IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, Plaintiff, v. XAVIER BECERRA, Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	No. 1:20-cv-3032

JOINT STATUS REPORT

On December 17, 2020, the Parties jointly moved to stay this case. ECF No. 12. The stay was to permit Plaintiff National Association of Community Health Center ("NACHC")—on behalf of its covered entity members—to pursue claims in the 340B Administrative Dispute Resolution ("ADR") process established in the final ADR rule, 85 Fed. Reg. 80,632 (published Dec. 14, 2020, effective Jan. 13, 2021). The Court granted the Parties' motion. The Parties submitted Joint Status Reports on February 16, 2021, April 19, 2021, May 19, 2021, and June 21, 2021 advising the Court of relevant developments and requesting that the stay remain in place. ECF Nos. 13, 14, 15, 16. Pursuant to the Court's June 22, 2021 Minute Order, the parties respectfully submit this fifth Joint Status Report.

This case was filed on October 21, 2020, seeking the promulgation of ADR regulations. ECF No. 1. HHS promulgated a final ADR Rule on December 14, 2020. On January 13, 2021, the first effective day of the ADR regulation, NACHC—on behalf of certain Federally-qualified health center (FQHC) members—filed a joint ADR claim against drug manufacturers Eli Lilly and

Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC (collectively, "the drug manufacturers") alleging ongoing and unlawful overcharging and seeking equitable relief.

On January 14, 2021, NACHC filed a motion in the ADR process seeking a preliminary injunction from the ADR Panel compelling the drug manufacturers' immediate compliance with their statutory obligation to offer FQHC covered entities covered outpatient drugs at or below 340B ceiling prices, regardless of whether those drugs are to be dispensed in-house or through a contract pharmacy. NACHC's initial petition and its motion for immediate equitable relief were served on the drug manufacturers by certified mail, as the ADR process requires. The ADR Rule provides that, "[u]pon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56." 42 C.F.R. § 10.21(f). To date, the drug manufacturers have not submitted a response to either NACHC's petition or motion.

On March 16, 2021, the U.S. District Court for the Southern District of Indiana issued an order granting Eli Lilly & Co.'s ("Lilly") motion to preliminarily enjoin the ADR rule, as to Lilly only, on procedural APA grounds. Preliminary Injunction and Order, *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 16, 2021), ECF Nos. 81, 82. Given its observation that the "preliminary injunction will put on hold [an ADR] process that is not even currently operational," the court found that the balance of harms and public interest factors weighed in favor of Lilly. *Id*. at 27.[1]

[1] As prior status reports have provided, Lilly's suit is one of several brought by drug manufacturers against HHS in district courts across the country. *See Eli Lilly v. Azar*, No. 1:21-cv-81 (S.D. Ind.) (filed Jan. 12, 2021); *Sanofi v. HHS*, No. 3:21-cv-634 (D. N.J.) (filed Jan. 12, 2021); *AstraZeneca v. Azar*, No. 21-cv-27 (D. De.) (filed Jan. 12, 2021); *Novo Nordisk Inc., et al v. Azar*, No. 3:21-cv-00806-FLW-LHG (D. N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-00198-PWG (D. Md. Jan. 22, 2021). The cases challenge the ADR regulation, sought to enjoin enforcement of a December 30, 2020 HHS OGC Advisory Opinion that has since been withdrawn, and/or challenge HHS guidelines related to manufacturers' audits of covered entities. HHS continues to vigorously defend each lawsuit.

On March 23, 2021, the Health Resources and Services Administration ("HRSA"), an HHS subcomponent to which oversight of the 340B Program has been delegated, advised NACHC, through counsel, that "HRSA has done an initial review of your petition and determined your petition is complete."

On May 17, 2021, HHS, through the Acting Administrator of HRSA, issued enforcement letters to six drug manufacturers, including the three against whom NACHC has pending ADR claims. *See* HHS, HRSA, *340B Drug Pricing Program*, https://www.hrsa.gov/opa/index.html (indicating "HRSA has determined that [drug manufacturer] policies that place restrictions on 340B Program pricing to covered entities that dispense medications through pharmacies under contract have resulted in overcharges and are in direct violation of the 340B statute") The letters required that each drug manufacturer update HRSA by June 1, 2021 "on its plan to start selling, without restriction, covered outpatient drugs at the 340B discount price to covered entities that dispense medications through contract pharmacy arrangements." *See, e.g.*, Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director Government Strategy, Eli Lilly & Co. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf. However, to date, no manufacturer has indicated it intends to comply with HRSA's directive to resume the unrestricted sale of drugs to covered entities that dispense the drugs through contract pharmacies.

On June 21, 2021, HHS Secretary Becerra signed a memorandum appointing ADR Board members pursuant to 42 C.F.R. § 10.20. No panel has yet been assigned by the HRSA Administrator to adjudicate NACHC's ADR petition or motion for immediate relief.

On August 5, 2021, Chantelle Britton, Senior Advisor in HRSA's Office of Pharmacy Affairs, emailed counsel for NACHC indicating that, due to the preliminary injunction ordered on

March 16, 2021 in *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081-SEB-MJD, HRSA would not be "able to move ahead with any ADR process involving Lilly" and would "not take any further action related to NACHC's current petition at this time." The email concluded with an invitation to "resubmit a new" ADR petition. HRSA agreed on August 24, 2021 that by submitting a "new" petition, NACHC would not lose its original filing date. NACHC intends to comply with HRSA's preference for separate, resubmitted petitions within the next week.

In light of the foregoing, the parties propose that the stay remain in effect through October 25, 2021, on which date a joint status report—which will indicate proposed next steps for this matter—will be due.

Dated: August 24, 2021

Respectfully submitted,

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