

**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)
1775 Dempster Street)
Park Ridge, IL 60068)

Case No. _____

COMPLAINT

ADVOCATE TRINITY HOSPITAL)
2320 East 93rd Street)
Chicago, IL 60617)

ALAMANCE REGIONAL MEDICAL CENTER)
1240 Huffman Mill Road)
Burlington, NC 27215)

AMITA HEALTH MERCY MEDICAL CENTER)
AURORA)
1325 North Highland Avenue)
Aurora, IL 60506)

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)

AMITA HEALTH ST. MARYS HOSPITAL)
KANKAKEE)
500 West Court Street)
Kankakee, IL 60901)
)
ASCENSION ALL SAINTS HOSPITAL - SPRING)
STREET CAMPUS)
3801 Spring Street)
Racine, WI 53405)
)
ASCENSION COLUMBIA SAINT MARY'S)
HOSPITAL MILWAUKEE)
2301 North Lake Drive)
Milwaukee, WI 53211)
)
ASCENSION NORTHEAST WISCONSIN SAINT)
ELIZABETH CAMPUS)
1506 South Oneida Street)
Appleton, WI 54915)
)
ASCENSION SACRED HEART HOSPITAL)
PENSACOLA)
5151 North Ninth Avenue)
Pensacola, FL 32504)
)
ASCENSION SAINT JOHN HOSPITAL)
22101 Moross)
Detroit, MI 48236)
)
ASCENSION SE WISCONSIN HOSPITAL - ST.)
JOSEPH CAMPUS)
5000 West Chambers Street)
Milwaukee, WI 53210)
)
ASCENSION SETON MEDICAL CENTER AUSTIN)
1201 West 38th Street)
Austin, TX 78705)
)
ASCENSION SETON NORTHWEST)
11113 Research Boulevard)
Austin, TX 78759)
)
ASCENSION ST. FRANCIS HOSPITAL)
3237 South 16th Street)
Milwaukee, WI 53215)
)

ASCENSION ST. MARY'S HOSPITAL)
800 South Washington Avenue)
Saginaw, MI 48601)

ASCENSION VIA CHRISTI HOSPITAL IN)
PITTSBURG)
1 Mount Carmel Way)
Pittsburg, KS 66762)

ASCENSION VIA CHRISTI HOSPITAL ST.)
FRANCIS)
929 North Saint Francis)
Wichita, KS 67214)

ATHENS-LIMESTONE HOSPITAL)
700 West Market Street)
Athens, AL 35611)

AURORA SAINT LUKE'S MEDICAL CENTER)
2900 West Oklahoma Avenue)
Milwaukee, WI 53215)

AURORA SHEBOYGAN MEMORIAL MEDICAL)
CENTER)
2629 North Seventh Street)
Sheboygan, WI 53083)

AURORA WEST ALLIS MEMORIAL HOSPITAL)
8901 West Lincoln Avenue)
West Allis, WI 53227)

AVERA MCKENNAN HOSPITAL & UNIVERSITY)
HEALTH CENTER)
1325 South Cliff Avenue)
Sioux Falls, SD 57117)

BAPTIST EASLEY HOSPITAL)
200 Fleetwood Drive)
Easley, SC 29640)

BAYHEALTH HOSPITAL, KENT CAMPUS)
640 South State Street)
Dover, DE 19901)

BAYHEALTH HOSPITAL, SUSSEX CAMPUS)
100 Wellness Way)
Milford, DE 19963)
)
BEAUMONT HOSPITAL – DEARBORN)
18101 Oakwood Boulevard)
Dearborn, MI 48124)
)
BEAUMONT HOSPITAL – FARMINGTON HILLS)
28050 Grand River Avenue)
Farmington Hills, MI 48336)
)
BEAUMONT HOSPITAL – GROSSE POINTE)
468 Cadieux Road)
Grosse Pointe, MI 48230)
)
BEAUMONT HOSPITAL – ROYAL OAK)
3601 West Thirteen Mile Road)
Royal Oak, MI 48073)
)
BEAUMONT HOSPITAL – TAYLOR)
10000 Telegraph Road)
Taylor, MI 48180)
)
BEAUMONT HOSPITAL – WAYNE)
33155 Annapolis Street)
Wayne, MI 48184)
)
BECKLEY ARH HOSPITAL)
306 Stanaford Road)
Beckley, WV 25801)
)
BETSY JOHNSON REGIONAL HOSPITAL)
800 Tilghman Drive)
Dunn, NC 28335)
)
BON SECOURS SAINT FRANCIS HOSPITAL)
2095 Henry Tecklenburg Drive)
Charleston, SC 29414)
)
BROCKTON HOSPITAL)
680 Centre Street)
Brockton, MA 02302)

