UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADVOCATE CHRIST MEDICAL CENTER
4440 West 95th Street
Oak Lawn, IL 60453

ADVOCATE ILLINOIS MASONIC MEDICAL CENTER
836 West Wellington Avenue
Chicago, IL 60657

ADVOCATE LUTHERAN GENERAL HOSPITAL
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Park Ridge, IL 60068

ADVOCATE TRINITY HOSPITAL
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Chicago, IL 60617

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AMITA HEALTH MERCY MEDICAL CENTER AURORA
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AMITA HEALTH SAINT FRANCIS HOSPITAL EVANSTON
355 Ridge Avenue
Evanston, IL 60202

AMITA HEALTH SAINTS MARY AND ELIZABETH MEDICAL CENTER SAINT MARY CAMPUS
2233 West Division Street
Chicago, IL 60622

AMITA HEALTH ST. ALEXIUS MEDICAL CENTER HOFFMAN ESTATES
1555 Barrington Road
Hoffman Estates, IL 60169

Case No. _____

COMPLAINT

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ASCENSION VIA CHRISTI HOSPITAL IN)
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FRANCIS)
929 North Saint Francis)
Wichita, KS 67214)
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700 West Market Street)
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AURORA SAINT LUKE'S MEDICAL CENTER)
2900 West Oklahoma Avenue)
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CENTER)
2629 North Seventh Street)
Sheboygan, WI 53083)
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BAPTIST EASLEY HOSPITAL)
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BAYHEALTH HOSPITAL, KENT CAMPUS)
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18101 Oakwood Boulevard)
Dearborn, MI 48124)
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BEAUMONT HOSPITAL – FARMINGTON HILLS)
28050 Grand River Avenue)
Farmington Hills, MI 48336)
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BEAUMONT HOSPITAL – GROSSE POINTE)
468 Cadieux Road)
Grosse Pointe, MI 48230)
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BEAUMONT HOSPITAL – ROYAL OAK)
3601 West Thirteen Mile Road)
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BEAUMONT HOSPITAL – TAYLOR)
10000 Telegraph Road)
Taylor, MI 48180)
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BEAUMONT HOSPITAL – WAYNE)
33155 Annapolis Street)
Wayne, MI 48184)
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BECKLEY ARH HOSPITAL)
306 Stanaford Road)
Beckley, WV 25801)
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COMMUNITY HOSPITAL EAST
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COMMUNITY HOSPITAL NORTH
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DALLAS COUNTY HOSPITAL DISTRICT)
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Dallas, TX 75235)
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DAY KIMBALL HOSPITAL)
320 Pomfret Street)
Putnam, CT 06260)
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DEACONESS HENDERSON HOSPITAL)
1305 North Elm Street)
Henderson, KY 42420)
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DENVER HEALTH)
777 Bannock Street)
Denver, CO 80204)
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EAST ALABAMA MEDICAL CENTER)
2000 Pepperall Pkwy)
Opelika, AL 36801)
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EAST ALABAMA MEDICAL CENTER–LANIER)
4800 48th Street)
Valley, AL 36854)
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EPHRAIM MCDOWELL REGIONAL MEDICAL)
CENTER)
217 South Third Street)
Danville, KY 40422)
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FIRELANDS REGIONAL MEDICAL CENTER -)
MAIN CAMPUS)
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FISHER-TITUS MEDICAL CENTER)
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FORREST GENERAL HOSPITAL)
6051 U.S. Highway 49)
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FRANCISCAN HEALTH HAMMOND)
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FRANCISCAN HEALTH LAFAYETTE EAST)
1701 South Creasy Lane)
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FRANCISCAN HEALTH MICHIGAN CITY)
3500 Franciscan Way)
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FRANCISCAN HEALTH OLYMPIA FIELDS)
CAMPUS)
20201 South Crawford Avenue)
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FRANKLIN WOODS COMMUNITY HOSPITAL)
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FROEDTERT HOSPITAL)
9200 West Wisconsin Avenue)
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GOOD SAMARITAN REGIONAL MEDICAL)
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3600 Northwest Samaritan Drive)
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GREENVILLE MEMORIAL HOSPITAL)
701 Grove Road)
Greenville, SC 29605)
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GREER MEMORIAL HOSPITAL)
830 South Buncombe Road)
Greer, SC 29650)
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GUNDERSEN LUTHERAN MEDICAL CENTER)
1900 South Avenue)
La Crosse, WI 54601)
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HARLAN ARH HOSPITAL)
81 Ball Park Road)
Harlan, KY 40831)
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HAZARD ARH REGIONAL MEDICAL CENTER)
100 Medical Center Drive)
Hazard, KY 41701)

HELEN KELLER HOSPITAL)
1300 South Montgomery Avenue)
Sheffield, AL 35660)
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HIGHLANDS ARH REGIONAL MEDICAL)
CENTER)
5000 Kentucky Route 321)
Prestonburg, KY 41653)
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HILLSDALE HOSPITAL)
168 South Howell St.)
Hillsdale, MI 49242)
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HOLSTON VALLEY MEDICAL CENTER)
130 West Ravine Road)
Kingsport, TN 37660)
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INDIAN PATH COMMUNITY HOSPITAL)
2000 Brookside Drive)
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IU HEALTH BALL MEMORIAL HOSPITAL)
2401 West University Avenue)
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IU HEALTH BLOOMINGTON HOSPITAL)
601 West Second Street)
Bloomington, IN 47403)
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IU HEALTH METHODIST HOSPITAL)
1701 North Senate Boulevard)
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JOHNSON CITY MEDICAL CENTER)
400 North State of Franklin Road)
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1700 East Broad Street.)
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LEHIGH VALLEY HOSPITAL - POCONO)
206 East Brown Street)
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LEHIGH VALLEY HOSPITAL-SCHUYLKILL S.)
JACKSON STREET)
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LENOX HILL HOSPITAL)
100 East 77th Street)
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LONESOME PINE HOSPITAL)
1990 Holton Avenue)
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LONG ISLAND JEWISH MEDICAL CENTER)
270-05 76th Avenue)
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LOWELL GENERAL HOSPITAL - MAIN CAMPUS)
295 Varnum Avenue)
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MADISON HEALTH)
210 North Main Street)
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MARSHALL MEDICAL CENTER SOUTH)
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MEMORIAL HOSPITAL)
615 North Michigan Street)
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MEMORIAL HOSPITAL AT GULFPORT)
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MIAMI VALLEY HOSPITAL)
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MYMICHIGAN MEDICAL CENTER ALMA)
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NORTH SHORE UNIVERSITY HOSPITAL)
300 Community Drive)
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NORTON COMMUNITY HOSPITAL)
100 15th Street Northwest)
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NORTON HOSPITAL)
200 East Chestnut Street)
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169 Riverside Drive)
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2001 Stults Road)
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PARKVIEW NOBLE HOSPITAL)
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CENTER)
703 Main Street)
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SAINT MARY'S HOSPITAL AT AMSTERDAM)
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Amsterdam, NY 12010)
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SAINT TAMMANY PARISH HOSPITAL)
1202 South Tyler Street)
Covington, LA 70433)
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SAINT THOMAS RIVER PARK HOSPITAL)
1559 Sparta Road)
McMinnville, TN 37110)
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SAINT VINCENT ANDERSON)
2015 Jackson Street)
Anderson, IN 46016)
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SAINT VINCENT EVANSVILLE)
3700 Washington Avenue)
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SAINT VINCENT INDIANAPOLIS HOSPITAL)
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1046 Southwest Sixth Avenue)
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SANFORD USD MEDICAL CENTER SIOUX FALLS)
1305 West 18th Street)
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SCHNECK MEDICAL CENTER)
411 West Tipton Street)
Seymour, IN 47274)
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SOUTH SHORE UNIVERSITY HOSPITAL)
301 East Main Street)
Bay Shore, NY 11706)
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SPECTRUM HEALTH UNITED HOSPITAL)
615 South Bower Street)
Greenville, MI 48838)
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STATEN ISLAND UNIVERSITY HOSPITAL)
475 Seaview Avenue)
Staten Island, NY 10305)
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TALLAHASSEE MEMORIAL HEALTHCARE)
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TAYLOR REGIONAL HOSPITAL)
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1200 North Elm Street)
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THE UNIVERSITY OF TOLEDO MEDICAL CENTER)
3000 Arlington Avenue)
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WEIRTON MEDICAL CENTER
601 Colliers Way
Weirton, WV 26062

WHITESBURG ARH HOSPITAL)
240 Hospital Road)
Whitesburg, KY 41858)
)
Plaintiffs,)
)
vs.)
)
XAVIER BECERRA)
Secretary of the United States Department of Health)
and Human Services)
Room 700-E)
200 Independence Avenue, S.W.)
Washington, D.C. 20201)
)
Defendant.)

COMPLAINT

The above-captioned 150 Plaintiff hospitals ("Plaintiffs" or "Hospitals"), by and through their undersigned counsel, bring this action against Xavier Becerra, in his official capacity as the Secretary of the Department of Health and Human Services, and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (the "Medicare Act") and the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* (the "APA") to challenge provisions of final rules issued on November 1, 2017, November 1, 2018, November 1, 2019, December 4, 2020, and November 2, 2021 by the Centers for Medicare and Medicaid Services ("CMS"). *See* 82 Fed. Reg. 52,356, 52,493–511, 52,622–25 (Nov. 13, 2017); 83 Fed. Reg. 58,818, 58,981 (Nov. 21, 2018); 84 Fed. Reg. 61,142, 61,317–27 (Nov. 12, 2019); 85 Fed. Reg. 85,866, 86,038 (Dec. 29, 2020); and 86 Fed. Reg. 63,458, 63,461 (Nov. 16, 2021). The final rules concern 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. The portions of the challenged rules reduced by nearly 30%

Medicare reimbursements to certain public and not-for-profit hospitals and clinics for prescription drugs purchased by those institutions on a discounted basis under section 340B of the Public Health Service Act (the "340B Program"). The 2020 Rule expanded the covered entities subject to the reduction to include non-excepted off-campus provider-based departments, and the 2021 and 2022 Rules continue that policy. The Secretary, in exceeding his scope of authority under the Medicare Act and by reducing reimbursement payment for drugs purchased under the 340B Program, unlawfully infringed on the Plaintiffs' efforts to care for low-income and vulnerable patients, in contravention of Congress's intent in enacting the 340B Program. The challenged rules took effect on January 1 of each year from 2018 to 2022.

