UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

OCHSNER CLINIC FOUNDATION D/B/A OCHSNER MEDICAL CENTER, 1514 Jefferson Hwy, New Orleans, LA 70121

OCHSNER MEDICAL CENTER - KENNER, L.L.C., 180 W Esplanade Ave., Kenner, LA 70065-2467

EAST BATON ROUGE MEDICAL CENTER LLC D/B/A OCHSNER MEDICAL CENTER BATON ROUGE, 17000 Medical Center Drive, Baton Rouge, LA 70816

OCHSNER MEDICAL CENTER - HANCOCK LLC, 149 Drinkwater Rd Bay Saint Louis, MS 39520

SOUTHERN REGIONAL MEDICAL CORPORATION D/B/A LEONARD J. CHABERT MEDICAL CENTER, 8166 Main St, Houma, LA 70360

HOSPITAL SERVICE DISTRICT OF THE PARISH OF ST BERNARD D/B/A ST. BERNARD PARISH HOSPITAL, 8000 W Judge Perez Dr., Chalmette, LA 70043

HOSPITAL SERVICE DISTRICT NO 1 OF ST. CHARLES PARISH D/B/A ST. CHARLES PARISH HOSPITAL, 1057 Paul Maillard Rd, Luling, LA 70070

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary, United States Department of Health and Human Services, 200 Independence Ave. S.W. Washington, District of Columbia 20201,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs, Ochsner Clinic Foundation d/b/a Ochsner Medical Center; Ochsner Medical Center - Kenner, L.L.C.; East Baton Rouge Medical Center LLC d/b/a Ochsner Medical Center Baton Rouge; Ochsner Medical Center - Hancock LLC; Southern Regional Medical Corporation d/b/a Leonard J. Chabert Medical Center; Hospital Service District of the Parish of St Bernard d/b/a St. Bernard Parish Hospital; and Hospital Service District No 1 of St. Charles Parish d/b/a St. Charles Parish Hospital (collectively "Plaintiffs") are hospitals that participate in the Medicare program and purchase drugs through the 340B Drug Pricing Program, bring this complaint against Defendant Xavier Becerra, in his official capacity as Secretary of Health and Heath Human Services ("Secretary"), and allege as follows:

INTRODUCTION

1. Plaintiffs seek judicial review of a final determination of the Secretary regarding the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Years ("CYs") 2018, 2019, 2020, 2021, and 2022. *See* 82 Fed. Reg. 52356, 52493-511, 52622-25 (Nov. 13, 2017) ("CY 2018 Final Rule"); 83 Fed. Reg. 58818, 58079-81 (Nov. 21, 2018) ("CY 2019 Final Rule") 84 Fed. Reg. 61142, 61317-27 (Nov. 12, 2019) ("CY 2020 Final Rule"), 85 Fed. Reg. 85866, 86042-55 (Dec. 29, 2020) ("CY 2021 Final Rule"), 86 Fed. Reg. 63458, 63644-49 (Nov. 16, 2021) ("CY 2022 Final Rule") (collectively, the "Final Rules"). Specifically, Plaintiffs challenge the Secretary's determination in the Final Rules to reduce Medicare reimbursement for prescription drugs purchased by certain safety net hospitals at prices required by section 340B of the Public Health Service Act ("PHSA") (the "340B Program").

2. Plaintiffs bring this action under the Social Security Act, 42 U.S.C. § 1395, *et seq.* (the "Medicare statute") and the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq*. (the "APA"). The Plaintiffs allege that the Secretary acted *ultra vires* and exceeded his scope of authority under the Medicare statute in contravention of Congressional intent by reducing reimbursement payment for drugs purchased under the 340B Program.

3. Congress enacted the 340B Program in 1992, lowering the cost of drugs for certain public and not-for-profit hospitals (like Plaintiffs) and federally funded clinics serving large numbers of low-income patients. By so doing, Congress enabled these hospitals 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), at 12 (1992); *see also* 82 Fed. Reg. at 52493 & n. 18 (quoting House Report and noting that "[t]h statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

4. As this Court explained, "hospitals participating in the 340B Program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe the 340B drugs to Medicare beneficiaries, they are reimbursed by HHS at OPPS rates." *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 69 (D.D.C. 2018), *reversed by Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, D.C.Cir., 2020), *cert. granted by Am. Hosp. Ass'n v. Azar*, 141 S. Ct. 2883 (July 2, 2021), *reversed and remanded by Am. Hosp. Ass'n v. Becerra*, 142 S.Ct. 1896 (June 15, 2022).

