UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, 100 Daingerfield Road Alexandria, VA 22314 AMERICAN PHARMACISTS ASSOCIATION, 2215 Constitution Avenue, N.W. Washington, D.C. 20037 COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS, 555 E. Wells Street, Suite 1100 Milwaukee, WI 53202 FRUTH INC. d/b/a FRUTH PHARMACY, 4016 Ohio River Road Point Pleasant, WV 25550 HI-SCHOOL PHARMACY SERVICES LLC, 916 W. Evergreen Boulevard Vancouver, WA 98660 KARE INC. d/b/a KARE DRUG, 100 Llano Street Aztec, NM 87410 TYSON DRUGS, INC. d/b/a TYSON DRUG CO., 145 E. Van Dorn Avenue Holly Springs, MS 38635 *Plaintiffs*, v. XAVIER BECERRA, Secretary United States Department of Health and Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201 *Defendant*.	Civ. No. 21-cv-00131-ABJ

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

NATURE OF SUIT

1. This is an action for judicial review of a policy of the Department of Health and Human Services ("HHS") that undermines Medicare beneficiaries' access to negotiated prices for prescription drugs and otherwise alters Medicare payment for those drugs in a way that reduces their availability. Despite having been reopened time and time again over the last several years, the agency's current definition of "negotiated prices" continues to enable Medicare Part D plan sponsors under the Medicare program (and the pharmacy benefit managers ("PBMs") with which they contract) to downward-adjust reimbursement to pharmacies for prescription drugs months after patients have paid cost-sharing for the prescription drugs based on artificially inflated prices. This dynamic results from an exception to the definition of "negotiated prices" for pharmacy price concessions that cannot "reasonably be determined" at the time of sale, an exception that HHS said would be narrow but never was. In reality, this exception swallows the rule and hereby threatens the solvency of community pharmacies and drives up the cost of prescription drugs for Medicare patients nationwide. Plaintiffs ask this Court to set aside that invalid exception and the agency's guidance on it.

2. The "reasonably determined" exception in the pharmacy price-concession clause of HHS' regulation—which remains on the books despite repeated and necessary reconsideration of it—is invalid for several reasons. First, excluding pharmacy price concessions that cannot be reasonably determined at the point-of-sale violates the Medicare statute's plain language and intent to require that Medicare drug plans give Medicare beneficiaries the benefit of *all* drug price concessions, without exception. Second, the agency's regulation containing the exception is arbitrary and capricious because it is internally inconsistent and reflects that the agency did not consider important factors, including significant comments from stakeholders, in redefining

"negotiated prices." In particular, the agency ignored comments from Plaintiffs explaining that the agency's proposed exception to the term "negotiated prices" would not be narrow, but would instead have immediate and far reaching consequences for community pharmacies, to the detriment of Medicare beneficiaries. Third, the rule is also arbitrary and capricious and not based on substantial evidence regarding the prevalence of drug price adjustments made after the point-of-sale. Fourth, the "reasonably determined" exception for pharmacy price concessions was adopted without proper notice-and-comment rulemaking because the final rule deviated substantially from the proposed rule, depriving Plaintiffs and other interested stakeholders of notice and opportunity to provide essential input on the proposal. In addition, aside from also violating the statute, the agency's annual guidance memorandums on Medicare Part D Direct and Indirect Remuneration ("DIR") Reporting Requirements unlawfully contravene the language and intent of the regulatory definition of "negotiated prices."

3. Plaintiffs thus seek an order setting aside the "reasonably determined" exception in the second clause of the regulation, which excludes from the definition of "negotiated prices" those "price concessions from network pharmacies . . . that cannot reasonably be determined at the point-of-sale" of a prescription drug. 42 C.F.R. § 423.100(2). Plaintiffs also seek an order setting aside the agency's policy guidance interpreting that exception in a manner that reaffirms and perpetuates the agency's unlawful and inappropriate definition of "negotiated prices."

PARTIES

4. National Community Pharmacists Association ("NCPA") is a non-profit organization based in Alexandria, Virginia.[1] NCPA represents the interests of the owners,

[1] *See generally* National Community Pharmacists Association, https://ncpa.org/ (last visited Apr. 22, 2021).

managers, employees, and patients of 21,000 independent community pharmacies across the United States. These pharmacies and their pharmacists are rooted in the communities that they serve and pride themselves on connecting and consulting with patients. Together, these independent pharmacies represent a $76 billion health care marketplace and employ more than 250,000 individuals on a full- or part-time basis. NCPA advocates on behalf of community pharmacists on public policy issues that directly affect their patients and the provision of care to them.

5. American Pharmacists Association ("APhA") is a non-profit organization based in the District of Columbia.[2] APhA, founded in 1852, is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA membership represents nearly 50,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, specialty pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. APhA's mission is to lead the pharmacy profession and equip members for their role as medication experts in team-based, patient-centered care.

6. Coalition of State Rheumatology Organizations ("CSRO") is a non-profit organization based in Milwaukee, Wisconsin.[3] Founded in 2003, CSRO is a coalition of 32 state rheumatology societies whose members are practicing rheumatologists. CSRO represents the

[2] *See generally* American Pharmacists Association, https://pharmacist.com (last visited Apr. 22, 2021).

[3] *See generally* Coalition of State Rheumatology Organizations, https://csro.info/ (last visited Apr. 22, 2021).

interests of rheumatologists and their patients nationwide by advocating for access to the highest quality medical care for rheumatic disease patients; providing a network for rheumatologists to exchange information; and educating insurers, government officials, corporations, and other entities about the impact and importance of rheumatic diseases and rheumatologic care when considering policy changes affecting such care.[4]

7. Fruth Inc. d/b/a Fruth Pharmacy ("Fruth") is a family-owned chain of 29 community pharmacies serving patients in Appalachian portions of West Virginia, Kentucky, and Ohio.[5] Fruth primarily operates in smaller communities that serve remote rural areas. In 2020, Fruth's nearly 500 employees served 103,000 patients (2,000 patients per day), approximately 31% of whom are Medicare beneficiaries, and filled 1.9 million prescriptions (6,000 prescriptions per day).

8. Hi-School Pharmacy Services LLC ("Hi-School") is an independently owned and operated chain of community pharmacies in Oregon and Southwest Washington.[6] Founded in the early 1900s in Vancouver, Washington, Hi-School provides a variety of medication and health care services to communities with smaller populations in remote rural areas. Eleven of Hi-School's pharmacy locations are the only pharmacy in their towns. Hi-School has approximately 400 employees across its 24 pharmacy locations and fills approximately 1.274 million prescriptions per year (more than 4,000 prescriptions per day).

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[4] Plaintiffs NCPA, APhA, and CSRO have standing, including associational standing, to bring this suit because (1) their members would otherwise have standing to sue in their own right; (2) the interests that Plaintiffs seek to protect are germane to their purpose as associations that advocate in favor of the rights and interests of their members; and (3) neither the claims asserted nor the relief requested requires the participation of Plaintiffs' individual members. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

[5] *See generally* Fruth Pharmacy, https://fruthpharmacy.com/ (last visited Apr. 21, 2021).

[6] *See generally* Hi-School Pharmacy, https://hi-schoolpharmacy.com/ (last visited Apr. 21, 2021).

9. Kare Inc. d/b/a Kare Drug ("Kare Drug") is an independent community pharmacy with two locations in rural Northern New Mexico.[7] Kare Drug has 19 employees across its two locations. Kare Drug provides health care services to more than 12,000 individuals and fills approximately 135,000 prescriptions annually (approximately 370 prescriptions per day). Specifically, Kare Drug sees 5,000 patients and fills 55,000 prescriptions at its Aztec, New Mexico location, and it serves between 7,000 to 8,000 patients and fills 80,000 prescriptions at its Bloomfield, New Mexico store.

10. Tyson Drugs, Inc. d/b/a Tyson Drug Co. ("Tyson Drug") consists of four locally owned and operated retail pharmacies in North Mississippi.[8] The original Tyson Drug location has served North Mississippi patients since the nineteenth century and is a staple in the community. Tyson Drug has two locations in Holly Springs, Mississippi; one location in Oxford, Mississippi; and one location in Potts Camp, Mississippi. In 2020, Tyson Drug served more than 73,000 patients (240 patients per day) and filled nearly 300,000 prescriptions (974 prescriptions per day).

11. Defendant Xavier Becerra[9] is the Secretary of the United States Department of Health and Human Services, the federal agency that administers the Medicare program. The Secretary is sued only in his official capacity. References to HHS are meant to refer to the Secretary, his subordinate agencies and officials, and his official predecessors or successors as the context requires.

12. The Centers for Medicare & Medicaid Services ("CMS") is an operating division of HHS with responsibility for day-to-day operation and administration of the Medicare

[7] *See generally* Kare Drug, http://www.karedrug.com/ (last visited Apr. 21, 2021).
[8] *See generally* Tyson Drug, https://tysondrugs.com/ (last visited Apr. 21, 2021).
[9] Under Fed. R. Civ. P. 25(d), new Secretary Becerra is automatically substituted as Defendant.

program. References to CMS are meant to refer to the agency and its organizational predecessors as context requires.

JURISDICTION AND VENUE

13. This action arises under the Medicare Act, title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq.*

14. Jurisdiction is proper under 28 U.S.C. § 1331.

15. Venue is proper in this judicial district under 28 U.S.C. § 1391.

STATUTORY AND REGULATORY BACKGROUND

A. Medicare and the Medicare Part D Prescription Drug Program

16. Medicare is a federally funded health insurance program primarily for elderly and disabled persons that was established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* Medicare Part A provides a hospital insurance benefits program, 42 U.S.C. §§ 1395c, 1395d; Medicare Part B offers a supplemental medical insurance benefits program, *id.* §§ 1395i, 1395k, 1395l; and Medicare Part C provides an optional managed care alternative to Parts A and B, *id.* §§ 1395w-21–1395w-28, *et seq.*

17. Medicare Part D, at issue here, provides prescription drug coverage to Medicare beneficiaries. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003) ("Medicare Modernization Act" or "MMA").

18. An individual may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or is enrolled under Part B. *See* 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

19. CMS contracts with organizations seeking to sponsor Part D plans for Medicare beneficiaries. 42 US.C. § 1395w-111. Prospective sponsors submit annual bids to CMS that

must reflect the costs of a uniform benefit package and address beneficiary premiums based on the plans' estimates of the average monthly costs to provide prescription drug coverage. *Id.* § 1395w-111(b); 42 C.F.R. § 423.265(c)(1)-(2). In rulemaking to implement the Part D program, CMS stated that plans costs, as indicated in its bid, do not include any cost sharing payments made by the enrollee. 70 Fed. Reg. 4,194, 4,289 (Jan. 28, 2005) (original Part D rule); *see also* 42 C.F.R. § 423.265(c)(2) (requiring that payments made by beneficiaries are excluded from plan cost projection).

