UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION,
100 Daingerfield Road
Alexandria, VA 22314

Plaintiff,

v.

ALEX M. AZAR, II, Secretary
United States Department of
Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

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 plans 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 a patient has paid cost-sharing for the prescription drugs based on an artificially inflated price. 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 independent community pharmacies and drives up the cost of prescription drugs for Medicare patients nationwide. Plaintiff asks 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." 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. 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 contravene the language and intent of the regulatory definition of "negotiated prices."

3. Plaintiff thus seeks 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). Plaintiff also seeks an order setting aside the agency's policy guidance addressing that exception.

PARTIES

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

5. Defendant Alex M. Azar II 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 to his official predecessors or successors as the context requires.

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

[1] Plaintiff has standing, including associational standing, to bring this suit because (1) its member pharmacies would otherwise have standing to sue in their own right; (2) the interests that Plaintiff seeks to protect are germane to its purpose as a pharmacy association that advocates in favor of the rights and interests of pharmacies; and (3) neither the claims asserted nor the relief requested requires the participation of Plaintiff's individual members. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

JURISDICTION AND VENUE

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

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

9. 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

10. 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, 1395*l*, and Medicare Part C provides an optional managed care alternative to Parts A and B, *id.* § 1395w-21–28, *et seq.*

11. 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").

12. 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).

13. The Medicare Part D statute establishes "cost sharing" obligations for plan enrollees. 42 U.S.C.§ 1395w-102(b)(4)(A)(i). 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 now realizes 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 larger share of the actual cost of a drug." 83 Fed. Reg. 62,152, 62,176 (Nov. 30, 2018).

14. 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. 4,194, 4,244 (Jan. 28, 2005). 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.

15. 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." 42 U.S.C. § 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(I), at 184

(2003) ("[A]ll PDP plans will be required to make available to their enrollees the benefit of *all* price discounts." (emphasis added)).

16. 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. 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) ("2017 Fact Sheet").[2] Accordingly, in order to determine the appropriate payment amounts to Part D sponsors, the agency requires—and has the legal authority to require—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.

B. Regulatory Definition of "Negotiated Prices"

[2] 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).

17. In January 2005, HHS promulgated its first regulatory definition of "negotiated prices." 70 Fed. Reg. 4,194, 4,534 (Jan. 28, 2005). 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).

18. In January 2009, HHS further amended its definition of negotiated prices. 74 Fed. Reg. 1,494, 1,544 (Jan. 12, 2009). 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).

19. 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.

20. In redefining negotiated prices in this manner, HHS said it that 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 and Aftermath

21. 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]." 79 Fed. Reg. at 1972. 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).

22. 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 CMS, at 10 (Mar. 7, 2014). 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*.

23. 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.* Although price concessions after the point of sale were increasingly common and significant in size,[3] the agency adopted what it said would be a narrow exception. *See* 79 Fed. 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

[3] *See, e.g.*, 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.").

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[.]"[4]

24. 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.

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

26. 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

[4] Letter from Steve Nelson, UnitedHealth Group to Marilyn Tavenner & Liz Richter, CMS, at 23 (Mar. 7, 2014), available at https://www.regulations.gov/document?D=CMS-2014-0007-1689 (last visited January 15, 2021).

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 pharmacies even though the rule otherwise acknowledged the import of the rules to pharmacies, many of which qualify as small businesses under the RFA. *See* 79 Fed. Reg. at 29,942, 29,947–48; 5 U.S.C. § 601.

27. 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 Remuneration (DIR) and Pharmacy Price Concessions* (Sept. 29, 2014).[5] 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.

28. 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). 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

[5] 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).

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.

29. HHS sought further stakeholder feedback on the definition in 2017. Specifically, in 2017, HHS issued 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. 56,336, 56,426 (Nov. 28, 2017).

30. 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.*, *but see supra* n.4 (comment letter informing CMS—in 2014—that the "entire health care industry" was moving toward "risk-based payment arrangements [that often] require retrospective performance review"). 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.

31. In 2018, after considerable evidence that the exception was being interpreted and utilized far more broadly than anticipated, HHS reconsidered its definition of "negotiated prices" once again. The agency proposed finally eliminating the "reasonably determined" pharmacy price-concession exception adopted in 2014. 83 Fed. Reg. 62,152, 62,177 (Nov. 30, 2018). 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 62,176 ("For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs."). Despite these conclusions, 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 the exception remains in effect. 84 Fed. Reg. 23,832, 23,867 (May 23, 2019).

D. HHS' Inconsistent Guidance

32. On April 27, 2016, without proper notice-and-comment rulemaking, HHS issued draft guidance regarding Medicare Part D DIR reporting requirements. CMS, *Final Medicare Part D DIR Reporting Requirements for 2015* (May 31, 2016).[6] HHS accepted comments until May 16, 2016 and then issued final guidance 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 would not be directly available to 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.* 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), because the difference between the effective rate and adjudicated rate is not contingent and 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' current regulatory definition of "negotiated price."

STATEMENT OF FACTS

33. NCPA is a non-profit organization representing the interests of the owners, managers, employees, and patients of thousands of independent community pharmacies across

[6] 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).

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

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

35. 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.[8] These fees take many forms, including preferred 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. In fact, DIR fees now average more than one percent of all prescription drug sales and more than five percent of gross pharmacy profits.[9]

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[7] NCPA, 2020 NCPA Digest at 7, available at https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf (last visited Jan. 15, 2021).

[8] 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).