5. The Final Rules eliminate all, or nearly all, of the differential between Medicare OPPS reimbursement rates and the discounted purchase costs mandated for 340B hospitals. The Secretary's decision to reduce payment rates in all five years is a violation of both the Secretary's authority under the Medicare statute and the purpose and design of the PHSA provisions establishing the 340B Program. It is also arbitrary and capricious agency action under the APA.

6. Starting January 1, 2018 (the effective date of the CY 2018 Final Rule), the Secretary began reimbursing covered outpatient drugs and biologicals acquired through the 340B Program at each drug's average sales price ("ASP") minus 22.5 percent. The Secretary extended that payment reduction through CYs 2019 through 2022. The CY 2020 Final Rule also extended the payment reduction to non-excepted off-campus provider-based departments, which policy remains in effect to the present.

7. From April, 2019 through February, 2020, Plaintiffs presented claims to the Secretary's claims processing contractors (the Medicare administrative contractors, or "MACs") challenging the payment reduction pursuant to the claims dispute process set forth in 42 U.S.C. § 1395ff. An example of a dispute letter, but without the accompanying data run, is included as **Exhibit A**. The MACs did not respond to these dispute letters.

8. The MACs presumably did not respond to these dispute letters because of their policies that they would not honor the statutory claims appeal processes for claims for reimbursement for 340B drugs. One of the MACs serving the Plaintiffs states that it "cannot accept appeals involving the application of the 340B payment adjustment." Accordingly the MAC categorically pronounces that it "will dismiss these redetermination requests." The other MAC similarly states that it is acting "[i]n accordance with Medicare's national payment policy." Under this policy "administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under Outpatient Prospective Payment System (OPPS)." As a result, without exception, the MAC asserts that "[a]ppeal requests for reimbursement of drugs purchased through the 340B program will be dismissed." Screen shots from the MACs' websites are included as **Exhibit B**. Given the futility of submission of these disputes, as evidenced by the

lack of a response to its dispute letters as well as the statements on the MACs' websites, the Plaintiffs suspended their submission practices.

9. This Court has found that, as to CYs 2018 and 2019, the Secretary exceeded his authority when he reduced the 2018 and 2019 Medicare reimbursement rate for drugs covered by the 340B Program. *See Am. Hosp. Ass'n*, 348 F. Supp. 3d at 79-83. On appeal, however, the Circuit Court for the District of Columbia found that the Secretary's interpretation is not "directly foreclosed" by the statute, and on that basis upheld the Secretary's action. *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 828 (DC Cir. July 31, 2020), *cert. granted by Am. Hosp. Ass'n v. Azar*, 141 S. Ct. 2883 (July 2, 2021), *reversed and remanded by Am. Hosp. Ass'n v. Becerra*, 142 S.Ct. 1896 (June 15, 2022). The Supreme Court granted certiorari and issued a decision on June 15, 2022. Like the District Court, the Supreme Court gave a close reading to the statute and declared that the reimbursement cuts were "contrary to the statute and unlawful." *Am. Hosp. Ass'n v. Becerra*, No. 20-1114, slip op. at *8 (U.S. June 15, 2022).[1] The Supreme Court has thus reversed the DC Circuit Court opinion and remanded to the lower courts for further action. *Id*.

10. The Supreme Court decision conclusively confirms that the Secretary acted, and continues to act, unlawfully by paying less than ASP plus 6 percent for 340B drugs. The Plaintiffs' dispute letters have thus rightfully demanded that the MACs pay the plaintiffs the full amount owed under the statute. Consistent with the Supreme Court's decisions and their rights under Medicare claims appeals statute (42 U.S.C. § 1395ff), Plaintiffs bring this action seeking declaratory relief from the Secretary's 340B Program payment reductions for CYs 2018 through 2022. (The 2020, 2021, and 2022 payment reductions are the same as the 2018 and 2019

[1] The Westlaw version cites to Am. Hosp. Ass'n v. Becerra, 142 S. Ct.1896 (2022). Since this is a new case, the version does not have formated page numbers. The citations listed in the Complaint are to the Slip Opinion.

reductions in all material respects.) Since the payment reductions have been declared unlawful, the Plaintiffs respectfully request that the Court order the Secretary to pay Plaintiffs' claims for 340B drugs for the period spanning CYs 2018 to 2022 at ASP plus 6 percent.

