any other aspect" of producing to CMS the information required by the Transparency Rule, including "historical net prices" and "machine-readable files." *Agency Information Collection Activities: Proposed Collection; Comment Request*, 85 Fed. Reg. 86567, 86567-68 (Dec. 30, 2020) ("Information Collection Request").

97. In response to the Information Collection Request, PCMA and others voiced concerns with the historical net price requirement, including that the requirement "was not included in the proposed rule" and PCMA and other stakeholders lacked "notice" that such a requirement was under consideration. PCMA Comment Letter on Information Collection Request at 1-5 (Mar. 1, 2021), https://www.regulations.gov/comment/CMS-2021-0002-0005; *see also*, *e.g.*, AHIP Comment Letter on Information Collection Request at 2 (Mar. 1, 2021), https://www.regulations.gov/comment/CMS-2021-0002-0008; UnitedHealth Group Comment Letter on Information Collection Request at 6 (Mar. 1, 2021), https://www.regulations.gov/comment/CMS-2021-0002-0003; CVS Health Comment Letter on Information Collection

Request at 3 (Mar. 1, 2021), https://www.regulations.gov/comment/CMS-2021-0002-0006. But by then, the Rule was already on the books, with the compliance date looming, and the only issue that remained was approval by the Office of Management and Budget for the information collection.

III. MULTIPLE PROVISIONS OF THE TRANSPARENCY RULE ARE CONTRARY TO LAW AND VIOLATE THE ADMINISTRATIVE PROCEDURE ACT

98. The Transparency Rule forces the public disclosure of historical net prices, and requires that this and other confidential information be disclosed through machine-readable files. Each of these two requirements exceeds the Departments' statutory authority and violates the APA for multiple, independent reasons.

A. The Transparency Rule's Historical Net Price Disclosure Requirement Is Unlawful

99. The Transparency Rule's requirement that plans disclose historical net prices is unlawful for three reasons. First, it violates the APA's notice-and-comment-rulemaking provisions because the requirement is not a logical outgrowth of the Proposed Rule, which never indicated that any requirement for plans to disclose historical net prices was being considered, therefore depriving PCMA and others in the public from a meaningful opportunity to comment. Second, the Departments lack statutory authority to mandate disclosure of confidential, proprietary information about drug prices, including net prices. Third, the requirement is arbitrary and capricious in violation of the APA.

1. The Historical Net Price Disclosure Requirement Is Not A Logical Outgrowth Of The Proposed Rule

100. The historical net price disclosure requirement falters at the outset because it is not a "logical outgrowth" of the Proposed Rule, as basic principles of administrative law require.

101. Under the APA, an agency must "make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible," *HBO, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977), and "describe the range of alternatives being considered with reasonable specificity," *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 192 (D.C. Cir. 2011). The agency necessarily must provide that notice *before* adopting the final rule so that the public can offer input and the agency can respond to it; otherwise, the "opportunity to comment is meaningless." *HBO*, 567 F.2d at 35.

102. Although an agency can adopt a rule that differs from its proposal, it may do so "only if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (quotation marks omitted). Put differently, "[t]he [notice of proposed rulemaking] and the final rule need not be identical," but the final rule must be a "logical outgrowth of [the] notice." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 461 (D.C. Cir. 2012) (quotation marks omitted). "A final rule qualifies as a logical outgrowth if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Id.* (quotation marks omitted). "The object, in short, is one of fair notice." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). And "the mere mention" of a possible alternative to the proposed regulation is insufficient alone to satisfy that "notice requirement." *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1082 (D.C. Cir. 2009).

103. Here, the Departments flouted these basic principles of administrative law by adopting a disclosure requirement that it never formally proposed or gave notice that it was

considering, and on which public input was neither invited nor provided. The Proposed Rule concerned disclosure of two kinds of information through machine-readable files: in-network provider negotiated rates, and historical out-of-network allowed amounts. 84 Fed. Reg. at 65477. But the Proposed Rule *never* proposed requiring the disclosure of a third, additional machine-readable file including historical net prices for prescription drugs. It *never* gave any indication that the Departments were considering doing so. And the Departments *never* solicited comment on such a requirement. Stakeholders, therefore, lacked notice to advise the Departments of the significant issues that would arise from this separate and distinct requirement.

104. The Departments' new historical net price disclosure requirement marks a significant departure from the original proposal and its historical antecedents, both substantively and structurally, as the Departments admit in the Transparency Rule. The Rule identifies the historical net price disclosure as an "additional" requirement that the Departments are "also adopt[ing]" on top of the two previously proposed requirements—not a mere "modificatio[n]" of a previously proposed requirement, like some other, more minor changes adopted. 85 Fed. Reg. at 72220-21. Indeed, the Transparency Rule had to "add" a definition for the "new" term "historic[al] net price" because that concept was admittedly "not included in the proposed regulations." *Id.* at 72178.

105. Substantively, the Transparency Rule's added requirement to disclose historical net prices raises unique and separate issues that the Departments have not adequately addressed. The asserted purpose of the disclosures in the Proposed Rule was to help consumers "effectively shop for items and services," 84 Fed. Reg. at 65464, but net prescription drug prices are not charged to consumers. The new disclosures thus do nothing to promote the objective of

guarding against "[s]urprise billing," 85 Fed. Reg. at 72161, because *net prices never appear on a bill*, *see*, *e.g.*, CVS Health Comment Letter on Information Collection Request, *supra*, at 2 ("Historical net price is not a consumer-facing price or cost and it provides consumers with no information on what they will be required to pay for a drug at the pharmacy counter under their plan."); UnitedHealth Group Comment Letter on Information Collection Request, *supra*, at 6 ("Therefore, the inclusion of historical net price does not follow CMS' stated intent of the transparency rule, which is to enable patients to shop for healthcare items and services most efficiently.").

106. The new historical net price disclosure requirement also raises important issues that are distinct from the issues raised by the Proposed Rule. The Departments, for example, concluded that "the final rules do not implicate trade secrets," as several commenters had objected, because "[c]ritically, . . . negotiated rates are routinely disclosed to beneficiaries" in explanations of benefits ("EOBs"). 85 Fed. Reg. at 72173, 72175; *see also Proposed Rule*, 84 Fed. Reg. at 65470 (concluding that because "all of the information that would be required to be disclosed under these proposed rules is currently disclosed in EOBs that plans and issuers provide to individuals as a matter of course after services have been furnished," the proposal "does not pose any greater risk to plan or issuer proprietary information"). Even if that were true, that reasoning does not apply to net prices, which are *not* disclosed on EOBs. PCMA Comment Letter on Information Collection Request, *supra*, at 4; *see also* AHIP Comment Letter on Information Collection Request, *supra*, at 2 ("CMS should seek stakeholder input on historical net prices through notice and comment rulemaking and align prescription drug reporting requirements to . . . ensure neither data reported to the Secretaries nor disclosed to the public discloses confidential or trade secret information."). These unexpected and unexamined

issues are precisely what notice and comment, and the logical-outgrowth doctrine, are designed to prevent.

107. Structurally, the belated addition of the historical net price disclosure requirement also fundamentally departs from the original proposal. The Proposed Rule repeatedly explained that it set out to provide a universal set of healthcare-pricing disclosures through one internet-based self-service tool and "two machine-readable files" reflecting, respectively, in- and out-of-network rates for both drugs and other services. 84 Fed. Reg. at 65464. But the Transparency Rule grafts onto this across-the-board structure an *additional*, drug-specific disclosure that purportedly "reflect[s] the unique attributes of prescription drug pricing." 85 Fed. Reg. at 72234. In other words, this new drug-only requirement admittedly addresses drug-specific issues distinct from the overarching transparency issues addressed in the Proposed Rule. Where a final rule "d[oes] more" and different things than a prior proposal, the agency's "flip-flop complies with the APA only if preceded by adequate notice and opportunity for public comment." *Env't Integrity Project*, 425 F.3d at 997; *see also Int'l Union, United Mine Workers v. MSHA*, 407 F.3d 1250, 1260 (D.C. Cir. 2005) (a final rule fails the logical-outgrowth test where it is "more expansive, more specific, and ha[s] a different emphasis in the regulatory structure" than the Proposed Rule).

