NO. 19-5198

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALEX M. AZAR II, in his official capacity, *et al.*,
Defendants-Appellants,

v.

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellees,

On Appeal from a Final Judgment of the
U.S. District Court for the District of Columbia,
(Honorable Rudolph Contreras)

APPELLEES' CONSENT MOTION TO EXPEDITE BRIEFING

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Plaintiffs-Appellees, three hospital associations and three hospital systems, move to expedite this appeal of the district court's issuance of a permanent injunction and finding that the Department of Health and Human Services (HHS) 2018 and 2019 Hospital Outpatient Prospective Payment System (OPPS) regulations are unlawful. *See* 28 U.S.C. § 1657(a) (appeals from preliminary injunction ruling to be expedited; appeals may be expedited for good cause). Appellees sought and obtained expedition when in January 2018 they appealed an adverse decision of the district court rejecting their identical challenge to the 2018 OPPS Rule.[1] As demonstrated below, the considerations supporting expedition in this action are even stronger here.

The provisions of the 2018 and 2019 OPPS regulations that the district court found to be illegal reduced by nearly 30% Medicare payments to certain public and non-profit hospitals for outpatient drugs purchased by those hospital under section 340B of the Public Health Service Act (the 340B Program). ECF No. 50; *Am. Hosp. Ass'n v. Azar,* 2019 WL 1992868 (D.D.C. 2019). Although the district court

[1] Appellees initially filed suit on November 13, 2017, the day the 2018 OPPS Rule was published in the Federal Register, against HHS and its Acting Secretary, seeking a preliminary injunction suspending implementation of the 340B Provisions of the OPPS Rule prior to its January 1, 2018 effective date. The district court dismissed the case on the grounds that the action was brought before Appellees could present the Secretary with claims for payment under the 2018 OPPS rule and this court affirmed. *Am. Hosp. Ass'n v. Hargan,* 289 F. Supp.3d 45 (D.D.C. 2017), *aff'd sub nom., Am. Hosp. Ass'n v. Azar,* 895 F.3d 822 (D.D.C. 2018).

granted plaintiffs' motion for a permanent injunction, it remanded the matter to the agency with directions to expeditiously resolve the remedy issue. ECF No. 50 at 22; *Am. Hosp. Ass'n v. Azar*, 2019 WL 1992868 at *11. Because the remedy issue has not been resolved, 340B hospitals continue collectively to lose $25 million per week.

Appellees are three hospital associations (American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH")), and three of their member hospital systems (Northern Light Health (Northern Light) formerly Eastern Maine Healthcare Systems (EMHS), Henry Ford Health System (Henry Ford), and Fletcher Hospital, Inc. d/b/a Park Ridge Health (Park Ridge)). On September 5, 2018, Appellees filed this action seeking to invalidate HHS's 2018 OPPS rule, which reduced by $1.6 billion reimbursements to 340B hospitals. ECF No. 1. At the same time, Appellees filed a motion seeking a preliminary and permanent injunction enjoining Appellants Secretary Alex Azar and the Department of Health and Human Services (collectively referred to as HHS) from implementing the 2018 and 2019 rules and requiring HHS to reimburse 340B hospitals the difference between what they had received under the 2018 OPPS and what they were entitled to receive under a correct application of the law. ECF No. 2.

On December 27, 2018, the district court held unlawful the reduced rate for 340B drugs in the 2018 OPPS Rule on the grounds that it exceeded the Secretary's authority under 42 U.S.C. § 1395*l*(t)(14)(iii)(II). ECF Nos. 24, 25; *Am. Hosp. Ass'n v. Azar*, 348 F. Supp.3d 62 (D.D.C. 2018). At that time, the court declined to apply its injunction to the 2019 OPPS Rule because Plaintiffs had not yet "presented the Secretary with a concrete claim for reimbursement under the 2019 rule." ECF No. 25 at 34 n.25; *Am. Hosp. Ass'n*, 348 F. Supp.3d at 85 n.25. The court ordered both parties to submit within 30 days supplemental briefing on the proper remedy for 2018 claims. ECF No. 25 at 36; *Am. Hosp. Ass'n*, 348 F. Supp.3d at 87.

Appellees proposed a remedy whereby hospitals would be reimbursed the difference between the illegal 2018 rate and the statutory rate which Appellants had paid in prior years. ECF Nos. 32 and 37. HHS did not propose a remedy but instead urged the court to remand the case to HHS. ECF Nos. 31 and 36. On February 8, 2019, Appellees filed a supplemental complaint (ECF No. 39) and on February 11, 2019, Appellees moved to permanently enjoin the 2019 OPPS Rule. ECF No. 35. On May 6, 2019, the court granted Appellees' motion and held unlawful the reduced rate for 340B Drugs in the 2019 OPPS Rule on the grounds that it exceeded the Secretary's authority under 42 U.S.C. § 1395*l*(t)(14)(iii)(II). ECF Nos. 49, 50; *American Hosp. Ass'n v. Azar*, 2019 WL 1992868 (D.D.C.

