UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

OREGON HEALTH & SCIENCE UNIVERSITY, Plaintiff, v. THOMAS J. ENGELS, *et al.*, Defendants;	Civil Action No.: Re Document Nos.:	24-2184 (RC) 18, 20
MAINEGENERAL MEDICAL CENTER, Plaintiff, v. THOMAS J. ENGELS, *et al.*, Defendants;	Civil Action No.: Re Document Nos.:	24-2187 (RC) 19, 21
UNIVERSITY OF ROCHESTER, Plaintiff, v. THOMAS J. ENGELS, *et al.*, Defendants;	Civil Action No.: Re Document Nos.:	24-2268 (RC) 18, 20
CHILDREN'S NATIONAL MEDICAL CENTER, Plaintiff, v.	Civil Action No.: Re Document Nos.:	24-2563 (RC) 15, 18

THOMAS J. ENGELS, *et al.*,	:	
	:	
Defendants;	:	
	:	
UNIVERSITY OF WASHINGTON MEDICAL CENTER,	:	
	:	
Plaintiff,	:	Civil Action No.: 24-2998 (RC)
	:	
v.	:	Re Document Nos.: 26, 28
	:	
ROBERT F. KENNEDY, JR., *et al.*,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION[1]

GRANTING DEFENDANTS' MOTIONS TO DISMISS; AND GRANTING JOHNSON & JOHNSON'S MOTIONS FOR LEAVE TO FILE AMICUS BRIEFS

I. INTRODUCTION

In April 2024, Johnson & Johnson Health Care Systems Inc. ("J&J"), a pharmaceutical drug manufacturer, contacted Plaintiffs, healthcare providers, regarding their utilization of drugs in the 340B Drug Pricing Program, 42 U.S.C. § 256b. The 340B Program requires that pharmaceutical drug manufacturers that participate in Medicaid and Medicare Part B, like J&J, sell drugs to statutorily covered entities, like the hospitals and medical centers operated by Plaintiffs,[2] at lower prices. The statute also authorizes manufacturers to conduct audits of

[1] This Memorandum Opinion addresses pending motions in the five cases listed above. For convenience, the Court will cite to docket numbers from the earliest filed case, *Oregon Health & Science University v. Engels*, No. 24-cv-2184, unless otherwise specified.

[2] Plaintiffs are Oregon Health & Science University ("OHSU"), MaineGeneral Medical Center ("MaineGeneral"), University of Rochester, Children's National Medical Center ("Children's National"), and University of Washington Medical Center ("UWMC").

covered entities, at the manufacturers' expense, to ensure compliance with statutory provisions related to those lower prices. J&J submitted audit plans for Plaintiffs to the Health Resources and Services Administration ("HRSA" or "Agency"), an agency within the Department of Health and Human Services ("HHS"), and HRSA approved the audit plans. But Plaintiffs objected, and brought this suit against the heads of HRSA and HHS, arguing that HRSA's allowance of J&J's audit without following certain procedures was arbitrary, capricious, and contrary to law under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706.[3] Defendants filed motions to dismiss each of the cases under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6), arguing that this Court lacks subject matter jurisdiction because the cases are not ripe and that Plaintiffs failed to state a claim because HRSA's approvals of J&J's audit plans were not "final agency action" subject to judicial review under the APA, 5 U.S.C. § 704. J&J has filed an amicus brief in each case in support of Defendants.[4] Because the Court concludes that there has been no final agency action, the motions to dismiss are granted.

II. BACKGROUND

A. Regulatory Background

Under § 340B of the Public Health Service Act, "manufacturers participating in Medicaid [and Medicare Part B] must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S.

[3] Pursuant to Federal Rule of Civil Procedure 25(d), these officials have been substituted for their successors. Plaintiff UWMC also named HRSA as a defendant. Compl., ECF No. 1, No. 24-cv-2998 ("UWMC Compl.").

[4] The overall dispute involves HRSA, Plaintiffs, and J&J, the manufacturer that requested the audits at issue. Because J&J is a key player that has unique information or perspective that can help the Court beyond the help that the lawyers for the parties are able to provide, *see Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 137 (D.D.C. 2008), J&J's motions for leave to file amicus briefs (ECF No. 20, No. 24-cv-2184; ECF No. 21, No. 24-cv-2187; ECF No. 20, No. 24-cv-2268; ECF No. 18, No. 24-cv-2563; ECF No. 28, No. 24-cv-2998) are granted over objection.