108. The new requirement also departs significantly from the precedents and prior authorities on which the Departments purported to build, which did not require disclosure of net prices, historical or otherwise. Specifically:

a. The Proposed Rule purports to "fulfill the Departments' responsibility under Executive Order 13877," 84 Fed. Reg. at 65465, but that Executive Order does not even mention net prices, rebates, or price concessions, *see* 84 Fed. Reg. 30849

(June 27, 2019). Instead, such practices were addressed by the Trump Administration in an entirely separate Executive Order implemented in a separate rulemaking proceeding, which is now in abeyance pending ongoing litigation by PCMA. Exec. Order 13939, *Lowering Prices for Patients by Eliminating Kickbacks to Middlemen*, 85 Fed. Reg. 45759, 45759 (July 24, 2020); *see generally PCMA v. HHS*, No. 1:21-cv-95 (D.D.C. filed Jan. 12, 2021); *see id.*, ECF No. 27 at 1 (postponing the effective dates of the rulemaking and staying the case).

b. The Proposed Rule also repeatedly relies on states' previous "transparency initiatives," 84 Fed. Reg. at 65467, but identifies no prior state regime that required disclosure of historical net prices.

c. The Proposed Rule claims to have "modeled" its disclosure requirements "on existing notices that plans and issuers generally provide to participants, beneficiaries, or enrollees after health care items and services have been furnished," 84 Fed. Reg. at 65470, but those notices do not disclose net prices or price concessions for prescription drugs.

d. The Proposed Rule purports to draw on the conclusions of the 2018 inter-Department report "Reforming America's Healthcare System Through Choice and Competition," *see* 84 Fed. Reg. at 65465 & n.2, but that report nowhere mentions net prices, pharmaceutical rebates, or price concessions, *see* Azar, Mnuchin, & Acosta, *Reforming America's Healthcare System Through Choice and Competition* (Dec. 3, 2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.

109. Not only does the historical net price disclosure requirement lack grounding in the precedents and prior authorities on which the Departments purport to rely, but the Proposed Rule itself gave no notice that the Departments were even *considering* requiring such disclosure. The closest the Proposed Rule ever came to this topic was a general request for "comment regarding whether a rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs, and 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." 84 Fed. Reg. at 65472. But this request says nothing about net prices. Instead, it mentions the opposite—the "undiscounted price." And it asks for comment about what disclosures would be needed to "ensure that individuals have access to meaningful cost-sharing liability estimates for prescription drugs," *id.*—a goal not furthered by the disclosure of historical net prices because net prices do not determine enrollees' cost-sharing obligations. Further, this "discussion in the preamble to the proposed rules occurred in the context of the third content element (negotiated rates) for the internet-based self-service tool"—*not* the machine-readable files, where the new historical net price disclosure requirement was ultimately added (in addition to negotiated rates). 85 Fed. Reg. at 72235 n.191; *see Proposed Rule*, 84 Fed. Reg. at 65472-73 (asking whether and how to disclose such information "when the consumer searches for cost-sharing information" on the internet-based tool).

110. Comment letters submitted during the rulemaking proceedings provide yet further proof that stakeholders lacked notice that disclosure of net prices was under consideration. Only a handful of comments on the Proposed Rule—out of "over 25,000" received, 85 Fed. Reg. at 72167—even mentioned "net prices" or price concessions. At least one commenter, the American Pharmacists Association ("APhA"), took advantage of the Proposed Rule to advocate

for disclosure of net prices. *See* APhA Comment Letter at 2-3 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19527 (advocating the wholesale substitution of "net price" for "negotiated price" in the proposed disclosures, an alternative that the Transparency Rule did not adopt). But this is of no moment. Commenters often go beyond a proposed rule in advocating for their own pet causes, and other "parties cannot be expected to monitor all other comments submitted to an agency." *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991); *see also AFL-CIO v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985) (two "isolated comments" on an issue, out of "some 1600" received, do not indicate "[r]easonable" notice of that issue).

111. Entities opposed to historical net price disclosure said nothing or very little in comments on the Proposed Rule, and have subsequently indicated, in response to CMS's December 30, 2020 Information Collection Request published after adoption of the final Rule, for purposes of Office of Management and Budget approval under the Paperwork Reduction Act, 85 Fed. Reg. 86567 (Dec. 30, 2020), that they lacked notice of this issue's consideration. For example, AHIP did not even mention net prices in its 57-page comments on the original Proposed Rule, *see* AHIP Comment Letter, *supra*, but later urged in response to the Transparency Rule that "CMS should seek stakeholder input on the requirement for historical net prices," which "was not included in the proposed rule" and raised "significant concerns" that caused AHIP to "strongly recommend CMS not proceed" with it. AHIP Comment Letter on Information Collection Request, *supra*, at 2. UnitedHealth Group likewise later objected that "[i]nclusion of historical net prices for prescription drugs was not required by the proposed transparency rule and, as a result, any feedback stakeholders might have otherwise provided regarding this data was not addressed in the [Transparency] Rule." UnitedHealth Group

Comment Letter on Information Collection Request, *supra*, at 6. And CVS Health later explained that "should CMS wish to proceed with requiring this data element despite the statutory concerns, the agency must issue a new notice of proposed rulemaking to allow full public comment and address the operational, competitive and policy concerns" raised by the "inclusion of historical net price," because "there was no public opportunity to comment on it or raise concerns about its inclusion"—a "fatal deficiency in the rulemaking process." CVS Health Comment Letter on Information Collection Request, *supra*, at 3.

112. PCMA, too, later explained that "[t]he final rule's provision regarding the inclusion of historical net prices for prescription drugs in the [machine-readable file] was not included in the proposed rule," and neither PCMA nor other stakeholders ever had "notice" that such a requirement was under consideration. PCMA Comment Letter on Information Collection Request, *supra*, at 2. If PCMA had properly "been given notice regarding the potential inclusion of this data element, PCMA would have commented in opposition for several reasons" that it did not otherwise see any need to raise in its comments on the Proposed Rule. *Id.* Indeed, PCMA *did* raise many of these same objections nearly a year earlier in comments on a separate rulemaking that actually did provide notice that information about price concessions was at issue. *See* PCMA Comment Letter on Rebate Rule, *supra*. There can thus be no question that PCMA's "comments would have been different" had it received proper notice. *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003).

113. In sum, the tiny fraction of comments to even touch on the issue of net prices evince no notice of any particular proposal by the Departments to require the disclosure of net prices, historical or otherwise, let alone the specific requirement ultimately adopted in the final Transparency Rule. Because the vast majority of affected stakeholders did not even think the

issue was relevant, much less being considered for embodiment in a new rule, a reviewing court "cannot conclude that the 'purposes of notice and comment have been adequately served.'" *Ass'n of Private Sector Colls. & Univs.*, 681 F.3d at 462. The historical net price disclosure requirement should be set aside for this reason alone.

2. The ACA Does Not Authorize The Disclosure Of Historical Net Prices

114. Like all federal agencies, the Departments "literally ha[ve] no power to act . . . unless and until Congress confers power upon [them]." *Am. Library Ass'n v. FCC*, 406 F.3d 689, 698 (D.C. Cir. 2005) (omission in original) (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Congress did not confer power on the Departments to require the disclosure of historical net prices.

115. As authority for the Transparency Rule, including the disclosure requirements for historical net prices, the Departments invoked 42 U.S.C. § 18031(e)(3)(A). The first eight subsections of that provision enumerate eight specific pieces of "information" that plans must "make available to the public." *Id.* § 18031(e)(3)(A)(i)-(viii). Historical net prices are not listed in the statute as information that must be disclosed, and the Departments did not contend otherwise in the Transparency Rule.

116. Instead, the Departments invoked the ninth subsection, a residual clause that delegates to the HHS Secretary the authority to require the disclosure of "[o]ther information as determined appropriate by the Secretary." 42 U.S.C. § 18031(e)(3)(A)(ix); *see Transparency Rule*, 85 Fed. Reg. at 72209, 72212. But this residual clause is not a roving license to command the disclosure of *any* information of the Departments' choosing. For several reasons, historical net prices do not fall within Congress's authorization.

117. The phrase "[o]ther information as determined appropriate by the Secretary," like all statutory provisions, must be read in its full context. Here, this phrase is preceded by a list of

eight specific kinds of information that Congress deemed necessary to disclose to the public. Under the well-worn, common-sense rule of *ejusdem generis*, a general residual clause is "limit[ed]" to "matters similar to those specified" in preceding enumerated items. *Gooch v. United States*, 297 U.S. 124, 128 (1936). The Departments recognized as much, explaining that the statute allowed the HHS Secretary "to add additional [disclosure] items as long as those items are of similar character to the items enumerated in the statute." 85 Fed. Reg. at 72167. Accordingly, the eight enumerated categories of information in Section 18031(e)(3)(A) ensure that the ninth residual clause is not "standardless." *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 221 (D.C. Cir. 2007) (interpreting the phrase "other factors as may be appropriate" in another statute).

