UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

American Hospital Association, et al.,

Plaintiffs,

-v-

Case No. 1:18-cv-2084 (RC)

Xavier Becerra, Secretary of Health and Human Services, *et al.*,

Defendants.

UNOPPOSED MOTION FOR CLARIFICATION OF THE COURT'S SEPTEMBER 28, 2022 ORDER

Defendants respectfully seek clarification of the Court's September 28, 2022 Order ("Order") in this matter. ECF No. 78. That Order directed "that the drug reimbursement rate for 340B hospitals in the 2022 OPPS Rule is hereby VACATED with respect to its prospective application." Since there are other claims remaining in the case and the Court has not entered final judgment pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, Defendants seek clarification that the Order is merely interlocutory and without immediate effect. If the Court intends the Order to have immediate effect, Defendants respectfully request the Court enter a Rule 54(b) judgment to enable prompt compliance without rulemaking.

Under Federal Rule of Civil Procedure 54(b), "any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). It follows that if a court nevertheless grants relief based on an interlocutory

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order, such relief would not be effective until entry of final judgment, with limited exceptions, such as an interlocutory injunction. *See* 28 U.S.C. § 1292(a)(1).

Here, the Court's Order adjudicated fewer than all of the claims in this case. The Order resolved Plaintiffs' claim for prospective relief as applied to the 2022 Outpatient Prospective Payment System ("OPPS") rule, but there are other claims pending in this case that have not yet been adjudicated. In particular, upon remand of this case, Plaintiffs filed a second supplemental complaint, which added claims challenging the OPPS rules that Defendants promulgated for 2020, 2021, and 2022, in addition to the previously asserted claims based on the 2018 and 2019 OPPS rules. ECF No. 66; *see also* Minute Order dated Aug. 4, 2022 (granting motion for leave to file second supplemental complaint). Plaintiffs also filed a motion asking the Court to hold the 2020 to 2022 rules unlawful and to order the agency to provide relief in connection with certain payments previously made under the 2018 to 2022 rules. ECF No. 69. That motion remains pending.

Rule 54(b) further provides that "[w]hen an action presents more than one claim for relief ... the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay." Fed. R. Civ. P. 54(b). "In order for a Rule 54(b) judgment to be effective, the district court must make an express direction for the entry of judgment." 10 Moore's Federal Practice - Civil § 54.24 (2022); *Blackman v. District of Columbia*, 456 F.3d 167, 175-76 (D.C. Cir. 2006) (explaining that Rule 54(b) requires an *express* determination that there is no reason for delay and an *express* direction for the entry of judgment); *see also, e.g., Cook Cty. v. Wolf*, 498 F. Supp. 3d 999, 1011 (N.D. Ill. 2020) (entering "a Rule 54(b) judgment vacating the Final Rule, to take effect immediately" where there were other unadjudicated claims in the litigation).

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Here, the Court has not entered a Rule 54(b) judgment expressly finding that "there is no just reason for delay," Fed. R. Civ. P. 54(b), and therefore the vacatur Order is without immediate effect. But because the Court's Memorandum Opinion states that "vacatur will immediately revert the 340B reimbursement rate to the default rate," Mem. Op., ECF No. 79, at 2, in an abundance of caution, Defendants seek clarification as to whether the Court intends to enter a Rule 54(b) final judgment, making the Order immediately effective.

Should the Court enter a Rule 54(b) final judgment, Defendants respectfully submit that the process of adjusting the 2022 OPPS payment rates for 340B hospitals would take approximately two weeks.¹ That process requires revisions to four different electronic data files and then testing by multiple offices to confirm that the revised files function appropriately before the files are loaded to the production environment where they will be used to calculate OPPS reimbursements on a prospective basis. The agency has begun preparing to adjust the payment rates in the event the Court clarifies that it intended the Order to have immediate effect. Without an immediately effective order, the agency would have to follow APA rulemaking procedures to adjust the payment rates, *see* 5 U.S.C. § 553, which could lengthen the time necessary to adjust the rates.

For these reasons, Defendants respectfully request the Court clarify whether it will enter a Rule 54(b) judgment. Defendants' counsel conferred with Plaintiffs' counsel about the relief sought herein, and Plaintiffs' position is as follows:

Plaintiffs understand the Court's Order of September 28, 2022, to require Defendants to reimburse, at ASP plus 6%, all claims for 340B drugs under the 2022 OPPS Rule that have not yet been paid as of the date of the Court's order. Counsel for Defendants has represented to counsel for Plaintiffs that Defendants are seeking

¹ Ordinarily, pricing file updates can take up to 90 days, but the agency has developed a plan to expedite the changes here.

a Rule 54(b) judgment only for the purpose of facilitating prompt compliance with the Court's order. On that basis, Plaintiffs do not oppose Defendants' motion.

Respectfully submitted,

BRIAN M. BOYNTON Principal Deputy Assistant Attorney General

ERIC B. BECKENHAUER Assistant Branch Director Federal Programs Branch

/s/ Joshua Kolsky

JOSHUA KOLSKY Trial Attorney D.C. Bar No. 993430 United States Department of Justice Civil Division, Federal Programs Branch 1100 L Street NW Washington, DC 20005 Tel.: (202) 305-7664 Fax: (202) 616-8470 E-mail: joshua.kolsky@usdoj.gov

Attorneys for Defendants