2. Congress enacted the 340B Program in 1992 and through the Program lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. By lowering hospitals' purchase costs for patient drugs, 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 52,493 & n.18 (quoting House report and noting that "[t]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

3. Commencing January 1, 2018, CMS began reimbursing covered outpatient drugs and biologicals acquired through the 340B Program at average sales price (ASP) minus 22.5% when billed by a hospital paid under the OPPS. CMS continued this payment policy in CYs 2019–2022. Beginning with the 2020 OPPS Rule, CMS extended this payment policy to non-excepted off-campus provider-based departments.

4. As explained in comments to the CY 2018 OPPS Rule, *see* 82 Fed. Reg. at 52,499–502, and by the United States District Court for the District of Columbia in the lawsuits that followed its passage and application, the establishment of this improper rate exceeds the Secretary's authority, *see Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 79-83 (D.D.C. 2018) ("*AHA I*") and *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019) ("*AHA II*") (holding that the Secretary exceeded his authority when he reduced the 2018 and 2019 Medicare reimbursement rate for pharmaceutical drugs covered by the "340B Program" by nearly 30%), *consolidated on appeal and rev'd, Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *decision pending*, No. 20-114 (U.S.).

5. In accordance with this Court's decisions in *AHA I* and *AHA II*, Plaintiffs bring this action to seek relief from the Secretary's prior actions and to secure injunctive relief from the 2022 OPPS Rule.

6. As noted above and as discussed in this Court's decisions in *AHA I* and *AHA II*, the 340B Program has lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. In 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). The 340B Provisions of the 2018– 2022 OPPS Rules specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The 2018–2022 OPPS Rules eliminate nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated $3.2 billion, in violation of both the Secretary's statutory authority under the Social

Security Act to reimburse hospitals for outpatient drugs and the purpose and design of the Public Health Service Act provisions establishing the 340B Program.

7. Plaintiffs have used the 340B Program to provide critical health care services to their communities. Those hospitals and their poor and underserved patient populations have suffered, and will continue to suffer, harm from the negation of the cost-reimbursement differential through the 340B Provisions of the 2018–2022 OPPS Rules.

8. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the 2022 OPPS Rule pending resolution of this action.

PARTIES

9. At all times relevant to this Complaint, Plaintiffs were qualified as Medicare-participating providers under the Medicare Act and have participated in the 340B Program.

10. Plaintiffs participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs to the vulnerable populations they serve. Plaintiffs have been significantly harmed by the elimination of this differential from Medicare payments in the 2018–2022 OPPS Rules and will continue to be significantly harmed if those Rules remain in effect.

11. The 340B Provisions of the 2018–2022 OPPS Rules severely threaten Plaintiffs' ability to provide critical health care programs to their communities, including the underserved populations in those communities, by depriving Plaintiffs of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

12. Defendant Xavier Becerra ("the Secretary") is the Secretary of the Department of Health and Human Services, the federal department which encompasses CMS. The Secretary, the

federal official responsible for the administration of the Medicare Program, has delegated to CMS the responsibility to administer that program. Secretary Becerra is sued in his official capacity.

JURISDICTION AND VENUE

13. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*., section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Administrative Procedure Act, 5 U.S.C. §§ 701–06.

14. This Court has subject matter jurisdiction over this action under 42 U.S.C. § 405 and 28 U.S.C. § 1331.

15. This judicial district is an appropriate venue pursuant to 28 U.S.C. § 1391(e), 42 U.S.C. § 405(g), and 42 U.S.C. § 1395ff(b)(2)(C)(iii).

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

16. Congress established the 340B Program in 1992 as part of the Public Health Service Act. The 340B Program provides certain hospitals serving a disproportionate share of low-income individuals and federally-funded clinics (called "covered entities" in the statute) with outpatient prescription drug discounts comparable to those that Congress had made available to state Medicaid agencies in 1990. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). The purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

17. Since the 340B Program was first implemented, covered entities have retained all savings generated through the program and have used those savings to provide additional critical

health care services for their communities, including underserved populations within those communities. Those critical health care services include the provision of patient education programs, translation services, transportation services and increased service locations.

18. Recognizing the value of the 340B Program, Congress has increased the categories of eligible "covered entities." In 1992, when Congress first created the Program, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O). Pursuant to the 2020 OPPS Rule, "covered entities" also include non-excepted off-campus provider-based departments. *See* 84 Fed. Reg. at 61,181.

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

B. Medicare OPPS Reimbursement

20. In 1997, Congress sought to control Medicare expenditures for outpatient services and directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

21. Beginning in 2004, Congress directed CMS to set reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled into the price of an outpatient service. These drugs include outpatient drugs covered under the 340B Program.

22. The statute provides two avenues to CMS for setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of the statute, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition costs are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition costs data are not available, CMS is required to reimburse based on average sales price ("ASP")—a defined quantity under a different statutory provision—plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

23. In 2012, after concluding that it could not obtain the acquisition cost required in order to reimburse under Subclause I based on acquisition cost, CMS adopted the reimbursement method under Subclause II—the statutory default rate of ASP plus 6%—for all separately payable drugs. This statutory default rate was applied without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's Reduction to Payment Rate for 340B Drugs

24. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the CY 2018. In addition to updating the OPPS with 2018 rates, CMS proposed to change how Medicare pays certain hospitals for separately payable drugs purchased under the 340B Program. 82 Fed. Reg. 33,558, 33,634 (July 20, 2017). Specifically, it proposed to lower the Medicare reimbursement rate for such drugs from the previous rate of ASP plus 6% to ASP minus 22.5%—a reduction of 28.5% in the reimbursement rate. *Id.* at 33,634.

25. On November 13, 2017, CMS issued the final version of the 340B Provisions of the 2018 OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. at 52,362.

26. This new reimbursement rate nearly eliminated the benefit of the 340B Program for certain covered entities by eliminating the difference between the purchase price paid *by* hospitals for those drugs and Medicare payments *to* hospitals for those drugs.

27. For its authority to reduce the reimbursement rate for certain 340B drugs by nearly 30%, CMS purported to rely on 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which allows the Secretary to "calculate" and "adjust" the statutory default rate of ASP plus 6%. *See, e.g.*, 82 Fed. Reg. at 52,499 (noting that "calculate and adjust" authority gives the Secretary "broad discretion" to adjust payments for drugs). The 340B Provisions of the 2018 OPPS Rule exceed the Secretary's authority because the reduction set forth in the Rule is expressly based on the estimated acquisition costs of 340B drugs, *i.e.*, a variation of the cost-based methodology set forth under Subclause I of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *See, e.g.*, 82 Fed. Reg. at 52,501. Because CMS, by its own admission, cannot now and has never been able to reliably collect the statistically significant cost data for each drug required under the statute to invoke Subclause I, it improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data in issuing the OPPS Rule – even though payment under Subclause II expressly must be based on average sales price, *not* acquisition costs. In doing so, the Secretary impermissibly invoked his authority under Subclause II to circumvent the requirements under Subclause I.

28. The Secretary's authority under Subclause II of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), to "calculate" and "adjust" the ASP-plus-6% formula, does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of drug-price savings totaling an estimated $1.6 billion (CMS's estimate). Rather, this authority only

permits the Secretary to calculate the ASP as set forth in the statute and to fine-tune the default rate.

29. The 340B Provisions of the 2018 OPPS Rule also exceed the Secretary's authority because they undermine the 340B Program by depriving eligible hospitals of a critical portion of the resources Congress intended to provide those hospitals through 340B discounts. Elimination of these resources has and will continue to put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential health care services and programs to their communities, including underserved populations within those communities. This is inconsistent with the intent of the 340B Program, which was designed to help covered entities stretch scarce federal resources to reach more eligible patients. CMS's efforts in the 340B Provisions of the 2018 OPPS Rule to "align" (82 Fed. Reg. at 52,495) the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congress' intent to create a differential between reimbursements and purchase prices and thereby to generate resources for covered entities to use in their communities.

30. The new payment rate set forth in the 340B Provisions of the 2018–2022 OPPS Rules have substantially impacted the day-to-day operations of many covered entities, including Plaintiffs. These Hospitals rely on the 340B savings, and the price differential Congress created through that program, to provide vital health services to their communities, including vulnerable and underserved populations within those communities. Elimination of the differential in connection with Medicare payments for 340B drugs have and will continue to threaten many of these critical programs, in direct contravention of the purpose and design of the 340B Program.

31. On November 16, 2021, CMS published the 2022 OPPS Rule, which "continues the 340B Program polies that were implemented in CY 2018 with the exception of the way we are

calculating payment for 340B-acquired biosimilars . . . and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off campus [Provider Based Departments] paid under the [Physician Fee Schedule]." 86 Fed. Reg. at 63,648.

ADMINISTRATIVE REVIEW OF PLAINTIFFS' CLAIMS FOR PAYMENT

32. After a health care provider performs Medicare-eligible services, it submits a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). The MAC makes an initial determination whether to pay the claim, and if so, how much to pay. *See* 42 C.F.R. § 405.920. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process. First, the provider may present its claim again to the MAC for "redetermination." *See* 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). *See* 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. Third, the provider may seek *de novo* review by an administrative law judge in the Office of Medicare Hearings and Appeals. *See* 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. § 405.1000–58. If, however, an appeal turns on a question of law or regulation and does not present any material disputes of fact, then after or simultaneous with requesting third-level review by an administrative law judge, a provider may ask the Departmental Appeals Board to certify the appeal for expedited access to judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A), (b)(2); 42 C.F.R. § 405.990. Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a part of the HHS Departmental Appeals Board. *See* 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

33. If HHS's final decision after this process is unfavorable, a provider may seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 1136.

A. Plaintiffs Presented Claims in Compliance with this Court's Decision in *AHA v. Azar*

34. Beginning in early 2018, Plaintiffs presented claims for payment to their respective MACs for separately payable drugs subject to the 340B Program.

35. Consistent with the payment reduction in the 340B Provisions of the 2018 and 2019 OPPS Rules, the MACs' payments on Plaintiffs' claims were approximately 30% less than what they had paid Plaintiffs on identical claims in 2017.

