UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, NW, Suite 100
Washington, DC 20001,

AMERICA'S ESSENTIAL HOSPITALS,
401 Ninth Street, NW, Suite 900
Washington, DC 20004,

EASTERN MAINE HEALTHCARE SYSTEMS,
43 Whiting Hill Road
Brewer, ME 04412,

HENRY FORD HEALTH SYSTEM,
1 Ford Place
Detroit, MI 48202, and

FLETCHER HOSPITAL, INC., d/b/a PARK RIDGE HEALTH,
100 Hospital Drive
Hendersonville, NC 28792,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. _____

COMPLAINT

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc. d/b/a Park Ridge Health bring this action against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of HHS, and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under the Social Security Act and the Administrative Procedure Act ("APA") to challenge certain provisions of a final rule issued on November 1, 2017, by the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS. *See* 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017). The rule concerns the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Year 2018. The portions of the rule being challenged in this case 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"). These challenged portions of the rule will hereafter be referred to as the "340B Provisions of the OPPS Rule" or "the OPPS Rule." The 340B Provisions of the OPPS Rule took effect on January 1, 2018.

2. Congress enacted the 340B Program in 1992 and through that 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"). The 340B Provisions of the new OPPS Rule specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The new OPPS Rule eliminates nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated (by CMS) $1.6 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.

3. Plaintiffs American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals (the "Association Plaintiffs") are hospital associations whose members, including Plaintiffs Eastern Maine Healthcare Systems, Park Ridge Health, and Henry Ford Health System (the "Hospital Plaintiffs"), have used the 340B Program to provide critical healthcare services to their communities, including to underserved patient populations in those 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 OPPS Rule. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the OPPS Rule pending resolution of this action.

PARTIES

4. Plaintiff American Hospital Association ("AHA") is a national not-for-profit organization headquartered in Washington, D.C. AHA represents and serves nearly 5,000

hospitals, health care systems, and networks, plus 43,000 individual members (largely hospital professional staff). AHA's mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to their communities and committed to health improvement. AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

5. Many of AHA's member hospitals 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 for the vulnerable populations they serve. These AHA members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

6. Plaintiff Association of American Medical Colleges ("AAMC") is a national not-for-profit association headquartered in Washington, D.C. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its membership consists of all 151 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

7. Many of AAMC's member teaching hospitals 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 for their communities, including vulnerable populations in those communities. These AAMC members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

8. Plaintiff America's Essential Hospitals ("AEH") is a national not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its 325 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

9. Almost all of AEH's member hospitals 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 for the communities they serve, including vulnerable populations within those communities. These AEH members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

10. Plaintiff Eastern Maine Healthcare Systems ("EMHS") is an integrated health care system headquartered in Brewer, Maine, near Bangor, Maine, and is a member of the Plaintiff AHA. EMHS provides services throughout virtually the entire State of Maine – including both the urban populations in south and central Maine and the rural populations

residing in Maine's economically challenged northern and eastern regions. EMHS-affiliated entities employ over 700 physicians providing access to care for the 93% of Maine's population living in EMHS service areas.

11. Maine has the oldest population of any state and the largest percentage of Medicare eligible citizens in the nation. A large percentage of EMHS's services is provided to elderly and disadvantaged populations.

12. The 340B Provisions of the OPPS Rule severely threaten EMHS's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

13. Plaintiff Henry Ford Health System ("Henry Ford") is a not-for-profit integrated health care delivery system headquartered in Detroit, Michigan. Henry Ford serves the metropolitan Detroit and Jackson areas of Michigan. The system has 30,000 employees, 26 medical centers, six acute care hospitals with a total of 2,405 inpatient beds, including its flagship hospital—Henry Ford Hospital ("HFH")—a large academic safety net hospital located within the city of Detroit, and Henry Ford Allegiance, ("HF Allegiance") located in the city of Jackson. HFH is a member of Plaintiffs AHA, AAMC, and AEH. HF Allegiance is a member of Plaintiff AHA.

14. Located in Detroit's Midtown, HFH has served the Detroit community—which has the highest rate of concentrated poverty among the top 25 metro areas in the United States—for over 100 years. HFH is an 877-bed tertiary care hospital, education and research center, which provides comprehensive and advanced inpatient and outpatient care. HFH is also a Level 1 trauma center and one of the largest U.S. teaching hospitals.