20. The Medicare Part D statute establishes "cost-sharing" obligations for plan enrollees based on their out-of-pocket costs. 42 U.S.C. §§ 1395w-102(b)(1)-(4). The statute and implementing regulations require beneficiaries to pay annual deductibles along with percentage copayments for their prescriptions, until they reach an upper "initial coverage" threshold. *Id.*; *see* 42 C.F.R. § 423.104(d)(4) (establishing cost-sharing percentages and initial coverage threshold). Enrollees who exceed this threshold fall into what CMS calls the "coverage gap" at which point some beneficiaries will face higher out-of-pocket costs. 42 C.F.R. § 423.104(d)(3)-(4).[10] The enrollee remains in the coverage gap until they reach a "catastrophic coverage" threshold at which point Medicare assumes the bulk of the enrollees' prescription costs. *Id.* at §§ 423.100 (defining "coverage gap"), 423.104(d)(3)-(5) (establishing "initial coverage limit,"

[10] *See* Kaiser Family Foundation, *How Will The Medicare Part D Benefit Change Under Current Law and Leading Proposals?* (Oct. 11, 2019) (examining changes to Part D program and concluding that many enrollees will face increased costs under changes to coverage gap), available at https://www.kff.org/medicare/issue-brief/how-will-the-medicare-part-d-benefit-change-under-current-law-and-leading-proposals/ (last visited Apr. 27, 2021).

enrollee cost-sharing obligations within coverage gap and catastrophic threshold).[11] Part D enrollees who fall into this coverage gap have historically been known to forego their medications, despite the obvious health risks. *See, e.g.*, HHS Office of Inspector General, *Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006*, at 19 (Mar. 2009) (concluding that "beneficiaries appeared to decrease the number of drugs that they purchased during the coverage gap," and warning of "potential health consequences of those actions").[12]

21. In its rules interpreting cost-sharing, HHS has stated that "[b]eneficiary cost sharing is a function of the negotiated price" paid by Part D plan sponsors. 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009). HHS continues to recognize that for enrollees with high prescription needs, "[w]hen pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point-of-sale (that is, are applied instead as [Direct and Indirect Remuneration] at the end of the coverage year), beneficiary cost-sharing increases, covering a

[11] Enrollee cost sharing under Medicare Part D has evolved over time. When the program was originally enacted in 2006, enrollees who exceeded the initial coverage threshold became responsible for 100% of their prescription costs in the coverage gap known as the "donut hole." *See* 42 U.S.C. § 1395w-102(b)(4) (2006) (establishing initial coverage limit and coverage gap); 42 C.F.R. § 423.104 (2006) (calling for cost sharing equal to "100 percent of actual costs" in coverage gap); *see also* 70 Fed. Reg. at 4,306 (original Part D final rule discussing coverage gap). The Patient Protection and Affordable Care Act called for a gradual reduction in enrollee cost responsibility in the coverage gap, with enrollee responsibility capped at 25% of drug costs by 2020 and drug manufacturers shouldering more of the costs until enrollees reach the catastrophic threshold, at which point the Medicare program becomes responsible for 80% of the prescription costs. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3301, 3315, 124 Stat. 119, 461-68, 479-80 (2010); 42 U.S.C. §§ 1395w-102(b)(2)(C)-(D) (establishing sliding scale of enrollee responsibility for prescription costs in coverage gap ending at 25% responsibility); *see also* 75 Fed. Reg. 71,190, 71,214 (Nov. 22, 2010). Subsequent legislation accelerated this timeline. *See* Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 53116, 132 Stat. 64, 306-07.

[12] This document is available at https://oig.hhs.gov/oei/reports/oei-05-07-00610.pdf (last visited Apr. 20, 2021)

larger share of the actual cost of a drug." 83 Fed. Reg. 62,152, 62,176 (Nov. 30, 2018); 82 Fed. Reg. 56,336, 56,426 (Nov. 28, 2017) (acknowledging "the shift by Part D sponsors and their PBMs towards … contingent pharmacy payment arrangements" has a negative impact on "price transparency, consistency, and beneficiary costs").

22. HHS' operating division administering the Part D program, CMS, contracts with private entities known as Part D plan sponsors to administer prescription drug plans and furnish Part D coverage. 70 Fed. Reg. at 4,244. In providing drugs to enrolled beneficiaries, plan sponsors regularly subcontract with "first tier entities," such as PBMs—companies that manage prescription drug benefits on behalf of Medicare Part D drug plans, health insurers, employers, and other payers. *See id.* at 4,554.

23. The Medicare Act requires plan sponsors to, among other things, "provide enrollees with access to negotiated prices used for payment for covered part D drugs." 42 U.S.C. § 1395w-102(d)(1)(A). The Act further requires that, "[f]or purposes of [part D], negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." *Id.* § 1395w-102(d)(1)(B). Congress intended that "negotiated price concessions" would include all pharmacy price concessions, without exception. *See* H.R. Rep. No. 108-391, at 438 (2003) (Conf. Rep.) ("Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable."); H.R. Rep. No. 108-178, pt. 1, at 184 (2003) ("[A]ll PDP plans will be required to make available to their enrollees the benefit of *all* price discounts." (emphasis added)).

24. Under the Medicare statute, the agency is required to base its payments to Part D plans on the plan sponsor's costs, which must be "actually paid" amounts. 42 U.S.C. § 1395w-115. The implementing regulations define "actually paid" costs as costs that "must be actually incurred by the Part D sponsor and *must be net of any direct or indirect remuneration* . . . from any source . . . that would serve to decrease the costs incurred under the Part D plan." 42 C.F.R. § 423.308 (emphasis added). Under agency policy, price concessions that are not included in the "negotiated price" must be reported to the agency as "direct or indirect remuneration" ("DIR") at the end of the coverage year and are used in the agency's calculation of final Medicare payments to Part D plans. *See* CMS, *2017 Fact Sheet: Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017) ("CMS 2017 Fact Sheet").[13] Accordingly, in order to determine the appropriate payment amounts to Part D sponsors, the agency requires Part D sponsors to report DIR data. 42 U.S.C. § 1395w-115(d)(2)(A) (conditioning payments to Part D sponsors upon the receipt of any information required by the agency). However, "when price concessions are applied after the point of sale, as DIR, the majority of the concession amount accrues to the plan, and the remainder accrues to the government." 83 Fed. Reg. at 62,175. Thus, when Part D plans and their PBMs report post-point-of-sale payment recoupments (referred to by HHS as pharmacy price concessions) as DIR, it has the ultimate effect of inflating the price of the drug at the point-of-sale. *See id.* at 62,174.

25. The Part D statute and agency rules establish a system of "risk corridors" for Part D plans that is intended to limit plan sponsors' exposure to unexpected expenses that were not accounted for in the Part D plan's contract bid. *See* 42 U.S.C. § 1395w-115(e) (risk corridor

[13] This document is available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir (last visited January 15, 2021).

statute); 42 C.F.R. § 423.336 (establishing annual risk corridors for Part D plans). Under this system, if a plan's expenditures exceed CMS prepayments by a certain amount, CMS will reimburse the plan sponsor a percentage of the difference. 42 C.F.R. § 423.336(b)(2). However, if CMS prepayments exceed plan expenditures, the agency will reduce future payments or otherwise recover a percentage of the payments made. *Id.* § 423.336(b)(3).

B. Regulatory Definition of "Negotiated Prices"

26. In January 2005, HHS promulgated its first regulatory definition of "negotiated prices." 70 Fed. Reg. at 4,534. The agency initially defined that term as follows:

> Negotiated prices means prices for covered Part D drugs that- (1) Are available to beneficiaries at the point of sale at network pharmacies; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees.

Id.; *see also* 42 C.F.R. § 423.100 (2005). HHS explained that, at that time, it interpreted the governing statute as "requir[ing] that 'discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations' be taken into account in establishing covered Part D drug negotiated prices." 70 Fed. Reg. at 4,245 (citation omitted).

27. In January 2009, HHS further amended its definition of negotiated prices. 74 Fed. Reg. at 1,544. Under that rule, HHS refined the definition of "negotiated prices" as follows:

> Negotiated prices means prices for covered Part D drugs that—(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Includes any dispensing fees.

Id.; 42 C.F.R. § 423.100 (2009).

28. The 2009 Rule and its 2005 predecessor differed in only one key respect: the revision of the first clause in the definition "negotiated prices" to refer to the "total" negotiated amount that would be received by the network pharmacy. According to HHS, this amendment was designed to increase price transparency and ensure "that Part D sponsors base beneficiary cost sharing and price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, also known as the pass-through price." 74 Fed. Reg. at 1,505.

29. In redefining negotiated prices in this manner, HHS said it sought to prevent plan sponsors from artificially inflating negotiated prices, which would have an adverse downstream effect on beneficiaries. *Id*. HHS emphasized the impact of negotiated prices on beneficiary costs, noting that "[b]eneficiary cost sharing is a function of the negotiated price, either directly as in coinsurance percentages of the negotiated price, or indirectly, as co-payments which are ultimately tied to actuarial equivalence requirements based on negotiated prices." *Id.* The agency reaffirmed this definition through subsequent rulemaking in 2010. *See* 75 Fed. Reg. 19,678, 19,816 (Apr. 15, 2010) (amending regulation at 42 C.F.R. § 423.100 but leaving "negotiated prices" definition intact).

C. HHS' 2014 Rulemaking on "Negotiated Prices" and Ensuing DIR Guidance

30. In 2014, HHS proposed yet another definition of "negotiated prices." In a proposed rule, HHS stated, "we propose to revise the definition of negotiated prices at § 423.100 to require that *all price concessions from pharmacies* are reflected in these prices." 79 Fed. Reg. 1,918, 1,974 (Jan. 10, 2014) (emphasis added). HHS explained its rationale for this proposal by noting that the previous rule "permits sponsors and their intermediaries to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the [prescription drug transaction event]." *Id.* at 1,972. By requiring all pharmacy price

concessions to be included in the negotiated price, HHS said that it sought to "ensure that negotiated prices have a consistent meaning, provide for increased transparency in cost reporting to CMS, and allow for meaningful price comparisons between Part D sponsors." 79 Fed. Reg. 29,844, 29,878 (May 23, 2014) (preamble to final rule).

31. NCPA submitted a comment in favor of this proposed new, all-inclusive definition of negotiated price, explaining that the prior regulation allowed price concessions to be "mischaracterized" by plan sponsors, making it "virtually impossible for the federal government/CMS and Part D beneficiaries alike to conduct a true 'apples to apples' comparison of the many different Part D plan options." Letter from Steve Pfister, NCPA to Centers for Medicare & Medicaid Services, at 10 (Mar. 7, 2014).[14] NCPA also commented that the proposed definition would have a positive impact on beneficiary cost-sharing because the then-current system, which allowed plans to report some price concessions as DIR, "produced a distortion in the treatment of costs that has significant effects on beneficiary cost sharing." *Id*.

32. NCPA's comment was just one among what the agency itself called "a significant number of comments in support of this provision based on the improved transparency of pharmacy price concessions." 79 Fed. Reg. at 29,878. HHS, however, did not adopt the proposed definition of negotiated prices in the final rule. *Id.* The agency instead opted, without advance notice or opportunity for comment, to exclude certain pharmacy price concessions from the regulatory definition. *Id.*

33. Although price concessions after the point-of-sale were increasingly common and significant in size, the agency adopted what it said would be a narrow exception. *See* 79 Fed.

[14] This document is available at http://www.ncpa.co/pdf/NCPA-Comments-to-CMS-Proposed-Rule-2015FINAL-3.7.14.pdf (last visited Apr. 21, 2021).