PARTIES

1. Plaintiff, Ochsner Clinic Foundation d/b/a Ochsner Medical Center, is a hospital located in New Orleans, Louisiana (Medicare Provider No. 190036) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

2. Plaintiff, Ochsner Medical Center - Kenner, L.L.C., is a hospital located in Kenner, Louisiana (Medicare Provider No. 190274) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

3. Plaintiff, East Baton Rouge Medical Center LLC d/b/a Ochsner Medical Center Baton Rouge, is a hospital located in Baton Rouge, Louisiana (Medicare Provider No. 190202) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

4. Plaintiff, Ochsner Medical Center - Hancock LLC, is a hospital located in Bay Saint Louis, Mississippi (Medicare Provider No. 250162) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

5. Plaintiff, Southern Regional Medical Corporation d/b/a Leonard J. Chabert Medical Center, is a hospital located in Houma, Louisiana (Medicare Provider No. 190183) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

6. Plaintiff, Hospital Service District of the Parish of St Bernard d/b/a St. Bernard Parish Hospital, is a hospital located in Chalmette, Louisiana (Medicare Provider No. 190308) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

7. Plaintiff, Hospital Service District No. 1 of St. Charles Parish d/b/a St. Charles Parish Hospital, is a hospital located in Luling, Louisiana (Medicare Provider No. 190079) that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

8. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services, which administers the Medicare program established under title XVIII of the Social Security Act. Defendant Becerra is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

JURISDICTION AND VENUE

9. This action arises under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, including 42 U.S.C. § 1395ff(b)(1)(A), and the APA, 5 U.S.C. § 551.

10. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rules, Plaintiffs have been paid amounts for covered 340B drugs that are approximately 30 percent lower than the rate prescribed by 42 U.S.C. § 1395*l*(t)(14)(A)(iii). Consistent with 42 U.S.C. § 1395ff(a)(3)(C), Plaintiffs have presented protested claims to their MACs notifying the MACs that they believe that they have been underpaid. *See* **Exhibit A**. The

MACs, however, have issued statements of general applicability that categorically deny the right to initiate such appeals. **Exhibit B**. Although the Plaintiffs had for a period filed individual claims protests all the same, the Plaintiffs suspended such activity due to the MACs' non-responsiveness. Pursuing appeals of the protested claims or initiating appeals for the claims not protested would have been futile. Accordingly, all such further actions may be deemed waived. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 154 (D.D.C. 2019) (finding that exhaustion of claims would have been futile because the Secretary did not argue that further administrative review was necessary or that it would give the agency opportunity to self-correct; the Secretary already considered and rejected plaintiffs' arguments; additional administrative review would not develop the factual record or provide the court with further agency expertise; and no administrative review body could override the agency's binding regulations).

11. The Supreme Court's decision conclusively decided the merits that are the crux of the Plaintiffs' filed disputes with the MACs. Those disputes are now ripe for review in Federal court, pursuant to 42 U.S.C § 1395ff(b)(1)(A) (cross-referencing 42 U.S.C. § 405(g)).

12. Alternatively, this Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because Plaintiffs' claims arise under the laws of the United States.

13. Venue is proper in this district under 28 U.S.C. § 1391 because Defendant resides in the District of Columbia and a substantial part of the events giving rise to this action occurred in this district.

14. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant the requested declaratory relief under 28 U.S.C. §§ 2201 & 2202, 5 U.S.C. § 706, and 42 U.S.C. § 405(g).

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

15. Under the 340B Program, certain hospitals serving a disproportionate share of low-income individuals and federally funded clinics (so-called "covered entities") may purchase outpatient prescription drugs at discounted prices. Drug manufacturer participation in the 340B Program is essentially mandatory: manufacturers must participate as a condition of having their drugs covered by Medicaid. 42 U.S.C. § 1396r-8(a)(5).

16. Covered entities are statutorily defined at PHSA § 340B(a)(4) and include qualifying hospitals, Ryan White HIV/AIDS program grantees, black lung clinics, rural referral centers, critical access hospitals, Title X family planning clinics, and other institutions that primarily serve the poor, indigent, or the under- or uninsured. The 340B Program is designed to enable covered entities to purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, at the reduced cost but still bill Medicare at the OPPS rate prescribed under the Medicare statute.

