IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Plaintiff,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity only
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendants.

Case No: 20-cv-3032

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF

Plaintiff, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally Qualified Health Center ("FQHC") members, brings this action against Defendants Alex M. Azar II and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

NATURE OF ACTION

1. This is a civil action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), to compel the promulgation of administrative dispute resolution ("ADR") regulations—to implement the only process available to Plaintiff and its members to adjudicate and remedy violations of Section 340B of the Public Health Service ("PHS") Act—as required by § 7102 of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 821-827 (March 23, 2010).

2. Defendants are, and have since September 2010 been, in violation of the clear and nondiscretionary statutory command in PPACA § 7102(a) to promulgate regulations by a date certain. As a direct result, FQHCs across the country that participate in the 340B Drug Pricing Program ("340B Program" or "340B") as "covered entities" are suffering the very harm the statutorily mandated ADR process is designed to remedy—drug manufacturer overcharging.

3. The 340B Program requires drug manufacturers to provide discounts on covered outpatient drugs purchased by covered entities for those manufacturers to have their products covered by Medicare and Medicaid. Since 1996, consistent with HHS guidance, drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' "contract pharmacies"—pharmacies that dispense drugs to the FQHC's patients under a contractual relationship with the FQHC. These contract pharmacy arrangements are consistent with longstanding HHS guidance, as well as with the authorizing statute for the FQHC program, Section

330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq*.

4. A handful of the nation's largest pharmaceutical companies recently announced that, with few exceptions, they would no longer allow covered entities (including FQHCs) to purchase their covered outpatient drugs at 340B Program discount prices when those drugs would be shipped to a covered entity's contract pharmacy.

5. The manufacturers' abrupt about-face, after decades of shipping FQHCs' purchases of 340B-priced drugs to their contract pharmacies—during a global pandemic and a recession—is not only callous, but also a clear violation of 340B statutory requirements and the binding pharmaceutical pricing agreements ("PPAs") manufacturers have with HHS. Both the 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

6. Indeed, the documented refusal by these manufacturers to make their covered outpatient drugs available to covered entities at or below 340B ceiling prices when shipped to a contract pharmacy is an emulation of the examples of "knowing and intentional" overcharging given by HHS, by way of illustration, in its civil monetary penalty ("CMP") regulations, 42 CFR § 10.11(b).

7. Although HHS publicly and rightly criticized at least one drug manufacturer's unilateral pricing actions, it has to Plaintiff's knowledge stopped short of

any enforcement or corrective action.

8. HHS's lack of action occurs in a world in which, by failing to promulgate regulations as required by statute, it has tied the covered entities' hands and deprived them of their exclusive means to protect themselves—the mandated ADR process. Per *Astra USA v. Santa Clara County*, 563 U.S. 110, 121–22 (2011), the 340B statute provides an exclusive remedy, and Congress, through the PPACA, opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaints, and to render the agency's resolution of those complaints binding, subject to review under the APA.

9. Outside of 340B's exclusive remedial scheme, covered entities have no other—much less an adequate—remedy available to them to challenge the drug manufacturers' violation of the 340B statute or to remedy the significant harm these violations have caused and will continue to cause.

10. As a direct result of Defendants' unlawful inaction, FQHCs and their patients, who are typically among the most vulnerable and medically underserved, are being irreparably harmed. Those harms, which include threats to FQHCs' patients' health and safety, will continue absent either an immediate enforcement action by HHS, or an injunction compelling the immediate implementation of the FQHCs' remedy for manufacturer overcharging.

PARTIES

11. NACHC is a national, nonprofit corporation whose primary objective is to

further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. FQHCs are community-based, patient-directed nonprofit organizations that play a vital role in our nation's health care safety net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services.

12. To facilitate that role, FQHCs are afforded special status, reimbursement rights, and other privileges in various federal health care programs, including a recognition as 340B Program covered entities since the program's 1992 inception. Each FQHC is obligated by the PHS Act and its implementing regulations to reinvest any program income—*e.g.* revenue generated through 340B, Medicare, Medicaid, or private insurance reimbursement for services—in furtherance of its health care safety net mission.