118. The eight enumerated items preceding the ninth residual clause require the disclosure of information relevant to a consumer's rights or benefits under a health plan. The list, in full, provides that health plans must disclose the following information:

> (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.
>
> (viii) Information on enrollee and participant rights under this title.
>
> (ix) Other information as determined appropriate by the Secretary.

42 U.S.C. § 18031(e)(3)(A)(i)-(ix).

119. Each of the eight enumerated items involves consumer-facing information that helps consumers understand what rights and benefits a plan or issuer provides under its health care coverage, and in turn helps consumers select among different health plans. *See* CVS Health Comment Letter, *supra*, at 4. With the statutory disclosures, consumers can learn information about the plan benefit coverage, such as what is covered under a plan, how the plan is rated, what they can expect when they claim covered benefits, how to receive benefits, and whether and how out-of-network services are covered. 42 U.S.C. § 18031(e)(3)(A)(i), (v)-(vii). Consumers can also learn information about the overall health of the plan or issuer. *Id.* § 18031(e)(3)(A)(i)-(iii). And consumers can learn information about what rights they would have were they to enroll in a plan. *Id.* § 18031(e)(3)(A)(viii). This kind of "practical information" gives "consumers insight into plan features and practices that affect how easily a patient might actually access care covered under a plan." Kaiser Family Found., *Health Insurance Transparency Under the Affordable Care Act* (Mar. 8, 2012), https://bit.ly/3kfb0dF. That such disclosures help a consumer understand their rights and benefits under a plan is unsurprising: The statute expressly aims to achieve "[t]ransparency *in coverage*." 42 U.S.C. § 18031(e)(3) (emphasis added).

120. Information about historical net prices, in contrast, is competitively sensitive information that is not consumer-facing and is not used by consumers to understand what rights and benefits they would have if they select any particular health plan. Net prescription drug prices "are not charged to members." PCMA Comment Letter on Information Collection Request, *supra*, at 4. They do not appear on a bill. They are "not a consumer-facing price" and provide consumers "with no information on what they will be required to pay for a drug at the pharmacy counter under their plan." CVS Health Comment Letter on Information Collection Request, *supra*, at 2. Providing historical net prices to the public is, in sum, not "*actionable*

transparency"—it is counterproductive transparency. PCMA Comment Letter, *supra*, at 1 (emphasis added). Accordingly, the historical net prices that must be disclosed under the Transparency Rule are wholly distinct from the kinds of information that Congress specified should be disclosed under the ACA's transparency in coverage requirement.

121. In addition, nothing in Section 18031(e)(3)(A) suggests that Congress intended to authorize the Departments to significantly alter the way that PBMs negotiate drug prices with manufacturers—much less that Congress "sp[oke] clearly" about this topic, as it must if it wished to assign the Departments authority over such an economically and politically significant question. *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014); *see also U.S. Telecom Ass'n v. FCC*, 855 F.3d 381, 417 (D.C. Cir. 2017) (Kavanaugh, J., dissenting from denial of rehearing en banc) (explaining that the Supreme Court requires "*clear* congressional authorization for major agency rules").

122. As discussed, private negotiations are utterly central and of enormous importance to PBMs, health plans, and the healthcare industry more broadly. Confidentiality allows PBMs and manufacturers to negotiate on a level playing field and at arms' length, which helps drive down the price of prescription drugs. *See supra* ¶¶ 44-51, 79. It is highly unlikely that Congress would give the Departments authority to upend that system and change how prescription drugs are competitively priced through a subtle, and generic, statutory residual clause. Congress does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

123. The Transparency Rule's conceded economic impact and public attention to it is further reason to doubt that Congress intended to authorize it *sub silentio*. As the Departments explained, the Transparency Rule is "likely to result in an annual effect on the economy of $100 million or more," and will impact "1,959" entities as well as all 50 states. *Transparency Rule*, 85

Fed. Reg. at 72294, 72269. And the country has been engaged in a years-long debate over how the health care industry operates and is priced. The Transparency Rule itself drew significant public attention. *See, e.g.*, Christine M. Clements et al., *Trump Administration Finalizes the Transparency in Coverage Rule*, Nat'l Law Review (Nov. 12, 2020), https://bit.ly/3hCuyqL. More broadly, drug prices (and who pays for them) is a prominent issue that will affect almost every American at some point in their lives. Given the massive economic and political consequences of changing how drug pricing works in this country, the Transparency Rule cannot be said to regulate an interstitial matter, and it cannot be said that authority to regulate other matters as deemed appropriate clearly gave the Departments authority to issue the Transparency Rule.

124. The statutory context further confirms that Section 18031(e)(A)(ix) does not permit the Departments to order the disclosure of historical net prices. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) ("[T]he court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."). A separate statutory provision, also part of the ACA, *already* requires some of the health insurance issuers and PBMs affected by the Transparency Rule—those that manage prescription drug coverage on behalf of health plans sold on the ACA Exchanges—to provide to the HHS Secretary information with the principal information needed to calculated historical net prices: information about the "amount" and "type" of "rebates, discounts, or price concessions . . . that the PBM negotiates that are attributable to patient utilization under the plan," as well as the "amount . . . passed through to the plan sponsors." 42 U.S.C. § 1320b-23(b)(2). To preserve the confidentiality of net prices, however, Congress limited the disclosure to "aggregate" data, *id.*, rather than drug-specific pricing information, *id.*; *see also* AHIP Comment Letter, *supra*, at 36.

Even as to this aggregate information, moreover, Congress required disclosure only to the HHS Secretary—*not* to the public—and required the HHS Secretary to keep this information "confidential." 42 U.S.C. § 1320b-23(c).

125. Courts must "interpret [a] statute as a symmetrical and coherent regulatory scheme," and fit "all parts into an harmonious whole." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quotation marks omitted). Reading the residual clause of Section 18031(e) as authorizing the HHS Secretary to order the public disclosure of net prices, when Congress elsewhere in the ACA *prohibited* the HHS Secretary from publishing information about health plan or PBM rebates and discounts, would improperly pit the two statutory provisions "at war with one another." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1619 (2018). And it would implausibly allow the HHS Secretary to turn a *general* statutory provision into one that is inconsistent with a "more specifi[c]" statutory provision that expresses Congress's intent. *Brown & Williamson Tobacco*, 529 U.S. at 133. Far from showing that the disclosure of historical net prices is appropriate, Section 1320b-23 shows that Congress wanted to keep confidential, rather than publicize, information about PBM discounts that underlie any given drug's net price.

126. Agencies cannot regulate beyond their statutory authorization. The Departments' attempt to smuggle in consequential forced disclosures of historical net prices through a residual clause that follows a list of enumerated information that looks nothing like historical net prices cannot be squared with Congress's terms. The Transparency Rule's requirement that plans disclose historical net prices thus exceeds the Departments' statutory authority and violates the APA.

3. The Historical Net Price Disclosure Requirement Is Arbitrary And Capricious

127. Even if this Court were to conclude that the historical net price disclosure requirement was a logical outgrowth of the Proposed Rule and that the Departments have the statutory authority to regulate in this manner, the requirement still must be vacated as arbitrary and capricious and contrary to the APA for multiple reasons.

i. Requiring Disclosure Of Historical Net Prices Is Arbitrary And Capricious Because It Will Create Harmful, Counterproductive Consequences

128. The historical net price disclosure requirement is arbitrary and capricious because it will not achieve its objective of lowering out-of-pocket medical spending and will only harm plan beneficiaries by raising premiums and undermining the delivery of value-based care.

a. The Requirement Will Increase Drug Prices Because Public Disclosure Of Competitively Sensitive Pricing Information Will Undermine PBMs' Bargaining Power

129. The historical net price disclosure requirement should be vacated because the Departments failed to adequately address the effect of forced net price disclosures on PBM bargaining power and, ultimately, prescription drug prices. The Departments repeatedly emphasized their "view that public availability of," among other things, "historical net prices for prescription drugs" could help "slow or potentially reverse the rising cost of health care items and services." 85 Fed. Reg. at 72212. But that conclusion is contrary to the evidence that was before the Departments.

130. As PCMA explained in its comments on the Proposed Rule, "releasing net drug prices would cause net drug prices to rise." PCMA Comment Letter, *supra*, at 11. PBMs' bargaining power and ability to achieve significant price concessions from manufacturers depends on their ability to conduct private negotiations, maintaining the minimum level of

discounts needed to achieve formulary coverage or preferred status as trade secrets that are not openly available to all manufacturers. Public disclosure of this sensitive pricing information would make it harder to negotiate and, thus, to save costs for plans and their enrollees.