36. Following receipt of the MACs' initial determinations, Plaintiffs submitted redetermination requests to their MACs, challenging the reimbursement. On their redetermination request forms, Plaintiffs contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate violates 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the authority to pay for this drug, because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable data on acquisition cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

37. The MACs have issued unfavorable decisions on Plaintiffs' redetermination requests, stating in their notice of redetermination that the amount they had already paid was "the maximum payment allowed by Medicare" for the services at issue.

38. Plaintiffs timely filed their second level of appeal, submitting reconsideration requests regarding their claims to their respective Qualified Independent Contractors ("QICs"). In their reconsideration requests, Plaintiffs presented the same argument that they had raised in their redetermination requests to their MAC.

39. The QICs either dismissed or denied Plaintiffs' reconsideration requests.

40. In late 2018, Plaintiffs' MACs posted notices on their respective websites that all 340B Program claims appeals would be dismissed on the grounds that 42 U.S.C. § 1395w-4(i)(1) prohibits administrative and judicial review of these periodic adjustments.

B. Notices Issued To Plaintiffs Expressly Disclaimed Any Right to Appeal

41. Plaintiffs sought to exercise and exhaust their administrative rights by adhering to the Secretary's appeal process. At each level of appeal, however, Plaintiffs' bases for review were rejected.

42. Additionally, Plaintiffs' MACs issued and posted notices expressly disclaiming Plaintiffs' appeal rights, stating:

> **340B Acquired Drugs and Appeals**
>
> In accordance with Medicare's national payment policy an administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under Outpatient Prospective Payment System (OPPS).

WPS Appeals, Guides and Resources. Available at: https://www.wpsgha.com/wps/portal/mac/site/appeals/guides-and-resources/340b-acquired-drugs-appeals/ (last accessed June 13, 2021).

> ***Appeals***
>
> Providers and beneficiaries have the right to appeal claim determinations made by NGS. The purpose of the appeals process is to ensure correct adjudication of claims. . . .
>
> If the drug was not reimbursed by Medicare and you believe the drug should have been covered, you should consider filing an appeal. However, when a service is reimbursed in accordance with Medicare's National payment policy for 340B-acquired drugs, the amount paid is final. The method of reimbursement is not an appropriate reason for an appeal and an appeal will not be considered when submitted to dispute CMS' 340B national payment policy.

National Government Services, Medicare Monthly Review, Issue No. MMR 2018-07 (July 2018) Available at: https://www.adminastar.com/ngs/wcm/connect/ngsmedicare/a910c091-b2f6-4359-9352-aaf8cd64caff/1079_0718_mmr.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE.Z18_69MIG982N05UD0QGR5I7CS2000-a910c091-b2f6-4359-9352-aaf8cd64caff-mhrR0vb (last accessed June 13, 2021).

43. Other MACs, including Noridian, CGS, Novitas, and Palmetto, also informed Plaintiffs that they have no appeal rights, advising that all redetermination requests would be dismissed.

44. All Plaintiffs have presented specific claims for payment to the Secretary's agents and appealed the agents' initial determinations. All appeals have been dismissed and/or denied. Accordingly, any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS and its agents have taken the position that there is no administrative review of 340B Program reimbursement disputes.

45. Furthermore, on December 27, 2018, this Court concluded, in the context of reimbursement requests for CY 2018, that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22 percent for that year. *See Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018) (declaring rate reduction *ultra vires* and, therefore, not subject to the Medicare statute's preclusion on review), *rev'd, Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *decision pending*, No. 20-114 (U.S.). Recognizing the "havoc that piecemeal review of OPPS payment could bring about," the district court ordered supplemental briefing on the appropriate remedy. *Id.*

46. On May 6, 2019, after receiving the parties' briefing on the remedy, the court issued an opinion which reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019—which had been finalized since the district court's initial order was entered—also exceeded his authority. *See Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 6-10 (D.D.C. 2019), *rev'd, Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *cert. petition pending*, No. 20-114 (U.S.). The matter was thereafter remanded to HHS to devise an appropriate remedy. *Id.* at 10-15.

47. On July 10, 2019, following review of the Secretary's motion for reconsideration, the District Court entered judgment for the plaintiffs and relinquished jurisdiction to facilitate the appeal. *See Am. Hosp. Ass'n v. Azar*, No. 18-cv-2084, unpublished slip op. at 3-5 (D.D.C. July 10, 2019), available at 2019 WL 3037306. The consolidated appeal (docketed as USCA Case Nos. 19-5048 and 19-5198) was decided by the D.C. Circuit in favor of the Secretary, *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (2020). The Supreme Court granted a petition for certiorari review and its decision is currently pending (docketed as Case No. 20-1114).

48. Notwithstanding its stated intent to take steps necessary to adhere to the District Court's ruling on CY 2018 and CY 2019 340B rates, the Agency finalized in the CY 2020, CY 2021, and CY 2022 OPPS rules the decision to continue this payment policy and, further, to extend its application to non-excepted off-campus provider-based departments. The CY 2020–2022 provisions, like those in CY 2018 and CY 2019, unlawfully exceed the Secretary's authority. The continued reimbursement rate for 340B drugs violates 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the authority to pay for 340B and other covered outpatient drugs, because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable data on such cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily created 340B Program.

CAUSES OF ACTION

COUNT I:
2018 OPPS Rule – Violation of the Social Security Act

49. Plaintiffs repeat and reallege paragraphs 1–48 as if set forth fully herein.

50. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

51. The nearly 30% reduction in payment for 340B drugs under the 2018 OPPS Rule is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT II:
2019 OPPS Rule – Violation of the Social Security Act

52. Plaintiffs repeat and reallege paragraphs 1–51 as if set forth fully herein.

53. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

54. The 2019 OPPS Rule, which carried forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT III:
2020 OPPS Rule –Violation of the Social Security Act

55. Plaintiffs repeat and reallege paragraphs 1–54 as if set forth fully herein.

56. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

57. The 2020 OPPS Rule, which carries forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT IV:
2021 OPPS Rule –Violation of the Social Security Act

58. Plaintiffs repeat and reallege paragraphs 1–57 as if set forth fully herein.

59. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

60. The 2021 OPPS Rule, which carried forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT V:
2022 OPPS Rule –Violation of the Social Security Act

61. Plaintiffs repeat and reallege paragraphs 1–60 as if set forth fully herein.

62. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

63. The 2022 OPPS Rule, which carries forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in their favor and against Defendant:

A. Declaring that the 340B Provisions of the 2018–2022 OPPS Rules are an unlawful exercise of Defendant's authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendant to strike the changes in the payment methodology for section 340B drugs from the 2018–2022 OPPS Rules and directing Defendant to use the methodology used in calendar year 2017 for all 340B Program payments for claims reflecting service dates in 2018–2022;

C. Directing Defendant to reimburse all Plaintiffs for the difference between amounts paid for 340B drugs pursuant to the 2018–2022 OPPS Rules and what would have been paid for those same drugs under the methodology used in calendar year 2017;

D. Directing Defendant to conform the payment methodology that they use for 340B drugs in 2022 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition costs to calculate prices unless Defendant has complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I);

E. Granting Plaintiffs' statutory interest, costs and attorney fees in accordance with 42 U.S.C. § 1395*oo*(f)(2); and

F. Granting such other relief to which Plaintiffs may be entitled at law or in equity.

Dated this 13th day of May, 2022.

Respectfully Submitted,

/s/ Sara Jean MacCarthy

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Case No. _____

COMPLAINT

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UNIVERSITY OF ILLINOIS MEDICAL CENTER
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Plaintiffs,

vs.

ALEX M. AZAR II
Secretary of the United States Department of Health and Human Services
Room 700-E
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

COMPLAINT

The above-captioned 18 Plaintiff hospitals ("Plaintiffs" or "Hospitals"), by and through their undersigned counsel, bring this action against Alex M. Azar II, in his official capacity as the Secretary of the Department of Health and Human Services, and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (the "Medicare Act") and the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* (the "APA") to challenge provisions of final rules issued on November 1, 2017, November 1, 2018, and November 1, 2019, by the Centers for Medicare and Medicaid Services ("CMS"). *See* 82 Fed. Reg. 52,356, 52,493–511, 52,622–25 (Nov. 13, 2017); 83 Fed. Reg. 58,818, 58,981 (Nov. 21, 2018) and 84 Fed. Reg. 61,142, 61,317–27 (Nov. 12, 2019). The final rules concern the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Years ("CYs") 2018, 2019 and 2020. The portions of the challenged rules reduced by nearly 30% Medicare reimbursements to certain public and not-for-profit hospitals and clinics for prescription drugs purchased by those institutions on a discounted basis under section 340B of the Public Health Service Act (the "340B Program"). The Secretary, in exceeding his scope of authority under the Medicare Act and by reducing reimbursement payment for drugs purchased under the 340B Program, unlawfully infringed on the Plaintiffs' efforts to care for low-income and vulnerable patients, in contravention of Congress's intent in enacting the 340B Program. The challenged rules took effect on January 1, 2018, and January 1, 2019. The 2020 Rule will take effect on January 1, 2020, and it expands the covered entities subject to the reduction to include non-excepted off-campus provider-based departments.

2. Congress enacted the 340B Program in 1992 and through the Program lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. By lowering hospitals' purchase costs for patient drugs, 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 52,493 & n.18 (quoting House report and noting that "[t]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

3. Commencing January 1, 2018, CMS began reimbursing covered outpatient drugs and biologicals acquired through the 340B Program at average sales price (ASP) minus 22.5% when billed by a hospital paid under the OPPS. CMS continued this payment policy in CY 2019, and finalized in the CY 2020 OPPS Rule the decision to continue this payment policy and to extend it to non-excepted off-campus provider-based departments.

4. As explained in comments to the CY 2018 OPPS Rule, *see* 82 Fed. Reg. at 52,499–502, and in the lawsuits that followed its passage and application, the establishment of this improper rate exceeds the Secretary's authority, *see Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 79-83 (D.D.C. 2018)("*AHA I*") and *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019)("*AHA II*")(holding that the Secretary exceeded his authority when he reduced the 2018 and 2019 Medicare reimbursement rate for pharmaceutical drugs covered by the "340B Program" by nearly 30%.), *consolidated appeal docketed*, Nos. 19-5048 and 19-5198 (D.C. Cir. July 16, 2019).

5. In accordance with this Court's decisions in *AHA I* and *AHA II*, Plaintiffs bring this action to seek relief from the Secretary's prior actions and to secure injunctive relief from the 2020 OPPS Rule.

