UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

CASE NO. 20-24523-CIV-CANNON/Otazo-Reyes

GILEAD SCIENCES, INC. and
GILEAD SCIENCES IRELAND UC,

Plaintiffs,

v.

AJC MEDICAL GROUP, INC. et al.,

Defendants.
_____/

ORDER DENYING MOTION TO DISMISS FOR LACK OF JURISDICTION

THIS CAUSE comes before the Court upon the Motion to Dismiss for Lack of Subject Matter Jurisdiction (the "Motion") [ECF No. 646], filed by Defendants United Clinical Laboratory, LLC, United Pharmacy, LLC, Community Health Medical Center, LLC, Kirill Vesselov, Mikhail Vesselov, and Roman Shekhet's (collectively, the "United Health Defendants'"). The Court has reviewed the Motion, the Notices of Adoption [ECF Nos. 647–48, 676], Plaintiffs' Response in Opposition to the Motion [ECF No. 670], the United Health Defendants' Reply in Support of the Motion [ECF No. 674], and the full record. For the reasons set forth below, the Motion is **DENIED**.

FACTUAL BACKGROUND[1]

I. Gilead's Free-Drug Programs

The plaintiffs in this case are Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead"). Gilead is a global pharmaceutical company that manufactures, among other

[1] This following section is an abbreviated recitation of the facts previously set forth in the Court's November 29, 2021 Omnibus Order [ECF No. 669].

things, medication for the treatment and prevention of HIV and AIDS [ECF No. 1 ¶ 2]. Gilead was the first company to develop FDA-approved drug therapies for the purpose of pre-exposure prophylaxis ("PrEP") [ECF No. 1 ¶ 2]. PrEP prevents the spread of HIV to at-risk individuals who have not yet contracted the virus [ECF No. 1 ¶ 2]. Gilead's two drug therapies for PrEP are called TRUVADA for PrEP ("Truvada") and DESCOVY for PrEP ("Descovy") [ECF No. 1 ¶ 2].

In 2004, Gilead created Advancing Access®, a patient assistance program that provides drug therapies at no charge to individuals who lack insurance and are unable to access alternative funding sources [ECF No. 1 ¶ 135]. Under Advancing Access®, the free-drug program for HIV *treatment* is called the Patient Assistance Program ("PAP"), and the free-drug program for HIV *prevention* is called the Medication Assistance Program ("MAP") [ECF No. 1 ¶ 136]. Thus, as preventive drug therapies, Truvada and Descovy are offered to eligible individuals at no cost through MAP. Gilead's programs are consistent with the federal government's 340B Drug Pricing Program (the "340B Program"), which requires drug manufacturers participating in Medicaid to make their drugs available at significantly reduced prices for participating entities ("Covered Entities") [ECF No. 1 ¶ 36].[2]

In order to enroll a patient in MAP, healthcare providers must certify that several conditions are met [ECF No. 1 ¶ 152]. Once enrolled in PAP or MAP, individuals receive a card that they can present at any U.S. retail pharmacy to receive their prescribed medication [ECF No. 1 ¶¶ 157–60]. Those pharmacies are tasked with submitting an enrollee's information for approval [ECF No. 1 ¶ 160]. If the claim (also known as a "redemption") is approved, Gilead pays the pharmacy a reimbursement along with a dispensing fee [ECF No. 1 ¶ 160]. Covered Entities under the 340B Program, including some of the defendants in this case, are able to

[2] The 340B Program is discussed in greater detail below. *See infra* Discussion (I).

purchase Gilead's medication at discounted prices, but receive reimbursements equal to the wholesale price [ECF No. 1 ¶ 226]. Gilead alleges that Defendants have taken advantage of that imbalance through a fraudulent scheme.

II. The Alleged Fraudulent Scheme

Starting in 2019, Gilead's Advancing Access® records began reflecting a disproportionate amount of redemptions submitted by the clinic and pharmacy defendants in this action [ECF No. 1 ¶ 165]. Gilead alleges that this disproportionate activity is proof of, and the result of, massive, multi-level, and interconnected conspiracies to engage in fraudulent conduct [ECF No. 1 ¶¶ 4–15]. Gilead alleges that the conspiracies generally operate as follows: the clinic defendants identify and fraudulently enroll patients in MAP, acquire heavily discounted PrEP medication for the pharmacy defendants to dispense, and purchase already-dispensed PrEP medication back from enrollees so that it may be redispensed or resold; the prescriber defendants perform sham "wellness checks" on patients, fraudulently enroll patients in MAP on behalf of the clinic defendants, and use their credentials to improperly write PrEP medication prescriptions and refills for enrollees; the lab defendants knowingly provide blood testing services in connection with the fraudulent MAP enrollments; the pharmacy defendants dispense repackaged PrEP medication, submit fraudulent redemptions, and receive significant fees and reimbursements from Gilead which are then divided among the rest of the defendants; and the officer defendants, by virtue of their control of the entity defendants, devise, implement, and enforce policies that enable the conspiracies to operate [ECF No. 1 ¶ 16]. According to Gilead, Defendants have reaped millions of dollars in illicit gains at Gilead's expense under this scheme [ECF No. 1 ¶¶ 234, 246].