110, 115 (2011); 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5). Participation in the 340B Program benefits both drug manufacturers and covered entities—it allows manufacturers to participate in Medicaid and Medicare Part B programs, and it allows covered entities to obtain drugs at lower cost. *See Astra*, 563 U.S. at 113; 42 U.S.C. § 1396r-8(a)(1), (5). But Congress identified two potential misuses of the Program: duplicate discounts, 42 U.S.C. § 256b(a)(5)(A), and diversions, *id.* § 256b(a)(5)(B). Duplicate discounts occur when a covered entity receives a discount or rebate for a unit of a drug under both the 340B Program and the Medicaid program. *Id.* § 256b(a)(5)(A). Diversions occur when drugs are sold or transferred "to a person who is not a patient of the entity," thereby defeating the purpose of affording the covered entity that status, such as providing "safety-net services to the poor." *Id.* § 256b(a)(5)(B); *Astra*, 563 U.S. at 113.

How are these prohibitions to be enforced? To "assure the integrity of the drug price limitation program," including these prohibitions, Congress provided for "auditing" by the Agency or drug manufacturers as a "requirement[] for covered entities." H.R. Rep. 102-384, pt. 2, at 16 (Sept. 22, 1992); 42 U.S.C. § 256b(a)(5)(C).

> A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) [duplicate discounts] or (B) [diversions] with respect to drugs of the manufacturer.

42 U.S.C. § 256b(a)(5)(C). Noncompliance with the prohibitions against duplicate discounts and diversions is sanctionable, including with liability to the manufacturer for underpayment for the drugs. *Id.* § 256b(a)(5)(d). But sanctions are levied "after audit as described in subparagraph (C) and after notice and hearing." *Id.*

In accordance with the statute, in 1996 HRSA promulgated a final notice titled "Manufacturer Audit Guidelines and Dispute Resolution Process" (the "Guidelines") after notice and comment. 61 Fed. Reg. 65406 (Dec. 12, 1996). The Guidelines describe the number, scope, and duration of audits, the procedures to be followed, and suggested steps for the audits. *See id.* at 65409–11. The Guidelines require that the manufacturer's auditor "be an independent public accountant employed by the manufacturer to perform the audit" in accordance with its ethical and legal obligations, as well as "[p]atient confidentiality requirements." *Id.* at 65409.

To initiate an audit, "[t]he manufacturer shall notify the covered entity in writing" when it has reasonable cause to believe that "the covered entity has violated provisions of section 340B." *Id.* at 65409–10. For example, "[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause." *Id.* at 65406. The manufacturer and covered entity then have at least 30 days "to attempt in good faith to resolve the matter." *Id.* at 65410. "If the matter is not resolved and the manufacturer desires to perform an audit, the manufacturer must file an audit work plan," a description of why it believes a duplicate discount or diversion has occurred, and "sufficient facts and evidence in support of the belief" with HRSA. *Id.* HRSA requires review to "ensure that the audits are performed where there are valid business concerns . . . with the least possible disruption to the covered entity." *Id.* at 65406. HRSA has 15 days to review the documentation after submission. *Id.* at 65410. If HRSA "finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene." *Id.* In that case, HRSA can also determine whether it will allow the manufacturer's auditor to proceed, or whether the

government will conduct the audit itself. *Id.* Regardless, the covered entity must have at least "15 days to prepare for the audit." *Id.*

These procedures do not affect the status quo of the 340B Program for the parties: "The filing of a[n] audit work plan does not affect the statutory obligations of the parties as defined in section 340B . . . . During the audit process, the manufacturer must continue to sell covered outpatient drugs at the section 340B ceiling price to the covered entity being audited, and the covered entity must continue to comply with the requirements of section 340B(a)(5)." *Id.*

After the audit is complete, the manufacturer must submit the audit report to the covered entity and HRSA. *Id.* The covered entity then has 30 days to respond to the reports' findings and recommendations, including whether it agrees or disagrees with the findings and its reasons. *Id.* "If a dispute concerning the audit findings and recommendations arises, the parties may file a request for dispute resolution" with HRSA. *Id.* "The administrative resolution of a claim" under the administrative dispute resolution process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

B. Factual and Procedural Background

Plaintiffs operate covered entities, such as hospitals and medical centers, that participate in the 340B Program. Compl. ¶ 29, ECF No. 1 ("OHSU Compl."); Compl. ¶ 29, ECF No. 1, No. 24-cv-2187 ("MaineGeneral Compl."); Compl. ¶ 29, ECF No. 1, No. 24-cv-2268 ("University of Rochester Compl."); Compl. ¶ 29, ECF No. 1, No. 24-cv-2563 ("Children's National Compl."); Compl. ¶ 17, ECF No. 1, No. 24-cv-2998 ("UWMC Compl."). On April 22, 2024, J&J sent Plaintiffs emails seeking to schedule meetings to discuss Plaintiffs' "340B utilization." OHSU Compl. ¶¶ 52–53; MaineGeneral Compl. ¶¶ 52–53; University of Rochester Compl. ¶¶ 54–55;