17. According to the Government Accountability Office, access to reduced price medications enables covered entities "to expand the type and volume of care they provide to the most vulnerable patient populations." U.S. Dep't of Health & Human Servs., Justification of Estimates for Appropriations Committees at 325 (2017).

18. Plaintiffs are "covered entities" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement for Drugs

19. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiffs provide hospital services to Medicare

beneficiaries that qualify for reimbursement through Medicare.

20. In 1997, Congress directed the Secretary to create a hospital Outpatient Prospective Payment System through which Medicare was to pay for services offered in hospital outpatient departments. *See* 42 U.S.C. § 1395*l*(t).

21. Starting in 2004, Congress ordered the Secretary to set reimbursement rates for separately payable drugs not otherwise bundled into the payment for an outpatient service. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 621, 117 Stat. 2307, codified at 42 U.S.C. § 1395*l*(t)(14). This payment rate covers all applicable drugs whether purchased through the 340B Program or on the open market by non-340B covered entities.

22. By statute, the Secretary is directed to set payment rates for all such drugs using one of two alternative processes:

a. The Secretary may set the payment rate at the average hospital acquisition cost for the drug for that year (to vary, at the discretion of the Secretary, by "hospital group" as defined by "relevant characteristics"), "as determined by the Secretary taking into account . . . hospital acquisition cost survey data," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I); or

b. If "hospital acquisition cost data are not available," the Secretary may use the average sales price for the drug established by 42 U.S.C. § 1395w-3a and "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

23. The Secretary had paid for such drugs pursuant to the second option, and adjusted the rate as required by statute to ASP plus 6 percent. 42 U.S.C. § 1395w-3a(b)(1)(A)-(B).

24. There is no separate statutory rate established only for 340B drugs or any alternative method for the Secretary to establish a different payment methodology for 340B drugs. This statutory default rate of ASP plus 6 percent was applied without adjustment until January 1, 2018.

25. Notwithstanding this clear statutory framework, on July 13, 2017, the Secretary proposed to lower the Medicare reimbursement rate for drugs purchased under the 340B Program by adopting a third methodology not authorized by the statute. The Secretary changed the payment rate for 340B drugs to ASP minus 22.5 percent. 82 Fed. Reg. 33558, 33634 (July 20, 2017). The Secretary did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug," and so instead relied on an estimate. *Id.* According to the Secretary, the new rate would better recognize "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," and "better represent[] the average acquisition cost for these drugs and biologicals." *Id.*

26. The Secretary finalized this proposal on November 13, 2017 over the strong objection of many commenters. 82 Fed. Reg. at 52362. This significant change in reimbursement has effectively made participation in the 340B Program punitive, at least as to Medicare beneficiary utilization of 340B drugs, as reimbursement no longer covers the full costs of the drugs, including carrying costs and 340B program compliance costs.

27. The Secretary attempts to rely on the language included in the second statutory option—42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)—as authority to make the change. *See*, *e.g.*, 82 Fed. Reg. at 52499 (alleging that that statutory "calculate and adjust" authority gives the Secretary "broad discretion" to "adjust" payments for drugs). However, the Secretary's policy clearly exceeds this statutory authority because the reduction made is expressly based on the estimated acquisition costs of 340B drugs, *i.e.* a variation of the cost-based methodology set forth under the first clause of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *See*, *e.g.*, 82 Fed. Reg. at 52501. The Secretary, by his own admission, has never been able to reliably collect the required cost data for each drug as required under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I).

See 82 Fed. Reg. at 33634 (acknowledging that the Secretary lacked the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug."). Therefore, he improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data, even though payment under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) must be based on average sales price, *not* acquisition costs. *Id.*

28. The detrimental and impermissible cuts were adopted again in CYs 2019, 2020, 2021, and 2022, all based on the same statutory interpretation. Indeed, the Secretary affirmatively elected not to rely on survey data, even after the Secretary conducted a 340B drug pricing survey, albeit an invalid one, in 2020. In the CY 2021 Final Rule, the Secretary discussed the results of the 2020 survey. As noted by the Secretary, only seven percent of survey recipient hospitals actually provided any detailed pricing information. Another 55 percent checked off a box provided by the Secretary on the survey to indicate that they were paying 340B pricing, but declining to provide any detail. Finally 38 percent opted not to respond at all. 85 Fed. Reg. 85866, 86045 (Dec. 29, 2020).