6. As noted above and as discussed in this Court's decisions in *AHA I* and *AHA II*, the 340B Program has lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. In 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). The 340B Provisions of the 2018, 2019 and 2020 OPPS Rules specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The 2018, 2019 and 2020 OPPS Rules eliminate nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated $3.2 billion, in violation of both the Secretary's statutory authority under the Social Security Act to reimburse hospitals for outpatient drugs and the purpose and design of the Public Health Service Act provisions establishing the 340B Program.

7. Plaintiffs have used the 340B Program to provide critical health care services to their communities. Those hospitals and their poor and underserved patient populations have suffered, and will continue to suffer, harm from the negation of the cost-reimbursement differential through the 340B Provisions of the 2018, 2019 and 2020 OPPS Rules.

8. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the 2020 OPPS Rule pending resolution of this action.

PARTIES

9. At all times relevant to this Complaint, Plaintiffs were qualified as Medicare-participating providers under the Medicare Act and have participated in the 340B Program.

10. Plaintiffs participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical

health care programs to the vulnerable populations they serve. Plaintiffs have been significantly harmed by the elimination of this differential from Medicare payments in the 2018 and 2019 OPPS Rules and will continue to be significantly harmed if those Rules, including the 2020 OPPS Rule, remain in effect.

11. The 340B Provisions of the 2018, 2019 and 2020 OPPS Rules severely threaten Plaintiffs' ability to provide critical health care programs to their communities, including the underserved populations in those communities, by depriving Plaintiffs of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

12. Defendant Alex M. Azar II ("the Secretary") is the Secretary of the Department of Health and Human Services, the federal department which encompasses CMS. The Secretary, the federal official responsible for the administration of the Medicare Program, has delegated to CMS the responsibility to administer that program. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

13. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*., section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Administrative Procedure Act, 5 U.S.C. §§ 701–06.

14. This Court has subject matter jurisdiction over this action under 42 U.S.C. § 405 and 28 U.S.C. § 1331.

15. This judicial district is an appropriate venue pursuant to 28 U.S.C. § 1391(e), 42 U.S.C. § 405(g), and 42 U.S.C. § 1395ff(b)(2)(C)(iii).

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

16. Congress established the 340B Program in 1992 as part of the Public Health Service Act. The 340B Program provides certain hospitals serving a disproportionate share of low-income individuals and federally-funded clinics (called "covered entities" in the statute) with outpatient prescription drug discounts comparable to those that Congress had made available to state Medicaid agencies in 1990. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). The purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

17. Since the 340B Program was first implemented, covered entities have retained all savings generated through the program and have used those savings to provide additional critical health care services for their communities, including underserved populations within those communities. Those critical health care services include the provision of patient education programs, translation services, transportation services and increased service locations.

18. Recognizing the value of the 340B Program, Congress has increased the categories of eligible "covered entities." In 1992, when Congress first created the Program, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and

sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O). Pursuant to the 2020 OPPS Rule, "covered entities" also include non-excepted off-campus provider-based departments. *See* 84 Fed. Reg. at 61,181.

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

B. Medicare OPPS Reimbursement

20. In 1997, Congress sought to control Medicare expenditures for outpatient services and directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

21. Beginning in 2004, Congress directed CMS to set reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled into the price of an outpatient service. These drugs include outpatient drugs covered under the 340B Program.

22. The statute provides two avenues to CMS for setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of the statute, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition costs are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition costs data are not available, CMS is required to reimburse based on average sales price ("ASP")—a defined quantity under a different statutory provision—plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

23. In 2012, after concluding that it could not obtain the acquisition cost required in order to reimburse under Subclause I based on acquisition cost, CMS adopted the reimbursement method under Subclause II—the statutory default rate of ASP plus 6%—for all separately payable

drugs. This statutory default rate was applied without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's Reduction to Payment Rate for 340B Drugs

24. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the CY 2018. In addition to updating the OPPS with 2018 rates, CMS proposed to change how Medicare pays certain hospitals for separately payable drugs purchased under the 340B Program. 82 Fed. Reg. 33,558, 33,634 (July 20, 2017). Specifically, it proposed to lower the Medicare reimbursement rate for such drugs from the previous rate of ASP plus 6% to ASP minus 22.5%—a reduction in the reimbursement rate of 28.5%. *Id.* at 33,634.

25. On November 13, 2017, CMS issued the final version of the 340B Provisions of the 2018 OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. at 52,362.

26. This new reimbursement rate nearly eliminated the benefit of the 340B Program for certain covered entities by eliminating the difference between the purchase price paid *by* hospitals for those drugs and Medicare payments *to* hospitals for those drugs.

27. For its authority to reduce the reimbursement rate for certain 340B drugs by nearly 30%, CMS purported to rely on 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which allows the Secretary to "calculate" and "adjust" the statutory default rate of ASP plus 6%. *See, e.g.*, 82 Fed. Reg. at 52,499 (noting that "calculate and adjust" authority gives the Secretary "broad discretion" to adjust payments for drugs). The 340B Provisions of the 2018 OPPS Rule exceed the Secretary's authority because the reduction set forth in the Rule is expressly based on the estimated acquisition costs of 340B drugs, *i.e.*, a variation of the cost-based methodology set forth under Subclause I of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *See, e.g.*, 82 Fed. Reg. at 52,501. Because CMS, by its own admission, cannot now and has never been able to reliably

collect the statistically significant cost data for each drug required under the statute to invoke Subclause I, it improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data in issuing the OPPS Rule – even though payment under Subclause II expressly must be based on average sales price, *not* acquisition costs. In doing so, the Secretary impermissibly invoked his authority under Subclause II to circumvent the requirements under Subclause I.

28. The Secretary's authority under Subclause II of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), to "calculate" and "adjust" the ASP-plus-6% formula, does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of drug-price savings totaling an estimated $1.6 billion (CMS's estimate). Rather, this authority only permits the Secretary to calculate the ASP as set forth in the statute and to fine-tune the default rate.

29. The 340B Provisions of the 2018 OPPS Rule also exceed the Secretary's authority because they undermine the 340B Program by depriving eligible hospitals of a critical portion of the resources Congress intended to provide those hospitals through 340B discounts. Elimination of these resources has and will continue to put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential health care services and programs to their communities, including underserved populations within those communities. This is inconsistent with the intent of the 340B Program, which was designed to help covered entities stretch scarce federal resources to reach more eligible patients. CMS's efforts in the 340B Provisions of the 2018 OPPS Rule to "align" (82 Fed. Reg. at 52,495) the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congress' intent to create a

differential between reimbursements and purchase prices and thereby to generate resources for covered entities to use in their communities.

30. The new payment rate set forth in the 340B Provisions of the 2018 and 2019 OPPS Rules have substantially impacted the day-to-day operations of many covered entities, including Plaintiffs. These Hospitals rely on the 340B savings, and the price differential Congress created through that program, to provide vital health services to their communities, including vulnerable and underserved populations within those communities. Elimination of the differential in connection with Medicare payments for 340B drugs have and will continue to threaten many of these critical programs, in direct contravention of the purpose and design of the 340B Program.

31. On November 12, 2019, CMS issued the 2020 OPPS Rule, which "continues the 340B Program polies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars . . . and continues the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off campus [Provider Based Departments] paid under the [Physician Fee Schedule]." 84 Fed. Reg. at 61,325.

ADMINISTRATIVE REVIEW OF PLAINTIFFS' CLAIMS FOR PAYMENT

32. After a health care provider performs Medicare-eligible services, it submits a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). The MAC makes an initial determination whether to pay the claim, and if so, how much to pay. *See* 42 C.F.R. § 405.920. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process. First, the provider may present its claim again to the MAC for "redetermination." *See* 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). *See* 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. Third, the provider may seek *de novo* review by an

administrative law judge in the Office of Medicare Hearings and Appeals. *See* 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. § 405.1000–58. If, however, an appeal turns on a question of law or regulation and does not present any material disputes of fact, then after or simultaneous with requesting third-level review by an administrative law judge, a provider may ask the Departmental Appeals Board to certify the appeal for expedited access to judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A), (b)(2); 42 C.F.R. § 405.990. Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a part of the HHS Departmental Appeals Board. *See* 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

33. If HHS's final decision after this process is unfavorable, a provider may seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 1136.

A. Plaintiffs Presented Claims in Compliance with this Court's Decision in *AHA v. Azar*

34. Beginning in early 2018, Plaintiffs presented claims for payment to their respective MACs for separately payable drugs subject to the 340B Program.

35. Consistent with the payment reduction in the 340B Provisions of the 2018 and 2019 OPPS Rules, the MACs' payments on Plaintiffs' claims were approximately 30% less than what they had paid Plaintiffs on identical claims in 2017.

36. Following receipt of the MACs' initial determinations, Plaintiffs submitted redetermination requests to their MACs, challenging the reimbursement. On their redetermination request forms, Plaintiffs contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate violates 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the authority to pay for this drug, because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable data on acquisition cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

37. The MACs have issued unfavorable decisions on Plaintiffs' redetermination requests, stating in their notice of redetermination that the amount they had already paid was "the maximum payment allowed by Medicare" for the services at issue.

38. Plaintiffs timely filed their second level of appeal, submitting reconsideration requests regarding their claims to their respective Qualified Independent Contractors ("QICs"). In their reconsideration requests, Plaintiffs presented the same argument that they had raised in their redetermination requests to their MAC.

39. The QICs either dismissed or denied Plaintiffs' reconsideration requests.

40. In late 2018, Plaintiffs' MACs posted notices on their respective websites that all 340B Program claims appeals would be dismissed on the grounds that 42 U.S.C. § 1395w-4(i)(1) prohibits administrative and judicial review of these periodic adjustments.

B. Notices Issued To Plaintiffs Expressly Disclaimed Any Right to Appeal

41. Plaintiffs sought to exercise and exhaust their administrative rights by adhering to the Secretary's appeal process. At each level of appeal, however, Plaintiffs' bases for review were rejected.

42. Additionally, Plaintiffs MACs issued and posted notices expressly disclaiming Plaintiffs' appeal rights, stating:

> **340B Acquired Drugs and Appeals**
>
> In accordance with Medicare's national payment policy an administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under the Outpatient Prospective Payment System (OPPS).