Children's National Compl. ¶¶ 52–53; UWMC Compl. ¶ 45. The parties corresponded via email in the following weeks and dispute at which point, if any, J&J gave written notice that it suspected that Plaintiffs had violated 42 U.S.C. § 256b(a)(5)(A)–(B)'s prohibitions against duplicate discounts or diversions. *Compare* Pl.'s Response to Def.'s Mot. to Dismiss ("Pl.'s Opp'n") at 1, ECF No. 22 ("In this case, J&J never provided written notice to OHSU of any potential duplicate discount or diversion violations . . . ."), *with* Defs.' Reply in Further Supp. of Mot. to Dismiss ("Defs.' Reply") at 10, ECF No. 25 ("If [J&J]'s April 22 email requesting time to discuss Oregon Health's '340B utilization' did not put Oregon Health on notice that [J&J] potentially had concerns with Oregon Health's compliance with 340B Program requirements then the May 15 email seeking specifically to discuss 'the growth of your entity's 340B utilization' should have . . . ."). Regardless, on June 20, 2024, four Plaintiffs received a letter from Deloitte & Touche, LLP, J&J's auditor, informing them that HRSA had approved J&J's audit request. OHSU Compl. ¶ 59; MaineGeneral Compl. ¶ 59; University of Rochester Compl. ¶ 61; UWMC Compl. ¶ 53. The other Plaintiff received a similar letter on July 16, 2024. Children's National Compl. ¶¶ 64–65. Plaintiffs requested that HRSA reconsider its prior approval of J&J's audits, which HRSA declined to do. OHSU Compl. ¶¶ 70, 73; MaineGeneral Compl. ¶¶ 70, 73; University of Rochester Compl. ¶¶ 72, 75; Children's National Compl. ¶¶ 80, 83; UWMC Compl. ¶¶ 67, 70.

From July through October 2024, Plaintiffs filed their Complaints in these cases, each alleging a single cause of action for violation of the APA. OHSU Compl. ¶¶ 116–20; MaineGeneral Compl. ¶¶ 116–20; University of Rochester Compl. ¶¶ 118–22; Children's National Compl. ¶¶ 126–30; UWMC Compl. ¶¶ 115–21. Four Plaintiffs allege that "HRSA's decision to authorize J&J's audit request, even though the manufacturer failed to provide the

required written notice to Plaintiff, was arbitrary, capricious, and unlawful." OHSU Compl. ¶ 117; MaineGeneral Compl. ¶ 117; University of Rochester Compl. ¶ 119; Children's National Compl. ¶ 127. Plaintiff UWMC slightly reframes HRSA's error as allowing "J&J to proceed with the manufacturer audit of UWMC without first going through the notice *and good-faith engagement procedures* set out in the Manufacturer Audit Guidelines," and adds that allowing the audit to proceed is also arbitrary, capricious, an abuse of discretion, contrary to law, in excess of authority, and without observance of legally required procedure because the audit's scope goes beyond that allowed by statute and the Guidelines. UWMC Compl. ¶¶ 116–18 (emphasis added).

In December 2024 and January 2025, Defendants moved to dismiss the Complaints in these cases, arguing in each motion that (1) this Court lacks subject matter jurisdiction because the claims are not ripe for review, and (2) the APA claims fail because HRSA's approval of a manufacturer audit is not a "final" agency action, and HRSA acted consistently with published guidance. Defs.' Mot. to Dismiss ("Mot. to Dismiss") at 1, ECF No. 18; Defs.' Mot. to Dismiss at 1, ECF No. 19, No. 24-cv-2187; Defs.' Mot. to Dismiss at 1, ECF No. 18, No. 24-cv-2268; Defs.' Mot. to Dismiss at 1, ECF No. 15, No. 24-cv-2563; Defs.' Mot. to Dismiss at 1, ECF No. 26, No. 24-cv-2998. Plaintiffs opposed the motions, arguing that (1) HRSA's approvals of J&J's audits and reservation of the right to remove Plaintiffs from the 340B Program were final agency actions, (2) this dispute is ripe for review, even if HRSA's actions were not "final," and (3) HRSA did not comply with its own Guidelines. Pl.'s Resp. to Def.'s Mot. to Dismiss ("Pl.'s Opp'n") at 2–3, 9, ECF No. 22; Pl.'s Resp. to Defs.' Mot. to Dismiss at 2–4, 10–11, ECF No. 23, No. 24-cv-2187; Pl.'s Resp. to Defs.' Mot. to Dismiss at 2–4, 9–10, ECF No. 22, No. 24-cv-2268; Pl.'s Resp. to Def.'s Mot. to Dismiss at 2–3, 17–18, ECF No. 16, No. 24-cv-2563; Mem.

of P. & A. in Opp'n to Defs.' Mot. to Dismiss at 16–33, ECF No. 30, No. 24-cv-2998 ("UWMC Opp'n"). The motions are now fully briefed and ready for review.