13. The 340B Program is designed to reduce drug costs for certain classes of safety net providers enumerated in the 340B statute, including FQHCs, that care for medically underserved and vulnerable populations. Any savings, or "nongrant income," the 340B Program generates for FQHCs is derived directly from the statutorily-mandated and defined discount pricing scheme that, by placing a non-discretionary duty on manufacturers to offer discount drugs to covered entities, costs taxpayers nothing.

14. The failure or refusal of HHS to implement the ADR process, despite a statutory mandate to do so, is an issue of substantial significance and considerable

importance to FQHCs across the nation and its territories and to their over 30 million patients. The ADR process provides an exclusive remedy for covered entities overcharged by drug manufacturers for covered outpatient drugs in violation of the 340B statute. *Astra USA*, 563 U.S. at 121–22. Until that process is implemented, FQHCs are left with no remedy, and are entirely dependent on HHS's unilateral enforcement authority.

15. As an association, NACHC has standing to bring this action on behalf of its FQHC members because: they would otherwise have standing to sue in their own right; the ability of FQHCs to effectively participate in the 340B Program and to remedy instances of manufacturer overcharging is directly linked to NACHC's own existence, as a trade association of and for FQHCs; and, the individual participation of FQHCs as parties is unnecessary, as the relief sought—namely, declaratory and injunctive relief (not damages)—applies equally to all covered entity FQHCs.

16. NACHC's board of directors voted unanimously to authorize this action.

17. Defendant Alex M. Azar II is Secretary of HHS and is sued in his official capacity.

18. Defendant HHS, a federal agency within the meaning of the APA, is responsible for administering a variety of federal health care programs, including the 340B Program, 42 U.S.C. § 256b, and the Section 330 Health Center Program, 42 U.S.C. § 254b. The Secretary of HHS has delegated responsibility for the 340B Program to HHS's Health Resources and Services Administration ("HRSA") division, which

oversees both the 340B Program and the Section 330 Health Center Program.

JURISDICTION AND VENUE

19. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1361. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants are agencies, officers, or employees of the United States and a substantial part of the events or omissions giving rise to the claim occurred in this District.

ALLEGATIONS

Federally Qualified Health Centers

20. "FQHCs occupy a unique place in the health services ecology," *Community Health Care Association of New York v. Shah et al*., 770 F.3d 129, 157 (2d Cir. 2014). Indeed, the FQHC designation reflects and is a product of a carefully reticulated legislative scheme, as between the PHS, Medicaid, Medicare, and 340B statutes.

21. By and large, and for purposes of this action, an FQHC is a community-based non-profit "health center" that receives (or is eligible to receive) federal grant funds under Section 330 of the PHS Act to provide care to medically underserved populations in communities that otherwise would not have those services available. 42 U.S.C. § 254b(a), (e), (k).

22. A health center is required by Section 330 to, among other things: (1) serve an area or population designated by the Secretary to be medically underserved; (2) have a community-based board of directors (*i.e*. a majority of its directors must be patients of the center "who, as a group, represent the individuals being served by the center . . ."); (3)

provide primary health care services, including "pharmaceutical services as may be appropriate for particular centers," and related services; (4) provide enabling services such as outreach and transportation, education, and patient case management; (5) participate in Medicaid; and (6) serve all residents of its community and make all of its "required" and "additional" services equally available to all of its patients, regardless of any individual's ability to pay for them. *See* 42 U.S.C. § 254b(a), (b), (j), (k).

23. Section 330 expressly authorizes each health center to provide its services, including pharmaceutical services, through its own staff or through "contracts or cooperative arrangements" with other entities, or a combination thereof. 42 U.S.C. § 254b(a)(1).

24. As HHS has long recognized, that statutory authority affords FQHCs the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy (one owned, controlled, and operated by the health center). *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010).

25. Section 330 grant funds are appropriated to cover or subsidize the cost of services to *un*insured or *under*insured individuals who are unable to pay for them. 42 U.S.C. § 254b(e)(5)(A). Section 330 grant funds are not to be used as a subsidy for

private or public health insurance programs, such as Medicaid. To prevent such a subsidy, health centers are statutorily (a) required to "make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits," including Medicaid. *id*. at § 254b(k)(3)(F). For the same reason, FQHCs are prohibited from giving discounts on their services absent a patient's inability to pay. *Id.* at § 254b(k)(3)(F), (G).