Reg. at 29,878 ("[W]e are revising our proposed definition of negotiated price to allow a narrow exception to the requirement that all pharmacy price concession [*sic*] be included in the negotiated price for those contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale."). Stakeholder comments confirmed the increased use of post-sale concessions, telling the agency that "[t]he entire health care industry is moving to more risk-based contracting in order to encourage cost-effective health management," and that "[o]ften risk-based payment arrangements require retrospective performance review[.]" Letter from Steve Nelson, UnitedHealth Group to Marilyn Tavenner and Liz Richter, Centers for Medicare & Medicaid Services, at 23 (Mar. 7, 2014).[15]

34. As a whole, HHS defined negotiated prices as follows:

> Negotiated prices means prices for covered Part D drugs that meet all of the following: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug. (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and (3) Include any dispensing fees; but (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale. (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

42 C.F.R. § 423.100.

35. At issue here, HHS made one change from the proposal to the final rule in the second clause of the regulation. Under the proposed rule, the term "negotiated prices" was to include "all price concessions and any other fees charged to network pharmacies," without limitation or qualification. *See* 79 Fed. Reg. at 2,062 (proposed regulation text). The final rule, however, adds the language, "except those contingent price concessions that cannot reasonably

[15] This document is available at https://www.regulations.gov/document?D=CMS-2014-0007-1689 (last visited Apr. 21, 2021).

be determined at the point-of-sale." 79 Fed. Reg. at 29,962 (final regulation text); 42 C.F.R. § 423.100(2).

36. In the final rulemaking, HHS noted that it limited its small business impact assessment under the Regulatory Flexibility Act ("RFA") to "Part D sponsors and [Medicare Advantage] plans," claiming that those were the only "entities that will be affected by the provisions of this rule." 79 Fed. Reg. at 29,944. HHS then "determined that there were very few [Medicare Advantage] plans and Part D sponsors that fell below the size thresholds for 'small' businesses established by the Small Business Administration," and the agency did not prepare a full and thorough small-business analysis "because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities." *Id.* The agency failed to address the impact on small pharmacies, such as Kare Drug and Tyson Drug, even though the rule otherwise acknowledged the import of the rule to pharmacies, many of which would qualify as small businesses under the RFA.[16] *See* 79 Fed. Reg. at 29,942, 29,947–48; 5 U.S.C. § 601.

37. In the wake of the 2014 final rule adopting a definition of "negotiated prices" not proposed, HHS issued "draft guidance" to "all Part D Sponsors and interested parties" concerning the changes that it had made to the definition. CMS, *Direct and Indirect*

[16] Pharmacy Plaintiffs Kare Drug and Tyson Drug qualify as small businesses under the thresholds established by the Small Business Administration that the agency cited in its small business analysis for the 2014 rule. *See* 79 Fed. Reg. at 29,943–44 (using NAICS size thresholds for Direct Health and Medical Insurance Carriers); *see also* U.S. Small Business Administration, *Table of Small Business Standards Matched to North American Industry Classification Standards* (Aug. 19., 2019) (setting $30M annual receipts threshold for pharmacies and drug stores to qualify as small businesses), available at https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf (last visited Apr. 21, 2021); 84 Fed. Reg. 34,261, 34,272 (July 18, 2019); 13 C.F.R. § 121.201 (2019).

Remuneration (DIR) and Pharmacy Price Concessions, at 1 (Sept. 29, 2014).[17] HHS at that time also specifically requested comments "with examples of pharmacy price concessions that cannot reasonably be determined or approximated at point-of-sale," but offered only about a two-week comment period. *Id.* at 3.

38. NCPA responded to HHS' request for comments with a strong warning that the "reasonably determined" exception to the definition of "negotiated price" was subject to manipulation by Part D sponsors and PBMs. Letter from Susan Pilch, NCPA to Amanda Johnson, Centers for Medicare & Medicaid Services, at 1 (Oct. 17, 2014).[18] Specifically, NCPA warned HHS that "some Part D sponsors have manipulated the DIR reporting mechanism by reporting many pharmacy price concessions as DIR under the guise that such price concessions could not be determined at the point of sale." *Id.* NCPA explained that this timing differential often results in higher cost-sharing for beneficiaries, while the "plan may also owe a substantial year-end adjustment/risk-corridor payment to CMS due to substantial DIR." *Id.* Anticipating pushback from PBMs and Part D sponsors, NCPA explained that "PBMs that have worked in the Part D marketplace have ample experience with the types of price concessions and fees associated with the adjudication of claims that should enable them to 'reasonably approximate' the appropriate amount." *Id.* at 2.

D. HHS' Inconsistent Guidance

39. On April 27, 2016, without proper notice-and-comment rulemaking, HHS issued draft guidance regarding Medicare Part D DIR reporting requirements. CMS, *Final Medicare*

[17] This document is available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012214694-xb-pharmacy_price_concessions_cy16_dir.pdf (last visited Jan. 15, 2021).

[18] This document is available at https://ncpa.org/sites/default/files/2021-04/letter-ncpa-to-amanda-johnson-cms.pdf (last visited Apr. 28, 2021).

Part D DIR Reporting Requirements for 2015 (May 31, 2016).[19] HHS accepted comments only until May 16, 2016. NCPA, along with 21 other industry stakeholders, including state pharmacy organizations, Pharmacy Services Administrative Organizations, drug wholesalers, and pharmacy buying groups, sent CMS a letter in support of two new reporting fields "aimed to capture 'DIR Fees' charged [to] pharmacies." Letter from NCPA *et al.*, to Amanda Johnson, Centers for Medicare & Medicaid Services, at 2 (May 16, 2016).[20] Specifically, NCPA and the other stakeholders recommended "requir[ing] the entity completing the report to explain why these particular fees cannot be reasonably estimated prior to the [point-of-sale] and included in the 'negotiated price.'" *Id.*

40. HHS issued its final guidance two weeks later on May 31, 2016. In the final guidance, HHS identified various categories of pharmacy price concessions that must be reported as DIR, and, necessarily, would not be included in the negotiated price (and thus would not be directly available to Medicare Part D enrollees as contemplated by Congress). CMS, *Final Medicare Part D DIR Reporting Requirements for 2015*, at 24. Specifically, HHS directed Part D sponsors to report as DIR "*any reconciliation amount* that accounts for *differences between the effective rate and the adjudicated rate achieved by the pharmacy at the point-of-sale* and *contingent* incentive fees . . . ." *Id.* (emphasis added). This definition of DIR is inconsistent with the 2014 definition of "negotiated price," which includes "all price concessions from network pharmacies *except those contingent price concessions that cannot reasonably be determined at the point-of-sale*." 42 C.F.R. § 423.100(2) (emphasis added). These definitions are inconsistent

[19] This document is available at https://www.npaonline.org/sites/default/files/PDFs/Final%20Medicare%20Part%20D%20DIR%20Reporting%20Requirements%20for%202015_1.pdf (last visited Jan. 15, 2021).

[20] This document is available at http://www.ncpa.co/pdf/ncpa-dir-may2016.pdf (last visited Apr. 18, 2021).

because the difference between the effective rate and adjudicated rate is *not* contingent and *can* reasonably be determined at the point-of-sale and thus should have been included in the negotiated price at the point-of-sale. Accordingly, HHS' May 31, 2016 final DIR reporting guidance and all successive annual issuances of DIR reporting guidance[21] are contrary to HHS' current regulatory definition of "negotiated price."

E. HHS' 2017 Formal "Request for Information" Regarding "Negotiated Prices"

41. HHS formally sought further stakeholder feedback on the definition of "negotiated prices" in 2017. Specifically, in 2017, HHS published in the Federal Register a "Request for Information" soliciting input and "comment from stakeholders on how [the agency] might update the requirements governing the determination of negotiated prices, to better reflect current pharmacy payment arrangements, so as to ensure that the reported price at the point of sale includes all pharmacy price concessions." 82 Fed. Reg. at 56,426.

42. In this request, HHS acknowledged the error of its ways in creating the exception. HHS explained that, despite its intention that the "reasonably determined exception" would be narrow in scope, the "exception . . . applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs." *Id.* As HHS has further explained, "[i]n recent years, only a handful of plans have passed through a

[21] The agency has continued to issue substantively similar Part D DIR Reporting Requirements every year since 2016. *See* CMS, *Final Medicare Part D DIR Reporting Requirements for 2016* (June 23, 2017); CMS, *Final Medicare Part D DIR Reporting Requirements for 2017* (May 30, 2018); CMS, *Final Medicare Part D DIR Reporting Requirements for 2018* (Mar. 13, 2019); CMS, *Final Medicare Part D DIR Reporting Requirements for 2019* (Apr. 23, 2020); CMS, *Final Medicare Part D DIR Reporting Guidance for 2020* (Apr. 28, 2021).

small share of price concessions to beneficiaries at the point of sale." *Id.* at 56,419. Rather, "because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005." *Id.*; *see also* CMS 2017 Fact Sheet ("Total DIR reported by Part D sponsors has been growing significantly in recent years. Part D sponsors and PBMs are engaging to a greater extent in arrangements that feature compensation after the point-of-sale, and the value of such compensation is also generally increasing."). To address this challenge, HHS advised that it was "considering revising the definition of negotiated price at § 423.100 to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price." 82 Fed. Reg. at 56,426.

43. Plaintiff NCPA responded to HHS' Request for Information explaining that it has been a "longtime advocate of an approach that would require Sponsors to recognize retrospective pharmacy concessions – so-called 'DIR Fees' – as price concessions in the 'negotiated price' used to adjudicate Part D claims at the point-of-sale rather than as DIR after termination of the plan year." Letter from Susan Pilch, NCPA to Seema Verma, Centers for Medicare & Medicaid Services, at 2 (Jan. 16, 2018).[22] NCPA lauded the agency for its recognition of the problems with the "reasonably determined" exception and expressed its support for a revised definition of "negotiated price" that would ensure "consistent recognition of … price concessions by Sponsors

[22] This document is available at https://www.regulations.gov/comment/CMS-2017-0156-1565 (last visited Apr. 21, 2021)

such that there is a more uniform reflection of the net cost of a drug out-the-door from a pharmacy for Medicare Part D beneficiaries and CMS alike." *Id.* at 4.

44. Plaintiff APhA also responded to HHS' Request for Information to express its support for including all price concessions in the "negotiated price" at the point-of-sale. Letter from Thomas E. Menighan, APhA to Seema Verma, Centers for Medicare & Medicaid Services, at 10 (Jan. 16, 2018).[23] APhA appreciated HHS' acknowledgment that PBMs were using DIR fees "beyond their original purpose" to retroactively extort pharmacies and reclaim reimbursements already paid often resulting in the pharmacy losing money when it fills a prescription. *Id.* APhA also praised HHS for recognizing, and proposing a remedy for, the harms being suffered by patients due to the abuse of DIR fees. *Id.* Specifically, APhA agreed with HHS that revising the definition of "negotiated prices" to "require price concessions between pharmacies and plan sponsors or their PBMs (e.g., DIR fees and/or similar policies/terminology…) be reflected in the negotiated price that is … made available at the time a medication is dispensed at the point-of-sale." *Id.* at 10–11. Moreover, APhA supported including all price concessions in the price adjudicated at the point-of-sale, as originally contemplated by HHS in its January 2014 proposed rule, because it would reduce beneficiary cost-sharing thereby improving beneficiary access to necessary medications leading to improved health outcomes. *Id.* at 10.