15. Located in Jackson, HF Allegiance is a 475-bed healthcare organization that has served as the sole health system for the south central Michigan community since 1918. With more than 400 physicians, HF Allegiance's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28,000 and a 36% poverty rate.

16. By depriving Henry Ford of millions of dollars previously generated by the differential between Medicare reimbursements and 340B discounts, the 340B Provisions of the OPPS Rule severely threaten the ability of Henry Ford, including HFH and HF Allegiance, to provide critical healthcare programs to their communities, including the underserved populations in those communities.

17. Plaintiff Park Ridge Health ("Park Ridge") is a not-for-profit health care system headquartered in Hendersonville, North Carolina, south of Asheville, North Carolina, and is a member of the Plaintiff AHA. Park Ridge employs 119 doctors, nurses and other healthcare professionals who practice at 30 locations across Henderson, Buncombe, and Haywood Counties. Park Ridge is part of Adventist Health System ("AHS"), a network of approximately 45 Seventh-day Adventist-affiliated hospitals, as well as skilled nursing facilities, physician offices, home health agencies, hospice providers, and urgent care facilities in nine states.

18. The communities Park Ridge serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 52% of Park Ridge's gross revenues. The 340B Provisions of the OPPS Rule severely threaten Park Ridge's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by

depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

19. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, SW, Washington, D.C. 20201. CMS, which issued the 340B Provisions of the OPPS Rule, is an agency within HHS.

20. Defendant Alex M. Azar II ("the Secretary") is the Secretary of Health and Human Services") and maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

21. 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.

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

23. 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

24. 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). As the Health Resources & Services Administration ("HRSA"), the agency within HHS responsible for administering the 340B Program, has recognized, 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.

25. 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 healthcare services for their communities, including underserved populations within those communities − for example, by increasing service locations, developing patient education programs, and providing translation and transportation services.

26. 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).

27. Each of the Hospital Plaintiffs and many other members of the Association Plaintiffs are "covered entities" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement

28. In 1997, Congress acted 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, for example rehabilitation services. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

29. Beginning in 2004, Congress required 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.

30. A provision of the statute provides CMS with two choices in setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of that statutory provision, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition cost are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition cost 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).

31. 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. CMS applied this statutory default rate without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's Proposed and Final Rule to Reduce Payment Rate for 340B Drugs

32. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the Calendar Year 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, CMS proposed lowering the government payment rate for such drugs from the previous (statutory default) rate of ASP plus 6% to ASP minus 22.5% - a reduction in the reimbursement rate of 28.5 %. *Id.* at 33,634.

33. CMS admitted that its reason for proposing this reduction was that a lower reimbursement rate would better reflect the acquisition cost of the drugs. According to CMS, the new rate would better recognize "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," *id.*, and "better represent[] the average acquisition cost for these drugs and biologicals," *id.* at 33634. On November 1, 2017, CMS issued the final version of the 340B Provisions of the OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. 52,356, 52,362.

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

35. In reducing the payment rate for certain 340B drugs by nearly 30%, CMS purported to rely on its authority under 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%. *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 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). *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.

36. 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.

37. The 340B Provisions of the 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 healthcare 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 patients. CMS's efforts in the 340B Provisions of the 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.

38. The new payment rate set forth in the 340B Provisions of the OPPS Rule has substantially impacted the day-to-day operations of many covered entities, including the Hospital Plaintiffs and other members of the Association Plaintiffs. These entities 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 will threaten many of these critical programs, and thus the poor and underserved populations who depend on 340B hospitals, in direct contravention of the purpose and design of the 340B program.

39. On July 25, 2018, HHS issued a notice of proposed rulemaking for the 2019 OPPS Rule. With minor modifications, the Proposed 2019 OPPS Rule would "continue the 340B Program policies that were implemented in [calendar year] 2018"—*i.e.* the policy of "pay[ing] for separately payable Medicare Part B drugs . . . that are acquired through the 340B Program at ASP minus 22.5 percent." CMS, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 37,046, 37,125–26 (July 31, 2018).

ADMINISTRATIVE REVIEW OF PLAINTIFFS' CLAIMS FOR PAYMENT

40. 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. 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." 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"). 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. 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. 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. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

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

A. Henry Ford Health System

42. On January 9, 2018, Henry Ford presented a claim for payment to WPS Government Health Administrators ("WPS"), a MAC, for separately payable drugs subject to the 340B Program. On January 25, 2018, WPS issued an initial determination advising Henry Ford

that the claim would be labeled 21800900583604MIA (hereinafter "Claim '604") and that $5,031.81 would be remitted to Henry Ford on that claim.

43. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000637704MIA (hereinafter "Claim '704") and that $10,533.62 would be remitted to Henry Ford on that claim.

44. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000640004MIA (hereinafter "Claim '004") and that $3,734.85 would be remitted to Henry Ford on that claim.

45. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, WPS's payments on Claims '604, '704, and '004 were approximately 30% less than what it had paid Henry Ford on identical claims in 2017. On February 8, 2018, Henry Ford submitted redetermination requests to WPS for each of the three claims in which it demanded full reimbursement in the amount of $7,344.77 on Claim '604, $14,876.96 on Claim '704, and $5,451.99 on Claim '004. On each of the three redetermination request forms, Henry Ford 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.

46. On March 6, 2018, WPS issued unfavorable decisions on each of Henry Ford's three redetermination requests, correctly explaining in each of the three redetermination letters

that the amount it had already paid was "the maximum payment allowed by Medicare" for the service at issue.

47. On March 27, 2018 (Claims '604 and '004) and April 10, 2018 (Claim '704), Henry Ford submitted reconsideration requests regarding its three claims to Maximus Federal Services ("Maximus"), a QIC. In each of its three reconsideration requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS.

48. Maximus initially issued favorable reconsideration decisions on each of Henry Ford's three claims on May 22, 2018 (Claim '004) and June 1, 2018 (Claims '604 and '704), stating that Henry Ford "was underpaid" on each claim. However, after CMS recouped the payments on Claims '704 and '004, it reprocessed those claims and reissued payments for exactly the same lower amounts that it had issued previously in conformity with the new OPPS Rule. CMS never reprocessed Claim '604. Henry Ford later learned that each of the three appeals had been reopened at the direction of CMS, which had determined that there are no administrative appeal rights for claims related to the 340B Program. Henry Ford subsequently received letters regarding each of its three reconsideration requests from Maximus, all dated July 11, 2018, in which Maximus stated that each of the three reopened appeals "ha[d] been deleted from our system" and that "MAXIMUS will not be issuing a new reconsideration decision at this time." These letters constituted dismissals of each of Henry Ford's three appeals. To date, Henry Ford has not been paid any amount of money on any of its three claims other than the deficient initial remittances made pursuant to the new OPPS Rule.

49. On August 2, 2018, Henry Ford submitted requests to the Office of Medicare Hearings and Appeals for review by an Administrative Law Judge ("ALJ") of Maximus's decisions on each of Henry Ford's three reconsideration requests. In each of its three ALJ

hearing requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS and in its reconsideration requests to Maximus.

50. On August 10, 2018, Henry Ford submitted a request to the Departmental Appeals Board for expedited access to judicial review pursuant to 42 C.F.R. § 405.990 on its three appeals. The request explained that there are no material facts in dispute and that Henry Ford's challenge to the remittances on its three claims turns on purely legal disputes about the whether the 2018 changes to the 340B Program exceeded Secretary's statutory authority to adjust reimbursement rates and whether administrative and judicial review of such challenges is available.

51. In light of these events, Henry Ford has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

B. Eastern Maine Healthcare Systems

52. On January 23, 2018, EMHS presented a claim for payment to National Government Services ("NGS"), a MAC, for separately payable drugs subject to the 340B Program. On February 6, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21802300601207MEA (hereinafter "Claim '207"), and that a total of $4,826.63 would be remitted to EMHS on that claim.

53. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700697107MEA

(hereinafter "Claim '107"), and that a total of $4,826.63 would be remitted to EMHS on that claim.

54. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700743607MEA (hereinafter "Claim '607") and that a total of $4,598.67 would be remitted to EMHS on that claim.

55. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700741907MEA (hereinafter "Claim '907") and that a total of $3,338.66 would be remitted to EMHS on that claim.

56. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 21, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700775907MEA (hereinafter "Claim '5907") and that a total of $3,083.06 would be remitted to EMHS on that claim.

57. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, NGS's payments on Claims '207, '107, '607, '907, and '5907 were approximately 30% less than what it had paid EMHS on identical claims in 2017. On March 19, 2018, EMHS submitted redetermination requests to NGS for each of the five claims in which it demanded full reimbursement in the amount of $7,045.30 on Claim '207, $7,045.30 on Claim '107, $6,712.57 on Claim '607, $4,873.33 on Claim '907, and $4,500.23 on Claim '5907. On each of the five

redetermination request forms, EMHS 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.