III. LEGAL STANDARD

"To survive a motion to dismiss" under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). But courts need not accept as true "mere conclusory statements" or "legal conclusions." *Id.*

Under the APA, courts may review "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Consistent with this rule, a "preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action." *Id.* Though "the requirement of finality is not jurisdictional," *Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1267 (D.C. Cir. 2018), absent final agency action or a statute specifically authorizing judicial review, there is no cause of action under the APA, *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003).

The Supreme Court has articulated a two-prong test to determine whether an agency action is "final": "First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citations omitted) (first quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948), then quoting *Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatlantic*,

400 U.S. 62, 71 (1970)). "An order must satisfy both prongs of the *Bennett* test to be considered final." *Sw. Airlines Co. v. U.S. Dep't of Transp.*, 832 F.3d 270, 275 (D.C. Cir. 2016). "This final order rule codifies the understanding that '[p]remature review squanders judicial resources,' and that litigants are generally 'best served by a system which prohibits piecemeal appellate consideration of rulings that may fade into insignificance by the time proceedings conclude.'" *Vanda Pharms., Inc. v. U.S. Food & Drug Admin.*, 123 F.4th 513, 521 (D.C. Cir. 2024) (alteration in original) (quoting *CSX Transp., Inc. v. Surface Transp. Bd.*, 774 F.3d 25, 31 (D.C. Cir. 2014)).

IV. ANALYSIS

If the Court finds that there has been no final agency action, then its analysis ends where it begins. This determination hinges on whether HRSA's approvals of J&J's audit plans constitute final agency action. Under *Bennett*'s first prong, HRSA's audit approvals are not the "consummation" of a decision-making process because they are a preliminary step to determine whether a covered entity has violated the prohibition on duplicate discounts or diversions. And under *Bennett*'s second prong, the legal consequences to which Plaintiffs object flow from their statutory obligations, not from HRSA's actions. The objections they raise can be made in the first instance to the Agency in its dispute resolution proceedings, should they be necessary. But at this stage, Plaintiffs' claims challenge "preliminary, procedural, or intermediate agency action," not final agency action that is immediately reviewable. *See* 5 U.S.C. § 704. Accordingly, Defendants' motions to dismiss for failure to state a claim are granted.[5]

[5] To determine whether a dispute is ripe for review, a court must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 n.4 (D.C. Cir. 2012) (quoting *Abbott Labs. v. Gardner,* 387 U.S. 136, 149 (1967)). "Although both the fitness and hardship prongs encompass a number of considerations, a dispute is not ripe if it is not fit,

A. Consummation of Agency's Decision-Making Process

As stated above, the first prong of the *Bennett* test for finality asks whether the agency action "mark[s] the 'consummation' of the agency's decisionmaking process." *Bennett*, 520 U.S. at 177–78 (quoting *Chicago & S. Air Lines*, 333 U.S. at 113). Defendants argue that HRSA's approval of the audits is not final under the APA, and analogize initiating an audit to starting an investigation because "[a]dditional steps are required before the Agency can take any action limiting [Plaintiffs'] participation in the 340B Program or any other action based on the audit." Mot. to Dismiss at 10–11; *see Harper v. Werfel*, 118 F.4th 100, 116–17 (1st Cir. 2024) (citing cases where circuit courts have concluded that "investigatory measures are not final agency action"). Plaintiffs counter that the relevant "final" decisions were the audit approvals, on which HRSA has "doubled down" by mentioning the possibility of removal from the Program if the covered entities do not cooperate with the audits. Pl.'s Opp'n at 8–9. Defendants have the better argument, as a decision not to intervene in the audit process based on a determination that there is reasonable cause to believe a violation has occurred is not a definitive determination, but rather a "threshold determination that further inquiry is warranted." *See Fed. Trade Comm'n v. Standard Oil Co.*, 449 U.S. 232, 241 (1980).