131. Generally, when a manufacturer has insights into the minimum level of discounts needed to achieve formulary coverage or preferred status, the manufacturer will rationally begin to pull back on more aggressive offers. Why offer a better deal than necessary? And because for some medical conditions there are relatively few treatments available, a seller can gain the upper hand and increase its margin with only a few data points. In effect, the public availability of pricing information allows tacit collusion between manufacturers, who will not be willing to offer prices below their competitors. Without the leverage afforded by the existing system of confidential net prices, the ability of PBMs to extract price concessions from manufacturers would be significantly weakened, and the total net cost paid by health plans and health insurance issuers and their enrollees would therefore *increase*.

132. Other federal agencies agree that government-enforced price disclosures will raise prescription drug costs by reducing PBMs' ability to negotiate affordable drug prices. The CBO, for example, recognized that "[t]he markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices." CBO Transparency Study, *supra*, at 4. In "highly concentrated" markets such as the prescription drug market, "where only a small number of firms operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them." *Id.* Hence, "reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers." *Id.*

133. The FTC shares the CBO's view of the damaging effect of forced disclosure of drug prices. Based on "extensive . . . experience with PBMs," the FTC has explained, "[i]f pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors . . . then tacit collusion among manufacturers is more feasible," so that government-mandated disclosures "may lead to higher prices for . . . pharmaceuticals." FTC Letter, *supra*, at 3, 9. Rules requiring such disclosure thus "may have the unintended consequences of limiting competition, thus increasing the cost of pharmaceuticals" by "mak[ing] it more difficult for PBMs to generate cost savings (including rebates)." *Id.* at 2.

134. The Departments failed to adequately address these concerns. Although the Departments acknowledged, in response to comments, the CBO's and "FTC's concerns about the potential negative impacts of price transparency on competition in the health insurance markets, including the possibility that providers (or sellers) will coordinate their behavior or bid less aggressively, leading to higher prices," 85 Fed. Reg. at 72257, the Departments offered no meaningful response.

135. The Departments simply asserted that the "Federal Government maintains laws and processes to investigate reports of collusive or other anticompetitive practices." 85 Fed. Reg. at 72258; *see also id.* at 72173 (discussing the Sherman Antitrust Act). But that is no answer to concerns over "[t]acit collusion" or "conscious parallelism," which is "not in itself unlawful" under the antitrust laws. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993).

136. The Departments also fell back on "studies that have investigated the impact of price transparency on other, non-health care markets," 85 Fed. Reg. at 72173, but they made no effort to explain why those studies would be applicable here, *see id.* at 72162 (discussing studies

on automobile, life insurance, and airline pricing). They would not. Unlike the industries the Departments cites, the markets for some healthcare services are "highly concentrated," as CBO has recognized. CBO Transparency Study, *supra*, at 4. There is no reason to believe—and the Departments offered no reason to suggest—that negotiating formulary placement with a drug manufacturer is subject to the same market dynamics as the standard consumer transaction in these other industries.

137. Because the Departments failed to adequately account for the effect of forced disclosure of historical net prices on PBM bargaining power, they failed to address the obvious and well-documented counterproductive consequences of the final Rule. The historical net price disclosure requirement is therefore arbitrary and capricious.

b. The Requirement Will Undermine The Delivery Of Value-Based Care

138. The historical net price disclosure requirement also threatens the continued use of value-based arrangements, which reward healthcare providers with incentive payments based on the quality of care provided. *See* CMS, *Value-Based Programs* (last updated Jan. 6, 2020), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.

139. Then-Secretary Azar previously declared that "[v]alue-based transformation of our entire healthcare system is a top HHS priority." *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, 83 Fed. Reg. 22692, 22696 (May 16, 2018). And the industry is making great strides to further that priority. As of the middle of 2018, there were at least 40 value-based contracts underway between commercial or public payers and drug manufacturers. *See* PhRMA, *Value-Based Contracts: 2009 – Q2 2018* (June 21, 2018), http://phrma-docs.phrma.org/files/dmfile/PhRMA_ValueBasedContracts_Q2.pdf. Commercially insured patients

in health plans with value-based contracts for diabetes, high cholesterol, and HIV medicines had copays that were, on average, 28% lower for those medicines compared to patients in other plans. *See* PhRMA, *Value-Based Contracts May Lower Patients' Out-of-Pocket Costs by 28 Percent* (Feb. 26, 2018), https://www.phrma.org/press-release/value-based-contracts-may-lower-patients-out-of-pocket-costs-by-28-percent. Many organizations participating in a recent CMMI demonstration chose prescription drug-based interventions, showing there is great appetite for value-based arrangements when all parties are adequately protected from risk. *See* CMS, *Medicare Advantage Value-Based Insurance Design Model* (last updated Dec. 14, 2020), https://innovation.cms.gov/initiatives/VBID.

140. The forced disclosure of historical net prices, however, will send the wrong signal to market participants, undermining the delivery of value-based care.

141. Mandatory disclosure of historical net prices could lead purchasers of group health insurance to focus on the unit prices of drugs purchased by their issuers and PBMs, rather than the value of the mix of drugs covered and dispensed. For example, an issuer's higher net price for certain brand-name drugs may not mean higher costs if the issuer is effective at moving enrollees to lower-cost therapeutic alternatives, including generics. To the contrary, a higher net price for a brand-name drug that is rarely dispensed is likely evidence of a PBM's efficiency at driving generic substitution. A third party's drug-by-drug analysis would likely miss this dynamic, sending the wrong market signals about how a PBM performs. This can lead consumers astray, encouraging them to choose less efficient plans that are not effective at reducing costs through generic substitution.

142. The Departments do not address how creating a fixation on unit prices could undermine the delivery of value-based care. This is not reasoned decisionmaking.

ii. The Departments Departed Without Reason Or Explanation From Prior Agency Positions

143. The historical net price disclosure requirement is arbitrary and capricious for another reason: It departs without explanation from prior agency policy and practice. Under bedrock principles of administrative law, an agency "changing its course must supply a reasoned analysis." *Lone Mountain Processing, Inc. v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)). This principle ensures that an agency policy or practice is "being deliberately changed, not casually ignored." *Id.* As a result, an "'[u]nexplained inconsistency' in agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (alteration in original) (quoting *Nat'l Cable & Telecommc'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)). And here, there are multiple unexplained inconsistencies in the Departments' approach.

144. *First*, the Departments' single-minded focus on transparency here cannot reasonably be squared with CMS's more cautious, confidentiality-protective approach adopted with respect to the agency's cornerstone prescription drug program (Medicare Part D). CMS (like the FTC and CBO) has recognized that PBMs' ability to maintain the confidentiality of sensitive financial information plays a critical role in keeping drug prices low. *See* PCMA Comment Letter, *supra*, at 17-18. As CMS explained, Medicare Part D "is based on a competitive business model," and "releas[ing] commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers." *Medicare Program; Medicare Part D Claims Data*, 73 Fed. Reg. 30664, 30668 (May 28, 2008).

Accordingly, CMS has recognized the strong "need to protect the sensitive data under the Part D program," *id.,* and has adopted regulations that retain the confidentiality of "commercially sensitive data of Part D sponsors," 42 C.F.R. § 423.505(m)(1)(iii).

145. The historical net price disclosure requirement takes an entirely different approach, forcing health plans and issuers, including their PBMs, to disclose highly sensitive financial information. *See supra* ¶¶ 85-86, 130-33. Gone are the days of HHS, through CMS, acting on the basis that disclosing drug prices to the public would *increase* drug prices. Now, HHS (alongside Treasury and DOL) takes the exact opposite view, claiming that it can "slow or potentially reverse" the purported rising cost of prescription drugs through disclosure rather than confidentiality. *Transparency Rule*, 85 Fed. Reg. at 72212; *see also supra* ¶ 89. Yet the Departments do not even acknowledge, much less reasonably explain, this inconsistency.

146. *Second*, and as detailed above, *supra* ¶¶ 138-42, HHS has previously declared that "[v]alue-based transformation of our entire healthcare system is a top HHS priority." *HHS Blueprint*, 83 Fed. Reg. at 22696. But focusing on unit prices could undermine the industry's transition to the value-based approaches HHS has long championed. *Supra* ¶¶ 140-42.

iii. The Departments Failed To Explain How Historical Net Prices Help Consumers Make Informed Decisions

147. The APA requires agencies to "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). Here, the Departments failed to articulate a coherent connection between the disclosure of historical net prices and the Departments' purported goal of helping consumers make informed choices when purchasing prescription drugs.