F. 2018 Further Rulemaking on "Negotiated Prices"

45. In 2018, after stakeholders presented considerable further evidence that PBMs were interpreting and utilizing the exception far more broadly than the agency had originally said

[23] This document is available at https://www.regulations.gov/comment/CMS-2017-0156-1619 (last visited Apr. 18, 2021).

it anticipated, HHS reconsidered its definition of "negotiated prices" once again in rulemaking. As recommended by NCPA's and APhA's responses to HHS' November 2017 Request for Information, 82 Fed. Reg. at 56,426, the agency proposed finally eliminating the "reasonably determined" pharmacy price-concession exception adopted in 2014. *See* 83 Fed. Reg. at 62,177. In a 2018 proposed rule, HHS moved away from its prior interpretation of "take into account" and acknowledged that the addition of the exception to the definition of "negotiated prices," cannot "be implemented in a manner that achieves . . . [m]eaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and prevention of cost-shifting to beneficiaries and taxpayers." *Id.* HHS also explained that "[w]hen price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing," and "when price concessions are applied after the point of sale, . . . the majority of the concession amount accrues to the plan, and the remainder accrues to the government." *Id*. at 62,175. Moreover, HHS acknowledged that the current regulatory scheme adversely affects Part D beneficiaries who are most in need, forcing individuals who require the most pharmacy benefits to pay more for their medications. *See id.* at 62,174. It said that "[w]hen pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in pharmacy price concessions in recent years, when the point-of-sale price of a drug that a Part D sponsor reports . . .as the negotiated price does not include such discount, the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor." *Id.*; *see id.* at 62,176 ("For many Part D beneficiaries who utilize

drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs.").

46. In this rulemaking, CMS also recognized that the use of DIR affects enrollee premiums in light of the plan sponsors' projections of DIR in bid submissions. *Id.* at 62,175. CMS explained that "to the extent that plan bids reflect accurate DIR estimates, the pharmacy and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums." *Id.* CMS indicated that beneficiary premiums grew slowly, about one percent annually between 2010 and 2017, but that the average premium had "declined each year since 2017 due in part to sponsors' projecting in their bids that DIR growth would outpace the growth in projected gross drug costs each year." *Id.* CMS did not, however, measure these premium reductions against the increased likelihood of beneficiaries falling into the coverage gap based on increased cost-sharing amounts. *Id.* at 62,176 (discussing cost-shifting in DIR context, and noting that the "potential for cost shifting to beneficiaries grows increasingly pronounced as pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price," which "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare"); *see also supra* ¶ 20 (explaining coverage gap).

47. HHS' reconsideration of its definition of "negotiated prices" was widely recognized as a necessary countermeasure to the skyrocketing retroactive pharmacy price concessions being leveraged against pharmacies. Even according to HHS itself, "[t]he data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017." 83 Fed. Reg. at 62,174. In addition, HHS has stated that

"[p]erformance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 225 percent per year between 2012 and 2017 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates." *Id.* Because of the exponential growth in pharmacy price concessions being reasonably determined by PBMs at the point-of-sale but being applied retroactively as DIR fees, pharmacies were forced to expend additional resources on vendors to estimate DIR fees and help them budget, predict cash flow, and otherwise manage their operations, including staffing and availability of services for patients. *See infra* ¶¶ 57, 60, 62, 66, 69.

48. NCPA wrote to HHS in support of its proposed rule to eliminate the "reasonably determined" pharmacy price-concession exception adopted in 2014. Letter from B. Douglas Hoey, NCPA to Alex Azar, U.S. Department of Health & Human Services and Seema Verma, Centers for Medicare & Medicaid Services (Jan. 25, 2019).[24] NCPA reiterated the harms being suffered by both community pharmacies and the Medicare patients they serve. *Id.* at 6–9. As NCPA explained, for pharmacies, the retroactive nature of pharmacy price concessions enables Part D plans and PBMs to claw back such significant amounts that the reimbursement is often rendered inadequate and lower than the cost of the drug. *Id.* at 7. For patients, out-of-pocket spending increases when pharmacy price concessions are applied retroactively because beneficiary cost-sharing increases, requiring patients to cover a larger share of the actual cost of a medication. *Id.* at 8. NCPA explained that eliminating the "reasonably determined" exception and shifting rebates to the point-of-sale "could reduce beneficiaries' costs so much that total beneficiary savings could amount to roughly $28 billion over 10 years." *Id.* (citing Milliman,

[24] This document is available at https://www.regulations.gov/comment/CMS-2018-0149-7396 (last visited Apr. 18, 2021).

Reducing Part D Beneficiary Costs through Point-of-Sale Rebates (Jan. 15, 2018)).[25] Importantly, in addition to enormous savings, eliminating the "reasonably determined" exception would improve patients' medication adherence because reduced costs lead to improved access to recommended medications and improved health outcomes. *Id.*

49. Plaintiff APhA similarly wrote to the agency to express its support for the proposed rule. Letter from Thomas E. Menighan, APhA to Seema Verma, Centers for Medicare & Medicaid Services, at 5–6 (Jan. 25, 2019).[26] APhA first reiterated its position "adopted by APhA's House of Delegates" that "APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies." *Id.* at 5. Accordingly, APhA supported the agency's proposal to require "price concessions" between pharmacies and Part D sponsors or their PBMs, such as DIR fees, be reflected in the "negotiated price" at the point-of-sale. *Id.* In fact, "[a]ccording to CMS estimates, this policy would reduce net beneficiary costs by $10.4 billion and give community pharmacies greater predictability regarding reimbursement rates." *Id.* APhA concluded by emphasizing its support for "requiring Part D sponsors to pass these savings onto beneficiaries." *Id.* at 6.

50. Plaintiff CSRO also wrote to HHS to advocate for revision of the definition of "price concessions" in order to help lower the cost of drugs for patients. Letter from CSRO to Seema Verma, Centers for Medicare & Medicaid Services (Jan. 25, 2019).[27] CSRO explained that "allowing PBMs to determine how to define (and thus classify) price concessions may

[25] This document is available at https://www.phrma.org/report/milliman-report-reducing-part-d-beneficiary-costs-through-point-of-sale-rebates (last visited Apr. 18, 2021).

[26] This document is available at https://www.regulations.gov/comment/CMS-2018-0149-7344 (last visited Apr. 18, 2021).

[27] This document is available at https://www.regulations.gov/comment/CMS-2018-0149-7221 (last visited Apr. 18, 2021).

negatively affect Part D and its beneficiaries," and therefore, CSRO "strongly support[s] CMS defining 'price concession' as broadly as possible, to include all forms of discounts, subsidies, and rebates (formulary and price protection), whether direct or indirect." *Id.* at 3. CSRO urged HHS to revise the definition as soon as possible so that beneficiaries can benefit from price concessions in the form of lower out-of-pocket costs. *Id.*

51. Plaintiffs Fruth and Hi-School, along with a group of multi-disciplined stakeholders, including patient advocacy organizations, health care providers, and pharmacy/pharmacist associations, wrote to Secretary Azar and Administrator Verma urging them to finalize the revised definition "to include all pharmacy price concessions at the point of sale, while excluding additional positive contingent amounts." Letter from Academy of Independent Pharmacy/Georgia Pharmacy Association *et al.*, to Alex Azar, U.S. Department of Health & Human Services and Seema Verma, Centers for Medicare & Medicaid Services (Jan. 25, 2019) (including signatories Fruth and Hi-School).[28] The stakeholders explained that the revised definition "would effectively eliminate retroactive pharmacy price concessions, which have a demonstrably negative impact on patients and pharmacies, and ensure all fees are charged at point of sale." *Id.* at 1. Importantly, the revised definition would accomplish HHS' and the stakeholders' "shared goal"—"lower[ing] beneficiary out-of-pocket costs in the Medicare program." *Id.* at 2. Specifically, "[w]hen a beneficiary's cost-sharing is calculated based on the negotiated price at the point of sale, the beneficiary will benefit from that lower negotiated price." *Id.* The stakeholders further explained that, "[i]n addition to positively impacting beneficiaries, the proposed change would improve the ability of pharmacies to participate in the

[28] This document is available at http://www.ncpa.co/pdf/stakeholders-letter-pharmacy-dir-proposed-rule.pdf (last visited Apr. 14, 2021).

Medicare program." *Id.* The stakeholders concluded by emphasizing that the revised definition of "negotiated prices" would provide "much-needed predictability, accountability, and transparency for all parties, including the Part D program and Medicare beneficiaries." *Id.*

52. On February 1, 2019, a bi-partisan coalition of 29 United States Senators also wrote to Secretary Azar to express support for the revised definition. Letter from Shelley Moore Capito *et al.*, Congress of the United States to Alex Azar, U.S. Department of Health & Human Services (Feb. 1, 2019).[29] The Senators explained that HHS' proposal reflects the Senators' goal of "eliminat[ing] all retroactive pharmacy DIR fees" and "requir[ing] that pharmacy DIR fees be accounted for at the point of sale." *Id.* at 1. Relying on CMS' own data, the Senators explained that the revised definition of "negotiated prices" needed to be implemented because "DIR fees on pharmacies participating in Medicare Part D networks have grown by more than 45,000 percent between 2010 and 2017." *Id.* Moreover, the "retroactive nature of pharmacy DIR fees means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or 'donut hole' phase of their benefit." *Id.* "Finally, all retroactive pharmacy DIR fees are taken back from pharmacies months later rather than deducted from claims on a real-time basis with no transparency to the process," which "makes it difficult for pharmacies to operate and care for their patients." *Id.* For all these reasons, the Senators implored then Secretary Azar to "amend the definition of 'negotiated price' to include all pharmacy price concessions at the point of sale, which would effectively eliminate the retroactive nature of pharmacy DIR fees," and "save Medicare beneficiaries $7.1 to $9.2 billion in reduced cost sharing over 10 years starting as early as 2020." *Id.* at 1-2.

[29] This document is available at https://www.tester.senate.gov/files/Letters/02-01-19%20Senate%20DIR%20letter.pdf (last visited Apr. 21, 2021).

53. Despite widespread support from pharmacies, health care providers and their patients and advocates, as well as Congress, repeated requests from the agency itself for feedback from stakeholders, and the agency's own commitment to reevaluate the definition of "negotiated prices" after observing its unintended real-world consequences, HHS did not finalize this 2018 proposed definition, and instead adopted a rule leaving the exception in effect. 84 Fed. Reg. 23,832, 23,867 (May 23, 2019).

FACTS SPECIFIC TO THIS CASE

A. Pharmacy Plaintiffs, Their Services, and Effects of Skyrocketing DIR Fees

54. Plaintiffs are four community pharmacies (Fruth, Hi-School, Kare Drug, and Tyson Drug) and three associations (NCPA, APhA, and CSRO) representing the interests of pharmacies, pharmacists, health care providers, and patients. Pharmacy Plaintiffs all provide essential prescription drugs and biologics and health care services to patients in underserved communities. Unfortunately, Plaintiff pharmacies—much like community pharmacies across the nation—have been significantly adversely impacted by the use of DIR fees to retroactively adjust pharmacy reimbursements months after the sale, often below the price paid by the pharmacy. As a result, Plaintiff pharmacies have been forced to lay off staff, reduce hours, and curtail the availability of medication and health care management services to rural, underserved communities. The ultimate victims of these changes are the patients in their communities, including innumerable Medicare beneficiaries, such as those served by the members of Plaintiff CSRO.

55. For many communities, pharmacies and pharmacists—like the members of NCPA and APhA—are the sites of the only health care professionals in the area. Across the nation, independent community pharmacies provide vital health care and care management services to

patients, particularly in very rural areas. In fact, 77% of independent pharmacies serve areas with a population of less than 50,000, and 38.5% of independent pharmacies serve areas with a population of less than 20,000.[30]

56. Community pharmacies have become increasingly important to their areas during the COVID-19 pandemic. In addition to the crucial health care and care management services community pharmacies furnish patients, these pharmacies are now on the front lines of the battle against COVID, from establishing vaccine clinics to expanding home delivery of life-saving prescription drugs and biologics. A recent NCPA analysis found that 20.5% of United States zip codes that have a retail pharmacy only have an independent pharmacy to serve the entire community.[31] Fruth, for example, was the first West Virginia pharmacy to offer every-day COVID testing and has conducted large scale vaccination events in both West Virginia and Ohio as well as provided vaccinations to nursing homes and low-income and minority communities. In fact, Fruth has collected nearly 30,000 COVID-19 tests and administered more than 22,000 COVID-19 vaccines.