To mark the consummation of the agency's decision making, the action must mark a "definitive" position, *id.*, rather than being "merely tentative or interlocutory," *Bennett*, 520 U.S. at 177–78. "[W]hen assessing the nature of an agency action (including whether it is final), courts should resist the temptation to define the action by comparing it to superficially similar actions in the caselaw. Rather, courts should take as their NorthStar the unique constellation of

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and (at least in an APA case) it is not fit if it does not involve final agency action." *Id.* (citations omitted). Thus, in light of the Court's finding of a lack of finality in HRSA's actions, the Court does not separately analyze ripeness.

statutes and regulations that govern the action at issue." *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 631 (D.C. Cir. 2019); *see also Soundboard Ass'n*, 888 F.3d at 1267 ("The decisionmaking processes set out in an agency's governing statutes and regulations are key to determining whether an action . . . represents the culmination of that agency's consideration of an issue."). Relatedly, "the extent to which the [party] may challenge" an action before the agency may also indicate how definitive the determination is. *See Standard Oil Co.*, 449 U.S. at 241.

For example, in *Reliable Automatic Sprinkler Co.*, a manufacturer of automatic sprinkler heads brought a pre-enforcement action against the Consumer Product Safety Commission ("CPSC") seeking a declaratory judgment that the Commission lacked statutory authority to regulate the manufacturer. 324 F.3d at 728–29. At the time the manufacturer sued, the Commission had conducted an investigation, notified the manufacturer of its intention to make a preliminary determination that the manufacturer's sprinkler heads presented a "substantial product hazard," and requested voluntary corrective action. *Id.* The manufacturer accepted that the agency had not made a final decision on the substantive question of whether its sprinkler heads were hazardous, but instead argued that the agency had made a final determination regarding its jurisdiction to regulate the manufacturer's product. *Id.* at 731. The court rejected this reasoning, explaining that "the agency ha[d] not yet taken the steps required under the statutory and regulatory scheme for its actions to have any legal consequences," including "formal, on-the-record adjudication." *Id.* at 732. The court's conclusion was the same, even considering the "practical consequences" for the manufacturer if it chose not to comply with the agency's request for corrective action, including "the prospect of having to defend itself in an administrative hearing should the agency actually decide to pursue enforcement." *Id.* The court

reiterated the purposes behind the final agency rule, and concluded that "[i]t conserves both judicial and administrative resources to allow the required agency deliberative process to take place before judicial review is undertaken." *Id.* at 732–33.

Here, the "constellation of statutes and regulations" points the Court to the conclusion that HRSA's decision to approve, and not intervene in, J&J's audits is not the consummation of the agency's decision making because the pertinent question—whether Plaintiffs unlawfully benefited from duplicate discounts or diversions—has not been definitively answered by anyone, let alone HRSA. *See Cal. Cmtys. Against Toxics*, 934 F.3d at 631. Rather, HRSA's satisfaction "that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred" is a preliminary determination that permits J&J to proceed with its audit, the scope of which must be limited to records "that directly pertain to the potential 340B violation(s)." *See* Guidelines I(b), II(c), 61 Fed. Reg. at 65409–10. The preliminary nature of the audit approval is further supported by the Guidelines' consideration that Plaintiffs may agree with an independent auditor's findings. *See, e.g.*, Guidelines II(g), 61 Fed. Reg. at 65410 ("When the covered entity agrees with the audit report's findings and recommendations either in full or in part . . . ."); Guidelines II(i), 61 Fed. Reg. at 65410 ("If a dispute concerning the audit findings and recommendations arises . . . ."). Further, "the agency has not yet done that which the statutory scheme requires for its conduct to constitute final agency action," including the dispute resolution process. *See Reliable Automatic Sprinkler Co.*, 324 F.3d at 734; 42 U.S.C. § 256b(d)(3)(C). Thus, the current dispute involves issues "that may fade into insignificance by the time proceedings conclude," which counsels against judicial intervention. *See Vanda Pharms.*, 123 F.4th at 521 (quoting *CSX Transp.*, 774 F.3d at 31).

Like the plaintiff in *Reliable* that framed its claim as jurisdictional, Plaintiffs frame their claims as procedural, challenging "whether required procedures were followed that would have enabled HRSA to authorize the audit[s] in the first place." Pl.'s Opp'n at 9. Their concerns are primarily that they did not receive adequate written notice from J&J, which would have triggered the thirty-day negotiation period, *id.* at 1–2, and that the audits HRSA approved go beyond the legally permissible scope, UWMC Opp'n at 12. In framing their complaints as procedural, Plaintiffs liken this dispute to *Ciba-Geigy Corporation v. EPA*, 801 F.2d 430 (D.C. Cir. 1986). There, the EPA notified the plaintiff, a manufacturer and seller of pesticides, that the EPA had reclassified an ingredient in its pesticide that required a change to the product's labeling. *Id.* at 431–33. The notice informed pesticide registrants that the EPA would cancel their registrations if they did not submit revised labels. *Id.* at 432–33. The plaintiff and the EPA corresponded via letters, in which the EPA reaffirmed its position, so the plaintiff sued. *Id.* at 433. Rather than challenging whether its pesticide should have been reclassified, the plaintiff's complaint raised "a pure legal question as to what procedures EPA was obliged to follow before requiring a labeling change." *Id.* at 435. Specifically, the EPA had taken the position that it was not required to hold a cancellation hearing before it could impose labelling changes, which the plaintiff argued violated the EPA's statutory authority. *Id.* at 437. In holding that the EPA's conduct constituted a final agency action ripe for review, the court explained that "[o]nce the agency publicly articulates an unequivocal position . . . and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review." *Id.* at 436.

