

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

AMERICAN HOSPITAL)
ASSOCIATION, *et al.*,)
)
Plaintiffs)
)
v.)
)
ROBERT F. KENNEDY, JR.,)
SECRETARY of the U.S. Department)
of Health and Human Services, *et al.*,)
)
Defendants)

No. 2:25-cv-00600-LEW

ORDER

This matter is before the Court on the parties’ Joint Motion for Vacatur and Remand (ECF No. 114). On December 1, 2025, Plaintiffs filed their Complaint alleging that the 340B Rebate Model Pilot Program violated the Administrative Procedure Act (APA) and moved for a Temporary Restraining Order¹ to prevent the Rebate Program from taking effect on January 1, 2026. *See* Compl. (ECF No. 1), Mot. for TRO (ECF No. 3). On December 29, 2025, I preliminarily enjoined Defendants from implementing the Program. *See* Order on Mot. for Prelim. Inj. (ECF No. 90). In so doing, I concluded that Plaintiffs’ were likely to succeed on the merits of their claims that Defendants were required to but did not consider significant reliance interests and costs, based on Defendants’ preview of the administrative record. *Id.* at 9-18. Defendants requested a stay of the preliminary

¹ Plaintiffs’ request was converted into a motion for a preliminary injunction.

injunction pending appeal, which the First Circuit denied. Defendants' have since dismissed their appeal.

Defendants now represent that, following the decisions of both this Court and the First Circuit, they do not believe the full administrative record would change the outcome of this litigation at summary judgment. *See* J. Mot. for Vacatur & Remand ¶ 7. The parties agree that the agency actions comprising the Rebate Program should be vacated and remanded to the Department of Health and Human Services, to “allow [the agency] to correct [its] own mistakes without expending the resources of the court in reviewing a record that is admittedly incomplete or incorrect.” *Bennett v. Murphy*, No. 14-cv-10275, 2016 WL 1449571, at *1 (D. Mass. Apr. 13, 2016).

It is therefore ORDERED that the 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025), the Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025) are VACATED and REMANDED to the agency. The Joint Motion for Vacatur and Remand (ECF No. 114) is GRANTED.

SO ORDERED.

Dated this 10th day of February, 2026.

/s/ Lance E. Walker
Chief U.S. District Judge