148. The Departments stated that disclosure of historical net prices "could" help "consumer health care purchasing decisions." *Transparency Rule*, 85 Fed. Reg. at 72238. In the Departments' view, disclosing information about historical net prices could 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," and in "these situations," consumers "will be able to make an informed decision regarding whether to utilize their plan or coverage when purchasing the prescription drug." *Id.*

149. The Departments failed to explain why consumers would base their drug-purchasing decisions on "the amount their plan or issuer ultimately paid" rather than on *their own out-of-pocket costs*. Nor could they provide a reasonable explanation. As discussed, when a consumer purchases a prescription drug, the consumer's out-of-pocket costs are either a fixed dollar amount or a percentage of the price charged at the pharmacy counter *before* applying manufacturer price concessions. *See supra* ¶¶ 8, 40. Historical net prices are not part of that equation. They are simply not helpful to consumers who seek to anticipate their individual costs for given drug purchases—as reflected by the fact that historical net prices do not appear on consumers' bills. *See* PCMA Comment Letter, *supra*, at 1; CVS Health Comment Letter on Information Collection Request, *supra*, at 2. Requiring disclosures that provide no actionable transparency for consumers does not further the Departments' goal of helping consumers make informed decisions.

150. The Departments' rational decision to exclude historical net prices from the separate internet-based self-service tool required by the Rule only underscores the irrationality of requiring disclosure of that information through machine-readable files. The self-service tool requirement, which PCMA supports, already requires plans and issuers to disclose estimates of a

consumer's cost-sharing liability. *See supra* ¶¶ 64, 84. This information directly relates to a consumer's own out-of-pocket costs, which helps consumers "make an informed decision regarding whether to utilize their plan or coverage" when purchasing a drug. *Transparency Rule*, 85 Fed. Reg. at 72238. The Departments failed to explain why it is necessary to mandate the public disclosure of historical net prices when another part of the Rule already provides consumers with information about how much *they* have to pay to purchase prescription drugs—the information consumers care about.

iv. The Departments Failed To Consider A Reasonable, Less Restrictive Alternative

151. Finally, the historical net price disclosure requirement is also arbitrary and capricious because the Departments failed to even consider whether a less burdensome alternative was available that could at least reduce—though by no means eliminate—the Rule's anticompetitive effects, such as by limiting disclosures of historical net prices to older data that is not as competitively sensitive and therefore less likely to skew market negotiations in real time.

152. "An agency is required to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) (quotation marks omitted). While this standard does not "broadly require an agency to consider all policy alternatives in reaching [a] decision," *Motor Vehicle Mfrs. Ass'n of U.S.*, 463 U.S. at 51, an agency must at least consider those alternatives that are "significant and viable," *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1511 n.54 (D.C. Cir. 1984).

153. Here, however, the Departments arbitrarily elected to require disclosure of historical net prices for the 90-day period "beginning 180 days before the date a particular [machine-readable file] is published." *Transparency Rule*, 85 Fed. Reg. at 72237. Disclosing

such recent data increases the risk of "anticompetitive effect[s]." PCMA Comment Letter on Information Collection Request, *supra*, at 5. As discussed, the disclosure of historical net price information generally opens the door to tacit collusion among drug manufacturers. *See supra* ¶¶ 46-47, 79. The Departments' decision to disclose historical net price information that is between 90 and 180 days old gives manufacturers a nearly real-time window into net prices, which increases the risk of (and effectiveness of) tacit collusion.

154. An obvious alternative—which might have at least "mute[d] some of the anticompetitive effect[s]" of the historical net price disclosure requirement, while not eliminating those effects entirely—would have been to impose a meaningful delay between when net prices are paid and when they are publicly revealed, such as data that is at least three years old. PCMA Comment Letter on Information Collection Request, *supra*, at 5. While disclosing *any* historical net price information facilitates tacit collusion, the "prescription drug market changes fairly rapidly," so disclosing more recent information is more impactful. *Id*. New drugs are approved or lose patent exclusivity with frequency, which increases competition among brands and with generics. *Id.* And the discounts needed to secure preferred formulary position three years before a machine-readable file is published may be less closely related to the composition of the prescription drug market in the current plan year, meaning that lagged net price information would have less salience to current manufacturer and PBM negotiations. *Id.* To be sure, even older data would allow drug manufacturers insight into their competitors' price concession practices that could strengthen ability to demand higher prices. But given the regular turnover in the prescription drug market, the release of data that is several years old would at least provide some tangible reduction in the opportunity for the tacit collusion as compared to the disclosure of recent data. *Id.* Conversely, the Departments have never articulated any reason why disclosing

more recent net price information would assist consumers in comparing competing plans or anticipating their out-of-pocket expenses—because the reality is that it does not assist consumers at all and provides no meaningful transparency to consumers.

155. PCMA did not suggest this alternative during the comment period for the Proposed Rule because the Proposed Rule gave no indication that the Departments were considering *any* disclosure requirement related to net price, let alone near-real-time historical net price information. But the alternative should have been obvious enough because the Departments had to choose a time period for the disclosure. And PCMA did ultimately identify the alternative *after* the Rule was promulgated—not as a panacea to the Rule's flaws, but at least as a less harmful option. *See* PCMA Comment Letter on Information Collection Request, *supra*, at 5. The Departments cannot hide behind commenters' failure to anticipate and propose an alternative to a requirement not even hinted at in the Proposed Rule.

156. Although this alternative should have been obvious, the Departments never considered it. And the Rule offers no evidence or reasoning suggesting that disclosing more recent net price information in anyway better achieves the Departments' objectives than disclosing information old enough to mitigate its impact on the industry. The Departments' requirement to disclose effectively real-time net price information is thus arbitrary and capricious. *See Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009) (rejecting the FCC's 30% subscriber cap as arbitrary and capricious because the agency failed to "examine the relevant data and articulate a satisfactory explanation for its action" (alterations and quotation marks omitted)).

157. By failing to consider this obvious alternative, the Departments have failed to engage in reasoned decisionmaking.

B. The Transparency Rule's Machine-Readable File Requirement Is Unlawful

158. The Transparency Rule's method for disclosing historical net prices and other information—through machine-readable files—is likewise unlawful, for two reasons. *First*, the machine-readable file requirement is inconsistent with the ACA's command that plans *themselves* (not third parties) must disclose information to the public, and that they must do so in "plain language." Machine-readable files flunk those requirements because the information contained in those files cannot readily be understood or used by ordinary consumers. Those files are composed of data sets designed to be automatically read and processed by *computers*, not human beings. *Second*, the machine-readable file requirement is arbitrary and capricious because the Departments failed to consider key defects in the use of machine-readable files.

1. Machine-Readable Files Do Not Comply With The ACA's "Plain Language" Requirement

159. The ACA requires that plans disclose certain information "to the public," and that information must be "provided in plain language" so that "the intended audience, including individuals with limited English proficiency, can readily understand and use" the information. 42 U.S.C. § 18031(e)(3)(A), (B). The meaning of the statute is straightforward: *Plans* must disclose information *to the public* in a format that is understandable *to the public*. The Transparency Rule, however, requires plans to disclose information in a machine-readable file format that *only third parties* can understand, in the hopes that third parties, in turn, will independently create tools that may allow consumers to understand the information contained in the machine-readable files. That aspect of the Rule is irreconcilable with the ACA's "plain language" requirement.

160. Congress made *plans*, not any third party using disclosed information, directly responsible for ensuring that the disclosed information is understandable. The parallel language

of paragraphs (A) and (B) of the disclosure provision, 42 U.S.C. § 18031(e)(3), makes this plain. Under paragraph (A), Exchanges may require "*health plans*" to "submit" certain information to the exchange and the government, and "make [that information] available to the public." *Id.* § 18031(e)(3)(A) (emphasis added); *see also* 42 U.S.C. § 300gg-15a (extending these same requirements to "group health plan[s]" and "health insurance issuer[s] offering group or individual health insurance coverage"). Paragraph (B), in turn, specifies that the "information required to be submitted under subparagraph (A)"—that is, the information submitted *by plans*—"shall be provided in plain language." *Id.* § 18031(e)(3)(B). Accordingly, the ACA's plain-language requirement applies to the transmission of information by plans, not by third-party intermediaries who obtain that information from plans and may or may not accurately decipher that information before passing it on to the public.