BRONXCARE DR. MARTIN LUTHER KING, JR.)
HEALTH CENTER)
1276 Fulton Avenue)
Bronx, NY 10456)
)
CAPE FEAR VALLEY HOKE HOSPITAL)
210 Medical Pavilion Drive)
Raeford, NC 28376)
)
CAPE FEAR VALLEY MEDICAL CENTER)
1638 Owen Drive)
Fayetteville, NC 28304)
)
CLIFTON SPRINGS HOSPITAL AND CLINIC)
2 Coulter Road)
Clifton Springs, NY 14432)
)
COLUMBUS REGIONAL HOSPITAL)
2400 East 17th Street)
Columbus, IN 47201)
)
COMMUNITY HOSPITAL ANDERSON)
1515 North Madison Avenue)
Anderson, IN 46011)
)
COMMUNITY HOSPITAL EAST)
1500 North Ritter Avenue)
Indianapolis, IN 46219)
)
COMMUNITY HOSPITAL NORTH)
7150 Clearvista Drive)
Indianapolis, IN 46256)
)
COMMUNITY HOWARD REGIONAL HEALTH)
3500 South Lafountain Street)
Kokomo, IN 46902)
)
COOKEVILLE REGIONAL MEDICAL CENTER)
1 Medical Center Boulevard)
Cookeville, TN 38501)
)
D. W. MCMILLAN MEMORIAL HOSPITAL)
1301 Belleville Avenue)
Brewton, AL 36426)

DALLAS COUNTY HOSPITAL DISTRICT)
5200 Harry Hines Boulevard)
Dallas, TX 75235)
)
DAY KIMBALL HOSPITAL)
320 Pomfret Street)
Putnam, CT 06260)
)
DENVER HEALTH)
777 Bannock Street)
Denver, CO 80204)
)
EAST ALABAMA MEDICAL CENTER)
2000 Pepperall Pkwy)
Opelika, AL 36801)
)
EAST ALABAMA MEDICAL CENTER-LANIER)
4800 48th Street)
Valley, AL 36854)
)
EPHRAIM MCDOWELL REGIONAL MEDICAL)
CENTER)
217 South Third Street)
Danville, KY 40422)
)
FIRELANDS REGIONAL MEDICAL CENTER -)
MAIN CAMPUS)
1111 Hayes Avenue)
Sandusky, OH 44870)
)
FISHER-TITUS MEDICAL CENTER)
272 Benedict Avenue)
Norwalk, OH 44857)
)
FORREST GENERAL HOSPITAL)
6051 U.S. Highway 49)
Hattiesburg, MS 39401)
)
FRANCISCAN HEALTH HAMMOND)
5454 Hohman Avenue)
Hammond, IN 46320)
)
FRANCISCAN HEALTH LAFAYETTE EAST)
1701 South Creasy Lane)
Lafayette, IN 47905)

FRANCISCAN HEALTH MICHIGAN CITY)
3500 Franciscan Way)
Michigan City, IN 46360)
)
FRANCISCAN HEALTH OLYMPIA FIELDS)
CAMPUS)
20201 South Crawford Avenue)
Olympia Fields, IL 60461)
)
FRANKLIN WOODS COMMUNITY HOSPITAL)
300 MedTech Parkway)
Johnson City, TN 37604)
)
FROEDTERT HOSPITAL)
9200 West Wisconsin Avenue)
Milwaukee, WI 53226)
)
GOOD SAMARITAN REGIONAL MEDICAL)
CENTER)
3600 Northwest Samaritan Drive)
Corvallis, OR 97330)
)
GREENVILLE MEMORIAL HOSPITAL)
701 Grove Road)
Greenville, SC 29605)
)
GREER MEMORIAL HOSPITAL)
830 South Buncombe Road)
Greer, SC 29650)
)
GUNDERSEN LUTHERAN MEDICAL CENTER)
1900 South Avenue)
La Crosse, WI 54601)
)
HARLAN ARH HOSPITAL)
81 Ball Park Road)
Harlan, KY 40831)
)
HAZARD ARH REGIONAL MEDICAL CENTER)
100 Medical Center Drive)
Hazard, KY 41701)
)
HELEN KELLER HOSPITAL)
1300 South Montgomery Avenue)
Sheffield, AL 35660)