2019). On the issue of remedies for both the 2018 and 2019 rules, the district court remanded to HHS to give it "the first crack at crafting appropriate remedial measures." ECF No. 50 at 2; *Am. Hosp. Ass'n,* 2019 WL 1992868 at *1. The court directed the parties to submit a status report on August 5, 2019 regarding the agency's progress. ECF No. 50 at 22; *Am.Hosp. Ass'n,* 2019 WL 1992868 at *11 .

On June 1, 2019, HHS filed a motion seeking immediate entry of final judgment, which the district court granted on July 17, 2019. ECF Nos. 58, 59; *Am. Hosp. Ass'n,* 2019 WL 3037306 (D.D.C. 2019). The following day, HHS filed its notice of appeal.

The Government's motion for a final judgment stated that HHS would seek expedited review in this Court and Appellees have consistently sought expedition in both the district court and when this case was previously before this Court. Appellees request that the Court establish the following expedited briefing schedule:

September 3	Appellants' Brief
September 24	Appellees' Brief
October 11	Appellants' Reply Brief

Appellees also respectfully request that the Court schedule oral argument and issue an opinion on an expedited basis.

Appellants' counsel has informed Appellees' counsel that HHS consents to this motion and to the proposed briefing schedule. HHS has not reviewed this motion and does not necessarily accept the arguments made in it.

ARGUMENT

I. THIS APPEAL SHOULD BE EXPEDITED UNDER 28 U.S.C. § 1657(a).

28 U.S.C. § 1657(a) provides that each court of the United States "shall expedite the consideration of any action . . . for temporary or preliminary injunctive relief." D.C. Circuit Rule 47.2(a) implements Section 1657(a) and directs that in such cases, the Clerk shall "prepare an expedited schedule for briefing and argument." Although in this case the district court entered a permanent injunction, Appellees sought both a preliminary and permanent injunction and the preliminary injunction was denied as moot. Thus, this is an action for "preliminary injunctive relief." ECF No. 2; ECF No. 25 at 36; *Am. Hosp. Ass'n*, 348 F. Supp.3d at 87.

II. THERE IS GOOD CAUSE TO EXPEDITE THIS APPEAL.

Section 1657(a) also mandates expedited review where "good cause therefor is shown." Good cause exists when "delay will cause irreparable injury and . . . the decision under review is subject to substantial challenge" or if "the public generally, or . . . persons not before the Court, have an unusual interest in prompt disposition." D.C. Cir. Handbook, § VIII.B; D.C. Cir. Rule 27(f). Each one of the

three good-cause grounds is present here—although, because this is an appeal from the grant of an injunction, the issue of good cause need not be reached.

A. Delay Will Cause Appellees Irreparable Injury.

Even though the district court found that the nearly 30% reduction in Medicare reimbursements is illegal, it did not order a remedy. Thus, HHS continues to implement the illegal cuts. Appellees will suffer increasing irreparable injury the longer the nearly 30% reduction remains in effect because Medicare reimbursements for 340B drugs, as intended by Congress, support 340B hospitals' ongoing operations and services. These operations and services allow those hospitals to provide critical care to their communities, including underserved populations in those communities, and are increasingly threatened if reimbursements continue to be reduced.

340B drugs are purchased under a statutory program that requires pharmaceutical companies to sell drugs at substantial discounts to certain public hospitals and certain nonprofit hospitals that disproportionately service the poor. *See* 42 U.S.C. § 256b(a)(1), (a)(4). Congress created the 340B Program to allow covered entities "to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive." H.R. REP. NO. 102-384(II), at 12 (1992). The Program furthers this purpose by lowering the acquisition cost of the 340B drugs while maintaining the

reimbursement rates to allow covered entities to generate savings that can be used to serve their communities.

Affidavits submitted with Appellees' motion for a preliminary and permanent injunction in the court below demonstrate that the reimbursement payments for 340B drugs are used by Hospital Appellees (as well as other members of the Association Appellees) to provide essential health services to their communities, including their vulnerable, poor and underserved patients. *E.g.*, ECF No. 2 at Exs. V-X.[2] For example, at Appellee Park Ridge, the 340B provisions of the OPPS Rule would threaten the continued availability of infusion services for the comprehensive treatment of cancer and the hospital's geriatric psychiatric program. ECF No. 2-27, Ex. X (Park Ridge Aff. ¶ 16).