26. The purpose of the FQHC designation (first established in 1989) and the associated payment right in Medicaid—is to "ensure that health centers receiving funds under [Section 330] would not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." *Three Lower Counties Community Health Services v. Maryland*, 498 F.3d 294, 297–98 (4th Cir. 2007) (citing H.R. Rep. No. 101-247, at 392–93, *reprinted in* 1989 U.S.C.C.A.N. 2118–19). This is accomplished through a requirement that states reimburse 100 percent of each FQHC's reasonable costs in furnishing covered ambulatory services to Medicaid beneficiaries. Consolidated Appropriations Act, 2001, Pub. L. 106-554, (Dec. 21, 2000), *codified at* 42 U.S.C. § 1396a(bb) (requiring states to pay each FQHC a prospective per-visit payment rate based on its historical costs in base years and with annual adjustments for inflation and changes in scope of services).

27. Given the purpose and history of the FQHC designation in Medicaid and Medicare, it should come as no surprise that FQHCs appear first on the statutory list of provider types that qualify as "covered entities" eligible to purchase discounted drugs

under the 340B Program. 42 U.S.C. § 256b(a)(4)(A). Those discounts complement and reinforce each FQHC's statutory duty to make all its services equally available to all its patients, regardless of any individual patient's ability to pay for them.

The 340B Program

28. The 340B Program, 42 U.S.C. § 256b, requires drug manufacturers (as a condition of having their drugs covered by Medicare and Medicaid) to enter into an agreement with HHS (known as a pharmaceutical pricing agreement, or PPA) to make "covered outpatient drugs" available to "covered entities" at prices that do not exceed a "ceiling price," as determined by a statutory formula. 42 U.S.C. § 256b(a)(1).

29. By reducing drug costs to FQHCs and other 340B covered entities—which are predominantly providers of safety net services to poor, underserved, and either *un*insured or *under*insured populations—the 340B Program furthers its legislative objective to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992).

30. Plaintiff's FQHC members use the savings they generated through the 340B Program to provide additional services in their federally designated service (or "catchment") area. For example, FQHCs use their 340B savings to cover the cost of medication for *un*insured or *under*insured patients who could not otherwise afford it. FQHCs also use the savings to expand access to necessary medical and crucial enabling services, including but not limited to medication therapy management, behavioral health

care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

31. FQHCs have some flexibility in determining how best to meet the needs of their patient population and community, but their use of any 340B savings must further their health center project. 42 U.S.C. § 254b(e)(5)(D).

32. Each 340B covered entity is statutorily prohibited from: (a) reselling or transferring a drug purchased at a 340B discount to a person who is *not* a patient of the covered entity ("diversion"), and (b) causing a manufacturer to provide a 340B discount and a fee-for-service Medicaid rebate for the same drug ("duplicate discount"). 42 U.S.C. § 256b(5)(A), (B).

33. Each covered entity is subject to audits by both HHS and manufacturers to ensure compliance with the diversion and duplicate discount prohibitions. 42 U.S.C. § 256b(a)(5)(C). Many, if not most, FQHC covered entities also perform their own internal auditing functions to ensure compliance. Each covered entity is ultimately solely responsible for its own compliance with 340B Program requirements.

34. Prior to 2010, HHS had implemented an informal dispute resolution process, akin to nonbinding mediation, to provide for adjudication and resolution of (a) claims by covered entities that drug manufacturers were charging above the ceiling price for their drugs ("overcharging"); and (b) claims by manufacturers that covered entities were causing or failing to adequately prevent diversion or duplicate discounts.

35. That process, however, was "underutilized (because it was a voluntary process)." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57233-01 (Sept. 20, 2010). It was underutilized by covered entities, in particular, because the entities could not independently verify the 340B ceiling prices they were being charged and thus could not identify or quantify any overcharge (as noted *infra*, such access was not provided until 2019).