WPS Appeals, Guides and Resources. Available at: https://www.wpsgha.com/wps/portal/mac/site/appeals/guides-and-resources/340b-acquired-drugs-appeals/ (last accessed January 27, 2020)

> ***Appeals***
>
> Providers and beneficiaries have the right to appeal claim determinations made by NGS. The purpose of the appeals process is to ensure correct adjudication of claims. . . .
>
> If the drug was not reimbursed by Medicare and you believe the drug should have been covered, you should consider filing an appeal. However, when a service is reimbursed in accordance with Medicare's National payment policy for 340B-acquired drugs, the amount paid is final. The method of reimbursement is not an appropriate reason for an appeal and an appeal will not be considered when submitted to dispute CMS' 340B national payment policy.

National Government Services News and Alerts 340B-Acquired Drugs: Medicare Reimbursement and Appeals. Available at: https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/news-alerts/news-articles/news-detail/340b-acquired%20drugs%20medicare%20reimbursement%20and%20appeals (last accessed January 27, 2020)

43. Other MACs, including Noridian, CGS, Novitas, and Palmetto, also informed Plaintiffs that they have no appeal rights, advising that all redetermination requests would be dismissed.

44. All Plaintiffs have presented specific claims for payment to the Secretary's agents and appealed the agents' initial determinations. All appeals have been dismissed and/or denied. Accordingly, any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS and its agents have taken the position that there is no administrative review of 340B Program reimbursement disputes.

45. Furthermore, on December 27, 2018, this Court concluded, in the context of reimbursement requests for CY 2018, that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22 percent for that year. *See Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018)(declaring rate reduction *ultra vires* and, therefore, not subject to the Medicare statute's preclusion on

review). Recognizing the "havoc that piecemeal review of OPPS payment could bring about," the district court ordered supplemental briefing on the appropriate remedy. *Id.*

46. On May 6, 2019, after receiving the parties' briefing on the remedy, the court issued an opinion which reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019—which had been finalized since the district court's initial order was entered—also exceeded his authority. *See Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 6-10 (D.D.C. 2019). The matter was thereafter remanded to HHS to devise an appropriate remedy. *Id.* at 10-15.

47. On July 10, 2019, following review of the Secretary's motion for reconsideration, the District Court entered judgment for the plaintiffs and relinquished jurisdiction to facilitate the appeal. *See Am. Hosp. Ass'n v. Azar*, No. 18-cv-2084, unpublished slip op. at 3-5 (D.D.C. July 10, 2019), available at 2019 WL 3037306. The consolidated appeal (docketed as USCA Case Nos. 19-5048 and 19-5198) is pending before the D.C. Circuit on an expedited calendar.

48. Notwithstanding its stated intent to take steps necessary to adhere to the District Court's ruling on CY 2018 and CY 2019 340B rates, the Agency finalized in the CY 2020 OPPS rule the decision to continue this payment policy and, further, to extend its application to non-excepted off-campus provider-based departments. The CY 2020 provisions, like those in CY 2018 and CY 2019, unlawfully exceed the Secretary's authority. The continued reimbursement rate for 340B drugs violates 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the authority to pay for 340B and other covered outpatient drugs, because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable date on such cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily created 340B Program.

CAUSES OF ACTION

COUNT I:
2018 OPPS Rule – Violation of the Social Security Act

49. Plaintiffs repeat and reallege paragraphs 1–48 as if set forth fully herein.

50. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

51. The nearly 30% reduction in payment for 340B drugs under the 2018 OPPS Rule is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT II:
2019 OPPS Rule – Violation of the Social Security Act

52. Plaintiffs repeat and reallege paragraphs 1–51 as if set forth fully herein.

53. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

54. The 2019 OPPS Rule, which carried forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT III:
2020 OPPS Rule –Violation of the Social Security Act

55. Plaintiffs repeat and reallege paragraphs 1–54 as if set forth fully herein.

56. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

57. The 2020 OPPS Rule, which carries forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in their favor and against Defendant:

A. Declaring that the 340B Provisions of the 2018, 2019 and 2020 OPPS Rules are an unlawful exercise of Defendant's authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendant to strike the changes in the payment methodology for section 340B drugs from the 2018, 2019 and 2020 OPPS Rules and directing Defendant to use the methodology used in calendar year 2017 for all 340B Program payments for claims reflecting service dates in 2018, 2019 and 2020;

C. Directing Defendant to reimburse all Plaintiffs for the difference between amounts paid for 340B drugs pursuant to the 2018, 2019 and 2020 OPPS Rules and what would have been paid for those same drugs under the methodology used in calendar year 2017;

D. Directing Defendant to conform the payment methodology that they use for 340B drugs in 2020 and subsequent years to the requirements of the Social Security Act,

and specifically not to use acquisition costs to calculate prices unless Defendant have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I);

E. Granting Plaintiffs' statutory interest, costs and attorney fees in accordance with 42 U.S.C. § 1395*oo*(f)(2); and

F. Granting such other relief to which Plaintiffs may be entitled at law or in equity.

Dated this 28th day of January, 2020.

Respectfully Submitted,

/s/ Sara Jean MacCarthy

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA d/b/a/ UAB Hospital
619 19th Street South, MEB 300
Birmingham, AL 35249

THE HEALTH CARE AUTHORITY FOR BAPTIST HEALTH, AN AFFILIATE OF UAB HEALTH SYSTEM d/b/a Baptist Medical Center East
301 Brown Springs Road
Montgomery, AL 36117

THE HEALTH CARE AUTHORITY FOR BAPTIST HEALTH, AN AFFILIATE OF UAB HEALTH SYSTEM d/b/a Baptist Medical Center South
301 Brown Springs Road
Montgomery, AL 36117

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services
United States Department of Health & Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:22-cv-504

COMPLAINT

Plaintiffs, three 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 the U.S. Department of Health and 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 Year ("CY") 2021. 85 Fed. Reg., 85866, 86050 (Dec. 29, 2020) ("CY 2021 Final Rule" or "Final Rule"). Effective FY 2018 through the present, the Secretary has reduced payments for separately payable 340B acquired drugs to average sales price ("ASP") minus 22.5 percent, in contravention of the clear statutory requirements for calculating such reimbursement. *See* 42 U.S.C. § 1395l(t)(14)(A)(iii)(I)-(II); s*ee* 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") and 84 Fed. Reg. 61142, 61317-27 (Nov. 12, 2019) ("CY 2020 Final Rule").

2. Specifically, Plaintiffs challenge the Secretary's CY 2021 continuation of the policy to reduce Medicare reimbursement rates for prescription drugs purchased by certain public and not-for-profit hospitals and clinics on a discounted basis under section 340B of the Public Health Service Act ("PHSA") (the "340B Program"). 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

3. 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*, exceeded his scope of authority under the Medicare statute in contravention of Congressional intent, as well as acted arbitrarily and capriciously, by reducing reimbursement payment for drugs purchased under the 340B Program.

4. 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]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

5. 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) *rev'd on other grounds*, 967 F.3d 818 (D.C. Cir. 2020)).

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 ASP minus 22.5 percent. The Secretary extended that payment reduction through CYs 2019 and 2020. The CY 2020 Final Rule also extended the payment reduction to non-excepted off-campus provider-based departments.

7. The Secretary's CY 2021 Final Rule continues the policy to eliminate 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 for CY 2021, just

as in CYs 2018 through 2020, 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.

8. For CY 2021, Plaintiffs presented claims to the Secretary challenging the payment reduction pursuant to 42 U.S.C. § 1395ff. Further engagement of the Medicare appeals process for such claims is futile as the Secretary's policy has not changed and his contractors dismiss those claim appeals as not subject to review. *See* Exhibits A, B, and C.

9. This Court has found that 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 and *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019), *consolidated appeal rev'd*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021). In accordance with these two decisions, Plaintiffs bring this action to seek declaratory relief from the Secretary's 340B Program payment reduction for CY 2021. (The CY 2021 payment reduction is the same as the 2018, 2019 and 2020 reductions in all material respects.)

10. The CY 2021 Final Rule severely threatens Plaintiffs' ability to provide critical healthcare programs to their communities, including underserved populations, by depriving them of millions of dollars of savings previously generated through the difference between Medicare OPPS reimbursement rates and 340B discounts. These payment reductions are unlawful and the Secretary must pay Plaintiffs the statutorily-mandated rate of ASP plus 6 percent for all 340B drug claims submitted during CY 2021.

PARTIES

11. Plaintiffs are three hospitals that participate in the Medicare program and the

340B Program that are affected by the unlawful reimbursement cut for 340B drugs:

a. The Board of Trustees of The University of Alabama d/b/a UAB Hospital, Medicare Provider No. 01-0033;

b. The Health Care Authority for Baptist Health, an Affiliate of UAB Health System d/b/a Baptist Medical Center East, Medicare Provider No. 01-0149; and

c. The Health Care Authority for Baptist Health, an Affiliate of UAB Health System d/b/a Baptist Medical Center South, Medicare Provider No. 01-0023.

12. 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

13. This action arises under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C. § 1395, section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the APA, 5 U.S.C. § 551.

14. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, 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). Pursuant to the procedures of 42 U.S.C. § 1395ff, Plaintiffs presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the

Secretary's authority to reduce reimbursement for covered 340B drugs contrary to 42 U.S.C. § 1395*l*(t)(14)(A)(iii). *See* Exhibits A, B, and C. Further administrative appeal and review of Plaintiffs' claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule and the Secretary has already determined that he will not revise this policy, leaving Plaintiffs with no recourse other than federal court review. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 154 (D.D.C. 2019) *rev'd on other grounds*, 964 F.3d 1230 (D.C. Cir. 2020), *cert. denied sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2853 (2021), *reh'g denied sub nom. Am. Hosp. Assn. v. Becerra*, No. 20-1113, 2021 WL 3711645 (U.S. Aug. 23, 2021) (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). Additionally, the Secretary's contractors have received Plaintiffs' claims challenging the OPPS rates for drugs acquired under the 340B Program and have dismissed those challenges based on the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *See* Exhibit A.[1]

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

[1] The outcome of the redetermination requests for hospitals identified in Paragraph 11.b. and 11.c. remain pending before the Medicare Administrative Contractor. As described herein, the Medicare Administrative Contractor's dimissal of the redetermination request is forthcoming as it is bound by the Secretary's Final Rule and has expressly stated that it will dismiss all such claims on its website.

16. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this action occurred in this district.