161. Nor is it sufficient that the third parties themselves be able to understand the disclosure. To satisfy the ACA's plain-language requirement, plan disclosures must be understandable to the *public*, not to third parties. The statute defines "plain language" to mean "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." 42 U.S.C. § 18031(e)(3)(B). And both paragraphs (A) and (B) make clear that the "intended audience" that must be able to "understand and use" the disclosure means the general public, including plan beneficiaries. Paragraph (A) requires plans to make the same required disclosures both to "the Exchange, the Secretary [of HHS], [and] the State [operating the Exchange]," and "*to the public*." *Id.* § 18031(e)(3)(A) (emphasis added). And paragraph (B) expressly says that the "intended audience" "include[s] individuals with limited English proficiency"—*i.e.*, ordinary consumers, not computer processors or sophisticated

third parties with such equipment and the necessary technical expertise to run them. *Id.* § 18031(e)(3)(B).

162. This interpretation—that the plans' submitted information must be directly understandable to consumers, not machines or third parties such as app developers—is reinforced by the Departments' definition of "plain language" in other parts of the Transparency Rule. In the context of the self-service tool for cost-sharing information, the Transparency Rule "define[s] 'plain language' to mean [information] written and presented in a manner calculated to be understood by the *average participant, beneficiary, or enrollee*." *Transparency Rule*, 85 Fed. Reg. at 72179 (emphasis added).

163. Applying the ACA's straightforward statutory language here, the Transparency Rule's requirement that plans disclose drug pricing information through machine-readable files does not comport with the statutory requirement that plans disclose information to the public in a format that is understandable to the public.

164. Indeed, the Departments conceded in the Transparency Rule's preamble that machine-readable files do not provide information in "plain language" to ordinary readers. They candidly acknowledged "the information included in the machine-readable files may not be easy for an average consumer to navigate." *Transparency Rule*, 85 Fed. Reg. at 72234; *see also id.* at 72215 (asserting that disclosure of "pricing information through the machine-readable files" will benefit consumers "even if it is difficult to navigate for the average consumer without the use of internet-based tools or applications").

165. The Departments are correct. As even a cursory review of a sample machine-readable file makes clear, *see supra* ¶ 94 and Ex. A, machine-readable information—a digital representation of data that uses particular formats such as JSON, XML, or CSV and that can be

imported or read by a computer system, *see supra* ¶ 68—cannot be readily understood or used by members of the public with limited English proficiency. A lengthy list of coding cannot be understood by an ordinary person. After all, machine-readable information is by definition designed to be read by a computer, not a person.

166. Moreover, the Transparency Rule requires plans and issuers to include in machine-readable files an avalanche of data so overwhelming that an ordinary person cannot meaningfully process it, even if they could read the file itself, despite the ACA's requirement that disclosures be "concise." 42 U.S.C. § 18031(e)(3)(B). A given plan's machine-readable file will collectively include information about *all* historical net prices of all drugs for a given period of time. But the vast majority of the information in each machine-readable file is not relevant to any given consumer, who may be purchasing only a single drug. It would be impractical and cumbersome, to say the least, for a consumer to comb through the numerous transactions and pieces of information in a single machine-readable file to identify the entries relevant to the purchase of a particular prescription drug from a particular pharmacy. *See Transparency Rule*, 85 Fed. Reg. at 72240 ("The Departments are aware that these files could be very large and could be difficult for laypersons to navigate.").

167. Even if consumers could identify and understand the entries for individual drug sales, moreover, that information is not what they are interested in. Instead, consumers want "aggregate" data. *Transparency Rule*, 85 Fed. Reg. at 72241. The machine-readable file, however, provides line-by-line, granular data that is unhelpful and "no[t] actionable" for consumers. PCMA Comment Letter, *supra*, at 2.

168. It is no answer, as the Departments claimed, to recharacterize the ACA's intended audience as third-party "researchers" and "application developers" who can use machine-

readable files to in turn create "easy-to-use" tools "that will present information to laypersons in easy-to-understand, plain language." *Transparency Rule*, 85 Fed. Reg. at 72169. The prospect that consumers might in theory, as downstream benefactors, eventually obtain understandable information from third parties does not change the conceded fact that the machine-readable files themselves are not in plain language. *See supra* ¶¶ 91, 94, 168. And if the machine-readable files themselves are not in plain language, the Transparency Rule does not comport with the statutory language imposing on *plans* the duty to submit information *to the public*. *See supra* ¶¶ 159-61.

169. Making plans, rather than third parties, responsible for providing understandable information to the public furthers Congress's goal of informing consumers about their health-care options because it reduces the risk of consumer confusion. Plans must answer to the Departments for the information they disclose, so there is a direct line of accountability between the speaker and the regulator. In addition, plans have the context to provide accurate, actionable information to consumers. Unlike third parties such as researchers, plans have an established relationship with covered beneficiaries and potential customers. Accordingly, plans can give consumers individualized (*i.e.*, *useful*) information that reflects what a consumer actually pays at the counter under the consumer's specific plan coverage in light of the prior payments that may, for example, count towards the consumer's deductible.

170. Conversely, "[t]hird parties who use the machine-readable files to present information to consumers are not accountable" to the Departments, and therefore may provide inaccurate, misleading, or confusing information. PCMA Comment Letter, *supra*, at 13-14. Third parties lack access to consumers' individual plan and coverage history, so they cannot accurately advise consumers about the cost of an individual drug purchase. Indeed, the

disclosure of historical *net* prices to consumers *at all* runs the risk of misleading consumers because, as commenters explained, *consumers generally do not pay net prices*. Giving consumers an overload of information that does not reflect what they actually "pay for a drug at the pharmacy counter under their plan" does not advance the Departments' goal of giving consumers more knowledge to make an informed decision about what plan they want to enroll in. CVS Health Comment Letter on Information Collection Request, *supra*, at 2; *see also* UnitedHealth Group Comment Letter on Information Collection Request, *supra*, at 6 ("[T]he inclusion of historical net price does not follow CMS' stated intent of the transparency rule, which is to enable patients to shop for healthcare items and services most efficiently.").

171. Finally, there is no assurance that third parties will actually develop plain-language tools or products that help consumers understand the disclosures. The Transparency Rule does not regulate these third parties or require them to develop helpful tools or products. The Departments' predictions that third parties will "be incentivized" to do so, *Transparency Rule*, 85 Fed. Reg. at 72214, is no substitute for statutory terms that require direct, rather than indirect, plain-language disclosures from plans to consumers.

172. Accordingly, the Transparency Rule's requirement that plans disclose information in machine-readable files is inconsistent with the ACA's "plain language" requirement.

2. The Machine-Readable File Requirement Is Arbitrary And Capricious

173. The machine-readable file requirement is also arbitrary and capricious for three independent reasons: It will not achieve the Rule's intended purposes, the Departments' cost-benefit analysis is fatally flawed, and the Departments imposed an unrealistically short implementation timeline for the machine-readable files.

i. The Rule Will Not Achieve Its Intended Purpose

174. The Departments acted unreasonably in imposing a mandate to disclose machine-readable files because that format will not further the Transparency Rule's asserted goals. An agency acts unreasonably where it "never established a reasonable connection between its stated purpose" and the regulatory means "selected" to implement that policy. *Farmers Union*, 734 F.2d at 1523.

175. Here, the primary stated objective of the Transparency Rule's disclosure requirements is to "help consumers" to "evaluate their options" while shopping for coverage. *Transparency Rule*, 85 Fed. Reg. at 72168. The Departments assert that "the information the final rules require to be disclosed … has a *direct* nexus to" that objective, *id.* at 72175 (emphasis added), even though the means the Departments chose are admittedly *indirect—i.e.*, disclosure to third parties. The Departments concede that the "raw data" contained in the machine-readable files "is likely to be difficult for the average consumer to understand and effectively use," but maintain that these requirements could still "ultimately" help consumers by indirect chains of causation: "For instance, third-party developers could develop mobile applications" that translate the disclosed data into a form that is actually useful for consumers. *Id.* at 72210. The Departments simply "assumed" that such innovation would "materialize" to make this connection. *Id.* at 72215.