HIGHLANDS ARH REGIONAL MEDICAL)
CENTER)
5000 Kentucky Route 321)
Prestonburg, KY 41653)
)
HILLSDALE HOSPITAL)
168 South Howell St.)
Hillsdale, MI 49242)
)
HOLSTON VALLEY MEDICAL CENTER)
130 West Ravine Road)
Kingsport, TN 37660)
)
INDIAN PATH COMMUNITY HOSPITAL)
2000 Brookside Drive)
Kingsport, TN 37660)
)
IU HEALTH BALL MEMORIAL HOSPITAL)
2401 West University Avenue)
Munice, IN 47303)
)
IU HEALTH BLOOMINGTON HOSPITAL)
601 West Second Street)
Bloomington, IN 47403)
)
IU HEALTH METHODIST HOSPITAL)
1701 North Senate Boulevard)
Indianapolis, IN 46202)
)
JOHNSON CITY MEDICAL CENTER)
400 North State of Franklin Road)
Johnson City, TN 37604)
)
LAKELAND MEDICAL CENTER, SAINT JOSEPH)
1234 Napier Avenue)
St. Joseph, MI 49085)
)
LEHIGH VALLEY HOSPITAL - CEDAR CREST)
1200 South Cedar Crest Boulevard)
Allentown, PA 18103)
)
LEHIGH VALLEY HOSPITAL - HAZLETON)
1700 East Broad Street.)
Hazleton, PA 18201)

LEHIGH VALLEY HOSPITAL - POCONO)
206 East Brown Street)
East Stroudsburg, PA 18301)
)
LEHIGH VALLEY HOSPITAL-SCHUYLKILL S.)
JACKSON STREET)
420 South Jackson Street)
Pottsville, PA 17901)
)
LENOX HILL HOSPITAL)
100 East 77th Street)
New York, NY 10075)
)
LONESOME PINE HOSPITAL)
1990 Holton Avenue)
Big Stone Gap, VA 24219)
)
LONG ISLAND JEWISH MEDICAL CENTER)
270-05 76th Avenue)
New Hyde Park, NY 11040)
)
LOWELL GENERAL HOSPITAL - MAIN CAMPUS)
295 Varnum Avenue)
Lowell, MA 01854)
)
MADISON HEALTH)
210 North Main Street)
London, OH 43140)
)
MARSHALL MEDICAL CENTER SOUTH)
2505 US Highway 431)
Boaz, AL 35957)
)
MEMORIAL HOSPITAL)
615 North Michigan Street)
South Bend, IN 46601)
)
MEMORIAL HOSPITAL AT GULFPORT)
4500 Thirteenth Street)
Gulfport, MS 39501)
)
METHODIST HOSPITAL)
1305 North Elm Street)
Henderson, KY 42420)

MIAMI VALLEY HOSPITAL)
 One Wyoming Street)
 Dayton, OH 45409)
)
 MIDDLESBORO ARH HOSPITAL)
 3600 West Cumberland Avenue)
 Middlesboro, KY 40965)
)
 MIDMICHIGAN MEDICAL CENTER - GRATIOT)
 300 East Warwick Drive)
 Alma, MI 48801)
)
 NORTH SHORE UNIVERSITY HOSPITAL)
 300 Community Drive)
 Manhasset, NY 11030)
)
 NORTON COMMUNITY HOSPITAL)
 100 15th Street Northwest)
 Norton, VA 24273)
)
 NORTON HOSPITAL)
 200 East Chestnut Street)
 Louisville, KY 40202)
)
 OUR LADY OF LOURDES MEMORIAL HOSPITAL)
 169 Riverside Drive)
 Binghamton, NY 13905)
)
 PARKVIEW HUNTINGTON HOSPITAL)
 2001 Stults Road)
 Huntington, IN 46750)
)
 PARKVIEW NOBLE HOSPITAL)
 401 Sawyer Road)
 Kendallville, IN 46755)
)
 PARKVIEW REGIONAL MEDICAL CENTER)
 11109 Parkview Plaza Drive)
 Fort Wayne, IN 46845)
)
 PARKVIEW WHITLEY HOSPITAL)
 1260 East State Road 205)
 Columbia City, IN 46725)