The nearly-30% reduction in reimbursements to 340B hospitals will jeopardize essential health programs that are currently funded by the difference between the amount that the government reimburses for outpatient drugs prescribed to Medicare patients and the discounted prices the hospitals pay for those drugs under the 340B program—an approximately $1.6 billion (by CMS's

[2] These affidavits were submitted, respectively, by (1) Tony Filer, Senior Vice President and Chief Financial Officer of Hospital Plaintiff/Appellee EMHS (Ex. V, EMHS Aff.); (2) Robin Damschroder, Chief Financial Officer of Hospital Plaintiff/Appellee Henry Ford (Ex. W, Henry Ford Aff.); and (3) Wendi Barber, Chief Financial Officer of Hospital Plaintiff/Appellee Park Ridge (Ex. X, Park Ridge Aff.). EMHS changed its name to Northern Light Health (ECF No. 21) but the affidavit was executed when it was still using the name EMHS.

own estimate) total differential each year for the individual Hospital Appellees and the members of the Association Appellees. *See* 82 Fed. Reg. 52,356, 52,623 (Nov. 13, 2017). The longer the reduction remains in effect, the more it will impact 340B hospitals' budgeted operations, bond covenants, and other systems and arrangements that allow those hospitals to offer essential care to their communities, as those agreements and arrangements are reviewed for renewal during the course of the year. For 340B hospitals, the ability to provide care to their communities is tied to receipt of third-party reimbursements; constriction in the flow of Medicare revenues to 340B hospitals will increasingly constrict funds for medical care for all their patients, most particularly those who are poor and underserved and most reliant on these services. *See* ECF No. 2-25, Ex. V (EMHS Aff. ¶¶ 14 and 19).

This restriction on Appellees' ability to provide health care constitutes irreparable harm that cannot be eliminated by a retrospective award of Medicare reimbursements, after sick patients have lost access to care, such as dialysis or a course of infusion services to treat cancer. *See, e.g., Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 244 & n.7 (D.D.C. 2014) (loss of funds threatening non-profit healthcare providers' essential services is "different in kind from economic loss suffered by a for-profit entity"; hospitals suffer irreparable harm if hospital programs "*may* be" eliminated—even temporarily) (emphasis added); *Ark. Med. Soc'y, Inc. v. Reynolds*, 834 F. Supp. 1097, 1101-02 (E.D. Ark. 1992)

(irreparable harm found where healthcare providers would not be able to provide services to Medicaid beneficiaries).

Expedition is also necessary to prevent the irreparable harm from continuing in 2020 since HHS is likely to propose its 2020 OPPS rule by the end of this month using the same illegal formula.[3] In fact, in their motion for entry of final judgment (ECF No. 54), HHS argued that an expedited appeal may allow the D.C. Circuit "to rule in time for HHS to account for its decision in the final 2020 OPPS rule, thereby obviating the continued multiplication of proceedings." ECF No. 54 at 3-4. During the status conference with the district court, counsel for HHS indicated that the government may no longer be able to account for the decision in its 2020 final OPPS rule. However, even if HHS cannot account for the decision when it issues its 2020 final OPPS rule in November, it could be required to stop paying the claims at an illegal rate soon after this Court issues its decision, if that decision is favorable to Appellees.

[3] HHS issued its proposed 2018 OPPS rule on July 20, 2017 and its proposed 2019 OPPS rule on July 31, 2018. *See* 82 Fed. Reg. 33,558 (July 20, 2017); 83 Fed. Reg. 37,046 (July 31, 2018). Appellants have argued and the district court agreed, that relief in this case will be difficult to implement for claims that HHS has already paid because relief could require retroactive fixes. ECF No. 31 at 7-9; ECF No. 50 at 18-19; *American Hosp. Ass'n*, 2019 WL 1992868 at *7, 8 . If that is true (and Appellees are not conceding that retroactive relief is the only option), then the longer the case lingers, the more complicated the remedy becomes.

B. The District Court's Decision Is Subject to Substantial Challenge.

The district court correctly found that HHS's reduced Medicare reimbursement rate was illegal. HHS, however, has vigorously defended the cut since it was first proposed in July of 2017. HHS rejected comments filed by Appellees and others challenging the legality of the cuts. After the district court ruled that the 2018 rule was illegal, HHS continued to defend that rule and defended the 2019 rule, which included the identical illegal cuts. Appellees expect HHS to continue its vigorous defense in the Court of Appeals and thus the district court's opinion is subject to substantial challenge.