57. DIR fees "place an undue burden on pharmacies, requiring them to make a substantial investment in accounting and financial systems which add unnecessary costs to the healthcare system, and divert funds from further investment in pharmacy care."[32] In particular, pharmacies are forced to expend additional resources on vendors to estimate the amount of DIR fees that will eventually be clawed back to help them budget and otherwise manage their

[30] NCPA, *2020 NCPA Digest*, at 12, available at https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf (last visited Jan. 15, 2021).

[31] NCPA, *2020 NCPA Digest*, at 1.

[32] Inmar Intelligence, *Direct and Indirect Remuneration (DIR) Performance and the Impact on Pharmacies Serving Medicare Part D Beneficiaries* ("Inmar"), at 2 (Revised July 2019), available at https://www.nacds.org/pdfs/government/2019/DIR_Performance_to_Date_2019.pdf (last visited Apr. 22, 2021).

operations. Pharmacies seek DIR estimates to better manage and predict cash flow and other aspects of their operations, including staffing and availability of services for patients.

1. Fruth

58. Fruth is a family-owned chain of 29 community pharmacies serving patients in Appalachian portions of West Virginia, Kentucky, and Ohio. Fruth primarily operates in smaller communities that serve remote rural areas. In 2020, Fruth had nearly 500 employees, served 103,000 patients (2,000 patients per day), and filled 1.9 million prescriptions (6,000 prescriptions per day). Nearly one-third of Fruth's patients are Medicare beneficiaries and a quarter of Fruth's patients are Medicaid. Fruth provides patients a full range of pharmacy and health care services including specialty medications, medication therapy management (*e.g.*, monitoring patient's response to treatment; identifying, resolving, and preventing medication-related problems, such as adverse drug events), medication synchronization (coordinating the refill of a patient's medications so they can be picked up on a single day each month), compliance packaging (pharmacist bundles multiple medications together in one package, which often improves medication adherence and health outcomes), home delivery, and immunizations. Fruth also partners with local hospitals and clinic providers to offer on-location clinics, which serve as the primary source of health care in the community.

59. Fruth—and its patients—have been particularly impacted by the exponential growth of DIR fees since 2014. By 2017, Fruth was charged just south of $1 million in DIR fees. In 2020, that number grew to more than $4.5 million, which is nearly 4.5% of Fruth's total revenue. As a result, Fruth has been forced to close five store locations since 2014, all of which were providing essential services to underserved communities with older, sicker populations. Although these pharmacy locations were always marginally performing, Fruth had kept them

open for the benefit of the communities, but the current loophole has now made it impossible to keep these pharmacies in business. Importantly, there is no market for community pharmacies in the Appalachian communities Fruth serves. Thus, when Fruth sold a location in 2019, it was forced to sell its prescription files for a nominal amount well below market value.

60. In addition to shuttering pharmacies, Fruth has been forced to: lay-off employees; freeze wages; eliminate the company's 401K match; cease paying any dividends to shareholders; lower annual salaries for all pharmacists; and reduce store hours, including closing on all holidays, thereby reducing the availability of services for patients. These changes have had dire consequences for Fruth's patients. While Fruth was able to serve more than 116,000 patients in 2016, Fruth was able to serve only 103,000 patients in 2020—a 12% reduction in a population desperately in need of medication and care management. The steady increase in retroactively imposed price concessions threatens Fruth's existence, and the pharmacy will be forced to continue closing locations if PBMs are allowed to continue escalating the substantial amounts of reimbursements clawed back under the ruse of price concessions that will ultimately be reported as DIR fees. Fruth contracts with a payment reconciliation company that estimates Fruth's DIR fees based on data it possesses, and Fruth anticipates that the amount of annual DIR fees will continue to significantly increase over time.

2. Hi-School

61. Hi-School is an independently owned and operated chain of 24 community pharmacies in Oregon and Southwest Washington. Founded in the early 1900s in Vancouver, Washington, Hi-School provides a variety of prescription drugs and health care services to communities with smaller populations in remote rural areas. Eleven of Hi-School's pharmacy locations are the only pharmacies in their towns. Hi-School is open six days per week, employs

approximately 400 individuals across its 24 pharmacy locations, and fills approximately 1.274 million prescriptions per year (more than 4,000 prescriptions per day). More than 50% of Hi-School's patients are Medicare or Medicaid. Hi-School offers patients medication therapy management, medication synchronization, compliance packaging, prescription and product selection counseling, blood pressure monitoring, and immunizations, including the COVID-19 vaccine. In fact, in some of its locations, Hi-School is the only pharmacy in town providing COVID-19 vaccines.

62. Hi-School and its patients have also been hit hard by DIR fees. In 2019, Hi-School had nearly $1.5 million in DIR fees clawed back, and in 2020, despite a significant drop in the number of prescriptions filled due to the COVID-19 pandemic, Hi-School had more than $1.2 million in DIR fees clawed back. Through the first four months of 2021, Hi-School is projecting nearly $500,000 in DIR fees. Hi-School contracts with a Pharmacy Services Administrative Organization ("PSAO") to administer its contract with PBMs. To assist in the management of cash flow and operations, the PSAO estimates the amounts of anticipated recoupments of DIR fees for Hi-School.

63. Hi-School was recently forced to close its pharmacy in the small rural town of Veneta, Oregon where Hi-School had been filling more than 200 prescriptions per day but lost $80,000 per year. The unchecked increase in DIR fees leaves Hi-School on the brink of closing other pharmacy locations that are either breaking even or losing money, and many of those pharmacies are the only option in their communities. To keep its pharmacies in business and providing much needed medication and health care services to patients, Hi-School has been forced to reduce hours and limit the number of pharmacists available to care for patients. Unfortunately, Hi-School expects PBMs to continue increasing the amount of DIR fees if left

unchecked. In recent years, Hi-School has observed PBMs increasing the amount of reimbursements to Hi-School at the point-of-sale such that they face even greater sums of reimbursements clawed back by the PBMs months later. The result is often that Hi-School receives less reimbursement than its cost for the drug, which makes it difficult, if not eventually impossible, to provide essential medication and health care services to its patient population.

3. Kare Drug

64. Kare Drug is an independent community pharmacy with two locations in rural Northern New Mexico. Kare Drug has 19 employees, provides health care services to more than 12,000 individuals and fills approximately 135,000 prescriptions annually (approximately 370 prescriptions per day). Specifically, Kare Drug sees 5,000 patients and fills 55,000 prescriptions at its store in Aztec, New Mexico, and it sees between 7,000 to 8,000 patients and fills 80,000 prescriptions at its Bloomfield, New Mexico location. Nearly all of Kare Drug's patients are either Medicare or Medicaid. In 2020, Kare Drug grossed approximately $7 million in revenue.

65. Kare Drug offers a variety of services to patients, including free medication delivery, medication adherence packaging and monitoring, blood pressure checks, immunizations, and Medicare coverage counseling during open enrollment. Kare Drug also participates in health fairs and small employer events, providing services such as diabetes and atrial fibrillation testing. Moreover, Kare Drug has been on the frontlines of the COVID-19 pandemic, including by offering patients drive-through vaccinations.

66. Similar to fellow pharmacy Plaintiffs, Kare Drug has been forced to reduce employee hours and limit the distance and frequency of its home delivery services after its two pharmacies were charged nearly $400,000 in DIR fees in 2019 and 2020 alone. Reduction in medication delivery is particularly detrimental to Kare Drug's patient population, which skews

elderly and low-income. Not even four months into 2021, Kare Drug has already had another $40,000 in DIR fees clawed back by the PBMs, and Kare Drug expects those numbers to steadily increase in the coming months. Kare Drug works with a vendor to estimate its DIR fees to help manage its revenue flow and pharmacy operations.

4. Tyson Drug

67. Tyson Drug consists of four locally owned and operated retail pharmacies in rural North Mississippi. The original Tyson Drug location in Holly Springs, Mississippi has served patients since the nineteenth century and is a staple in the community. In 2020, Tyson Drug served more than 73,000 patients (240 patients per day) and filled nearly 300,000 prescriptions (974 prescriptions per day). Tyson Drug made approximately $14 million in revenue in 2020.

68. Tyson Drug offers a range of services, including free local delivery and an innovative service called medication synchronization that enables patients to receive their medications in one convenient monthly trip to the pharmacy and has shown improved medication adherence. In addition to monitoring medication adherence for more than 2,500 patients, including providing compliance packaging for approximately 550 patients, Tyson Drug provides a range of care management services including annual wellness exams, patient screenings, diabetes education, and immunizations. Tyson Drug also offers COVID-19 testing and vaccinations.

69. Likewise, Tyson Drug began experiencing substantial annual increases in after-the-fact price concessions in 2015. Tyson Drug first realized DIR fees were being clawed back in 2015, but it took several months to figure out what the fees were for, because each PBM coded the fees differently. In fact, Tyson Drug needed to hire a vendor, thereby incurring additional expenses, just to calculate and track the DIR fees being assessed against it. Tyson Drug's DIR

fees have grown from a few thousand dollars in 2015 to nearly $500,000 in 2020, and Tyson Drug anticipates $600,000 in 2021. As a result of these increasing DIR fees, by 2017, Tyson Drug was forced to make drastic cutbacks in staff and hours for pharmacists and staff. Job descriptions were then combined, meaning extra work for the employees who remained. Tyson Drug also was forced to reduce the availability of much needed patient services, including its robust medication adherence program, which currently involves contacting 2,500 patients each month to review their medications and monitor health concerns. Tyson Drug's pharmacists would be able to monitor significantly more patients per month if not for the DIR-related staffing issues. The growth in DIR fees has prevented Tyson from expanding to additional locations and offering additional care management services. In 2014, prior to the abuse of DIR fees, Tyson Drug made a significant net profit. In 2020, Tyson Drug operated at a loss, and the impetus for the swing from profit to loss is DIR fees. Indeed, annual DIR increases are becoming an existential threat to Tyson Drug and a majority of other community pharmacies across the nation as these pharmacies are forced to choose between operating at a loss and shuttering their doors to patients in underserved communities who have nowhere else to turn for their medication and health care needs.

B. Association Plaintiffs and Their Missions

1. National Community Pharmacists Association ("NCPA")

70. NCPA is a non-profit organization representing the interests of the owners, managers, employees, and patients of thousands of independent community pharmacies across the United States. Collectively, these independent community pharmacies represent a $76 billion health care marketplace and employ more than 250,000 individuals nationwide. Many of NCPA's members are small businesses, with a 2019 average annual revenue of roughly $3.4

million.[33] NCPA's mission is to promote the professional and proprietary interests of independent community pharmacists as well as the health and well-being of the patients they serve.

