

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**THE AMERICAN HOSPITAL
ASSOCIATION, et al.,**

Plaintiffs,

v.

**THE DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.**

Defendants.

Civil Action No. 18-2112 (JDB)

ORDER

Plaintiffs, a collection of hospitals, hospital associations, and healthcare providers, have brought this action against the Department of Health and Human Services (“HHS”) and Secretary of HHS Alex M. Azar II, in his official capacity, arguing that HHS’s decision to continue to delay implementation of a final rule (the “Rule”) it issued on January 5, 2017, is arbitrary and capricious and constitutes “unreasonably delayed” agency action under the Administrative Procedure Act (“APA”), 5 U.S.C. § 500 *et seq.* Compl. [ECF No. 1] ¶¶ 21–22, 57–62 (quoting 5 U.S.C. §§ 706(1)–(2)). Concurrent with the filing of their complaint, plaintiffs moved for summary judgment. The government now moves to stay the case pending the outcome of an anticipated rule that would advance the effective date of the Rule, or, in the alternative, to stay briefing of summary judgment until after the Court has decided the government’s yet-to-be-filed motion to dismiss. For the reasons described below, the government’s motion will be denied.

The Rule at issue is part of the 340B Program, which was established by the Veterans Health Care Act of 1992, Pub. L. No. 102–585, § 602, 106 Stat. 4943, 4967–71 (1992), and codified in section 340B of the Public Health Service Act, 42 U.S.C. § 256b (1992). The 340B Program lowered drug costs for certain federally-funded health providers serving low-income

communities, setting maximum prices for covered outpatient drugs. See 42 U.S.C. § 256b. In 2010, Congress instructed the Secretary of HHS to improve compliance by drug manufacturers with the 340B Program by, among other things, (1) developing and publishing standards and methodology for the calculation of ceiling prices for covered drugs; (2) establishing refund procedures for instances of manufacturer overcharges; (3) providing covered health care providers with access to the applicable ceiling prices via the HHS website; and (4) imposing sanctions on noncompliant manufacturers. See Patient Protection and Affordable Care Act, Pub. L. 111–148, § 7102, 124 Stat. 119, 823–27 (2010).

Pursuant to Congress’ mandate, HHS promulgated a 340B final rule on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017). The Rule “set forth the calculation of the 340B ceiling price and application of civil monetary penalties” to “provide increased clarity in the marketplace for all 340B Program stakeholders as to the calculation of the 340B ceiling price.” Id. at 1210–11.

Nearly twenty-two months have passed since HHS issued the final Rule. During this period, the government has pushed back implementation of the Rule five times, most recently delaying the effective date to July 1, 2019. Compl. ¶¶ 51–56. Plaintiffs allege that these delays have caused significant harm to the approximately 2,487 covered 340B entities, including by causing them to be overcharged for drugs. Compl. ¶¶ 9, 25–27.

The government now moves the Court to stay this case pending the outcome of HHS’s planned rulemaking. See Mem. in Supp. of Defs.’ Mot. for a Stay (“Gov’t’s Mot.”) [ECF No. 15] at 1. On October 31, 2018, HHS filed a notice of proposed rulemaking that would change the effective date of the Rule from July 1, 2019 to January 1, 2019. See Notice Regarding Pub. of Notice of Proposed Rulemaking [ECF No. 18]. The proposed rule was published in the Federal

Register on November 2, 2018, and gives stakeholders 21 days to submit comments. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 55,135, 55,135 (Nov. 2, 2018). According to HHS, January 1 is the earliest the Rule could take effect because the 340B program runs on a quarterly system, and the next quarter starts January 1. Gov't's Mot. at 4. HHS argues that moving the effective date to January 1, 2019 "would effectively provide plaintiffs with all the relief they have sought in their Complaint . . . and thereby moot the case," or at least narrow the relevant issues. Id.

Plaintiffs respond that there is no guarantee that HHS will issue a final rule advancing the effective date of the Rule, or that it will become effective on January 1, 2019, given the length of the comment period and the requirement that the final rule be published 30 days before it becomes effective. See Pls.' Mem. in Opp'n to Gov't's Mot. ("Pls.' Opp'n") [ECF No. 16] at 4–5. Because the 340B program is organized on a quarterly basis, if the effective date falls after January 1, 2019, the Rule would not be implemented in practice until April 1, 2019. Id. at 5.

The Court declines to stay the case pending the outcome of the government's proposed rule. As the government notes, "it is not certain" the proposed rulemaking moving the effective date will moot the case. Reply in Supp. of Gov't's Mot. ("Gov't's Reply") [ECF No. 17] at 2 (emphasis omitted). Nor is it certain that the proposed rulemaking moving the effective date to January 1 will become final by that date. Although the government has curtailed the typical comment period from 30 days to 21 days, see 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. at 55,135, it is not clear that any rule moving the effective date would become final sufficiently in advance of January 1, 2019. See 5 U.S.C. § 533(d) (requiring publication of final rule to be made 30 days before its effective date unless certain exceptions apply). And HHS cannot guarantee that the proposed rule advancing the

effective date will become final at all, as HHS is required to consider any comments made before it issues a final rule. See Am. Civil Liberties Union v. FCC, 823 F.2d 1554, 1581 (D.C. Cir. 1987) (“Notice and comment rulemaking procedures obligate the [agency] to respond to all significant comments, for ‘the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.’” (citation omitted)).

