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–

ERIC D. HARGAN, in his official capacity as the Acting 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

Plaintiffs American Hospital Association, 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 (collectively, "Plaintiffs") bring this complaint against Defendants Department of Health and Human Services ("HHS") and Eric D. Hargan, in his official capacity as the Acting Secretary of Health and Human Services (collectively, "Defendants"), and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under 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 ("CMS"), an agency within the Defendant HHS. *See* 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017). The final 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 would reduce 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 Services Act (the "340B Program"). These 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 are scheduled to take 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 drugs furnished to their patients, Congress has 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 reimbursement reduction set forth in the 340B Provisions of the OPPS Rule purports to eliminate the differential between Medicare reimbursement rates and discounted purchase costs, costing hospitals an estimated (by CMS) $1.6 billion in lost savings, in violation of both the Secretary's statutory authority to reimburse hospitals for outpatient drugs under the Social Security Act and the purpose and design of the 340B program.

3. Plaintiffs American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals are hospital associations whose members, including Plaintiffs Eastern Maine Healthcare Systems, Henry Ford Health System, and Park Ridge Health (the "Hospital Plaintiffs"), have used the 340B Program to provide critical healthcare services to their communities, including to underserved patient populations in those communities. The Hospital Plaintiffs and other members of the Association Plaintiffs, and the populations they serve, would suffer significant and immediate 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 from this Court, including a preliminary injunction preventing the 340B Provisions of the OPPS Rule from taking effect on January 1, 2018, until the resolution of this legal challenge.

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-level 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 their communities, including vulnerable populations in those communities. These AHA members would be significantly harmed by the 340B Provisions of the OPPS Rule seeking to eliminate this differential from Medicare payments.

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 149 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies.

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 would be significantly harmed by the OPPS Rule seeking to eliminate this differential from Medicare payments.

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 would be significantly harmed by the OPPS Rule seeking to eliminate this differential from Medicare payments.

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 per capita in the United States, and the largest percentage of Medicare eligible citizens in the nation. A large percentage of EMHS's services is provided to the elderly and other disadvantaged populations.

12. The 340B Provisions of the OPPS Rule would 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 currently 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. The 340B Provisions of the OPPS Rule would severely threaten Henry Ford's, including HFH and HF Allegiance's, ability to provide critical healthcare programs to their communities, including the underserved populations in those communities, by depriving it of millions of dollars of savings currently generated from the differential between Medicare reimbursements and 340B discounts.

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.

18. 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.

19. 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.

20. The 340B Provisions of the OPPS Rule would 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 currently generated from the differential between Medicare reimbursements and 340B discounts.

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

22. Defendant Eric D. Hargan ("the Secretary") is the Acting Secretary of Health and Human Services and maintains offices at 200 Independence Avenue, 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 Hargan is sued in his official capacity.

JURISDICTION AND VENUE

23. This action arises under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, and section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

24. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331.

25. The APA authorizes a court to set aside agency action, findings, and conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" (5 U.S.C. § 706(2)(A)) or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). The APA also provides a right to judicial review of all "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

26. HHS and CMS's issuance of the 340B Provisions of the OPPS Rule on November 1, 2017, constitutes final agency action of which Plaintiffs are entitled to judicial review under the APA.

27. Plaintiffs, as either (1) hospitals that would be adversely affected by the 340B Provisions of the OPPS Rule or (2) associations representing the interests of member hospitals that would be adversely affected by the Rule, have standing to challenge this final agency action.

28. There exists an actual substantial and continuing controversy between the parties regarding the 340B Provisions of the OPPS Rule. This Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201–2202.

29. Venue lies in this judicial district pursuant to 28 U.S.C. § 1391(e).

30. The Court has personal jurisdiction over Defendant HHS because it is an agency of the United States that resides in the District of Columbia and because a substantial part of the events that gave rise to Plaintiffs' claims occurred here. This Court has personal jurisdiction over the Defendant Secretary in his official capacity because his office is located, and a substantial part of the events giving rise to the claims occurred, in the District of Columbia.

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

31. Congress established the 340B Program in 1992 as part of the Public Health Service Act to provide certain hospitals serving a disproportionate share of low-income individuals and federally-funded clinics ("covered entities" in the statute's parlance) with outpatient prescription drug discounts that were 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.

32. 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.

33. 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).

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

B. Medicare OPPS Reimbursement

35. As part of the Balanced Budget Act of 1997, to control Medicare expenditures for outpatient services, Congress directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient

departments ("OPD Services"), for example rehabilitation services. CMS updates the OPPS payment rates annually.

36. In 2003, Congress amended the Social Security Act ("SSA") to require CMS, starting in 2004, to set Medicare reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled as part of an OPD service. These drugs include some of the outpatient drugs covered under the 340B program.

37. The SSA provides CMS with two choices in setting Medicare reimbursement rates for separately payable drugs starting in 2006. CMS must set rates based on the acquisition costs of these drugs if statistically sound survey data on acquisition cost are available. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("Reimbursement Option I"). If acquisition cost data are not available, CMS must use a mandatory default rate of average sales price ("ASP") plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("Reimbursement Option II").

38. In 2012, after concluding that it could not reliably collect the acquisition cost data it needed to use Reimbursement Option I, CMS formally adopted Reimbursement Option II - the statutory default payment rate of ASP plus 6% - for all separately payable drugs. From 2012 onward, CMS applied this statutory default rate without further adjustments for each subsequent year, until this year.