58. On May 30, 2018 (Claim '607), May 31, 2018 (Claims '207 and '107), and June 1, 2018 (Claims '907 and '5907), NGS issued letters dismissing EMHS's five redetermination requests on the grounds that "[42 U.S.C. § 1395w-4(i)(1)] prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395*l*(t)(12)(A), (C), (E))."

59. On July 17, 2018 EMHS submitted reconsideration requests regarding its five claims to C2C Solutions, Inc., a QIC. In each of its five reconsideration requests, EMHS raised the same argument that it had raised in its redetermination requests to NGS.

60. In light of these events, EMHS has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

C. Park Ridge Health

61. On February 5, 2018, Park Ridge presented a claim for payment to First Coast Service Options, Inc. ("First Coast"), a MAC, for separately payable drugs subject to the 340B Program. On February 20, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled 21803603179407FLA (hereinafter "Claim '407"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

62. On February 7, 2018, Park Ridge presented a claim for payment to First Coast for separately payable drugs subject to the 340B Program. On February 22, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled 21803900902607FLA (hereinafter "Claim '2607"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

63. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, First Coast's payments on Claims '407 and '2607 were approximately 30% less than what it had paid Park Ridge on identical claims in 2017. On May 11, 2018, Park Ridge submitted redetermination requests to First Coast for both claims in which it demanded full reimbursement in the amount of $5,342.66 on Claim '407 and $5,342.66 on Claim '2607. On both of its redetermination request forms, Park Ridge 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.

64. On June 1, 2018, First Coast issued letters dismissing Park Ridge's redetermination requests on the grounds that "administrative review is not available for this issue."

65. On July 23, 2018, Park Ridge submitted reconsideration requests regarding both of its two claims to C2C Solutions, Inc., a QIC. In both of its reconsideration requests, Park Ridge raised the same argument that it had raised in its redetermination requests to First Coast.

66. In light of these events, Park Ridge has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator

within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

COUNT 1

OPPS RULE – VIOLATION OF THE SOCIAL SECURITY ACT

67. Plaintiffs incorporate by reference the foregoing paragraphs.

68. 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).

69. The nearly 30% reduction in payment for 340B drugs under the 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 2

HENRY FORD CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

70. Plaintiffs incorporate by reference paragraphs 1 through 51.

71. 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).

72. The remittances to Henry Ford for Claims '604, '704, and '004 reflected a nearly 30% reduction in payment that was 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 3

EMHS CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

73. Plaintiffs incorporate by reference paragraphs 1 through 41 and 52 through 60.

74. 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).

75. The remittances to EMHS for Claims '207, '107, '607, '907, and '5907 reflected a nearly 30% reduction in payment that was 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 4

PARK RIDGE CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

76. Plaintiffs incorporate by reference paragraphs 1 through 41 and 61 through 66.

77. 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).

78. The remittances to Park Ridge for Claims '407 and '2607 reflected a nearly 30% reduction in payment that was 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 its favor and against Defendants:

A. Declaring that the 340B Provisions of the OPPS Rule are an unlawful exercise of Defendants' authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendants to strike the changes in the payment methodology for section 340B drugs from the OPPS Rule and directing Defendants to use the methodology used in calendar year 2017 for all future 340B Program payments in 2018;

C. Directing Defendants to: reimburse Henry Ford $2,312.96 in connection with Claim '604, $4,343.34 in connection with claim '704, and $1,717.14 in connection with claim '004; reimburse EMHS $2,218.67 in connection with Claim '207, $2,218.67 in connection with Claim '107, $2,113.90 in connection with Claim '607, $1,534.67 in connection with Claim '907, and $1,417.17 in connection with Claim '5907; and reimburse Park Ridge $1,657.54 in connection with Claim '407 and $1,657.54 in connection with Claim '2607, plus prejudgment interest;

D. Directing Defendants to reimburse all Hospital Plaintiffs and all Organizational Plaintiffs' provider members for the difference between amounts already paid in 2018 for 340B drugs pursuant to the OPPS Rule and what would have been paid for those same drugs under the methodology used in calendar year 2017.

E. Directing Defendants to conform the payment methodology that they use for 340B drugs in 2019 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition costs to calculate prices unless Defendants have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I); and

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

Dated: September 5, 2018

Respectfully submitted,

/s/ William B. Schultz

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