2. American Pharmacists Association ("APhA")

71. APhA is the largest association of pharmacists in the United States representing nearly 50,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others in all practice settings interested in improving medication use and advancing patient care. APhA is governed by an active and committed Board of Trustees, as well as a House of Delegates that develops policy for APhA and the pharmacy profession as a whole. APhA's mission is to lead the pharmacy profession and prepare members for their role as medication experts in team-based, patient-centered care. Optimizing medication and advancing patient care are critical to this mission. APhA advances this mission by, among other things, providing opportunities for professional development, recognition, differentiation, and leadership; disseminating timely relevant information and state-of-the-art tools and resources, including about quality measures and patient safety; and creating unique opportunities for members to connect and share with peers across practice settings.

3. Coalition of State Rheumatology Organizations ("CSRO")

72. CSRO, as an advocate for rheumatologists and their patients, approximately 50% of whom are Medicare beneficiaries, is keenly aware of the ever-increasing out-of-pocket burdens on Medicare beneficiaries. CSRO is a coalition of state and regional professional rheumatology societies around the country organized to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management

[33] NCPA, *2020 NCPA Digest*, at 7.

of rheumatologic and musculoskeletal diseases. CSRO represents the interests of rheumatologists and their patients nationwide by advocating for access to the highest quality medical care for rheumatic disease patients; providing a network for rheumatologists to exchange information; and educating insurers, government officials, corporations and other entities about the impact and importance of rheumatic diseases and rheumatologic care when considering policy changes affecting such care. The medications rheumatologists prescribe to their patients are often expensive biologic agents. For example, CSRO estimates that rheumatologic patients account for roughly two percent of Medicare beneficiaries, but their medication needs comprise 15-20% of all Medicare drug spending. CSRO has significant experience with the harms suffered by patients because of PBM manipulation of pharmacy price concessions. Specifically, the unfortunate result for many patients is the rationing or abandonment of necessary, sometimes life-saving prescribed drugs and biologics. *See* Alexandra Erath & Stacie B. Dusetzina, *Assessment of Expected Out-of-Pocket Spending for Rheumatoid Arthritis Biologics Among Patients Enrolled in Medicare Part D, 2010-2019*, JAMA, Apr. 27, 2020, at 6 ("For Medicare patients, having [Rheumatoid Arthritis] is associated with a 3-fold increase in risk of cost-related treatment nonadherence, with research showing that patients with [Rheumatoid Arthritis] with the highest levels of cost exposure are almost 30 times more likely to abandon their initial prescription.").[34]

C. How DIR Fees Are Used by PBMs to Harm Plaintiffs and Patients

73. The professional and proprietary interests of pharmacists and health and well-being of patients are being severely harmed by the agency's definition of "negotiated price" and

[34] This document is available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764813 (last visited Apr. 27, 2021).

the resulting imposition of exorbitant post-point-of-sale payment recoupments (referred to by HHS as pharmacy price concessions) by Part D sponsors and PBMs.

74. Recoupments imposed on pharmacies participating in Medicare Part D networks by sponsors and their PBMs have exploded in recent years. In 2016, for example, pharmacies received $211 million in performance payments from Part D plans, but paid more than $2.3 *billion* to Part D plans.[35] In fact, DIR fees now average more than one percent of all prescription drug sales, more than six percent of Medicare Part D pharmacy sales, and more than five percent of gross pharmacy profits.[36]

75. The treatment of these recouped amounts as reportable DIR fees rather than as reductions in the "negotiated prices" of drugs is problematic for a number of reasons.

76. First, retrospective pharmacy concessions in the form of DIR fees eliminate a pharmacy's ability to account timely and accurately for reimbursement on prescription drug claims and to manage their operations accordingly. Specifically, pharmacies are reimbursed for prescription drugs on the basis of "negotiated prices" absent any accounting for later-in-time, often sizeable payment recoupments. Such reimbursement may initially appear adequate and appropriate. Months later, however, a sponsor or its PBM suddenly withholds or claws back a large amount of money, immediately rendering the reimbursement on claims inadequate and often lower than cost. A recent study by health care analytics company Inmar Intelligence found that "[v]ariations in assessment methodology and timing of assessments among PBMs and plans create significant business uncertainty and operational challenges for pharmacies." *Id.* at 6.

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[35] Adam Fein, *Pharmacy DIR Fees Hit a Record $9 Billion in 2019 – That's 18% of Total Medicare Part D Rebates* (Feb. 13, 2020), available at https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html (last visited Jan. 15, 2021).

[36] Inmar, at 2, 3, 14.

These assessments come in different varieties, including preferred pharmacy network fees, "true ups" to various effective rates, and payment adjustments due to performance compared to other pharmacies in sponsors' Part D networks based on quality measures.[37] The amount of DIR fees has proliferated in recent years, resulting in a significant loss of revenue for pharmacies.[38] Moreover, PBMs are able to continually increase DIR fees because of a power imbalance between them and the pharmacies in negotiating contracts. *Id.* at 2; *see also* Drug Channels, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation* (Apr. 6, 2021) (explaining top three PBMs processed 77% of all equivalent prescription claims in 2020 and top six PBMs handled more than 95% of total equivalent prescription claims).[39] The pharmacies "have little or no market power to amend these contracts."[40] Accordingly, PBMs have implemented various performance criteria for calculating DIR fees, including various clinical criteria and cost containment metrics. *Id*. at 6. The problem for pharmacies is that often the "metrics employed are either out of the direct control of the pharmacy or are simply unattainable." *Id.* Ultimately, Inmar Intelligence concluded that, "[i]f DIR fees were calculated during the claim adjudication process at the point-of-sale, the pharmacy would know exactly what price they are selling the product for and how much it cost them. When DIR fees are applied after point-of-sale, pharmacies lose control over their own revenues and profitability, creating undue financial risk." *Id.* at 5.

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[37] Frier Levitt, LLC, *PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues*, at 12 (Jan. 2017), available at https://communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf (last visited Apr. 22, 2021).

[38] Inmar, at 5.

[39] This document is available at https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html (last visited Apr. 26, 2021).

[40] Inmar, at 7.

77. Second, by including such price concessions in DIR rather than in the "negotiated price" at the point-of-sale, beneficiary cost-sharing, which is based on that price at the time of sale, is higher than it should be. Medicare beneficiaries suffer because their Part D cost-sharing obligations are based on prescription costs at the point-of-sale. When PBMs later recoup payment amounts from pharmacies, there is no corresponding offset to the beneficiaries' cost-sharing, and the beneficiary ultimately bears more of the true cost of their prescription drugs and biologics. These artificially inflated copayment amounts push more beneficiaries into the coverage gap of Part D coverage, under which some beneficiaries face higher cost-sharing amounts, and into the catastrophic coverage phase in which Medicare assumes responsibility for 80% of prescription costs. *See supra* ¶ 20; 83 Fed. Reg. at 62,176 (HHS explaining that the "potential for cost shifting to beneficiaries grows increasingly pronounced as pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price," which "can impede beneficiary access to necessary medications [leading to] poorer health outcomes and higher medical care costs for beneficiaries and Medicare.").

78. Third, the "reasonably determined" exception has allowed for market distortions with Part D plans' preferred pharmacies. Certain brand and generic drugs appear cheaper at the point-of-sale at preferred pharmacies when, at the end of the year and considering all the price concessions in DIR, the cost to beneficiaries and the Medicare Part D program as a whole is actually higher than it would be at non-preferred pharmacies. Letter from Shelley Moore Capito *et al.*, Congress of the United States to Andy Slavitt, U.S. Department of Health & Human Services, at 1 (June 15, 2016) ("DIR fees prevent the pharmacy from knowing the true

reimbursement amount of drugs being dispensed at the point of sale, and in some cases DIR fees have resulted in preferred pharmacy prices appearing lower than they actually are.").[41]

79. NCPA recently learned of additional 2020 data illustrating how PBMs are taking advantage of the definition of "negotiated prices" to secure enormous profits on DIR fees.[42] According to this data, "DIR pharmacy fees overall have skyrocketed by 1,600% in the last five years, totaling $8.5B since 2013." *Id.* In 2017 alone, PBMs used DIR fees to squeeze more than $4 billion out of pharmacies, which drives up the cost of prescription drugs for patients. *Id.* In effect, this "loophole in the [Medicare Part D] program allows health plans and PBMs to pocket an excessive amount of pharmacy DIR fees rather than offset prescription costs for seniors." *Id.*

80. In fact, according to a recent survey, the rampant manipulation of "negotiated price" and DIR fees by PBMs has a majority of independent community pharmacies concerned that they will be forced out of business in the next couple of years.[43] An estimated 63% of these independent community pharmacies say that "back-door pharmacy DIR fees are their biggest problem," while another 22% attribute their financial struggles to the related issue of decreasing reimbursement. *Id.* Between December 2012, the first year of pharmacy DIR fees, and December 2017, the number of independent community pharmacies decreased by 4.9%, while a lower 3.3% of all retail pharmacies closed between June 2018 and June 2019. *Id.*

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[41] This document is available at http://www.ncpa.co/pdf/senate-dir-letter-061516.pdf (last visited Apr. 26, 2021).

[42] NCPA, *Analysis Blows Lid Off $8.5 Billion PBM Scam, Says Community Pharmacy* (Feb. 12 2020), available at https://ncpa.org/newsroom/news-releases/2020/02/12/analysis-blows-lid-85-billion-pbm-scam-says-community-pharmacy (last visited Jan. 15, 2021).

[43] Christine Blank, *Independents Prepare to Close Up Shop* (Oct. 17, 2019), available at https://www.drugtopics.com/view/independents-prepare-close-shop (last visited Jan. 15, 2021).

81. In 2020, the top three PBMs processed 77% of all equivalent prescription claims and the top six processed more than 95% of total equivalent prescription claims.[44] As a result, PBMs are able to "exert monopoly like control on pharmacies."[45] Such consolidation also acts as a deterrent to smaller PBMs and community pharmacies' use of a Pharmacy Services Administrative Organization ("PSAO") to contract on their behalf.[46] A PSAO is no match for the PBMs. In 2013, the Government Accountability Office ("GAO") conducted a study on the role and ownership of PSAOs and stated that "[o]ver half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs' use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely nonnegotiable." *Id.* at 17. Therefore, as long as the definition's "reasonably determined" exception remains in effect, PBMs will continue to charge pharmacies exorbitant DIR fees, which will directly impact the health and well-being of millions of Americans. "Local pharmacies do a lot more for their community than dispense pills."[47] In addition to employing hundreds of thousands of individuals, these pharmacies are often the only health care source for underserved communities, and the Part D sponsors and "PBMs are forcing them to make some very unfortunate decisions, and potentially millions of people will be affected." *Id.*

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[44] Drug Channels, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*.

[45] NCPA, *Local Pharmacies Pushed to Brink by Pharmacy Benefit "Monopolies" (PBMs), National Survey Shows* (Oct. 15, 2019), available at https://ncpa.org/newsroom/news-releases/2019/10/16/local-pharmacies-pushed-to-brink-by-pharmacy-benefit-monopolies (last visited Jan. 15, 2021).

[46] *See generally* GAO-13-176, *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations* (Feb. 28, 2013), available at https://www.gao.gov/products/GAO-13-176 (last visited Apr. 26, 2021).

[47] NCPA, *Local Pharmacies Pushed to Brink by Pharmacy Benefit "Monopolies" (PBMs), National Survey Shows*.

ASSIGNMENT OF ERRORS

82. The applicable provisions of the APA provide that the "reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; [or] (E) unsupported by substantial evidence[.]" 5 U.S.C. § 706(2). The exception from the definition of "negotiated prices" for pharmacy price concessions that cannot "reasonably be determined at the point-of-sale" should be set aside for a number of reasons, including those set forth below.