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

39. 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, the proposed rule sought to lower the Medicare reimbursement rate for such drugs

from the current (statutory default) rate of ASP plus 6% to ASP minus 22.5% - which is a 28.5 percentage point (and 27%) reduction in the reimbursement rate. *Id.* at 33634.

40. CMS justified this proposed change by stating that the new rate better recognizes "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," *id.*, and "better represents the *average acquisition cost* for these drugs and biologicals," *id.* at 33634 (emphasis added). However, CMS invoked as the authority for the reduction 42 U.S.C. § 1395*l*(t)(14)(A)(III)(ii) (*i.e.*, "Reimbursement Option II"), which authorizes the Secretary to use a statutory default rate based on average sales price, *not* acquisition cost (which is the rate-setting basis under Reimbursement Option I). Moreover, the nearly-30% payment reduction is not based on actual, statistically significant acquisition cost data, as would be required to rely on Reimbursement Option I under 42 U.S.C. § 1395*l*(t)(14)(A)(III)(i). Rather, it is based on estimates of average acquisition cost compiled by the Medicare Payment Advisory Commission ("MedPAC").

41. 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.

42. This new reimbursement rate would significantly reduce 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.

43. CMS initially proposed this drastic reduction of nearly 30% without consulting the Advisory Panel on Hospital Outpatient Payment ("OPPS Advisory Panel"), a panel of outside experts, even though such a consultation is required under law. 42 U.S.C. § 1395*l*(t)(9)(A).

Indeed, when the OPPS Advisory Panel reviewed the proposed OPPS Rule at its annual meeting on August 21, 2017, it recommended that CMS not finalize the 340B Provisions of the OPPS Rule. Instead, the OPPS Advisory Panel recommended that CMS should collect additional data "on the potential impact of revising the payment rate," including the "potential impact on 340B hospitals." CMS, Advisory Panel on Hospital Outpatient Payment: Recommendations 2 (Aug. 21, 2017), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2017-08-21-Panel-Recommendations.pdf.

44. In reducing the payment rate for certain 340B drugs by nearly 30%, CMS purports to rely on its authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), *i.e.*, "Reimbursement Option 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). This authority to "calculate" and "adjust" does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of 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 ASP-based statutory default rate to reflect changes in overhead and related expenses.

45. The 340B Provisions of the OPPS Rule also exceed the Secretary's authority under Reimbursement Option II 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 in, and allowed only under, Reimbursement Option 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 required under the statute to invoke Reimbursement Option I, it improperly sought to use *aggregate* acquisition costs as *estimated* by MedPAC as a proxy for

that data – even though Reimbursement Option II expressly must be based on average sales price, *not* acquisition costs (much less estimates of acquisition costs). In doing so, the Secretary impermissibly invokes his authority under Reimbursement Option II to circumvent the requirements under Reimbursement Option I.

46. The 340B Provisions of the OPPS Rule also exceed the Secretary's authority because they thoroughly undermine the 340B Program by depriving eligible hospitals of critical resources Congress intended to provide those hospitals through 340B discounts. Elimination of these resources will, in turn, threaten the ability of covered entities to provide essential healthcare services and programs to their communities, including underserved populations within those communities. This is flatly 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. If implemented, the new payment rate set forth in the 340B Provisions of the OPPS Rule would substantially impact 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, in direct contravention of the purpose and design of the 340B program.

COUNT 1

VIOLATION OF THE SOCIAL SECURITY ACT

47. Plaintiffs incorporate by reference the foregoing paragraphs.

48. The APA requires this Court to hold unlawful any agency action that is arbitrary and capricious or contrary to law and that is in excess of the agency's statutory authority. 5 U.S.C. § 706(2)(A), (C).

49. The nearly 30% reduction rate for 340B drugs under the OPPS Rule is arbitrary and capricious and contrary to law and in excess of the Secretary's authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 2

RELIEF PENDING REVIEW UNDER THE APA

50. Plaintiffs incorporate by reference the foregoing paragraphs.

51. Under 5 U.S.C. § 705, Plaintiffs are entitled to interim injunctive relief staying implementation of the 340B Provisions of the OPPS Rule, pending resolution of this matter on the merits and any appeal therefrom.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in its favor and against Defendants and issue the following relief:

A. A declaratory judgment that the 340B Provisions of the OPPS Rule are an unlawful exercise of Defendants' authority under the Social Security Act and unlawfully impair the program established by section 340B of the Public Health Service Act;

B. An order 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;

C. As an alternative to the relief requested in paragraphs A and B, a preliminary injunction suspending the effective date of the 340B Provisions of the OPPS Rule pending resolution of this action and any appeal therefrom; and

D. Such other relief as this Court may deem just and proper.

Dated: November 13, 2017

Respectfully submitted,

/s/ Carlos T. Angulo

Carlos T. Angulo (DC Bar. No. 466257)
Alexandra W. Miller (DC Bar. No. 474325)
Wen Shen (DC Bar No 1035578)
ZUCKERMAN SPAEDER LLP
1800 M St, NW
Washington, DC 20036
Tel: 202-778-1800
Fax: 202-822-8136
cangulo@zuckerman.com
smiller@zuckerman.com
wshen@zuckerman.com

Attorneys for Plaintiffs