36. In its 1996 informal dispute resolution guidance, 61 Fed. Reg. 65406-01, HHS stated that a manufacturer must extend the ceiling price to covered entities even if it believes it has ample evidence to indicate prohibited entity activity (diversion or duplicate discounts). In that case, the guidance states that "the manufacturer may bring the claim to the Department through the informal dispute process." Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406-01 (Dec. 12, 1996). But HHS stresses that only if "the entity is found *guilty* [by HHS] of prohibited activity and a decision is made to *remove the entity from the covered entity list*, will the manufacturers no longer be required to extend the discount." *Id.* (emphasis added).

37. Over the years, the HHS Office of Inspector General ("OIG") has concluded that a lack of drug price transparency and statutory "oversight mechanisms" hampered HHS's ability to administer the 340B Program. *See, e.g.,* HHS OIG, D. Levinson, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, p. ii (OEI-05-02-00072, Oct. 2005) ("HRSA lacks the oversight mechanisms and authority to

ensure that [covered] entities pay at or below the 340B ceiling price."); HHS OIG, D. Levinson, *Review of 340B Prices*, p. 11 (OEI–05–02–00073, July 2006) (estimating that covered entities overpaid $3.9 million in June 2005 alone); *accord Astra USA*, 563 U.S. at 121 (recognizing and citing same).

The PPACA's 2010 Improvements to 340B Program Integrity

38. In 2010, the PPACA made significant changes and improvements to the 340B Program. First, it expanded the program by adding new categories of covered entities. Second, and especially important here, it directed the HHS Secretary to promulgate regulations to implement an ADR process to adjudicate and remedy disputes between the program's participants. PPACA, §§ 7101, 7102; *see also Astra USA*, 563 U.S. at 121–22.

39. In particular, § 7102(a)(3), under the title "Improvements to 340B Program Integrity," provides in pertinent part:

> *Not later than* 180 days after the date of enactment of the [PPACA], the Secretary *shall promulgate regulations* to establish and implement an administrative process *for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section*, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B),[1] including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

42 U.S.C. § 256b(d)(3) (emphasis added).

40. The clear purpose and plain meaning of § 256b(d)(3) is to impose a

[1] Subsections (a)(5)(A) and (B) of § 256b prohibit duplicate discounts and diversion, respectively.

nondiscretionary duty on the HHS Secretary to implement, within 180 days of PPACA's enactment, a dispute resolution process capable of fairly and expeditiously resolving program participant claims of noncompliance—such as those at issue here—through binding and enforceable decisions of a designated HHS official or body (the "HHS adjudicator").

41. The Secretary's statutory deadline to implement the ADR process expired on September 19, 2010, 180 days after the PPACA became law on March 23, 2010. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 46 (D.D.C. October 14, 2015) (noting, in 2015, that HHS was "five years overdue in complying with Congress's mandate that it set up an administrative dispute resolution process within 180 days of the ACA's passage").

42. Instead of promulgating the mandated regulations by the statutory deadline, HHS waited until the eve of its expiration to issue two *advance* notices of proposed rulemaking: one for the ADR process, and one covering both CMPs to be levied against manufacturers that knowingly and intentionally overcharge a covered entity and ceiling price calculation requirements. It is unclear why HHS split the rulemaking in this manner, but § 256b(d)(3) explicitly commands the implementation of the entire set of program integrity rules within the same 180-day deadline.

43. In the advance notice of proposed rulemaking ("ANPRM") for the ADR process, HHS solicited information and public comments "to help" develop and draft a proposed rule, even though HHS had fourteen years of experience under its informal

dispute resolution process by then. *See* 75 Fed. Reg. 57233 (publishing informal dispute resolution guidance four years after the program's enactment). The ANPRM specifically sought comments on the following issues: "(1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act." *Id*. at 57234.

44. Both ANPRMs afforded a 30-day comment period (until November 19, 2010) for interested parties, but otherwise said nothing about a timeline for either anticipated rulemaking. And thereafter HHS proceeded with no hint of urgency, despite the statutory deadline and the rules' important purpose.

45. To the contrary, it was not until five years later that HHS issued its first notice of proposed rulemaking ("NPRM") for its Ceiling Price and CMP rules. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34583-01 (June 17, 2015). The NPRM indicated that "[t]he administrative dispute resolution process remains under development" and "HHS intends to address dispute resolution in future rulemaking." *Id*. at 34584.