III. Procedural History

On November 3, 2020, Gilead initiated the instant action [ECF No. 1], bringing a total of nineteen (19) causes of action against fifty-eight (58) defendants. Since then, several defendants have entered into consent final judgments and been dismissed from this action [ECF Nos. 657, 661, 663–64, 678]. In February and March 2021, a total of eleven (11) motions to dismiss for failure to state a claim were filed by various combinations of defendants [ECF No. 423–25, 427, 429–30, 432, 440–41, 443, 517], including the United Health Defendants [ECF No. 440]. The Court granted in part and denied in part those motions in November 2021 [ECF No. 669].

In addition to moving to dismiss Gilead's complaint under Rule 12(b)(6), the United Health Defendants filed this motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) [ECF No. 646], raising a subject matter jurisdiction challenge to Counts I–VIII. The Motion has been adopted by other defendants, some of whom offer additional arguments in support of the subject matter jurisdiction challenge [ECF Nos. 647–48, 676]. Gilead opposes the Motion [ECF No. 670]. The Motion is ripe for adjudication.

RULE 12(b)(1) LEGAL STANDARD

A Rule 12(b)(1) motion challenges the district court's subject matter jurisdiction and takes one of two forms: a "facial attack" or a "factual attack." *Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990); *see* Fed. R. Civ. P. 12(b)(1). A facial attack on the complaint requires the court merely look to see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction, taking as true the allegations in the plaintiff's complaint. *Id.* "By contrast, a factual attack on a complaint challenges the existence of subject matter jurisdiction using material extrinsic from the pleadings, such as affidavits or testimony." *Stalley ex rel. U.S. v. Orlando Reg'l Healthcare Sys., Inc.*, 524 F.3d 1229, 1233 (11th Cir. 2008). Regardless of whether a challenge is facial or factual,

"[t]he burden for establishing federal subject matter jurisdiction rests with the party bringing the claim." *Williams v. Poarch Band of Creek Indians*, 839 F.3d 1312, 1314 (11th Cir. 2016) (quoting *Sweet Pea Marine, Ltd. v. APJ Marine, Inc.*, 411 F.3d 1242, 1247 (11th Cir. 2005)). If a court determines that it lacks subject matter jurisdiction, the court must dismiss the action. *See* Fed. R. Civ. P. 12(h)(3). Unlike other grounds for dismissal under Rule 12(b), a challenge to subject matter jurisdiction generally may be raised at any time in a civil action. *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004); *see* Fed. R. Civ. P. 12(b).

DISCUSSION

The instant dispute centers around the meaning and application of the law governing the 340B Program. The Court reviews the framework surrounding the 340B Program, discusses the relevant legal principles, and applies the relevant legal principles to the jurisdictional argument raised in the Motion.

I. The 340B Program and the ADR Rule

The 340B Program was first established by Congress in 1992 and is administrated by the Health Resources and Services Administration ("HRSA"), a sub-department of the U.S. Department of Health and Human Services ("HHS") [ECF No. 646 p. 2; ECF No. 670 p. 10]. The 340B Program requires participating pharmaceutical manufacturers to sell medications to Covered Entities at discounted prices [ECF No. 670 pp. 10–11 (citing 42 U.S.C. § 256b)]. Pharmaceutical manufacturers are required to participate in the 340B Program as a condition of participating in Medicare and Medicaid B [ECF No. 646 pp. 2–3 (citing 42 U.S.C. § 256b)]. To qualify as a Covered Entity, clinics must comply with, among other things, a duplicate discount prohibition, which prohibits entities from requesting both a 340B discount and a Medicaid rebate for the same medication, and a drug resale prohibition, which prohibits entities from "resell[ing] or otherwise

transfer[ing] drug[s] to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(A)–(B).