C. The Public Interest Favors Expedited Review.

The public—in particular, the poor and underserved communities served by the Hospital Appellees and members of the Association Appellees—also has a strong interest in expedited review. These communities, particularly their vulnerable patients, have a compelling interest in ensuring that the critical services made possible by the 340B program continue with minimal disruption. *E.g.*, ECF No. 2-25, Ex. V (EMHS Aff. ¶ 13); ECF No. 2-26, Ex. W (Henry Ford Aff. ¶¶ 15-19); ECF No. 2-27, Ex. X (Park Ridge Aff. ¶¶ 15-17). This can only be assured through an expedited review by this Court.

CONCLUSION

For the foregoing reasons, Appellees respectfully request that the Court expedite this appeal and set the briefing schedule requested in this motion.

Respectfully Submitted,

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CERTIFICATE AS TO PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Pursuant to D.C. Circuit Rule 27 (a)(1)(4) and 28(a)(1)(A), Appellees American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), Northern Light Health (Northern Light), Henry Ford Health System (Henry Ford) and Fletcher Hospital, Inc., d/b/a/ Park Ridge Health (Park Ridge) state as follows:

(1) Parties and Amici

AHA, AAMC, AEH, Northern Light, Henry Ford, and Park Ridge were Plaintiffs before the District Court and are Appellees in this Court.

Alex M. Azar, in his official capacity as the Secretary of Health and Human Services, and the Department of Health and Human Services were Defendants before the District Court and are Appellants in this Court.

The Federation of American Hospitals submitted a brief in the District Court as *amicus curiae.*

(2) Rulings Under Review

Appellants are seeking review of the District Court's opinion and order entering final judgment on July 10, 2019 (ECF Nos. 58, 59); and all prior orders and decisions that merge into the final judgment, including the December 27, 2018 opinion and order (ECF Nos. 24, 25), and the May 6, 2019 opinion and order (ECF Nos. 49, 50). The rulings were issued by the Honorable Rudolph Contreras in Case

No. 1:18-cv-02084-RC (D.D.C). The December 28, 2018 opinion is reported at 348 F. Supp.3d 62. The May 6, 2019 opinion is unreported but available at 2019 WL 1992868. The July 10, 2019 opinion is unreported but available at 2019 WL 3037306.

(3) Related Cases

This Court previously issued an opinion involving the same dispute between the same parties. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).

Appellees are not aware of any pending cases related to this appeal.

/s/ William B. Schultz
William B. Schultz
Attorney for the Plaintiffs-Appellees

CORPORATE DISCLOSURE STATEMENT

Pursuant to D.C. Circuit Rule 26.1, Appellees AHA, AAMC, AEH, Northern Light, Henry Ford, and Park Ridge state as follows:

1. Appellee AHA is a not-for-profit association headquartered in Washington, D.C. It represents and serves nearly 5,000 hospitals, healthcare systems, and networks, plus 43,000 individual members. Its 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 the community and committed to health improvement.

2. Appellee AAMC is a not-for-profit association headquartered in Washington, D.C. 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. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research.

3. Appellee AEH is a not-for-profit association headquartered in Washington, D.C. It represents 325 hospital members that are vital to their communities, providing primary care through trauma care,

disaster response, health professional training, research, public health programs, and other services. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable.

4. Appellee Northern Light is a not-for-profit integrated health care system headquartered in Brewer, Maine. The system provides a broad range of health care and related services in Northern, Eastern and Southern Maine through its subsidiaries and affiliated entities.

5. Appellee Henry Ford is a not-for-profit health care system headquartered in Detroit, Michigan. The system provides a broad range of health care and related services to the people of southeastern and southcentral Michigan.

6. Appellee Park Ridge is a not-for-profit health care system headquartered in Hendersonville, North Carolina. It is a member of the Adventist Health System, a faith-based not-for-profit health care system that provides health care services to communities in 9 states. Park Ridge in particular provides health care and related services at 30 locations across Henderson, Buncombe, and Haywood Counties in North Carolina.

7. No publicly held corporation has a 10 percent or greater ownership interest in any Appellee.

CERTIFICATE OF COMPLIANCE

This Motion to Expedite complies with the type-volume limitation of FRAP 27(d)(2) and 32(c) because, excluding the parts of the document exempted by FRAP 32(f), this document contains 2,410 words. This document also complies with the typeface and type-style requirements of FRAP 32(a)(5) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point font size and Times New Roman type style.

/s/ William B. Schultz
William B. Schultz
Attorney for the Plaintiffs-Appellees

CERTIFICATE OF SERVICE

I hereby certify that, on July 24, 2019, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ William B. Schultz
William B. Schultz
Attorney for the Plaintiffs-Appellees