46. More than a year later—and nearly six years beyond the statutory deadline—HHS issued a NPRM for the ADR rules, indicating that, in developing the

proposal, it had considered the comments it received in response to the 2010 ANPRM. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53381-01 (Aug. 12, 2016). The 2016 NPRM afforded a two-month comment period (until October 11, 2016) and indicated that the ADR rules, when finalized, would "replace" the informal, nonbinding dispute resolution process HRSA had published twenty years earlier in December 1996. *Id*. at 53382.

47. On January 5, 2017, after an earlier reopening of the applicable comment period, HHS issued its final Ceiling Price and CMP rules, with a delayed effective date of March 6, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210-01 (Jan. 5, 2017). In the preamble, HHS noted that "CMPs provide a critical enforcement mechanism for HHS *if manufacturers do not comply with statutory pricing obligations under the 340B Program*." *Id*. (emphasis added). At the same time, HHS noted that "issues related to overcharges," since the program's inception, "have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation." *Id.* at 1227. HHS anticipated that the imposition of a CMP "would occur very rarely if at all" because such penalties are reserved for manufacturer overcharging that is "knowing and intentional." *Id*. at 1227–28.

48. Even though HHS, in publishing its January 5, 2017 rules, "envision[ed] using these penalties in rare situations," it did provide illustrations of the sort of "rare" situation it would consider as "knowing and intentional" overcharging by a manufacturer.

Id. at 1221–27.

49. HHS's examples of knowing and intentional manufacturer overcharges included situations in which a covered entity places an order for non-340B priced drugs where the covered entity was doing so *because the manufacturer had refused to sell or make the drug available at the 340B ceiling price. Id*. at 1224–26. HHS explained, in other words:

> Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging. An example of 'documented refusal' would include *any type of manufacturers' written communication related to reasons a manufacturer is not providing 340B ceiling prices* to either a single covered entity or group of covered entities. *HHS does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements*.

Id. at 1226 (emphasis added).

50. Per the Federal Register notice, multiple commenters suggested that a manufacturer should be able, as an exception to an otherwise knowing and intentional overcharge, to deny a covered entity a 340B price (and charge retail prices) if, in doing so, the manufacturer is acting on "credible evidence that a covered entity is engaged in diversion of 340B drugs." *Id.* at 1223. The commenters asserted that "if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling price." *Id.* The commenters suggested

that manufacturers would be in a better position than HHS to provide this "check on 340B drug diversion, since manufacturers have better and timelier access to sales data than does HHS." *Id.*

51. HHS squarely rejected the notion that a manufacturer can exercise such self-help or act as judge and jury of disputes between covered entities and manufacturers. In particular, HHS stated:

> HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly.

Id.

52. On the issue of knowledge and intent, HHS also explained that the manufacturer need not have acted knowingly or intentionally at the time of the covered entity's drug purchase. That is, the requisite knowledge and intent for a civil monetary penalty could arise thereafter, if the manufacturer subsequently learned of the overcharge and refused to refund or issue a credit to the covered entity. *Id*. at 1225–26. Such a willful disregard for the fact that a covered entity had been overcharged would constitute a reverse liability, so to speak.

53. Finally, in the January 5, 2017 Ceiling and CMP final rule notice, HHS indicated that it "anticipates finalizing the administrative dispute resolution regulation after the comments [to its 2016 NPRM, 81 Fed. Reg. 53381-01] have been reviewed and

considered." 82 Fed. Reg. at 1212.

54. But no ADR regulation was ever made final. Instead, HHS withdrew its proposed ADR rules on August 1, 2017, with no indication as to when future action on those already long-overdue rules would be forthcoming.

55. HHS also delayed the effective date of its Ceiling Price and CMP rules several times, until it was sued, on September 11, 2018, for arbitrarily and unlawfully withholding or delaying a mandatory agency action, in violation of the APA. *See, American Hosp. Ass'n v. U.S. Dept. of Health and Human Serv.*, No. 18-cv-02112 (D.D.C. voluntarily dismissed Apr. 25, 2019).