COUNT ONE – APA CLAIM TO SET ASIDE AGENCY ACTION THAT IS CONTRARY TO LAW

83. Plaintiffs repeat the allegations in paragraphs 1 through 82 of this complaint as if fully set forth herein.

84. The "reasonably determined" pharmacy price concession exception in the second clause of the negotiated price regulation violates the plain language and intent of the Medicare Act. That exception therefore must be set aside.

85. When it created the Medicare Part D program, Congress required that Part D plans "*shall* provide enrollees with access to negotiated prices," and that "[f]or purposes of [Part D], negotiated prices *shall* take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." 42 U.S.C. § 1395w-102(d)(1)(A)-(B) (emphasis added). By repeatedly using the mandatory term "shall," Congress evinced its intent that plan sponsors must reflect pharmacy price concessions in the negotiated price, without exception. *See, e.g., Kingdomware Techs., Inc. v. United States*, 136 S.Ct. 1969, 1977 (2016)

("[T]he word 'shall' usually connotes a requirement."); *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) (recognizing that "shall" is "mandatory" and "normally creates an obligation impervious to judicial discretion"); *Appalachian Voices v. McCarthy*, 989 F. Supp. 2d 30, 54 (D.D.C. 2013) ("Use of the word 'shall' in a statute generally creates a mandatory duty.").

86. By contrast, nothing in the statute authorizes the "reasonably determined" exception that HHS adopted in the second clause of the regulation. 79 Fed. Reg. at 29,878; 42 C.F.R. § 423.100. In fact, the legislative history strongly supports the inclusion of all pharmacy price concessions in the definition of negotiated prices. *See* H.R. Rep. No. 108-391, at 438 (Conf. Rep.) ("Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable."); H.R. Rep. No. 108-178, pt. 1, at 184 ("[A]ll PDP plans will be required to make available to their enrollees the benefit of *all* price discounts" (emphasis added)). Under HHS' current regulations, beneficiaries do not receive the benefit of all pharmacy price discounts, and those most in need instead face "higher overall out-of-pocket costs." 83 Fed. Reg. at 62,176.

87. In addition, the "reasonably determined" exception is contrary to the "any willing pharmacy" provision of the Medicare Act because Part D sponsors and PBMs are recouping from pharmacies exorbitant pharmacy price concessions long after the point-of-sale (with those price concessions often being far more exorbitant than those recouped from preferred pharmacies). This effectively precludes many pharmacies from participating in certain Part D sponsors' pharmacy networks. Section 1395w-104(b)(1)(A) of the Medicare Act and section 423.120(a)(8)(i) of the implementing regulations require a Part D plan sponsor to "contract with

any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation." 83 Fed. Reg. 16,440, 16, 589 (Apr. 16, 2018); 42 C.F.R. § 423.120(a)(8)(i). Section 423.505(b)(18) of the implementing regulations further requires Part D plan sponsors "to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. § 423.505(b)(18). Because the "reasonably determined" exception enables Part D sponsors and PBMs effectively to exclude pharmacies from their networks—by forcing those pharmacies to suffer significant financial detriment when the sponsors and PBMs recoup enormous sums months after sales, the "reasonably determined" exception contravenes the "any willing pharmacy" requirement of the Medicare Act.

88. Finally, HHS' May 31, 2016 final DIR reporting guidance and all successive annual issuances of DIR reporting guidance are contrary to HHS' own regulatory definition of "negotiated price" in 42 C.F.R. § 423.100.[48] HHS' guidance identified various categories of pharmacy price concessions that must be reported as DIR, which, as a corollary, means that those price concessions are not included in the negotiated price (and thus are not directly available to Medicare Part D enrollees as contemplated by Congress). *Id.* at 24. Specifically, HHS directed Part D sponsors to report as DIR "*any reconciliation amount* that accounts for *differences between the effective rate and the adjudicated rate achieved by the pharmacy at the point-of-sale* and *contingent* incentive fees . . . ." *Id.* (emphasis added). This definition of DIR is inconsistent with the definition of "negotiated prices," which includes "all price concessions from network pharmacies *except those contingent price concessions that cannot reasonably be determined at the point-of-sale*," 42 C.F.R. § 423.100(2) (emphasis added), because the difference between the

[48] CMS, *Final Medicare Part D DIR Reporting Requirements for 2015.*

effective rate (i.e., the reimbursement rate that ultimately applies after accounting for later-in-time price concessions) and the adjudicated rate (i.e., the initial reimbursement rate at the point-of-sale) (1) is not contingent on any performance or other requirement on the part of the pharmacy and (2) can reasonably be determined at the point-of-sale. Accordingly, HHS' May 31, 2016 final DIR reporting guidance (and all successive annual issuances of DIR reporting guidance) is contrary to HHS' 2014 regulatory definition of "negotiated prices" and must be set aside under the APA.

89. The "reasonably determined" exception in 42 C.F.R. § 423.100(2) adopted in the 2014 final rule is therefore contrary to law and must be set aside.

COUNT TWO – APA CLAIM TO SET ASIDE AGENCY ACTION THAT IS ARBITRARY AND CAPRICIOUS AND UNSUPPORTED BY SUBSTANTIAL EVIDENCE

90. Plaintiffs repeat the allegations in paragraphs 1 through 89 of this complaint as if fully set forth herein.

91. Agency action is arbitrary and capricious when the agency fails to explain its decision-making adequately, offers insufficient reasons for treating similar situations differently, or fails to consider an important aspect of the problem. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*"). Moreover, "to survive arbitrary and capricious review, the [agency] must show that it engaged in 'reasoned decisionmaking.'" *Am. Fed'n of Gov't Emps., AFL-CIO, Local 1929 v. Fed. Labor Rels. Auth.*, 961 F.3d 452, 456 (D.C. Cir. 2020) (citation omitted). When making a decision, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (same). "This means that an agency

must 'examine all relevant factors and record evidence'" and "must 'adequately analyze . . . the consequences' of [its] actions." *Stewart v. Azar*, 313 F. Supp. 3d 237, 259 (D.D.C. 2018) (first alteration in original) (quoting *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923, 932 (D.C. Cir. 2017)). A "fundamental requirement of administrative law is that an agency set forth its reasons for decision." *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014). "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the Court] must undo its action." *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999).

92. Here, in adopting the final rule creating an exception for pharmacy price concessions that could not be reasonably determined at the point-of-sale, *see* 42 C.F.R. § 423.100(2), HHS concluded that this exception would be narrow. 79 Fed. Reg. at 29,878 ("[W]e are revising our proposed definition of negotiated price to allow a narrow exception [for] . . . contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale."). The agency, however, did not explain its belief that the reasonably determined exception would be "narrow." *See id.* The agency did not propose that exception, and cited nothing for its "belief." *See id.*; *see also Mirror Lake Vill., LLC v. Wolf*, 971 F.3d 373, 376–77 (D.C. Cir. 2020) (agency's decision not only "not 'reasonably explained,'" its "'explanation' is no explanation at all" (internal citation omitted)). Indeed, the comments filed in response to the 2014 proposed rule and subsequent agency issuances reopening the exception, including comments filed by Plaintiffs, showed that price concessions outside the point-of-sale were commonly used. *See supra* ¶¶ 31, 32, 38, 43, 44, 48–51.

93. In 2017, HHS acknowledged that, despite its statement that the "reasonably determined" exception would be narrow in scope, the "exception . . . applies more broadly than

we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements." 82 Fed. Reg. at 56,426. Notwithstanding its own acknowledgement that PBMs were abusing pharmacy price concessions by calculating the price at the point-of-sale and then retroactively assessing them as DIR fees, HHS left the "reasonably determined" exception in place. This exception has forced pharmacies to expend additional resources on vendors to estimate the amount of DIR fees that will eventually be clawed back to help them budget and otherwise manage their operations. Accordingly, HHS' recognition that DIR fees can be reasonably estimated at the point-of-sale and its corresponding failure to "articulate a satisfactory explanation for its action," *State Farm*, 463 U.S. at 43, or "'adequately analyze . . . the consequences' of [its] actions" is arbitrary and capricious, *Stewart*, 313 F. Supp. 3d at 259 (quoting *Am. Wild Horse*, 873 F.3d at 932).

94. Moreover, as adopted, the regulatory definition of negotiated prices is also internally inconsistent and unworkable to the extent that it excludes certain pharmacy price concessions "that cannot reasonably be determined at the point-of-sale" from the negotiated prices that must be made available to beneficiaries. *See* 42 C.F.R. § 423.100(2); *ANR Storage Co. v. Fed. Energy Reg. Comm'n*, 904 F.3d 1020, 1024 (D.C. Cir. 2018) (agency "must give a 'reasoned analysis' to justify the disparate treatment of [circumstances] that seem similarly situated," and "its reasoning cannot be internally inconsistent" (internal citations omitted)). That "reasonably determined" exception in the second clause of the regulation is inconsistent with other parts of the regulation. For example, the first clause of the regulation defines negotiated prices as prices that a pharmacy "*will* receive, *in total*, for a particular drug." 42 C.F.R. § 423.100(1) (emphasis added). The requirement that negotiated prices must reflect the *total* amount that a pharmacy *will* be paid mandates inclusion of all pharmacy price concessions in the

negotiated price. Similarly, the fifth clause of the rule requires that negotiated prices paid to pharmacies "[m]ust not be rebated back to the Part D sponsor (or other intermediary contracting organization) *in full or in part*." *Id.* § 423.100(5) (emphasis added). HHS instituted this rule to stop the practice of sponsors forcing pharmacies to return a portion of the negotiated prices after the point-of-sale. *See* 79 Fed. Reg. at 29,877. But that is precisely what is permitted in practice. Relying on HHS' current definition of "negotiated prices," plan sponsors report a negotiated price that does not subtract later-in-time price concessions that are reasonably known at the point-of-sale and then requires pharmacies to pay back to the Part D sponsor or PBM part of that negotiated price. That practice is flatly inconsistent with the fifth clause's clear prohibition on rebating any portion of the negotiated price back to the Part D sponsors or PBMs, as HHS has apparently acknowledged. *See, e.g.*, 83 Fed. Reg. at 62,177 (HHS 2018 proposed rule explaining that "reasonably determined" exception could not "be implemented in a manner that achieves . . . consistent application of all pharmacy payment concessions by all Part D sponsors").

95. Further, the agency's failure to acknowledge, let alone dutifully analyze, the significant financial impact of its final rule on pharmacies—such as small business Plaintiffs Kare Drug ($7 million in gross revenue) and Tyson Drug ($14 million in gross revenue) in this action and others whose interests Plaintiffs NCPA and APhA represent—as required under the Regulatory Flexibility Act only underscores that the final rule is arbitrary and capricious. *See* 79 Fed. Reg. at 29,942; 5 U.S.C. §§ 604, 605; *Advocs. for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1146–47 (D.C. Cir. 2005) (explaining that agency failed to consider important aspect of problem with respect to economic effects); *Resolute Forest Prods., Inc. v. U.S. Dep't of Agric.*, 187 F. Supp. 3d 100, 106–07, 113–14, 122–24 (D.D.C. 2016) (holding that agency's decision was arbitrary and capricious where, *inter alia*, it conflicted with

duties under RFA and "provided neither a coherent analysis" of impact on small entities "nor a reliable source of data for its estimates"). Despite referring to pharmacies more than two hundred times in the 2014 final rule, *see* 79 Fed. Reg. 29,844 *et seq.*, HHS inexplicably concluded with respect to its fiscal impact analysis that Part D sponsors and Medicare Advantage plans were the only "entities that will be affected by the provisions of this rule." *Id.* at 29,944. The agency simply ignored the many small and vulnerable pharmacies that the rule also impacts, such as NCPA's members. In tension with this omission, HHS otherwise acknowledged some effects of its definition on pharmacies, stating, "[w]e expect that the effect of regulation to require consistent and transparent pricing will . . . promote increased price competition among network pharmacies," and asserting "[w]e believe pharmacies will support including the full price concession in the point-of-sale price." *Id.* at 29,948.