But the procedural questions raised in *Ciba-Geigy* and here are materially different, justifying different outcomes on finality. In *Ciba-Geigy* the EPA determined that it could bring

an enforcement action for violation of primary conduct—the selling of pesticides—without a cancellation hearing. *Id.* at 437. Here, HRSA has approved the first step in a series of procedures distinct from primary conduct—the purchase of 340B drugs at reduced cost—which procedures include a hearing, should one be necessary. *See* 42 U.S.C. § 256b(a)(5)(D). Whereas the decision to make a substantive determination without a hearing is definitive and final, the decision to proceed with investigatory steps is preliminary. *See Ciba-Geigy*, 801 F.2d at 437; *see also Reliable Automatic Sprinkler Co.*, 324 F.3d at 731 (holding that the CPSC's determination that it had jurisdiction was "a statement of the agency's intention to make a preliminary determination" rather than a final agency action); *Harper*, 118 F.4th at 116 (holding that an IRS summons of records was a "preliminary investigative step, far upstream of any potential tax enforcement actions" rather than a consummation of the agency's decision-making process).

To be sure, Plaintiffs do not challenge a final decision on the substantive question regarding duplicate discounts or diversions. *See* Pl.'s Opp'n at 17 (arguing Plaintiffs are "not challenging the appropriateness of the audit or any conclusion that [they] engaged in sanctionable conduct"); UWMC Opp'n at 30 ("UWMC does not challenge the merits of the audit or any conclusion by HRSA that the audit revealed UWMC to have engaged in sanctionable conduct."). Instead, Plaintiffs challenge "whether HRSA should have approved the audit[s] in the first place." Pl.'s Opp'n at 17. But courts have previously rejected similar attempts to segment agency processes in an effort to define intermediary steps as "definitive." *See Standard Oil Co.*, 449 U.S. at 241 (reasoning that even if "the issuance of the complaint is definitive on the question whether the [agency] avers reason to believe that the respondent to the complaint is violating the Act," the action is not "definitive" based on the ability to challenge that averment in further proceedings). Though HRSA's approval can be construed as definitive on the issue of

whether J&J's audit may proceed,[6] the audit must occur before HRSA can make any decision on the underlying issue.[7] Thus, Plaintiffs' reframing of their challenge does not make the agency action final.

Maybe seeking to frame their injuries as "final," Plaintiffs assert in a conclusory manner that the alleged "harm and legal consequence" they will suffer "cannot be reviewed or remedied at a later time." *See, e.g.*, Pl.'s Opp'n at 13–14. But Plaintiffs fail to explain *why* they cannot raise alleged procedural deficiencies in potential future proceedings, including "dispute resolution with the Department," as contemplated by the Guidelines, Guidelines II(i), 61 Fed. Reg. at 65410, the consummation of which constitutes a "final agency action" under the statute, 42 U.S.C. § 256b(d)(3)(C). And if the Agency rejected Plaintiffs' procedural complaints in those proceedings, then Plaintiffs fail to explain why they would not then be able to make those arguments in court. *See* 5 U.S.C. § 706. Thus, the Court need not accept these conclusions as true. *See Iqbal*, 556 U.S. at 678. The fact that Plaintiffs will be able to make their points in subsequent proceedings before the Agency further supports that HRSA's actions thus far are not the consummation of its decision making. *See Standard Oil Co.*, 449 U.S. at 241.

UWMC's additional arguments are unavailing. For example, UWMC seeks to distinguish this case from others because the audit will be conducted by a "private, adverse third

[6] UWMC emphasizes a November 12, 2024 letter from HRSA in which HRSA "reserves the right to remove UWMC from the 340B Program" if it does not comply with J&J's audit. UWMC Opp'n at 16 n.3, 18–19. Defendants do not dispute the contents of this letter. Defs.' Reply Further Supp. Mot. to Dismiss at 3, ECF No. 34, No. 24-cv-2998. But this correspondence does not change the Court's analysis: HRSA reminding Plaintiffs of their statutory duties for eligibility does not transform a preliminary, procedural decision into a definitive one. *See Holistic Candlers*, 664 F.3d at 944–45 (holding that FDA warning letters informing the recipients of potential regulatory actions did not constitute final agency action).