56. While the lawsuit remained pending, Defendants, for the first time, provided two things: a final effective date of January 1, 2019 for its Ceiling Price and CMP regulation, and covered entity access—as of April 1, 2019 and through an HHS website—to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary," as required by 42 U.S.C. § 256b(d)(B)(iii). 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563-01 (Nov. 30, 2018). Within the first 24 hours the pricing system was accessible to covered entities, it was accessed by over 275 authorized users. Decl. of Krista Pedley, ECF No. 35-1, *The American Hosp. Ass'n*, 18-cv-02112.

57. Thereafter, on April 25, 2019, the parties stipulated to the dismissal of the lawsuit as moot, under Federal Rule of Civil Procedure 41(a)(1)(A)(ii). Joint Status Report and Stipulation of Dismissal, ECF No. 36, *American Hosp. Ass'n*, 18-cv-02112.

Recent Drug Manufacturer Actions
Contrary to 340B Program Requirements

58. On or about July 1, 2020, pharmaceutical company Eli Lilly and Company ("Eli Lilly") posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer distribute multiple formulations of the drug Cialis purchased at 340B pricing to the covered entities' contract pharmacies.

59. On or about September 2, 2020, Eli Lilly disseminated another notice (which HHS declined to post on its webpage) informing 340B covered entities that, effective the day prior, it would no longer distribute *any* of its 340B-priced products to any contract pharmacies of a covered entity, providing an infeasible exception for certain insulin products and allowing for possible mercy for covered entities that had no other pharmacy outlet.

60. The Cialis notice in early July preceded (or triggered) a series of other actions. Merck Sharpe & Dohme Corp., Sanofi, and Novartis, through a vendor called Second Sight Solutions, threatened "less collaborative" and "substantially more burdensome" steps (Merck) or to withhold shipping 340B drugs to contract pharmacies altogether beginning October 1 (Sanofi and Novartis) unless covered entities handed their patient contract pharmacy claims data over to the vendor for the vendor's perpetual use. Neither the manufacturers nor Second Sight Solutions had any right to access or exploit the valuable data, so they threatened to hold 340B drugs hostage instead. Novartis and Merck have not yet followed through with their threats (though they have not withdrawn

them), but Sanofi did on October 1, 2020.

61. In August 2020, drug manufacturer AstraZeneca informed covered entities that it would no longer ship 340B drugs purchased by covered entities to their contract pharmacies effective October 1, 2020. AstraZeneca followed through on its threat, with limited exceptions for covered entities that lack any other pharmacy outlet.

62. By imposing such conditions, these other drug manufacturers are (like Eli Lilly) effectively refusing to make their covered outpatient drugs available to covered entities at 340B pricing, as required by the 340B statute and their respective PPAs. The result is that FQHCs and other covered entities must purchase the manufacturers' drugs at retail prices to make those drugs available to their patients through a contract pharmacy.

Defendants' Preliminary Response to Eli Lilly's Unilateral Pricing Action

63. In a September 21, 2020 letter, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Eli Lilly for an advisory opinion as to whether Eli Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." HHS posted a copy of General Counsel Charrow's letter on HHS's 340B webpage. *See* Charrow Letter, attached hereto as Exhibit A, at 1.

64. Although General Counsel Charrow indicated that HHS "has significant initial concerns" with Eli Lilly's new policy, it "has yet to make a final determination as to any potential action." Exh. A at 1.

65. In any event, HHS has not taken any action to ensure that Eli Lilly, and the other drugs manufacturers described *supra*, are making their covered outpatient drugs

available at 340B discount prices to covered entities for dispensing at their contract pharmacies.

Mandated ADR Process and Remedies

66. The mandated ADR regulations are the only recourse available to covered entities—those whom the 340B program is designed to benefit—when drug manufacturers overcharge them for 340B drugs. *Astra USA*, 563 U.S. at 121–22.

67. Once implemented, the mandated ADR regulations would afford FQHC covered entities a substantial remedy against the manufacturer's unilateral pricing and overcharging actions.

68. In particular, the ADR regulations will implement a process and procedures by which the HHS adjudicator reviews and resolves covered entity claims of manufacturer overcharging, such as those at issue here, "fairly, efficiently, and expeditiously," through a final and binding decision, subject only to APA review. 42 U.S.C. § 256b(d).