PENN STATE HEALTH MILTON S. HERSHEY)
MEDICAL CENTER)
500 University Drive)
Hershey, PA 17033)

PENN STATE HEALTH SAINT JOSEPH - MAIN)
CAMPUS)
2500 Bernville Road)
Reading, PA 19605)

PHELPS MEMORIAL HOSPITAL CENTER)
701 North Broadway)
Sleepy Hollow, NY 10591)

PRINCETON COMMUNITY HOSPITAL)
122 Twelfth Street)
Princeton, WV 24740)

PRISMA HEALTH RICHLAND HOSPITAL)
5 Richland Medical Park Drive)
Columbia, SC 29203)

PUNXSUTAWNEY AREA HOSPITAL)
81 Hillcrest Drive)
Punxsutawney, PA 15767)

REGIONAL MEDICAL CENTER)
106 Blanca Avenue)
Alamosa, CO 81101)

RHODE ISLAND HOSPITAL)
593 Eddy Street)
Providence, RI 02903)

RIVERSIDE REGIONAL MEDICAL CENTER)
500 J. Clyde Morris Boulevard)
Newport News, VA 23601)

RMC ANNISTON)
400 East Tenth Street)
Anniston, AL 36202)

ROCHESTER GENERAL HOSPITAL)
1425 Portland Avenue)
Rochester, NY 14621)

SAINT CATHERINE HOSPITAL)
4321 Fir Street)
East Chicago, IN 46312)
)
SAINT JOSEPH'S UNIVERSITY MEDICAL)
CENTER)
703 Main Street)
Paterson, NJ 07503)
)
SAINT MARY'S HOSPITAL AT AMSTERDAM)
427 Guy Park Avenue)
Amsterdam, NY 12010)
)
SAINT TAMMANY PARISH HOSPITAL)
1202 South Tyler Street)
Covington, LA 70433)
)
SAINT THOMAS RIVER PARK HOSPITAL)
1559 Sparta Road)
McMinnville, TN 37110)
)
SAINT VINCENT ANDERSON)
2015 Jackson Street)
Anderson, IN 46016)
)
SAINT VINCENT EVANSVILLE)
3700 Washington Avenue)
Evansville, IN 47750)
)
SAINT VINCENT INDIANAPOLIS HOSPITAL)
2001 West 86th Street)
Indianapolis, IN 46260)
)
SAMARITAN ALBANY GENERAL HOSPITAL)
1046 Southwest Sixth Avenue)
Albany, OR 97321)
)
SANFORD BISMARCK MEDICAL CENTER)
300 North Seventh Street)
Bismarck, ND 58501)
)
SANFORD MEDICAL CENTER FARGO)
5225 23rd Avenue South)
Fargo, ND 58104)

SANFORD USD MEDICAL CENTER SIOUX)
 FALLS)
 1305 West 18th Street)
 Sioux Falls, SD 57117)
)
 SCHNECK MEDICAL CENTER)
 411 West Tipton Street)
 Seymour, IN 47274)
)
 SOUTHSIDE HOSPITAL)
 301 East Main Street)
 Bay Shore, NY 11706)
)
 SPECTRUM HEALTH UNITED HOSPITAL)
 615 South Bower Street)
 Greenville, MI 48838)
)
 STATEN ISLAND UNIVERSITY HOSPITAL)
 475 Seaview Avenue)
 Staten Island, NY 10305)
)
 TALLAHASSEE MEMORIAL HEALTHCARE)
 1300 Miccosukee Road)
 Tallahassee, FL 32308)
)
 TAYLOR REGIONAL HOSPITAL)
 1700 Old Lebanon Road)
 Campbellsville, KY 42718)
)
 THE MOSES H. CONE MEMORIAL HOSPITAL)
 1200 North Elm Street)
 Greensboro, NC 27401)
)
 THE UNIVERSITY OF TOLEDO MEDICAL)
 CENTER)
 3000 Arlington Avenue)
 Toledo, OH 43614)
)
 TUG VALLEY ARH REGIONAL MEDICAL)
 CENTER)
 260 Hospital Drive)
 South Williamson, KY 41503)
)
 TWIN LAKES REGIONAL MEDICAL CENTER)
 910 Wallace Avenue)
 Leitchfield, KY 42754)