In 2010, as part of the Patient Protection and Affordable Care Act quoted below, Congress directed the Secretary of HHS to establish a resolution process for disputes concerning the 340B Program:

> [T]he Secretary [of HHS] shall promulgate regulations to establish and implement an administrative process for the resolution of claims by [C]overed [E]ntities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsection (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

42 U.S.C. § 256b(d)(3)(A).[3] "HHS did not issue a Notice of Proposed Rulemaking . . . proposing ADR procedures until August 12, 2016." *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 400 (S.D. Ind. 2021). On December 14, 2020, over one month after this action was initiated, HHS published its final administrative dispute resolution rule (the "ADR Rule"). *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80632, 80632–80646 (Dec. 14, 2020) (codified at 42 C.F.R. §§ 10.20–10.24). The ADR Rule directed the Secretary to establish a 340B Administrative Dispute Resolution Board (the "ADR Board") tasked with reviewing certain 340B claims while sitting in three-person panels (the "ADR Panels"). 42 C.F.R. § 10.20. Those claims include "claims by a manufacturer, after it has conducted an audit

[3] Prior to Congress's 2010 directive, *see* 42 U.S.C. § 256b(d)(3)(A), "there was no formal ADR process in place for addressing disputes between [C]overed [E]ntities and drug manufacturers regarding implementation of the 340B Program." *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 400 n.3 (S.D. Ind. 2021). There existed a "voluntary dispute resolution" in which manufacturers and Covered Entities were encouraged to participate before seeking remedies in a court of law. *Id.* (citing Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406, 65406–65411 (Dec. 12, 1996)).

of a [C]overed [E]ntity . . . that the [C]overed [E]ntity has violated . . . the duplicate discount prohibition, or . . . the diversion prohibition, including claims that an individual does not qualify as a patient for 340B Program purposes and claims that a [C]overed [E]ntity is not eligible for the 340B Program." 42 C.F.R. § 10.21(c)(2). ADR Panel decisions constitute "final agency decision[s] and are binding on the parties involved, "unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C); *see also* 42 C.F.R. § 10.24(d). The ADR Rule has an effective date of January 13, 2021. 85 Fed. Reg. 80632-01.

II. Parties' Arguments

The crux of the United Health Defendants' argument is that the ADR Rule applies to Counts I–VIII[4] in this action and that, because Gilead failed to conduct an audit and submit the relevant claims for review by the ADR Board, those claims must be dismissed for lack of subject matter jurisdiction [ECF No. 646]. In response, Gilead argues that the ADR Rule constitutes, at most, a *claim-processing* rule, rather than a *jurisdictional* rule, and that Defendants therefore forfeited their current argument by failing to raise it in their earlier motion to dismiss [ECF No. 670 pp. 13–18]. Even if Defendants have not forfeited their jurisdictional argument, Gilead adds, the ADR Rule went into effect *after* the commencement of this lawsuit, and so applying the ADR Rule to Gilead's claims would violate the presumption against retroactivity [ECF No. 670 pp. 18–21]. As a final argument, Gilead asserts that the ADR Rule does not apply to Counts I–VIII as a matter of substance because none of the United Health Defendants is a

[4] Count I alleges common law fraud; Counts II–III allege aiding and abetting fraud; Counts IV–V allege civil conspiracy to commit fraud; Count VI alleges violations of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"); and Counts VII–VIII alleges civil conspiracy to violate the FDUTPA [ECF No. 1 pp. 96–119].

Covered Entity under the 340B Program,[5] and because those claims allege violations of law wholly distinct from the 340B Program [ECF No. 670 pp. 21–25]. In reply, Defendants insist that the ADR Rule is jurisdictional in nature [ECF No. 674 pp. 1–3; ECF No. 676 pp. 1–2], and that applying the ADR Rule to this action is appropriate [ECF No. 674 pp. 5–7; ECF No. 676 pp. 2–3].

III. Legal Principles

A. Jurisdictional Rules and Nonjurisdictional Rules

Because a Rule 12 motion to dismiss for lack of subject matter jurisdiction can be brought at any point in the litigation, "[c]haracterizing a rule as a limit on subject-matter jurisdiction 'renders it unique in our adversarial system.'" *Fort Bend Cty., Texas v. Davis*, 139 S. Ct. 1843, 1849 (2019) (quoting *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013)). "Tardy jurisdictional objections can . . . result in a waste of adjudicatory resources and can disturbingly disarm litigants." *Auburn*, 568 U.S. at 154 (citing *Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 434–36 (2011)). Accordingly, "[t]o ward off profligate use of the term 'jurisdiction,' [the Supreme Court has] adopted a 'readily administrable bright line' for determining whether to classify a statutory limitation as jurisdiction": absent a clear indication that Congress wanted a rule to be jurisdictional, courts should treat the rule as nonjurisdictional. *Auburn*, 568 U.S. at 153 (citing *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 515–16 (2006)). "This is not to say that Congress must incant magic words in order to speak clearly." *Auburn*, 568 U.S. at 153. Rather, context and past interpretations of similar provisions are "probative of whether Congress intended a particular provision to rank as jurisdictional." *Id.* at 153–54.