69. The procedures will permit covered entities to "discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price," and present such "documents and information" for the designated official's or body's consideration in adjudicating the claim. 42 U.S.C. § 256b(d)(3)(B)(iii).

70. The ADR procedures will also "permit multiple covered entities to jointly

assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members." 42 U.S.C. § 256b(d)(3)(B)(vi).

71. The HHS adjudicator's resolution of a claim or claims under the ADR process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

72. For example, if the HHS adjudicator were to substantiate an overcharge claim, the adjudicator would require the manufacturer to "issue refunds . . . with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued." 42 U.S.C. § 256b(d)(1)(B)(ii). Thereafter, the HHS adjudicator would exercise continuing "[o]versight" authority "to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." *Id*.

73. Moreover, if a manufacturer's overcharging is alleged or found to be knowing and intentional, the matter would be referred to the Office of Inspector General for the potential imposition of "sanctions in the form of civil monetary penalties," up to "$5,000 for each instance of overcharging." 42 U.S.C. § 256b(d)(1)(B)(vi). Such penalties will be assessed "according to standards established in regulations to be

promulgated by the Secretary not later than 180 days after March 23, 2010." *Id*.

74. As explained above, the CMP regulations were not timely promulgated, but they are now final, with an effective date of January 1, 2019.

Irreparable Harms

75. Had the Secretary implemented the mandatory ADR process, as and when required, Plaintiff would have been able to submit a claim—as an association on behalf of FQHCs—as to each manufacturer listed above, and had those claims adjudicated and resolved expeditiously.

76. Indeed, had there been a final, binding ADR regulation providing covered entities a way to challenge prohibited overcharges, drug manufacturers may well have been reticent to take the unauthorized, unilateral actions at the heart of this suit.

77. There are no disputed facts. The manufacturers unilaterally stopped making their covered drugs available at or below ceiling prices to FQHC covered entities when those drugs are being shipped to contract pharmacies.

78. Moreover, it is highly likely that Plaintiff's claims, presented in such a process, would be successful, as HHS, in the preamble to its CMP rules (three years ago), described similar refusals to allow covered entities to purchase drugs at 340B discount pricing as examples of "knowing and intentional" overcharging.

79. By not implementing the mandatory ADR process, and by not exercising their enforcement authority independent of the ADR process, Defendants are depriving FQHCs of the only remedy they have to protect against manufacturer overcharging, and

Defendants are abdicating their statutory enforcement duties.

80. Plaintiff, as an association of and for FQHCs, is also aware of irreparable harm to FQHC patients that has occurred, is occurring, and will occur due to the drug manufacturers' overcharging activity and the lack of an administrative remedy to expeditiously hold them to account.

81. FQHC covered entities serve a patient population that is largely low-income and/or poor, and many FQHC patients are *under*insured (with, for example, high-deductible plans) or entirely uninsured, making them especially vulnerable to shifts in pharmaceutical pricing.

82. Many covered entity patients experience significant barriers to accessing healthcare—some caused by geography and infrastructure, some by the quotidian realities of life for low-income, working poor, migrant farmworker, or homeless individuals—and others caused by health or disability status, including comorbid chronic conditions such as diabetes and heart disease, mental and behavioral health diagnoses, and substance use disorder. For example, many of these patients have little to no disposable income to allocate to healthcare expenses, lack access to reliable transportation, live far from service providers in areas with extreme weather and/or poor infrastructure, communicate in a language other than English, or are mobility impaired.

83. The significant, irreparable harm these patients have suffered and will suffer is both direct and indirect.

84. Direct harm to covered entity patients has included, and will include,

drastic increases in the price of life-sustaining medications for chronic conditions like diabetes, respiratory diseases, cardiovascular disease, HIV/AIDS, and substance use disorder (*e.g.* opioid addiction). For example, uninsured health center patients accustomed to paying less than $16 for Eli Lilly insulin—purchased at 340B pricing and dispensed through their health center's contract pharmacy—now have to shoulder a cost of nearly $550 in some areas (and upwards of $700 in others) for the same amount of medication, or coordinate with and wait for their providers to approve the substitution of a more affordable alternative medication, if such substitution is possible.