29. While not conceding that his data was thus wholly flawed, the Secretary nevertheless acknowledged that:

> [A]s described above, the utilization of the survey data is complex, and we wish to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy. We appreciate the feedback from commenters and will continue to assess it as we explore whether survey data should be considered hospital acquisition cost data for purposes of paying for drugs acquired under section 1833(t)(14)(A)(iii)(I) in future years.

Id. at 86052. Given the potential issues with the survey data, the Secretary thus did not rely on the data for setting 340B drug reimbursement rates in 2021. Nor was that data used to support the continuation of the policy in CY 2022.

C. Supreme Court Decision and the Secretary's Response

30. After this Court ruled in favor of the American Hospital Association, and the DC Circuit Court reversed, the Supreme Court reviewed the DC Circuit Court's decision and reversed again. *Am. Hosp. Ass'n*, No. 20-1114, slip op. at *8. The Supreme Court found that there are two statutory pathways for setting hospital outpatient department reimbursement: either (a) CMS conducts a valid drug pricing survey meeting the statutory requirements, or (b) hospitals get paid at ASP plus 6 percent. *Id.* at *6. As the Secretary readily acknowledged that a survey had not been conducted, the Supreme Court found that the Secretary "acted unlawfully by reducing the reimbursement rates for 340B hospitals." *Id.* at *7.

31. The Supreme Court remanded to the lower courts to implement the decision. *Id.* at 8. Although it did not mandate any specific relief, it was unequivocal that 340B drugs were to be reimbursed at ASP plus 6 percent. Every claim where that rate has not been paid constitutes an underpayment that remains outstanding, notwithstanding the Supreme Court decision.

32. The Secretary's agency, however, has thus far opted not to consider itself bound by the Supreme Court's instruction. In a proposed rule pertaining to hospital outpatient department reimbursement for CY 2023, CMS has stated:

> We are still evaluating how to apply the Supreme Court's recent decision to prior calendar years. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, "[a]t this stage, we need not address potential remedies." We are interested in public comments on the best way to craft any potential remedies affecting cost years 2018-2022 given that the Court did not resolve that issue.

87 Fed. Reg. 44502, 44505 (July 26, 2022). CMS's reference to "any potential remedies" does not reflect an understanding of the unambiguous instruction it received from the Supreme Court to reconcile prior payments to the statutorily mandated reimbursement rate.

D. Judicial Review and Plaintiffs' Claims

33. A plaintiff must typically satisfy two requirements before seeking judicial review under 42 U.S.C. § 405(g): a plaintiff must "present" its claim to the Secretary for a decision, and then must exhaust all available administrative remedies. *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). The presentment requirement is not waivable, although the exhaustion may be. *See Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825-26 (D.C. Cir. 2018). Exhaustion may be excused where "an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law[.]" *DL v. District of Columbia*, 450 F. Supp. 2d 11, 17 (D.D.C. 2006). For example, courts have recognized the futility of exhaustion where plaintiffs "do not challenge an individual … decision by [the agency] . . . but instead challenge the agency's 'policy, pattern, and practice' or 'systemic failure to comply with' federal law. *See id*. at 18; *see also Tataranowicz v. Sullivan*, 753 F. Supp. 978, 987 (D.D.C. 1990), *rev'd on other grounds*, 959 F.2d 268 (D.C. Cir. 1992).

34. The Plaintiffs have presented claims for payment to the Medicare program for its separately payable drugs affected by the Final Rules. For CYs 2018 through 2022, Medicare has paid drug claims submitted by the Plaintiff hospitals at ASP minus 22.5 percent.

35. Dissatisfied with that payment amount, the Plaintiffs had filed protests with their MACs, including a listing of all of the claims subject to dispute for the period covered by each individual protest. Exhibit A (cover letter without the accompanying claims detail). Nothing more was required under 42 U.S.C. § 1395ff to initiate a protest. 42 U.S.C. § 1395ff(a)(3)(C)(i) (merely requiring that "notice" of the dispute be filed).

36. The MACs, however, did not respond, presumably because of their blanket statements published on their websites that notify hospitals, such as the Plaintiffs, that appeals of 340B drug payment disputes will not be accepted. Exhibit B.

