UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al*., *Plaintiffs,* –v– THE DEPARTMENT HEALTH AND HUMAN SERVICES, *et al*., *Defendants.*	Case No. 1:18-cv-2112

JOINT STATUS REPORT AND STIPULATION OF DISMISSAL

Plaintiffs the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges, 340B Health, Genesis HealthCare System, Kearny County Hospital and Rutland Regional Medical Center (collectively, "Plaintiffs"), and Defendants the Department of Health and Human Services (HHS) and the Secretary of HHS (collectively, "Defendants"), file this joint status report pursuant to the Court's April 4, 2019 minute order and stipulate to the dismissal of this action pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii).

In further support the parties state as follows:

1. Congress created the 340B Program in 1992 to provide certain hospitals, community health centers and other federally funded clinics serving low-income patients (known as "covered entit[ies]," 42 U.S.C. § 256b(a)(4)) with outpatient drug discounts comparable to those Congress had made available to state Medicaid agencies. Under the 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through

Medicaid, are required to enter into a 340B Pharmaceutical Pricing Agreement with the Secretary of HHS pursuant to which they must offer covered entities outpatient drugs at or below an applicable, discounted, statutorily-determined price, referred to as the "ceiling price." 42 U.S.C. § 256b(a)(1).

2. In 2010, to improve the accuracy of ceiling prices, Congress required the Secretary to "develop[] . . . a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers." 42 U.S.C. § 256b(d)(1)(B)(i).

3. On January 5, 2017, the Department issued a Final Rule. *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (the "Final 340B Rule"). The Final 340B Rule set an effective date of March 6, 2017, with enforcement to begin April 1, 2017. *Id.* at 1,210-11. The effective date of the Final 340B Rule was delayed a number of times. See, e.g., *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 83 Fed. Reg. 25,943, 25,945 (June 5, 2018).

4. On September 11, 2018, Plaintiffs filed this action. Plaintiffs challenged Defendants' most recent delay of the Final 340B Rule on the grounds that the delay was arbitrary and capricious, an abuse of discretion, and contrary to law, in violation of section 706(2)(A) of APA. Plaintiffs also challenged Defendants' action on the grounds that the Defendants have unreasonably delayed implementing the Final 340B Rule in violation of section 706(1) of the APA.

5. On November 30, 2018, Defendants issued a final rule making the effective date of the Final 340B Rule January 1, 2019. *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Money Penalties Regulation*, 83 Fed. Reg. 61,563 (Nov. 30, 2018).

6. On April 1, 2019, Defendants provide covered entities access through an HHS website to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary," as required by 42 U.S.C. § 256b(d)(B)(iii). Declaration of Krista Pedley, Director of the Office of Pharmacy Affairs, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Service (ECF 35-1). Although there are some minor operational issues with the website, Plaintiffs expect to be able to work with HRSA to have these issues resolved.

In light of the foregoing, the parties stipulate to the dismissal of this action as moot pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii).

Dated: April 25, 2019

Respectfully submitted,

/s/ William B. Schultz

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