17. 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 and 5 U.S.C. § 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

18. 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, *see* H.R. Rep. 102-384, at 12 (1992), and they cannot discriminate against covered entities in the distribution of drugs by, *e.g.*, setting minimum purchase amounts or treating covered entities differently from other purchasers during drug shortages, *see* 59 Fed. Reg. 25110, 25111 (May 13, 1994).

19. 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.

20. 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).

21. Plaintiffs are each a "covered entity" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement

22. 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.

23. 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*.

24. 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.

25. 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).

26. The Secretary has 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); *see also* 77 Fed. Reg. 68210, 68387-89 (Nov. 15, 2012) (acknowledging that hospital acquisition data is not available and adding the 6 percent to account for overhead and administrative costs).

27. There is no separate 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.

28. 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.*

29. The Secretary finalized this proposal on November 13, 2017 over the strong objection of commenters. 82 Fed. Reg. at 52362; *see also*, *e.g.*, Exhibit D (comments submitted to CY 2018 Final Rule). This significant change in reimbursement has effectively eliminated the

benefit of the 340B Program for covered entities like Plaintiff because it eliminates the difference between the steep discounts offered by the 340B Program and full OPPS reimbursement.

30. 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 (noting 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.*

31. The Secretary did not perform his own independent analysis of 340B discounts and instead applied MedPAC's estimate of the average 340B discount (22.5 percent) to the ASP. *See id*. However, "because the required acquisition cost was not available . . . and the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*." *Am. Hosp. Ass'n*, 348 F. Supp. 3d at 82 (emphasis original). Consequently, the Secretary impermissibly invoked authority under one section of the

statute to circumvent the requirements of another. The net effect is a third methodology that exists nowhere in the statute.

32. Under the binding statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the Secretary has no authority to reduce the statutory rate as he has in the Final Rule. As this Court has held, "the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not make 'basic and fundamental changes' under the purported auspices of making mere 'adjustments' to the rates statutorily imposed by that subsection." *Id.*, 348 F. Supp. 3d at 80; *see also id.*, 348 F. Supp. 3d at 81 ("the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining . . . rates, thereby exceeding the Secretary's authority to 'adjust' . . . .")

33. The Secretary's CY 2018 Final Rule also exceeds his authority in that it undermines the 340B Program by depriving eligible hospitals of a critical portion of resources Congress intended to provide those hospitals via the 340B Program. Elimination of these resources has put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential healthcare services and programs in their communities. Therefore, the Secretary's efforts to "align," 82 Fed. Reg. at 52495, the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congressional intent to create a differential between reimbursement and purchase price to generate additional resources for covered entities.

34. The detrimental and impermissible cuts were adopted again in CYs 2019 and 2020. *See* 83 Fed. Reg. at 58981 ("we are finalizing our proposals without modification [to] continu[e] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars"); *see also* 84 Fed. Reg. at 61325 ("we are

finalizing our proposal . . . to pay ASP minus 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus [provider-based departments] . . . [continuing] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars").

35. In CY 2021, the Secretary continued the policy to reduce Medicare reimbursement rates 340B drugs. *See* 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

C. Judicial Review and Plaintiff's Claim

36. A plaintiff must typically satisfy two requirements before seeking judicial review under 42 U.S.C. § 405(g): a plaintiff must "present" their 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).

37. The Plaintiff hospitals presented claims for payment to the Medicare program for their separately payable drugs affected by the Final Rule. For CY 2021, Medicare has paid drug claims submitted by the Plaintiff hospitals at ASP minus 22.5 percent.

38. The Plaintiff hospitals filed "Requests for Redetermination" to the Secretary's contractor pursuant to 42 U.S.C. § 1395ff. In these requests for administrative appeals of Medicare's failure to pay them the statutorily-prescribed rate for their services, Plaintiffs affirmatively presented a demand for proper payment and expressed dissatisfaction with the application of the Secretary's policy. *See* Exhibits A, B, and C (objecting to the ASP minus 22.5 percent payment rate as exceeding the Secretary's authority and requesting payment at ASP plus 6 percent).

39. The Secretary's contractor has denied the Plaintiffs' claims for the statutorily-required rate. *See id*.[2] The contractor dismissed the challenges to the OPPS rates for drugs acquired under the 340B Program under the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *Id*. Similarly, the Medicare contractor governing Plaintiffs' claims has a statement on its website stating that "[i]n accordance with Medicare's national payment policy for drugs acquired under the 340B drug program, drugs reimbursed under OPPS are not eligible for an administrative review. Appeal requests received by Palmetto GBA will be dismissed."[3]

40. Immediate judicial review is therefore appropriate because Plaintiffs' claims raise pure legal issues, there are no factual disputes that could impede their jurisdictional resolution, and there is nothing to indicate that the administrative appeals process could result in the agency overturning the Final Rule. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23-24 (D.D.C. 2009) ("exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to law" (quotation omitted)); *see also Am. Hosp. Ass'n*, 410

[2] *Id*.

[3] https://www.palmettogba.com/palmetto/jma.nsf/DIDC/B2RKND4347~Appeals~Frequently%20Asked%20Questions (February 25, 2022).

F. Supp. 3d at 154. As evidenced by the redetermination decisions and the posting on the contractor's website, the Secretary has taken the position that there can be no administrative review of 340B Program reimbursement disputes. Further administrative review is futile.

COUNT 1
CY 2021 Final Rule:
Violation of the Social Security Act and Administrative Procedure Act

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

42. 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).

43. 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*, 134 S. Ct. 2427, 2446 (2014).

44. 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 may adjust the average sales price. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Secretary's CY 2021 Final Rule, as a continuation of his CYs 2018, 2019, and 2020 Final Rules, did not utilize either method, but instead relied on an estimate of aggregate acquisition costs as a proxy for appropriate data. The Secretary's change to lower the

Medicare reimbursement rate for drugs purchased under the 340B Program to ASP minus 22.5 percent is therefore *ultra vires*, contrary to clear statutory directive, and beyond the Secretary's limited authority.

45. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

COUNT 2
CY 2021 Final Rule:
Violation of the Social Security Act and Administrative Procedure Act

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

47. The APA permits judicial review of agency actions, findings and conclusions that are "arbitrary, capricious" or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

48. The Secretary's decision in the CY 2021 Final Rule to continue to decrease reimbursement rates for separately payable drugs purchased under the 340B Program by nearly 30 percent impermissibly conflates two alternative statutory methods for setting payment rates and is therefore arbitrary and capricious and an abuse of discretion.

49. The Secretary's policy is also inconsistent with Congress's intent in enacting he 340B Program, which was to assist covered entities in "stretch[ing] 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.

50. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request an Order:

a. Declaring that the CY 2021 Final Rule is *ultra vires* and exceeds the Secretary's statutory authority in violation of the Social Security Act, as well as arbitrary and capricious in violation of the APA;

b. Vacating and setting aside the Final Rule as to the changes made to the 340B drug payment methodology;

c. Directing the Secretary to use the methodology used in CY 2017 for all 340B Program payments for dates of service in CY 2021;

d. Requiring the Secretary to reimburse Plaintiffs for the difference between amounts paid for 340B drugs pursuant to the Final Rule (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);

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

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

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

Respectfully submitted,

/s/ *Christopher P. Kenny*
Christopher P. Kenny (D.C. Bar No. 991303)
Mark D. Polston (D.C. Bar No. 431233)
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Date: February 25, 2022

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY 400 Cambridge Street Kansas City, KS 66160 Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services United States Department of Health & Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201 Defendant.	)	Civil Action No. 1:21-cv-3114

COMPLAINT

Plaintiff, a hospital that participates in the Medicare program and purchases drugs through the 340B Drug Pricing Program, brings this complaint against Defendant Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services ("Secretary"), and alleges as follows:

INTRODUCTION

1. Plaintiff seeks 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 Year ("CY") 2021. 85 Fed. Reg., 85866, 86050 (Dec. 29, 2020) ("CY 2021 Final Rule" or "Final Rule"). Effective FY 2018 through the present, the Secretary has reduced payments for separately payable 340B acquired drugs to average sales price ("ASP") minus 22.5 percent, in contravention of the clear statutory requirements for calculating such reimbursement. *See* 42 U.S.C. § 1395l(t)(14)(A)(iii)(I)-(II); s*ee* 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") and 84 Fed. Reg. 61142, 61317-27 (Nov. 12, 2019) ("CY 2020 Final Rule").

2. Specifically, Plaintiff challenges the Secretary's CY 2021 continuation of the policy to reduce Medicare reimbursement rates for prescription drugs purchased by certain public and not-for-profit hospitals and clinics on a discounted basis under section 340B of the Public Health Service Act ("PHSA") (the "340B Program"). 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

3. Plaintiff brings 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 Plaintiff alleges that the Secretary acted *ultra vires*, exceeded his scope of authority under the Medicare statute in contravention of Congressional intent, as well as acted arbitrarily and capriciously, by reducing reimbursement payment for drugs purchased under the 340B Program.

4. Congress enacted the 340B Program in 1992, lowering the cost of drugs for certain public and not-for-profit hospitals (like Plaintiff) 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]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

5. 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) *rev'd on other grounds*, 967 F.3d 818 (D.C. Cir. 2020)).

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 ASP minus 22.5 percent. The Secretary extended that payment reduction through CYs 2019 and 2020. The CY 2020 Final Rule also extended the payment reduction to non-excepted off-campus provider-based departments.

7. The Secretary's CY 2021 Final Rule continues the policy to eliminate 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 for CY 2021, just

as in CYs 2018 through 2020, 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.

8. For CY 2021, Plaintiff has presented claims to the Secretary challenging the payment reduction pursuant to 42 U.S.C. § 1395ff. Further engagement of the Medicare appeals process for such claims is futile as the Secretary's policy has not changed and his contractors have dismissed those claim appeals as not subject to review. *See* Exhibit A (Plaintiff submitted patient-level detail to the Secretary's contractor identifying affected claims for which the Plaintiff has been underpaid. Plaintiff omits that attachment from the Exhibit A of this Complaint due to the significant amount of protected health information contained therein, but can submit a redacted copy if requested by the Court.).

9. This Court has found that 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 and *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019), *consolidated appeal rev'd*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021). In accordance with these two decisions, Plaintiff brings this action to seek declaratory relief from the Secretary's 340B Program payment reduction for CY 2021. (The CY 2021 payment reduction is the same as the 2018, 2019 and 2020 reductions in all material respects.)