[7] Plaintiffs are not challenging their removal from the 340B Program or the Guidelines themselves, so their reliance on *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253, 262 (4th Cir. 2022), is misplaced.

party" rather than a government agency. UWMC Opp'n at 19–20. UWMC seems to misunderstand who will conduct the audit. *Id.* at 20 (claiming UWMC "will be forced to turn over highly sensitive and confidential records and information concerning UWMC's patients, employees, and business operations *to a private pharmaceutical manufacturer*" (emphasis added)). Deloitte—an independent public accountant with ethical and legal responsibilities, including patient confidentiality requirements—will conduct the audit, not J&J. *See* Guidelines I, 61 Fed. Reg. at 65409. Moreover, UWMC does not explain why the identity of the auditor should change the Court's finality analysis.

UWMC also confusingly distinguishes *Benefitalign, LLC v. Center for Medicare & Medicaid Services*, No. 24-cv-2429 (D.D.C. Sept. 30, 2024), explaining that there, "the District Court found that there had been no final agency action because plaintiffs were challenging an ***interim*** suspension imposed by CMS while the agency was in the process of conducting an audit that would determine the plaintiff's final status." UWMC Opp'n at 22. By that logic, HRSA's audit approval is final and ripe for review now, but were HRSA to suspend Plaintiffs from the 340B Program on an interim basis while allowing the audits to proceed, then the audit approval would no longer be reviewable because the suspension would not be final. Surely, Plaintiffs do not seek that result.

Lastly, UWMC relies on *Music Choice v. Copyright Royalty Board*, 970 F.3d 418 (D.C. Cir. 2020), for the proposition that "an agency's failure to adhere to its established procedures in approving a third-party's audit request constitutes grounds for reversal." UWMC Opp'n at 23. Again, this argument counsels against UWMC's position. There, the finality of the "Final Determination" was not at issue, and the appellate court vacated an agency action based on

procedural deficiencies—which would seemingly be a potential remedy here, should further proceedings be necessary. *See Music Choice*, 970 F.3d at 428–30.

Context matters, especially when determining whether an action is the "consummation" of a decision-making process. Based on the relevant statutory and regulatory scheme, and for the reasons set forth above, HRSA's approvals of J&J's audit plans do not satisfy the first *Bennett* prong.

B. Determination of Rights or Obligations

The Court reaches the same result on the second prong of the *Bennett* test for finality, which asks whether the agency action is "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett*, 520 U.S. at 178 (quoting *Port of Boston Marine Terminal*, 400 U.S. at 71). This inquiry is a "pragmatic" one. *Sierra Club v. EPA*, 955 F.3d 56, 62–63 (D.C. Cir. 2020) (quoting *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016)). Thus, the Supreme Court has found that an agency decision "had direct and appreciable legal consequences" where "under the applicable statutes and regulations, if petitioners failed to heed the determination they did so at the risk of significant criminal and civil penalties." *Cal. Cmtys. Against Toxics*, 934 F.3d at 637 (discussing *Hawkes Co.*, 578 U.S. 590).

Here, as in *Reliable*, "the agency has not yet taken the steps required under the statutory and regulatory scheme for its actions to have any legal consequences," including "formal, on-the-record adjudication." 324 F.3d at 731–32. The parties' statutory obligations are not altered by the "filing of a[n] audit work plan" or "[d]uring the audit process." *See* Guidelines II(d), 61 Fed. Reg at 65410. And the agency can make a finding that a "covered entity is in violation" of the prohibitions against duplicate discounts or diversions only "after audit . . . and after notice

and hearing." 42 U.S.C. § 256b(a)(5)(D). So, it follows that HRSA's audit plan review has not affected Plaintiffs' or J&J's statutory obligations under the 340B Program.

The only question, then, is whether HRSA's actions have determined Plaintiffs' other legal obligations in a "direct and appreciable" way. *See Cal. Cmtys. Against Toxics*, 934 F.3d at 637. Defendants argue that all HRSA requires at this point is that Plaintiffs "cooperate with the auditor," and that any additional "practical consequences" of having to defend oneself in potential future administrative hearings are insufficient to make the actions final. Defs.' Mot. at 12–13. Plaintiffs respond that the consequences to their day-to-day business operations demonstrate that the audit approvals have determined Plaintiffs' obligations. Pl.'s Opp'n at 10–11. UWMC emphasizes the "extreme penalty of [its] termination from the 340B Program for failure to cooperate with the audit" as further buttressing its position that legal consequences flow from HRSA's decisions. UWMC Opp'n at 25. The Court is unpersuaded.