85. Patients' geographic, transportation, and time-availability barriers also hinder access to discount medications, even where a health center's existing in-house pharmacy or pharmacies could theoretically make such medications available. For example, without contract pharmacy access or services, certain FQHCs serve patients would have to travel several hours to reach an in-house pharmacy at which they could fill a prescription purchased at 340B pricing.

86. A delay in obtaining certain health maintenance and life-sustaining medications can cause significant adverse health effects. In some cases, such a delay can be fatal. Likewise, a shift to a similar, but not identical, clinical alternative medication—assuming one exists—may not be well-tolerated or of the same efficacy, may result in serious side effects, or may cause medication compliance issues due to patient confusion or difficulty in adapting to a new regimen.

87. Covered entity patients also stand to be indirectly harmed by cuts to non-

reimbursable services that FQHCs currently support with 340B savings. These services—which may be drastically reduced or eliminated entirely due to significant decreases in 340B savings—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE

87. The allegations contained in paragraphs 1–86 above are re-alleged and incorporated by reference.

88. The APA provides a remedy to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

89. Defendants have failed to comply with 42 U.S.C. § 256b(d)(3)'s clear and unequivocal mandate to establish and implement by regulation an ADR process to fairly, efficiently, and expeditiously adjudicate and remedy claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers participating in the 340B Program.

90. The PPACA became law on March 23, 2010. The statutory deadline for the mandated regulations expired on September 19, 2010. They are now more than ten years overdue.

91. Thus, Defendants have unlawfully withheld and unreasonably delayed the promulgation of final rules within the meaning of 5 U.S.C. § 706(1).

92. In the absence of the required rules and process, FQHCs are being deprived of an exclusive statutory remedy for manufacturer overcharging.

93. Neither Plaintiff nor FQHCs have any other adequate remedy to pursue or exhaust under the 340B Program or otherwise. An action under 5 U.S.C. § 706(1) is the only available means for Plaintiff or FQHCs to compel Defendants' compliance with 42 U.S.C. § 256b(d)(3).

94. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s clear mandate, within the specified period, and despite the significant interests it seeks to protect, warrants declaratory and injunctive relief under 5 U.S.C. § 706(1).

COUNT TWO

95. The allegations contained in paragraphs 1–94 above are re-alleged and incorporated by reference.

96. A federal court may issue a writ in the nature of mandamus under 28 U.S.C. § 1361 to compel a federal official or agency to perform a mandatory duty.

97. Defendants have failed to perform a clear, nondiscretionary duty required by 42 U.S.C. § 256b(d)(3)—and owed to FQHC and other covered entities—to promulgate regulations by a certain (long past) deadline to implement an administrative process for the resolution of claims by covered entities that participating manufacturers have overcharged them for drugs purchased under the 340B Program.

98. Defendants' statutory deadline to do so expired more than ten years ago.

99. By failing to promulgate the mandated ADR regulations, Defendants are

depriving FQHCs and other covered entities of their exclusive statutory remedy for drug manufacturer overcharging.

100. FQHCs and other covered entities are currently experiencing that very harm—manufacturer overcharging—without a remedy.

101. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s mandate, within the specified period, warrants a writ of mandamus under 28 U.S.C. § 1361.

PRAYER FOR RELIEF

WHEREFORE Plaintiff respectfully requests the Court:

A. Declare that Defendants violated 42 U.S.C. § 256b(d)(3) by failing to promulgate ADR regulations to implement a process to adjudicate and remedy 340B Program violations;

B. Declare that Defendants violated 5 U.S.C. § 706(1) by unlawfully withholding or unreasonably delaying ADR regulations mandated by 42 U.S.C. § 256b(d)(3);

C. Order Defendants to promulgate final ADR regulations, as required by 42 U.S.C. § 256b(d)(3), no later than 60 days from the Court's order;

D. Retain jurisdiction over this matter pending Defendants' promulgation of the final ADR regulations;

E. Award Plaintiff's reasonable litigation expenses, including attorneys' fees; and

F. Order such other relief as this Court deems just and proper.

Dated October 21, 2020

Respectfully submitted,

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