The government also requests, in the alternative, that the Court defer full briefing of plaintiffs’ “premature” summary judgment motion and instead consider the defenses the government intends to assert pursuant to Federal Rule of Civil Procedure 12. Gov’t’s Mot. at 5. The government notes that the Federal Rules of Civil Procedure afford it 60 days to respond to a complaint, including by filing a motion to dismiss. Gov’t’s Reply at 5. Its response may raise threshold, non-merits issues, the government contends, such as whether plaintiffs have standing to assert their claims. See id. The government also argues that jurisdictional discovery may be required to determine whether the case may proceed, and consideration of plaintiffs’ summary judgment motion would therefore be improper. Id. at 5–6.¹

Plaintiffs argue that a stay pending any decision regarding the government’s anticipated motion to dismiss would be inappropriate because there is a “need for an expedited decision.” Pls.’ Opp’n at 6. And there is no need to delay summary judgment briefing, plaintiffs contend, because judicial review will be based solely on the administrative record. See id.

The Court agrees with plaintiffs that postponing summary judgment briefing pending the resolution of the government’s anticipated motion to dismiss would not serve the orderly disposition of this case. Federal Rule of Civil Procedure 56(b) provides that “a party may file a

¹ Although the government suggests that jurisdictional discovery may be required, no motion requesting such discovery is currently before the Court.

motion for summary judgment at any time until 30 days after the close of all discovery.” Fed. R. Civ. P. 56(b) (emphasis added).² Although “in many cases the motion will be premature until the nonmovant has had time to file a responsive pleading,” Fed. R. Civ. P. 56 advisory committee’s notes (2010 amendment), in APA cases early summary judgment motions are often appropriate, as “[t]he entire case on review is a question of law, and only a question of law,” Marshall Cty. Health Care Auth. v. Shalala, 988 F. 2d 1221, 1226 (D.C. Cir. 1993). The line that divides the motion-to-dismiss stage of proceedings from summary judgment is therefore less clear. Even when a motion to dismiss is filed in an APA case, a court “may convert the motion into a motion for summary judgment under Rule 12(d).” Bates v. Donley, 935 F. Supp. 2d 14, 17 (D.D.C. 2013).

The Court finds that it is in the interest of the sound administration of judicial—and the parties’—resources to proceed with one combined briefing schedule for plaintiffs’ summary judgment motion and any motion to dismiss or cross-motion for summary judgment the government may file.³ See Grimes v. District of Columbia, 794 F.3d 83, 90 (D.C. Cir. 2015) (“Typically, a district court enjoys broad discretion in managing its docket and determining the order in which a case should proceed”); Fed. R. Civ. P. 56 advisory committee’s notes to 2010 amendment (noting courts “can regulate [the timing of summary judgment motions] to fit the needs of the case”). It is therefore hereby

² The government characterizes plaintiffs’ summary judgment motion as an “ersatz motion for emergency relief.” Gov’t’s Mot. at 6. Although plaintiffs do assert that they require “an expedited decision,” Pls.’ Opp’n at 6, that is beside the point. Rule 56(b) does not provide that summary judgment is only appropriate when the party has demonstrated a pressing need for it; “‘at any time’ does in fact mean ‘at any time.’” Parker v. Hoglander, Civ. Action No. 15-926 (JDB), 2016 WL 3527014, at *3 (D.D.C. June 23, 2016).

³ The potential jurisdictional issue the government has flagged—plaintiffs’ standing—may equally be considered at the summary judgment stage. See, e.g., All. for Nat. Health U.S. v. Sebelius, 775 F. Supp. 2d 114, 119 (D.D.C. 2011) (addressing at summary judgment stage the “threshold question” of “whether the plaintiffs have standing” in light of the affidavits that had been filed).

ORDERED that [15] the government's motion to stay the case or, in the alternative, to stay briefing of plaintiffs' summary judgment motion is **DENIED**; it is further

ORDERED that the parties shall file by not later than November 8, 2018 a joint proposed briefing scheduling in accordance with the following specifications:

1. The government shall file in one consolidated brief its opposition to plaintiffs' motion for summary judgment and the government's motion to dismiss or cross-motion for summary judgment, if any, by not later than November 13, 2018.
2. The government shall file a certified list of the contents of the administrative record with the Court, in accordance with Local Rule 7(n), simultaneously with any consolidated motion or opposition.
3. Plaintiffs shall file in one consolidated brief any reply to the government's opposition to plaintiffs' motion for summary judgment and any response in opposition to the government's motion to dismiss or cross-motion for summary judgment.
4. The government may file a reply to plaintiffs' opposition to the government's motion to dismiss or cross-motion for summary judgment.

SO ORDERED.

/s/

JOHN D. BATES
United States District Judge

Dated: November 2, 2018