176. But as AHIP and other stakeholders noted in comments on the Proposed Rule, "the machine-readable provisions" would actually "not advance" the Departments' stated goals for several reasons, including that "the preponderance of consumers do not want to obtain information about costs from a third-party," as the Departments assumed. AHIP Comment Letter, *supra*, at 6, 31; *see also* UnitedHealth Group Comment Letter, *supra*, at 14 (offering additional reasons why the disclosed information "will not necessarily be useful" to consumers

"even with the assistance of a third-party application"). "[N]early every individual and group health plan parent organization already offers enrollee-specific cost-sharing self-service tools." PCMA Comment Letter, *supra*, at 14. These tools provide actionable information, clearly disclosing the amounts a consumer will actually pay based on that consumer's actual benefits. "Tools created outside of the plan's purview," in contrast, would likely be "duplicative and w[ould] only confuse enrollees, particularly given third parties are not accountable to enrollees to provide accurate information and do not have all context to provide consumers with accurate, actionable information." *Id*.

ii. The Cost-Benefit Analysis Is Fatally Flawed

177. The Departments also acted unreasonably by failing to adequately quantify and assess the costs and benefits of the machine-readable file requirement. *See*, *e.g.*, *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708-09 (D.C. Cir. 2014) (holding that agency action based on "sheer speculation" rather than "evidence" was arbitrary and capricious). As the U.S. Chamber of Commerce noted, the Proposed Rule itself listed some "10 specific cost elements that it did not attempt to quantify," failed to account for some costs altogether, and "grossly underestimated" other costs while failing to quantify offsetting benefits. U.S. Chamber Comment Letter at 7-8 (Jan. 29, 2020), www.regulations.gov/comment/CMS-2019-0163-19418.

178. The final rule similarly failed to quantify relevant costs and benefits. The Rule identifies 14 specific costs that the Departments never attempted to quantify, including the "increase in cyber security costs . . . to prevent data breaches," the "increase in health care costs if consumers confuse cost with quality and value of service," the cost "to conduct quality control reviews of the information" required to be disclosed in the machine-readable files, the costs of "renegotiat[ing] contracts in order to remove gag clauses in order" to disclose the information required by the final rule, and the "increase in costs to consumers and issuers if providers or

prescription drug manufacturers engage in anticompetitive behaviors." *Transparency Rule*, 85 Fed. Reg. at 72260. Because these costs could be significant, the Departments' failure even to attempt to quantify them is arbitrary and capricious.

iii. The Implementation Date For The Machine-Readable Files Is Arbitrary And Capricious

179. Even if the machine-readable file requirement could be justified, the Departments did not allow sufficient time to implement that requirement. Developing machine-readable files is a time-consuming, resource-intensive process. Health plans must develop new IT systems, develop new data-collection processes, test those processes, and renegotiate contracts that prohibit the disclosure of information that must be disclosed under the Transparency Rule. *See supra* ¶ 77. Moreover, rushing out the machine-readable files could compromise the integrity of the files and, given the "volume of data being aggregated," introduce "additional opportunity for error" that would in turn harm consumers by providing them with incomplete or inaccurate information. WellFirst Health Comment Letter at 9 (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19274. Because of these concerns, commenters urged the Departments to provide a multi-year window between the final rule's effective date and the date by which plans must implement the machine-readable file requirement, rather than the one-year window proposed by the Departments. AHIP Comment Letter, *supra*, at 40, 42 (proposing a three-year window); UnitedHealth Group Comment Letter, *supra*, at 26 (same).

180. The Departments acknowledged that the "*majority* of commenters *strongly* recommended delaying the proposed applicability date for the . . . machine-readable file requirements." *Transparency Rule*, 85 Fed. Reg. at 72252 (emphases added). But the Departments dismissed these industry participants' practical, experience-based concerns, and

stuck with a one-year implementation window—meaning that the relevant provisions regarding "requirements for public disclosure" of machine-readable files would "apply for plan years beginning on or after January 1, 2022." *Id.* at 72304; *see also id.* at 72252. The Departments were "of the view that developing the machine-readable files should be straightforward for most plans and issuers" because the "development activities needed to establish the machine-readable files involve gathering, formatting, and making publicly available already existing data." *Id.* at 72253. Moreover, the Departments stated that plans "will incur limited additional administrative burdens or costs *after* the one-time initial file development." *Id.* (emphasis added).

181. The Departments' response missed the mark. The problem was never that the data for machine-readable files did not "exis[t]." *Transparency Rule*, 85 Fed. Reg. at 72253. The problem was that it would take more than a year to develop the necessary *systems* to collect data that was scattered across different platforms, process the data, and convert the data into machine-readable files. *See supra* ¶¶ 77-78. As commenters confirmed in response to CMS's request to collect information in 2021, the machine-readable files would require plans to "compile and organize the large volume of health data spread across multiple systems and platforms." CVS Health Comment Letter on Information Collection Request, *supra*, at 4. Moreover, the Departments' prediction that plans' administrative burdens would diminish over time is beside the point: Commenters expressed concern that the Transparency Rule imposes burdens that hinder plans' ability to *comply in the first instance* with the machine-readable file requirement *by January 2022*, when that requirement became effective. *See supra* ¶ 78. The Departments' explanation for retaining the applicability date for the machine-readable files thus failed to meaningfully engage with commenters' actual concerns.

182. Making the rushed rollout of the machine-readable requirement even more dire was the COVID-19 pandemic and *other* disclosure mandates imposed by another CMS rule, each of which required plans to stretch their resources ever thinner. UnitedHealth Group Comment Letter on Information Collection Request, *supra*, at 2. CMS's Health Plan Interoperability Rule, for its part, attempts to modify health information technology systems so that health information and data can be exchanged more easily between systems. *See Medicare and Medicaid Programs; Interoperability and Patient Access*, 85 Fed. Reg. 25510, 25511-12 (May 1, 2020). The rule requires qualified health plan issuers (among others) to implement and maintain a "Patient Access API," or Application Programming Interface, that would allow third-party applications to retrieve data held by such plans. *Id.* at 25513. These "data exchange[s] must be fully implemented by January 1, 2022," *id.* at 25513—meaning that health plans and issuers have been driving to meet concurrent deadlines for both the Health Plan Interoperability Rule and the Transparency Rule, each of which requires its own set of significant administrative investments. Given the investments of time and manpower that plans were making to comply with the CMS interoperability rule, plans were not realistically positioned to invest the "innumerable hours and dollars" necessary to "buil[d] up their IT systems to comply" with the Transparency Rule in the same timeframe. PCMA Comment Letter on Information Collection Request, *supra*, at 6-7.

183. The Departments' rejection of commenters' concerns about the implementation timeline was even more puzzling because previous experiences had shown that "[t]wo years is a bare minimum to stand up a new reporting paradigm." PCMA Comment Letter on Information Collection Request, *supra*, at 7. In January 2020, for example, CMS detailed a collection of certain prescription benefit information that PBMs must provide to HHS under a different provision of the ACA. *See* CMS, *Supporting Statement for Pharmacy Benefit Manager*

Transparency for Qualified Health Plans at 1, CMS-10725 (Sept. 11, 2020), https://go.cms.gov/3eDHr1G. That program would not begin collecting data until 2022 at the earliest, *see HHS Notice of Benefit and Payment Parameters for 2022*, 85 Fed. Reg. 78572 (Dec. 4, 2020) (proposed rule). HHS appeared to recognize the time and resources it takes to construct a new data-reporting regime in that context, but—along with DOL and Treasury—discarded the same considerations when promulgating the Transparency Rule.

184. Like the machine-readable file requirement itself, therefore, the Transparency Rule's timeline for implementing that requirement is arbitrary and capricious.

COUNT I
(CONTRARY TO LAW)

185. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

186. The Transparency Rule constitutes final agency action.

187. PCMA and its members are adversely affected and aggrieved by the challenged portions of the Rule.

188. The Transparency Rule's requirement that plans and issuers disclose historical net prices exceeds the Defendants' statutory authority because the statute does not permit the Departments to require the disclosure of that type of information.

189. The Transparency Rule's machine-readable file requirement also violates the ACA's requirement that information submitted and disclosed by plans must be submitted and disclosed in "plain language," because machine-readable files cannot be readily understood or used by ordinary consumers.

190. Accordingly, these parts of the Transparency Rule are not in accordance with law, in violation of 5 U.S.C. § 706(2)(A), and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

COUNT II
(NOTICE-AND-COMMENT RULEMAKING)

191. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

192. Defendants' promulgation of the Transparency Rule's requirement that plans and issuers disclose historical net prices through a machine-readable file violates the APA's notice-and-comment-rulemaking requirement, 5 U.S.C. § 553, because the requirement to disclose historical net prices was not disclosed in the Proposed Rule and is not a logical outgrowth of the Proposed Rule.

193. Accordingly, this part of the Transparency Rule was promulgated without observance of procedures required by law, in violation of 5 U.S.C. § 706(2)(D).