96. Yet pharmacies and their patients have been severely harmed by the agency's definition of "negotiated prices" and the resulting imposition of exorbitant post-point-of-sale payment recoupments (which HHS considers pharmacy price concessions) by Part D sponsors and PBMs. Because the top three PBMs control more than three-quarters of all equivalent prescription claims and the top six control more than 95% of total equivalent prescription claims,[49] these PBMs are able to "exert monopoly like control" on pharmacies.[50] As a result, PBMs are squeezing billions out of pharmacies, which forces the pharmacies out of business and directly impacts the health and well-being of their millions of patients nationwide. *Id.* By neglecting the thousands of small pharmacy businesses affected by this rule, HHS' decision was

[49] Drug Channels, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*.

[50] NCPA, *Local Pharmacies Pushed to Brink by Pharmacy Benefit 'Monopolies' (PBMs), National Survey Shows*.

arbitrary and capricious. *See Resolute*, 187 F. Supp. 3d at 106–07, 113–14, 122–24. The "reasonably determined" exception must also be set aside because the agency did not examine the relevant data before making its decision, and therefore did not consider an important aspect of the problem. *State Farm*, 463 U.S. at 43.

97. Because the agency has not adequately explained its decision-making, failed to provide any explanation to reconcile the conflicting requirements in the first and fifth clauses of the definition of "negotiated prices," has adopted inconsistent interpretations of the term "negotiated prices" across the statute, and did not examine the relevant data before making its decision, and therefore did not consider an important aspect of the problem, the "reasonably determined" exception in the second clause of the regulation is arbitrary and capricious and must be set aside.

98. Indeed, not only was there inadequate "support in the record" for the agency's decision, but "[s]ubsequent events have borne out" the fatal flaws in the agency's approach. *Wold Commc'ns, Inc. v. FCC*, 735 F.2d 1465, 1478 & n.29 (D.C. Cir. 1984) (considering subsequent events in assessing the validity of agency prediction in APA action). To be sure, APA review is ordinarily based on the administrative record, but "rule-making is necessarily forward-looking, and by the time judicial review is secured events may have progressed sufficiently to indicate the truth or falsity of agency predictions." *Amoco Oil Co. v. EPA*, 501 F.2d 722, 729 n.10 (D.C. Cir. 1974). This Court need not "blind itself" to such obvious developments. *Id.*; *see also Nio v. U.S. Dep't of Homeland Sec.*, 385 F. Supp. 3d 44, 61–62 (D.D.C. 2019) (similar).

99. In the 2017 request for information reopening the definition of negotiated price, HHS admitted that the 2014 final rule was instituted based on obsolete information that did not

reflect the true nature of Medicare Part D pharmacy payments. 82 Fed. Reg. at 56,426. The agency said that the 2014 rule relied on data from 2012 that did not accurately reflect "the growth of performance-based pharmacy payment arrangements." *Id.* When the agency considered the more recent and relevant data, it realized that the exception it adopted in 2014 "prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs." *Id.* And by 2018, following receipt of comments from interested stakeholders, including NCPA and APhA, HHS recognized that pharmacy price concessions had increased by an astounding 45,000 percent between 2010 and 2017. 83 Fed. Reg. at 62,174. For example, NCPA submitted a comment letter in January 2018 warning the agency that "accounting for retrospective pharmacy price concessions as DIR rather than concessions in the 'negotiated price' at the point-of-sale permits sponsors to artificially moderate premiums at the expense of higher cost-sharing for beneficiaries." Letter from Susan Pilch, NCPA to Seema Verma, Centers for Medicare & Medicaid Services, at 2 (Jan. 16, 2018). Unsurprisingly, by the end of 2018, HHS admitted that the "reasonably determined" exception to the definition of "negotiated prices," cannot "be implemented in a manner that achieves . . . meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and prevention of cost-shifting to beneficiaries and taxpayers." 83 Fed. Reg. at 62,177. Far from "narrow," the exception is quite the opposite.

100. Because the 2014 final rule relied on outdated information that did not reflect the growth of performance-based pharmacy payment arrangements, HHS' addition of the "reasonably determined" pharmacy price concession exception is arbitrary and capricious in that it failed to consider the relevant data and therefore did not consider an important aspect of the problem.

101. The definition of negotiated prices adopted in the 2014 final rule is arbitrary and capricious because HHS failed to explain its decision-making, both because the rule as adopted is internally inconsistent and because the rule failed to consider all relevant data.

102. For similar reasons, the agency's 2014 final rule is unsupported by substantial evidence. 5 U.S.C. § 706. Not even having proposed the reasonably determined exception, the agency lacked substantial evidence that this exception would be narrow. The "reasonably determined" pharmacy price-concession exception added to the second clause of the 2014 final rule was unsupported by substantial evidence and must be set aside. *See AT&T Corp. v. FCC*, 86 F.3d 242, 247 (D.C. Cir. 1996) (substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion" taking into account "whatever in the record fairly detracts from its weight.") (quoting *NLRB v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939) and *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951)); *cf. Defs. of Wildlife & Ctr. for Biological Diversity v. Jewell*, 815 F.3d 1, 9 (D.C. Cir. 2016) (applying substantial evidence test in challenge to agency rule).

103. Any of the shortcomings described above require the Court to set aside the "reasonably determined" exception that was adopted in the 2014 final rule.

COUNT THREE – FAILURE TO OBSERVE PROCEDURE REQUIRED BY LAW

104. Plaintiffs repeat the allegations in paragraphs 1 through 103 of this complaint as if fully set forth herein.

105. The "reasonably determined" pharmacy price-concession exception in 42 C.F.R. § 423.100(2) was not adopted in accordance with the notice-and-comment rulemaking requirements of the APA and Medicare Act, and therefore must be set aside.

106. Both the APA and the Medicare Act require HHS to provide the public with adequate notice of a proposed rule and the opportunity to submit comments in response. *See* 5 U.S.C. §§ 552(b)-(c), 706(2) (APA), 42 U.S.C. § 1395hh(a), (b)(1) (Medicare Act) ("[B]efore issuing in final form any regulation . . . the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.").

107. "Notice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Int'l Union, United Mine Workers v. MHSA*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

108. An agency may promulgate a final rule that is different from a proposed rule, but only if the final rule is a "logical outgrowth" of the proposed rule, *i.e.*, 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.'" *Id.* (quoting *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004). Thus, a proposed rule cannot require an interested party to "divine [an agency's] unspoken thoughts," *see Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000), and must "adequately frame the subjects for discussion," *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019). Likewise, an agency "cannot bootstrap notice from a comment," *Shell Oil Co. v. EPA*, 950 F.2d 741, 760 (D.C. Cir. 1991) (quoting *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983)), and "ambiguous comments and weak signals from the agency" are not

sufficient to give interested parties the "opportunity to anticipate and criticize the rules or to offer alternatives." *Int'l Union*, 407 F.3d at 1261 (citation omitted).

109. Interested parties, including Plaintiffs, could not have anticipated, and thus did not have the opportunity to comment on, the "reasonably determined" exception to the definition of "negotiated prices" that HHS ultimately adopted in the second clause of the regulation during the 2014 rulemaking.

110. The proposed rule would have "revise[d] the definition of negotiated prices at § 423.100 to require that all price concessions from pharmacies are reflected in these prices." 79 Fed. Reg. at 1,974. There was no discussion of any exceptions to that all-inclusive definition.

111. In the final rulemaking, the agency adopted a definition of "negotiated prices" that included an exception for "contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale." 79 Fed. Reg. at 29,878, 42 C.F.R. § 423.100(2). That exception could not have been reasonably anticipated by interested parties.

112. Because the final rule "deviates too sharply from the proposal," Plaintiffs and other interested stakeholders were therefore "deprived of notice and an opportunity to respond to the proposal." *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985) (quoting *Small Refiner*, 705 F.3d at 547).

113. The "reasonably determined" exception adopted in the second clause of the 2014 final rule must be vacated. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109–11 (D.C. Cir. 2014); *see also Allina Health Servs. v. Price*, 863 F.3d 937, 945 (D.C. Cir. 2017). And under the Medicare Act, the "reasonably determined" exception, which is not a logical outgrowth of the proposed rule, "shall be treated as a proposed regulation and shall not take effect until

there is the further opportunity for public comment and a publication of the provision again as a final regulation." 42 U.S.C. § 1395hh(a)(4); *see Allina*, 863 F.3d at 945.

114. Similarly, certain related supplemental guidance issued by HHS after the final rule violated the notice-and-comment requirements imposed by the Medicare Act and the APA. *See* 42 U.S.C. § 1395hh(a)(2); 5 U.S.C. § 553. Following its publication of the final rule defining negotiated prices, the agency issued guidance, including guidance on Direct and Indirect Remuneration (DIR) beginning in 2016 and each year thereafter. There is no question that the guidance "govern[s] the scope of benefits, the payment for services, or the eligibility . . . to furnish or receive services or benefits." *See* 42 U.S.C. § 1395hh(a)(2). Nor is there any question that this guidance effectuated a "substantive legal standard" and a "substantive rule," thus triggering the rulemaking requirements of the Medicare Act and APA, respectively. *See Allina*, 863 F.3d at 943 (characterizing substantive standard under Medicare Act), *aff'd Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810–14 (2019) (discussing relationship between substantive rule under APA and Medicare Act); *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005) (characterizing substantive standard under APA); *see also* 5 U.S.C. § 553(b), (d); *id.* § 551(4) (defining "rule"). Yet the guidance failed to comply with these applicable notice-and-comment requirements. For example, the agency afforded the public a comment period of only approximately two weeks, less than the 60 days required under the Medicare Act. *See* 42 U.S.C. § 1395hh(b)(1). Likewise, in violation of both the Medicare Act and the APA, the agency failed to both publish its notice and respond to public comments in the Federal Register. *See id.* § 1395hh(b); 5 U.S.C. § 553(b), (c). HHS cannot escape the applicable rulemaking requirements by labeling its guidance as interpretive. *See U.S. Telecom*, 400 F.3d at 35 ("[F]idelity to the rulemaking requirements of the APA bars courts from permitting agencies to avoid those

requirements by calling a substantive regulatory change an interpretative rule."); *Allina*, 139 S. Ct. at 1810–14 (explaining that Medicare rulemaking statute does not borrow APA's exception for interpretive rules).

REQUEST FOR RELIEF

115. For the foregoing reasons, Plaintiffs request an order:

a. declaring invalid and setting aside the "reasonably determined" pharmacy price concession exception in the final rule, 79 Fed. Reg. at 29,878-79, 29,962, and 42 C.F.R. § 423.100(2)—providing that "negotiated prices" excludes "those contingent price concessions that cannot reasonably be determined at the point-of-sale";

b. declaring invalid and setting aside the agency's DIR reporting guidance;

c. directing HHS to pay Plaintiffs' legal fees and other costs of suit; and

d. providing such other relief as the Court may deem appropriate.

Respectfully Submitted,

/s/ Stephanie A. Webster

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