[9] Inmar Intelligence, *Direct and Indirect Remuneration (DIR) Performance and the Impact on Pharmacies Serving Medicare Part D Beneficiaries*, (Revised July 2019), at 3, 14, available at https://www.nacds.org/pdfs/government/2019/DIR_Performance_to_Date_2019.pdf (last visited Jan. 15, 2021).

36. The treatment of these recouped amounts as DIR rather than as reductions in the "negotiated price" of a drug is problematic for a number of reasons.

37. First, retrospective pharmacy concessions eliminate a pharmacy's ability to timely and accurately account for profit on a prescription drug claim. Specifically, pharmacies are reimbursed for a prescription drug on the basis of "negotiated price" absent any accounting for these 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. And, importantly, pharmacies are unable to forecast or model for this withholding because pharmacies often do not know the total amounts that will be recouped in advance.

38. 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.

39. 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.

40. A 2020 report by a top pharmacy industry analyst illustrates how PBMs are taking advantage of the definition of "negotiated price" to secure enormous profits on DIR fees.[10]

[10] 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).

According to the report, "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.* The report concluded that 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.*

41. In fact, according to a recent survey, the rampant manipulation of "negotiated price" and DIR fees by PBMs has a majority of independent pharmacists concerned that they will be forced out of business in the next couple of years.[11] An estimated 63% of these independent pharmacists 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.*

42. PBMs are able to "exert monopoly like control on pharmacies" because "[e]ighty-five percent of all prescriptions filled in the US are controlled by three PBMs."[12] Therefore, as long as the definition's "reasonably determined" exception remains in effect, PBMs will continue to charge independent community pharmacies exorbitant DIR fees, which will directly impact the health and well-being of millions of Americans. "Local pharmacies do a lot more for

[11] 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).

[12] 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).

their community than dispense pills." *Id.* 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.*

ASSIGNMENT OF ERRORS

43. 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

44. Plaintiffs repeat the allegations in paragraphs 1 through 43 of this complaint as if fully set forth herein.

45. 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.

46. 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)(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.").

47. 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* House Conf. Rep. No. 108-391, p. 438 (2003) ("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."); House Report No. 108-178(I), p. 184 (June 25, 2003) ("[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.

48. 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 independent 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 independent 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.

49. 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.[13] 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

[13] Centers for Medicare & Medicaid Services, *Final Medicare Part D DIR Reporting Requirements for 2015* (May 31, 2016), https://www.hhs.gov/guidance/document/final-medicare-part-d-dir-reporting-requirements-2015.

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.* 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 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.

50. 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

51. Plaintiffs repeat the allegations in paragraphs 1 through 50 of this complaint as if fully set forth herein.

52. 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 Mutual 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; *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." *Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999).

53. 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 to include 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* 79 Fed. Reg. at 29,878. 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." (citation omitted)). Indeed, the comments filed in response to the 2014

proposed rule showed that price concessions outside the point of sale were commonly used. *See supra* ¶¶ 22–23.

54. 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 (citation 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(2) (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.* (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 PBM, 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").

55. Further, the agency's failure to acknowledge, let alone dutifully analyze, the significant financial impact of its final rule on pharmacies—such as those independent, small businesses whose interests Plaintiff represents—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 Prod., Inc. v. U.S. Dep't of Agric.*, 187 F. Supp. 3d 100, 106–107, 113–14, 122–124 (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"); *see also* 5 U.S.C. § 604(a)(4). 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 the 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." 78 Fed. Reg. at 29,948.

56. Yet independent community 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 "[e]ighty-five percent of all prescriptions filled in the U.S. are controlled by three PBMs," these PBMs are able to "exert monopoly like control" on independent community pharmacies.[14] As a result, PBMs are squeezing billions out of independent community pharmacies, which forces the pharmacies out of business and directly impacts the health and well-being of their millions of patients nationwide. *See id.* By neglecting the thousands of small pharmacy businesses affected by this rule, HHS' decision was arbitrary and capricious. *See Resolute*, 187 F. Supp. 3d at 106–107, 113–14, 122–124. 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.

57. 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

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

determined" exception in the second clause of the regulation is arbitrary and capricious and must be set aside.

58. Indeed, not only was there inadequate "support in the record" for the agency's decision, but "subsequent 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).

59. 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." 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, 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 (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." *Id.* at 62,177. Far from "narrow," the exception is quite the opposite.

60. 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.

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

62. 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).

63. 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

64. Plaintiffs repeat the allegations in paragraphs 1 through 63 of this complaint as if fully set forth herein.

65. 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.

66. 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.").

67. "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).

68. 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. Fed. Commc'ns Comm'n*, 921 F.3d 1102, 1115 (D.C. Cir. 2019). Likewise, an agency "cannot bootstrap notice from a comment," *Shell Oil Co. v. E.P.A*, 950 F.2d 741, 760 (D.C. Cir. 1991) (quoting *Small Refiner Lead Phase-Down Task Force v. E.P.A.*, 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 rule or to offer alternatives." *Int'l Union*, 407 F.3d at 1261 (quoting *Small Refiner*, 705 F.2d at 549).

69. Interested parties, including Plaintiff, 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.

70. 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 1974. There was no discussion of any exceptions to that all-inclusive definition.

71. 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.

72. Because the final rule "deviates too sharply from the proposal," Plaintiff 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).

73. 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.A. § 1395hh(a)(4); *see Allina*, 863 F.3d at 945.

74. 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. F.C.C.*, 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* 42 U.S.C. 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

75. For the foregoing reasons, Plaintiff requests 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 Plaintiff's legal fees and other costs of suit; and

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

Respectfully Submitted,

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