COUNT III
(ARBITRARY AND CAPRICIOUS)

194. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

195. Defendants' decision to promulgate the Transparency Rule's historical net price disclosure requirement and the machine-readable file requirement was arbitrary and capricious. Among other things, the Departments: failed to engage in reasoned decisionmaking; to acknowledge and provide good reasons for changing policy positions; to act in accordance with the evidence before them; to consider important aspects of the problem they believed they faced; and to adequately address the costs and benefits of their final action.

196. Accordingly, the challenged parts of the Transparency Rule are arbitrary, capricious, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A), and were promulgated without observance of procedures required by law, in violation of 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

Plaintiff prays that this Court:

1) Declare the Transparency Rule's historical net price disclosure requirement and machine-readable file requirement unlawful.

2) Vacate and set aside those requirements or, in the alternative, the effective date of the machine-readable file requirement.

3) Award Plaintiff its costs and reasonable attorney's fees as appropriate.

4) Grant such further and other relief as this Court deems just and proper.

Respectfully submitted,

Dated: August 12, 2021

/s/ Helgi C. Walker
Helgi C. Walker, D.C. Bar No. 454300
Matthew S. Rozen, D.C. Bar No. 1023209
Brian A. Richman, D.C. Bar No. 230071
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HWalker@gibsondunn.com

Attorneys for Plaintiff Pharmaceutical Care Management Association

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. _____

Declaration of Matthew S. Rozen in Support of Complaint

Pursuant to 28 U.S.C. § 1746, I, Matthew S. Rozen, declare as follows:

1. I am an attorney and am admitted to practice law in the District of Columbia and Virginia. I represent Plaintiff Pharmaceutical Care Management Association ("PCMA") in this matter.

2. I am over the age of eighteen and make this declaration from personal knowledge based on information reviewed and/or referenced herein.

3. This declaration is submitted in support of the Complaint filed today by PCMA.

4. Attached hereto as Exhibit A is a true and correct copy of the contents of a Price Transparency Guide published by the Centers for Medicare & Medicaid Services on the website Github, *available at* https://github.com/CMSgov/price-transparency-guide/blob/master/examples/prescription-drugs/prescription-drugs.json, as viewed on August 9, 2021.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on August 12, 2021
Washington D.C.

Matthew S. Rozen

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. _____

Declaration of Matthew S. Rozen in Support of Complaint

EXHIBIT A

CMSgov / price-transparency-guide

Code Issues 8 Pull requests 3 Discussions Actions Projects

master

price-transparency-guide / examples / prescription-drugs / prescription-drugs.json

shaselton adding an additional example History

1 contributor

53 lines (49 sloc) 1.49 KB

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CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

Pharmaceutical Care Management Association

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 11001 (D.C.)
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

United States Department of Health and Human Services; Centers for Medicare & Medicaid Services; U.S. Department of the Treasury; Internal Revenue Service; U.S. Department of Labor; Employee Benefits Security Administration; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Chiquita Brooks-LaSure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; Janet Yellen, in her official capacity as Secretary of the Department of Treasury; Charles P. Rettig, in his official capacity as Commissioner of the Internal Revenue Service; Douglas O'Donnell, in his official capacity as Deputy Commissioner for Services and Enforcement; Martin J. Walsh, in his official capacity as Secretary of the Department of Labor; and Ali Khawar, in his official capacity as Acting Assistant Secretary for the Employee Benefits Security Administration.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Helgi C. Walker, GIBSON, DUNN & CRUTCHER LLP,
1050 Connecticut Avenue, N.W., Washington, D.C. 20036,
Telephone: (202) 955-8500

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ A. *Antitrust*

- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ C. *Administrative Agency Review*

- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	○ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	○ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

Administrative Procedure Act, 5 U.S.C. § 702 -- Complaint challenging agency rulemaking

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☒ NO ☐ If yes, please complete related case form

DATE: 8/12/21 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Helgi C. Walker

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

CLERK=S OFFICE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CO-932
Rev. 4/96

NOTICE OF DESIGNATION OF RELATED CIVIL CASES PENDING
IN THIS OR ANY OTHER UNITED STATES COURT

Civil Action No. _____
(To be supplied by the Clerk)

NOTICE TO PARTIES:

Pursuant to Rule 40.5(b)(2), you are required to prepare and submit this form at the time of filing any civil action which is related to any pending cases or which involves the same parties and relates to the same subject matter of any dismissed related cases. This form must be prepared in sufficient quantity to provide one copy for the Clerk=s records, one copy for the Judge to whom the cases is assigned and one copy for each defendant, so that you must prepare 3 copies for a one defendant case, 4 copies for a two defendant case, etc.

NOTICE TO DEFENDANT:

Rule 40.5(b)(2) of this Court requires that you serve upon the plaintiff and file with your first responsive pleading or motion any objection you have to the related case designation.

NOTICE TO ALL COUNSEL

Rule 40.5(b)(3) of this Court requires that as soon as an attorney for a party becomes aware of the existence of a related case or cases, such attorney shall immediately notify, in writing, the Judges on whose calendars the cases appear and shall serve such notice on counsel for all other parties.

The plaintiff , defendant or counsel must complete the following:

I. RELATIONSHIP OF NEW CASE TO PENDING RELATED CASE(S).

A new case is deemed related to a case pending in this or another U.S. Court if the new case: [Check appropriate box(e=s) below.]

- ☐ (a) relates to common property
- ☒ (b) involves common issues of fact
- ☐ (c) grows out of the same event or transaction
- ☐ (d) involves the validity or infringement of the same patent
- ☐ (e) is filed by the same pro se litigant

2. RELATIONSHIP OF NEW CASE TO DISMISSED RELATED CASE(ES)

A new case is deemed related to a case dismissed, with or without prejudice, in this or any other U.S. Court, if the new case involves the same parties and same subject matter.

Check box if new case is related to a dismissed case: ☐

3. NAME THE UNITED STATES COURT IN WHICH THE RELATED CASE IS FILED (IF OTHER THAN THIS COURT):

_____

4. CAPTION AND CASE NUMBER OF RELATED CASE(E=S). IF MORE ROOM IS NEED PLEASE USE OTHER SIDE.

Pharmaceutical Care Management Ass'n v. **U.S. Dep't of Health and Human Services** C.A. No. **21-cv-95**

08/12/21
DATE

/s/ Helgi C. Walker | Counsel for Plaintiff
Signature of Plaintiff /Defendant (or counsel)

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Internal Revenue Service
1111 Constitution Avenue, N.W.
Washington, D.C. 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association *Plaintiff(s)* v. United States Department of Health and Human Services, et al. *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Employee Benefits Security Administration
200 Constitution Avenue, N.W.
Washington, D.C. 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Xaviar Becerra, in his official capacity as Secretary of the Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Chiquita Brooks-LaSure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janet Yellen, in her official capacity as Secretary of the Department of Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association *Plaintiff(s)* v. United States Department of Health and Human Services, et al. *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Charles P. Rettig, in his official capacity as Commissioner of the Internal Revenue Service
1111 Constitution Avenue, N.W.
Washington, D.C. 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Douglas O'Donnell, in his official capacity as Deputy Commissioner for Services and Enforcement
1111 Constitution Avenue, N.W.
Washington, D.C. 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Martin J. Walsh, in his official capacity as Secretary of the Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ali Khawar, in his official capacity as Acting Assistant Secretary for the Employee Benefits Security Administration
200 Constitution Avenue, N.W., Suite N-5677
Washington, D.C. 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association *Plaintiff(s)* v. United States Department of Health and Human Services, et al. *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Merrick B. Garland, Attorney General
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Pharmaceutical Care Management Association

Plaintiff(s)

v.

United States Department of Health and Human Services, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Civil Process Clerk
United States Attorney's Office
District of Columbia
555 Fourth Street, N.W.
Washington, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Helgi C. Walker
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
HWalker@gibsondunn.com
Counsel for Plaintiff Pharmaceutical Care Management Association

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. _____

CERTIFICATE RULE LCvR 26.1

I, the undersigned, counsel of record for Pharmaceutical Care Management Association ("PCMA"), certify that to the best of my knowledge and belief, PCMA does not have any parent companies, subsidiaries, or corporate affiliates that have outstanding securities in the hands of the public because PCMA is a non-profit § 501(c)(6) corporation. These representations are made in order that judges of this Court may determine the need for recusal.

Respectfully submitted,

Dated: August 12, 2021

/s/ Helgi C. Walker
Helgi C. Walker, D.C. Bar No. 454300
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
Telephone: (202) 955-8500
Facsimile: (202) 467-0539
HWalker@gibsondunn.com

Attorney for Plaintiff Pharmaceutical Care Management Association