37. Although the MACs' refusal to initiate proceedings denied the Plaintiffs their right to an administrative adjudication, the Plaintiffs' disputes continued to develop all the same. The Plaintiffs' claims have both a legal component and a factual component. The legal component relates to whether, generally, the Secretary has the right to make the disputed payment cuts. In that regard, the American Hospital Association, on behalf of safety net hospitals including Plaintiffs, vindicated their rights to full payment for 340B drugs administered in the hospital outpatient department. The Supreme Court decision removes any question as to whether the Plaintiffs' position expressed in their dispute letters was correct as a matter of law.

38. With the legal questions answered, the factual aspects of the Plaintiffs' disputes are now ripe for review. Specifically, the Plaintiffs request this Court to determine factually the amount of the underpayment now due the Plaintiffs. The Plaintiffs had submitted listings of their underpaid claims, along with their dispute letter preserving their rights to seek payment in court once the law had been clarified through the initial judicial process. The Plaintiffs continued submitting these disputes until it became clear that the MACs were taking no action on those submissions. Additionally, even up to the current moment, the MACs still decline, as stated on their websites, to process disputes of claims of underpayment for 340B drugs. Thus, it is, and always has been, futile to either initiate an individual claims appeal proceeding or seek to pursue any appeals, once initiated. As this categorical denial of these appeals is a matter of general applicability and is antithetical to applicable, Federal law, waiver of exhaustion is warranted in this case.

39. Since the Plaintiffs' dispute is thus now properly before this Court, this Court has the statutorily granted ability to affirm, modify, or reverse the decision of the Secretary, without remand. 42 U.S.C. § 405(g). The Plaintiffs thus respectfully request that the Court modify the Secretary's decision to require the Secretary to pay every underpaid claim for a 340B program drug (as identified on each such claim) at the full ASP plus 6 percent rate.

CAUSE OF ACTION
(Administrative Procedure Act)
The Secretary Has Violated Congress's Unambiguous Directive that 340B Drugs are to be Reimbursed at the Full Rate of ASP Plus 6 Percent

40. The allegations set forth in paragraphs 1 through 44 are incorporated by reference as if fully set forth herein.

41. The APA permits judicial review of agency actions, findings, and conclusions that are "not in accordance with law" or are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. §§ 706(2)(A), 706(2)(C).

42. When "Congress has directly spoken to the precise question at issue," this Court must give effect to Congress's unambiguously stated intent. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). It is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Gp. v. EPA*, 573 U.S. 302, 328 (2014).

43. Congress has unequivocally permitted the Secretary two avenues—and no others—to adjust reimbursement for covered outpatient drugs and biologicals. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)–(II). On the one hand, the Secretary may set reimbursement based on hospital acquisition cost survey data. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). On the other, if such data are not available, the Secretary must reimbursed at the average sales price. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Secretary's Final Rules did not utilize either method, but instead

relied on an estimate of aggregate acquisition costs as a proxy for appropriate data. As declared by the Supreme Court, the Secretary's change to lower the Medicare reimbursement rate for drugs purchased under the 340B Program to ASP minus 22.5 percent is *ultra vires*, contrary to clear statutory directive, and beyond the Secretary's limited authority.

44. For these and other reasons, the Secretary's rate cut in the Final Rules is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request an Order:

a. Declaring that the Supreme Court's holding applies to the Plaintiffs' claims for 340B drugs administered in the hospital outpatient department;

b. Directing the Secretary to use the methodology used in CY 2017 for all payments for Plaintiffs' 340B Drugs for dates of service in CYs 2018 through 2022;

c. Requiring the Secretary to reimburse Plaintiffs for the difference between amounts paid for 340B drugs pursuant to the Final Rules (ASP minus 22.5 percent) and what would have been paid for those same drugs under the CY 2017 methodology required by statute (ASP plus 6 percent);

d. Requiring the Secretary to pay legal fees and costs of suit incurred by the Plaintiffs pursuant to 28 U.S.C. § 2412;

e. Awarding Plaintiffs interest pursuant to 42 U.S.C. § 1395*l*(j) and § 1395ff(b)(2)(C)(iv); and

f. Providing such other just and proper relief as the Court may consider appropriate.

Respectfully submitted,

/s/ *Andrew D. Ruskin*
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