Plaintiffs' obligations to comply with manufacturer audits flow directly from the 340B statute—"[a] covered entity shall permit . . . the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity . . . to audit at . . . the manufacturer's expense." 42 U.S.C. § 256b(a)(5)(C). Thus, this legal obligation does not flow directly from HRSA's decision "not [to] intervene." *See* Guidelines II(d), 61 Fed. Reg. at 65410. Its source is instead the statute.

The "day-to-day business" consequences about which Plaintiffs' complain demonstrate why these consequences flow from Plaintiffs' statutory obligations, and not HRSA's actions. Plaintiffs assert that they will have to "engage [with J&J] to further limit the scope of the requests" and "attempt to negotiate a confidentiality agreement." Pl.'s Opp'n at 10. Those consequences would seem to flow from approval of *any* manufacturer audit and not be particular

to HRSA's actions here. *See* 42 U.S.C. § 256b(a)(5)(C). What is further befuddling is that these negotiations are what Plaintiffs claim they were deprived of because they never received adequate written notice to trigger the 30-day good faith bargaining period. *See* UWMC Opp'n at 17. Thus, it does not seem that HRSA's actions have caused these consequences.

True, a manufacturer must act "in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." 42 U.S.C. § 256b(a)(5)(C). But that does not make HRSA's determination that a manufacturer has complied with those procedures immediately reviewable; even if complying with a manufacturer audit at the manufacturer's expense is a substantial burden, "the burden of responding to the charges made against it . . . is different in kind and legal effect from the burdens" that come with final agency action. *See Standard Oil Co.*, 449 U.S. at 242. And the risk of penalty if Plaintiffs choose not to comply with the audits again comes not from HRSA's audit review decisions but from Plaintiffs' 340B Program eligibility requirements under 42 U.S.C. § 256b(a)(5)(C). Through that lens, this dispute concerns "preliminary, procedural" agency decisions not immediately reviewable, but that can be reviewed after a final agency action. *See* 5 U.S.C. § 704.

Plaintiffs make much of their fear that they will be unable "to limit J&J's use and application of its knowledge" of Plaintiffs' business practices against them in the future. Pl.'s Opp'n at 10. But that concern again seems focused on the statute's authorization of manufacturer audits, rather than requiring that all audits be agency-conducted. And though Plaintiffs are understandably concerned about confidentiality, they merely speculate that HRSA "shirked" its audit review responsibilities regarding Plaintiffs' proprietary and confidential business information. Pl.'s Opp'n at 12. Plaintiffs also provide no plausible reason to believe that Deloitte, the independent auditor, will violate its legal and ethical obligations, or otherwise

share confidential information in a way that is not contemplated by the 340B statute. Plaintiffs' arguments based on the HIPAA Privacy Rule likewise miss the mark because the disclosures made during manufacturer audits are required by law—that is, the 340B statute. *See* Pl.'s Opp'n at 14–15; UWMC Opp'n at 33; 42 U.S.C. § 256b(a)(5)(C) ("A covered entity *shall permit* . . . the manufacturer . . . to audit . . . ." (emphasis added)); *see also* Guidelines II(e)(5), 61 Fed. Reg. at 65410 (requiring that the audit plan "describe in detail . . . procedures to be used to protect patient confidentiality and proprietary information").

Because any legal consequences flow from Plaintiffs' statutory obligations and not HRSA's actions, the Court concludes that Plaintiffs have failed to satisfy *Bennett*'s second prong for finality as well. The Court's conclusion here is also pragmatic. It is hard to imagine why every covered entity subject to a future audit would not make similar objections to those raised here, dissecting the sufficiency of written correspondence and the scope of materials to be reviewed by the auditor, "turning prosecutor into defendant before adjudication concludes," or even begins in earnest. *See Standard Oil Co.*, 449 U.S. at 242–43. It is not hard to imagine how that outcome could lead to an "interference with the proper functioning of the agency and a burden for the courts." *See id.* at 242. Such a precedent seems unwise and unwarranted. The Court instead concludes that HRSA's audit plan approvals lack the necessary finality for immediate judicial review.

V. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss (ECF No. 18, No. 24-cv-2184; ECF No. 19, No. 24-cv-2187; ECF No. 18, No. 24-cv-2268; ECF No. 15, No. 24-cv-2563; ECF No. 26, No. 24-cv-2998) are **GRANTED**; and J&J's motions for leave to file amicus briefs (ECF No. 20, No. 24-cv-2184; ECF No. 21, No. 24-cv-2187; ECF No. 20, No. 24-cv-2268; ECF

No. 18, No. 24-cv-2563; ECF No. 28, No. 24-cv-2998) are **GRANTED**. Orders consistent with this Memorandum Opinion are separately and contemporaneously issued.

Dated: June 17, 2025

RUDOLPH CONTRERAS
United States District Judge