10. The CY 2021 Final Rule severely threatens Plaintiff's ability to provide critical healthcare programs to their communities, including underserved populations, by depriving it of millions of dollars of savings previously generated through the difference between Medicare OPPS reimbursement rates and 340B discounts. These payment reductions are unlawful and the

Secretary must pay Plaintiff the statutorily-mandated rate of ASP plus 6 percent for all 340B drug claims submitted during CY 2021.

PARTIES

11. Plaintiff, University of Kansas Hospital Authority, Medicare Provider No. 17-0040, is a hospital that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

12. 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

13. This action arises under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C. § 1395, section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the APA, 5 U.S.C. § 551.

14. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, Plaintiff has 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). Pursuant to the procedures of 42 U.S.C. § 1395ff, Plaintiff has presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to reduce reimbursement for covered 340B drugs contrary to 42 U.S.C. §

1395*l*(t)(14)(A)(iii). *See* Exhibit A. Further administrative appeal and review of Plaintiff's claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule and the Secretary has already determined that he will not revise this policy, leaving Plaintiff with no recourse other than federal court review. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 154 (D.D.C. 2019) *rev'd on other grounds*, 964 F.3d 1230 (D.C. Cir. 2020), *cert. denied sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2853 (2021), *reh'g denied sub nom. Am. Hosp. Assn. v. Becerra*, No. 20-1113, 2021 WL 3711645 (U.S. Aug. 23, 2021) (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). Additionally, the Secretary's contractors have received Plaintiff's claims challenging the OPPS rates for drugs acquired under the 340B Program and have dismissed those challenges based on the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *See* Exhibit A.

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

16. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this action occurred in this district.

17. 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 and 5 U.S.C. § 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

18. 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, *see* H.R. Rep. 102-384, at 12 (1992), and they cannot discriminate against covered entities in the distribution of drugs by, *e.g.*, setting minimum purchase amounts or treating covered entities differently from other purchasers during drug shortages, *see* 59 Fed. Reg. 25110, 25111 (May 13, 1994).

19. 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.

20. 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).

21. Plaintiff is a "covered entity" under the 340B Program and is paid under the OPPS system.

B. Medicare OPPS Reimbursement

22. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiff provides hospital services to Medicare beneficiaries that qualify for reimbursement through Medicare.

23. 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*.

24. 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.

25. 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).

26. The Secretary has 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); *see also*

77 Fed. Reg. 68210, 68387-89 (Nov. 15, 2012) (acknowledging that hospital acquisition data is not available and adding the 6 percent to account for overhead and administrative costs).

27. There is no separate 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.

28. 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.*

29. The Secretary finalized this proposal on November 13, 2017 over the strong objection of commenters. 82 Fed. Reg. at 52362; *see also*, *e.g.*, Exhibit B (comments submitted to CY 2018 Final Rule). This significant change in reimbursement has effectively eliminated the benefit of the 340B Program for covered entities like Plaintiff because it eliminates the difference between the steep discounts offered by the 340B Program and full OPPS reimbursement.

30. 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 (noting 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.*

31. The Secretary did not perform his own independent analysis of 340B discounts and instead applied MedPAC's estimate of the average 340B discount (22.5 percent) to the ASP. *See id*. However, "because the required acquisition cost was not available . . . and the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*." *Am. Hosp. Ass'n*, 348 F. Supp. 3d at 82 (emphasis original). Consequently, the Secretary impermissibly invoked authority under one section of the statute to circumvent the requirements of another. The net effect is a third methodology that exists nowhere in the statute.

32. Under the binding statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the Secretary has no authority to reduce the statutory rate as he has in the Final Rule. As this Court has held, "the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not make 'basic and fundamental changes' under the purported auspices of making mere 'adjustments' to the rates statutorily imposed by that subsection." *Id.*, 348 F. Supp. 3d at 80; *see*

also id., 348 F. Supp. 3d at 81 ("the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining . . . rates, thereby exceeding the Secretary's authority to 'adjust' . . . .")

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34. The detrimental and impermissible cuts were adopted again in CYs 2019 and 2020. *See* 83 Fed. Reg. at 58981 ("we are finalizing our proposals without modification [to] continu[e] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars"); *see also* 84 Fed. Reg. at 61325 ("we are finalizing our proposal . . . to pay ASP minus 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus [provider-based departments] . . . [continuing] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars").

35. In CY 2021, the Secretary continued the policy to reduce Medicare reimbursement rates 340B drugs. *See* 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

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36. A plaintiff must typically satisfy two requirements before seeking judicial review under 42 U.S.C. § 405(g): a plaintiff must "present" their 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).

37. The Plaintiff hospital has presented claims for payment to the Medicare program for its separately payable drugs affected by the Final Rule. For CY 2021, Medicare has paid drug claims submitted by the Plaintiff hospital at ASP minus 22.5 percent.

38. The Plaintiff hospital has filed "Requests for Redetermination" to the Secretary's contractor pursuant to 42 U.S.C. § 1395ff. In these requests for administrative appeals of Medicare's failure to pay them the statutorily-prescribed rate for their services, Plaintiff has affirmatively presented a demand for proper payment and expressed dissatisfaction with the application of the Secretary's policy. *See* Exhibit A (objecting to the ASP minus 22.5 percent payment rate as exceeding the Secretary's authority and requesting payment at ASP plus 6 percent).

39. The Secretary's contractor has denied the Plaintiff's claims for the statutorily-required rate. *See id*. The contractor dismissed the challenges to the OPPS rates for drugs acquired under the 340B Program under the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *Id*. Similarly, the Medicare contractor governing Plaintiff's claims has a statement on its website stating that "[i]n accordance with Medicare's national payment policy an administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under [the] Outpatient Prospective Payment System (OPPS)."[1]

40. Immediate judicial review is therefore appropriate because Plaintiff's claims raise pure legal issues, there are no factual disputes that could impede their jurisdictional resolution, and there is nothing to indicate that the administrative appeals process could result in the agency overturning the Final Rule. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23-24 (D.D.C. 2009) ("exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to law" (quotation omitted)); *see also Am. Hosp. Ass'n*, 410 F. Supp. 3d at 154. As evidenced by the redetermination decisions and the posting on the contractor's website, the Secretary has taken the position that there can be no administrative review of 340B Program reimbursement disputes. Further administrative review is futile.

COUNT 1
CY 2021 Final Rule:
Violation of the Social Security Act and Administrative Procedure Act

[1] https://www.wpsgha.com/wps/portal/mac/site/appeals/guides-and-resources/340b-acquired-drugsappeals/!ut/p/z1/jZBNDoIwEIXP4gGajlQJWzRKY2hwg9ZuTKW1NsGCBVx4eklcW5jN_7ycMCcyycfFsje9s4WY__RcTXI6UxXSaQFxEDSNnRHZJvsmKNT4HAAIZwWKOHv5cC0AUCE7Q9TAeMCkWdbZrBoZf9A1t0bzM1gle6QdAp53TWDr3SHOVnBDcnqNVivFVJMCPStlrW3VhUBKJ-U02VbZ9lyT85BZsuvsFdV1k!/dz/d5/L2dBISEvZ0FBIS9nQSEh/# (November 22, 2021).

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

42. 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).

43. 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*, 134 S. Ct. 2427, 2446 (2014).

44. 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 may adjust the average sales price. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Secretary's CY 2021 Final Rule, as a continuation of his CYs 2018, 2019, and 2020 Final Rules, did not utilize either method, but instead relied on an estimate of aggregate acquisition costs as a proxy for appropriate data. The Secretary's change to lower the Medicare reimbursement rate for drugs purchased under the 340B Program to ASP minus 22.5 percent is therefore *ultra vires*, contrary to clear statutory directive, and beyond the Secretary's limited authority.

45. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

COUNT 2
CY 2021 Final Rule:
Violation of the Social Security Act and Administrative Procedure Act

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

47. The APA permits judicial review of agency actions, findings and conclusions that are "arbitrary, capricious" or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

48. The Secretary's decision in the CY 2021 Final Rule to continue to decrease reimbursement rates for separately payable drugs purchased under the 340B Program by nearly 30 percent impermissibly conflates two alternative statutory methods for setting payment rates and is therefore arbitrary and capricious and an abuse of discretion.

49. The Secretary's policy is also inconsistent with Congress's intent in enacting he 340B Program, which was to assist covered entities in "stretch[ing] 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.

50. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests an Order:

a. Declaring that the CY 2021 Final Rule is *ultra vires* and exceeds the Secretary's statutory authority in violation of the Social Security Act, as well as arbitrary and capricious in violation of the APA;

b. Vacating and setting aside the Final Rule as to the changes made to the 340B drug payment methodology;

c. Directing the Secretary to use the methodology used in CY 2017 for all 340B Program payments for dates of service in CY 2021;

d. Requiring the Secretary to reimburse Plaintiff for the difference between amounts paid for 340B drugs pursuant to the Final Rule (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);

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

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

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

Respectfully submitted,

/s/ *Christopher P. Kenny*
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Mark D. Polston (D.C. Bar No. 431233)
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Date: November 24, 2021

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDERBILT UNIVERSITY MEDICAL CENTER 1211 Medical Center Drive Nashville, TN 37232 Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services United States Department of Health & Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201 Defendant.	Civil Action No. 1:21-cv-3246

COMPLAINT

Plaintiff, a hospital that participates in the Medicare program and purchases drugs through the 340B Drug Pricing Program, brings this complaint against Defendant Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services ("Secretary"), and alleges as follows:

INTRODUCTION

1. Plaintiff seeks 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 Year ("CY") 2021. 85 Fed. Reg., 85866, 86050 (Dec. 29, 2020) ("CY 2021 Final Rule" or "Final Rule"). Effective FY 2018 through the present, the Secretary has reduced payments for separately payable 340B acquired drugs to average sales price ("ASP") minus 22.5 percent, in contravention of the clear statutory requirements for calculating such reimbursement. *See* 42 U.S.C. § 1395l(t)(14)(A)(iii)(I)-(II); s*ee* 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") and 84 Fed. Reg. 61142, 61317-27 (Nov. 12, 2019) ("CY 2020 Final Rule").