UMASS MEMORIAL HEALTHALLIANCE –)
CLINTON HOSPITAL – LEOMINSTER CAMPUS)
60 Hospital Road)
Leominster, MA 01453)
)
UMASS MEMORIAL MARLBOROUGH HOSPITAL)
157 Union Street)
Marlborough, MA 01752)
)
UMASS MEMORIAL MEDICAL CENTER –)
UNIVERSITY CAMPUS)
55 Lake Avenue North)
Worcester, MA 01655)
)
UNION HOSPITAL)
1606 North Seventh Street)
Terre Haute, IN 47804)
)
UNIONTOWN HOSPITAL)
500 West Berkeley Street)
Uniontown, PA 15401)
)
UNITED MEMORIAL MEDICAL CENTER)
127 North Street)
Batavia, NY 14020)
)
UNITY HOSPITAL)
1555 Long Pond Road)
Rochester, NY 14626)
)
UNIVERSITY OF ILLINOIS MEDICAL CENTER)
1740 West Taylor Street)
Chicago, IL 606012)
)
UNIVERSITY MEDICAL CENTER AT)
BRACKENRIDGE)
601 East 15th Street)
Austin, TX 78701)
)
WAKE FOREST BAPTIST MEDICAL CENTER)
Medical Center Boulevard)
Winston-Salem, NC 27157)
)
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 151 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, and December 4, 2020 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); and 85 Fed. Reg. 85,866, 86,038 (Dec. 29, 2020). 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 and 2021. 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 Rule continues 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, 2018; January 1, 2019; January 1, 2020; and January 1, 2021.

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, CY 2020, and CY 2021. 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), *cert. petition 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 2021 OPSS 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, 2020, and 2021 OPSS Rules specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The 2018– 2021 OPSS 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 2018–2021 OPSS Rules.

8. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the 2021 OPSS 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 2018–2021 OPSS Rules and will continue to be significantly harmed if those Rules remain in effect.

11. The 340B Provisions of the 2018–2021 OPSS 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. § 1395l. 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. § 1395I(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. § 1395I(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. § 1395l(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 OPSS 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. § 1395l(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 OPSS 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. § 1395l(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 OPSS 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 OPSS 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 2018–2021 OPSS 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 December 29, 2020, CMS published the 2021 OPSS Rule, which "continues the 340B Program policies 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]." 85 Fed. Reg. at 86,053.

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 OPSS 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. § 1395l(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), *cert. petition 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), and a petition for certiorari review is currently pending before the Supreme Court (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 and CY 2021 OPSS 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 and CY 2021 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. § 1395l(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 OPSS 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 OPSS 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. § 1395l(t)(14)(A)(iii).

**COUNT II:
2019 OPPTS 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 OPPTS Rule, which carried forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPTS 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. § 1395l(t)(14)(A)(iii).

**COUNT III:
2020 OPPTS 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 OPPTS Rule, which carries forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPTS 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. § 1395l(t)(14)(A)(iii).

**COUNT IV:
2021 OPPTS 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 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. § 1395l(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, 2020 and 2021 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, 2020 and 2021 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, 2020 and 2021;
- C. Directing Defendant to reimburse all Plaintiffs for the difference between amounts paid for 340B drugs pursuant to the 2018, 2019, 2020 and 2021 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 2021 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. § 1395l(t)(14)(A)(iii)(I);

- E. Granting Plaintiffs' statutory interest, costs and attorney fees in accordance with 42 U.S.C. § 1395oo(f)(2); and
- F. Granting such other relief to which Plaintiffs may be entitled at law or in equity.

Dated this 18th day of June, 2021.

Respectfully Submitted,

/s/ Sara Jean MacCarthy

Sara Jean MacCarthy, D.C. Bar No. WI0037

Daniel F. Miller, D.C. Bar No. WI0032

Heather D. Mogden, D.C. Bar No. WI0039

HALL, RENDER, KILLIAN, HEATH &
LYMAN, P.C.

330 East Kilbourn Avenue, Suite 1250

Milwaukee, WI 53202

Telephone: (414) 721-0442

Facsimile: (414) 721-0491

Email: smacCarthy@hallrender.com

Email: dmiller@hallrender.com

Email: hmogden@hallrender.com

Attorneys for Plaintiffs