2. Specifically, Plaintiff challenges the Secretary's CY 2021 continuation of the policy to reduce Medicare reimbursement rates for prescription drugs purchased by certain public and not-for-profit hospitals and clinics on a discounted basis under section 340B of the Public Health Service Act ("PHSA") (the "340B Program"). 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

3. Plaintiff brings 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 Plaintiff alleges that the Secretary acted *ultra vires*, exceeded his scope of authority under the Medicare statute in contravention of Congressional intent, as well as acted arbitrarily and capriciously, by reducing reimbursement payment for drugs purchased under the 340B Program.

4. Congress enacted the 340B Program in 1992, lowering the cost of drugs for certain public and not-for-profit hospitals (like Plaintiff) 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]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients").

5. 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) *rev'd on other grounds*, 967 F.3d 818 (D.C. Cir. 2020)).

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 ASP minus 22.5 percent. The Secretary extended that payment reduction through CYs 2019 and 2020. The CY 2020 Final Rule also extended the payment reduction to non-excepted off-campus provider-based departments.

7. The Secretary's CY 2021 Final Rule continues the policy to eliminate 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 for CY 2021, just

as in CYs 2018 through 2020, 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.

8. For CY 2021, Plaintiff has presented claims to the Secretary challenging the payment reduction pursuant to 42 U.S.C. § 1395ff. Further engagement of the Medicare appeals process for such claims is futile as the Secretary's policy has not changed and his contractors have dismissed those claim appeals as not subject to review. *See* Exhibit A (Plaintiff submitted patient-level detail to the Secretary's contractor identifying affected claims for which the Plaintiff has been underpaid. Plaintiff omits that attachment from the Exhibit A of this Complaint due to the significant amount of protected health information contained therein, but can submit a redacted copy if requested by the Court.).

9. This Court has found that 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 and *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019), *consolidated appeal rev'd*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021). In accordance with these two decisions, Plaintiff brings this action to seek declaratory relief from the Secretary's 340B Program payment reduction for CY 2021. (The CY 2021 payment reduction is the same as the 2018, 2019 and 2020 reductions in all material respects.)

10. The CY 2021 Final Rule severely threatens Plaintiff's ability to provide critical healthcare programs to their communities, including underserved populations, by depriving it of millions of dollars of savings previously generated through the difference between Medicare OPPS reimbursement rates and 340B discounts. These payment reductions are unlawful and the

Secretary must pay Plaintiff the statutorily-mandated rate of ASP plus 6 percent for all 340B drug claims submitted during CY 2021.

PARTIES

11. Plaintiff, Vanderbilt University Medical Center, Medicare Provider No. 44-0039, is a hospital that participates in the Medicare program and the 340B Program that is affected by the unlawful reimbursement cut for 340B drugs.

12. 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

13. This action arises under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C. § 1395, section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the APA, 5 U.S.C. § 551.

14. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, Plaintiff has 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). Pursuant to the procedures of 42 U.S.C. § 1395ff, Plaintiff has presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to reduce reimbursement for covered 340B drugs contrary to 42 U.S.C. §

1395*l*(t)(14)(A)(iii). *See* Exhibit A. Further administrative appeal and review of Plaintiff's claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule and the Secretary has already determined that he will not revise this policy, leaving Plaintiff with no recourse other than federal court review. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 154 (D.D.C. 2019) *rev'd on other grounds*, 964 F.3d 1230 (D.C. Cir. 2020), *cert. denied sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2853 (2021), *reh'g denied sub nom. Am. Hosp. Assn. v. Becerra*, No. 20-1113, 2021 WL 3711645 (U.S. Aug. 23, 2021) (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). Additionally, the Secretary's contractors have received Plaintiff's claims challenging the OPPS rates for drugs acquired under the 340B Program and have dismissed those challenges based on the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *See* Exhibit A.

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

16. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this action occurred in this district.

17. 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 and 5 U.S.C. § 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

18. 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, *see* H.R. Rep. 102-384, at 12 (1992), and they cannot discriminate against covered entities in the distribution of drugs by, *e.g.*, setting minimum purchase amounts or treating covered entities differently from other purchasers during drug shortages, *see* 59 Fed. Reg. 25110, 25111 (May 13, 1994).

19. 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.

20. 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).

21. Plaintiff is a "covered entity" under the 340B Program and is paid under the OPPS system.

B. Medicare OPPS Reimbursement

22. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiff provides hospital services to Medicare beneficiaries that qualify for reimbursement through Medicare.

23. 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*.

24. 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.

25. 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).

26. The Secretary has 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); *see also*

77 Fed. Reg. 68210, 68387-89 (Nov. 15, 2012) (acknowledging that hospital acquisition data is not available and adding the 6 percent to account for overhead and administrative costs).

27. There is no separate 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.

28. 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.*

29. The Secretary finalized this proposal on November 13, 2017 over the strong objection of commenters. 82 Fed. Reg. at 52362; *see also*, *e.g.*, Exhibit B (comments submitted to CY 2018 Final Rule). This significant change in reimbursement has effectively eliminated the benefit of the 340B Program for covered entities like Plaintiff because it eliminates the difference between the steep discounts offered by the 340B Program and full OPPS reimbursement.

30. 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 (noting 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.*

31. The Secretary did not perform his own independent analysis of 340B discounts and instead applied MedPAC's estimate of the average 340B discount (22.5 percent) to the ASP. *See id*. However, "because the required acquisition cost was not available . . . and the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*." *Am. Hosp. Ass'n*, 348 F. Supp. 3d at 82 (emphasis original). Consequently, the Secretary impermissibly invoked authority under one section of the statute to circumvent the requirements of another. The net effect is a third methodology that exists nowhere in the statute.

32. Under the binding statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the Secretary has no authority to reduce the statutory rate as he has in the Final Rule. As this Court has held, "the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not make 'basic and fundamental changes' under the purported auspices of making mere 'adjustments' to the rates statutorily imposed by that subsection." *Id.*, 348 F. Supp. 3d at 80; *see*

also id., 348 F. Supp. 3d at 81 ("the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining . . . rates, thereby exceeding the Secretary's authority to 'adjust' . . . .")

33. The Secretary's CY 2018 Final Rule also exceeds his authority in that it undermines the 340B Program by depriving eligible hospitals of a critical portion of resources Congress intended to provide those hospitals via the 340B Program. Elimination of these resources has put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential healthcare services and programs in their communities. Therefore, the Secretary's efforts to "align," 82 Fed. Reg. at 52495, the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congressional intent to create a differential between reimbursement and purchase price to generate additional resources for covered entities.

34. The detrimental and impermissible cuts were adopted again in CYs 2019 and 2020. *See* 83 Fed. Reg. at 58981 ("we are finalizing our proposals without modification [to] continu[e] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars"); *see also* 84 Fed. Reg. at 61325 ("we are finalizing our proposal . . . to pay ASP minus 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus [provider-based departments] . . . [continuing] the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars").

35. In CY 2021, the Secretary continued the policy to reduce Medicare reimbursement rates 340B drugs. *See* 85 Fed. Reg., at 86050 (continuing the Secretary's current policy of paying ASP minus 22.5 percent for 340B acquired drugs).

C. Judicial Review and Plaintiff's Claim

36. A plaintiff must typically satisfy two requirements before seeking judicial review under 42 U.S.C. § 405(g): a plaintiff must "present" their 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).

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39. The Secretary's contractor has denied the Plaintiff's claims for the statutorily-required rate. *See id*. The contractor dismissed the challenges to the OPPS rates for drugs acquired under the 340B Program under the statutory preclusion of administrative and judicial review under 42 U.S.C. Sections 1395ff and 1395oo. *Id*. Similarly, the Medicare contractor governing Plaintiff's claims has a statement on its website stating that "[i]n accordance with Medicare's national payment policy an administrative review is not available for applicable drugs acquired under the 340B drug program that are reimbursed under [the] Outpatient Prospective Payment System (OPPS)."[1]

40. Immediate judicial review is therefore appropriate because Plaintiff's claims raise pure legal issues, there are no factual disputes that could impede their jurisdictional resolution, and there is nothing to indicate that the administrative appeals process could result in the agency overturning the Final Rule. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23-24 (D.D.C. 2009) ("exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to law" (quotation omitted)); *see also Am. Hosp. Ass'n*, 410 F. Supp. 3d at 154. As evidenced by the redetermination decisions and the posting on the contractor's website, the Secretary has taken the position that there can be no administrative review of 340B Program reimbursement disputes. Further administrative review is futile.

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

[1]https://www.palmettogba.com/palmetto/providers.nsf/DocsR/Providers~JJ%20Part%20A~Browse%20by%20Topic~Appeals~B2RKND4347?open (December 10, 2021).

42. 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).

43. 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*, 134 S. Ct. 2427, 2446 (2014).

44. 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 may adjust the average sales price. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Secretary's CY 2021 Final Rule, as a continuation of his CYs 2018, 2019, and 2020 Final Rules, did not utilize either method, but instead relied on an estimate of aggregate acquisition costs as a proxy for appropriate data. The Secretary's change to lower the Medicare reimbursement rate for drugs purchased under the 340B Program to ASP minus 22.5 percent is therefore *ultra vires*, contrary to clear statutory directive, and beyond the Secretary's limited authority.

45. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

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CY 2021 Final Rule:
Violation of the Social Security Act and Administrative Procedure Act

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

47. The APA permits judicial review of agency actions, findings and conclusions that are "arbitrary, capricious" or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

48. The Secretary's decision in the CY 2021 Final Rule to continue to decrease reimbursement rates for separately payable drugs purchased under the 340B Program by nearly 30 percent impermissibly conflates two alternative statutory methods for setting payment rates and is therefore arbitrary and capricious and an abuse of discretion.

49. The Secretary's policy is also inconsistent with Congress's intent in enacting he 340B Program, which was to assist covered entities in "stretch[ing] 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.

50. For these and other reasons, the Secretary's rate cut in the CY 2021 Final Rule is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests an Order:

a. Declaring that the CY 2021 Final Rule is *ultra vires* and exceeds the Secretary's statutory authority in violation of the Social Security Act, as well as arbitrary and capricious in violation of the APA;

b. Vacating and setting aside the Final Rule as to the changes made to the 340B drug payment methodology;

c. Directing the Secretary to use the methodology used in CY 2017 for all 340B Program payments for dates of service in CY 2021;

d. Requiring the Secretary to reimburse Plaintiff for the difference between amounts paid for 340B drugs pursuant to the Final Rule (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);

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

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

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

Respectfully submitted,

/s/ *Christopher P. Kenny*
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