[5] The United Health Defendants' Motion was adopted by other defendants, including Allied Health Organization, Inc., which *is* a Covered Entity under the 340B Program [ECF No. 676].

"Among the rules that should not be described as jurisdictional are 'claim-processing rules,' which seem to promote the orderly progress of litigation by requiring parties to take certain procedural steps are specified times." *Henderson*, 562 U.S. at 428. "Filing deadlines . . . are quintessential claim-processing rules." *Id.* at 435. And a requirement that would otherwise be classified as nonjurisdictional "does not become jurisdictional simply because it is placed in a section of a statute that also contains jurisdictional provisions." *Auburn*, 568 U.S. at 155 (citing *Gonzalez v. Thaler*, 565 U.S. 134, 146 (2012)); *see also United States v. Harris*, 989 F.3d 908, 911 (11th Cir. 2021) (concluding that the exhaustion requirement in 18 U.S.C. § 3582(c)(1)(A) is nonjurisdictional even though § 3582(c) "is, broadly speaking, a grant of jurisdiction allowing courts to modify sentences under certain conditions . . . ."). Thus, courts must perform a provision-by-provision analysis of rules to determine which, if any, provisions are jurisdictional pursuant to a clear indication from Congress.

Some degree of confusion exists because "[c]ourts—including [the Supreme Court]—have sometimes mischaracterized claim-processing rules or elements of a cause of action as jurisdictional limitations, particularly when that characterization was not central to the case, and thus did not require close analysis." *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 161 (2010) (citing *Arbaugh*, 546 U.S. at 515–16). However, the Supreme Court's "recent cases evince a marked desire to curtail such 'drive-by jurisdictional rulings,' . . . which too easily can miss 'the critical differences' between true jurisdictional conditions and nonjurisdictional limitations on causes of action . . . ." *Reed Elsevier*, 559 U.S. at 161 (citations omitted).

B. Restricting Judicial Review

Even when an administrative rule that is jurisdictional in nature applies, "[p]rovisions for agency review do not restrict judicial review unless the '***statutory scheme***' displays a 'fairly

discernible' intent to limit jurisdiction, and the claims at issue 'are of the type Congress intended to be reviewed within th[e] statutory structure.'" *Free Enterprise Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 489 (2010) (alteration in original and emphasis supplied) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207, 212 (1994)); *see also Mercury Motor Exp., Inc. v. Brinke*, 475 F.2d 1086, 1092 (5th Cir. 1973) (recognizing that there are cases for which administrative agencies and courts have concurrent jurisdiction in the first instance).[6] Typically, "when Congress creates procedures 'designed to permit agency expertise to be brought to bear on particular problems,' those procedures 'are to be exclusive.'" *Free Enterprise*, 561 U.S. at 489 (quoting *Whitney Nat. Bank in Jefferson Parish v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420 (1965)). But in the context of statutory limitations on judicial review, "[courts] presume that Congress does not intend to limit jurisdiction if 'a finding of preclusion could foreclose all meaningful judicial review'; if the suit is 'wholly collateral to a statute's review provisions'; and if the claims are 'outside the agency's expertise.'" *Free Enterprise*, 561 U.S. at 489 (quoting *Thunder Basin*, 510 U.S. at 212–13).

C. The Presumption Against Retroactivity

Lastly, as a general matter, "[r]etroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). In applying this presumption against retroactivity to administrative rules, the Eleventh Circuit has held that the inclusion of an effective date cuts against retroactive application, as "[t]here is no point in specifying an effective date if a provision is to be applied retroactively." *Sierra Club v.*

[6] The Eleventh Circuit has adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

Tennessee Valley Auth., 430 F.3d 1337, 1351 (11th Cir. 2005); *see also Hargress v. Soc. Sec. Admin., Comm'r*, 883 F.3d 1302, 1308 (11th Cir. 2018).

IV. Analysis

The Court is satisfied that it has subject matter jurisdiction over Counts I-VIII notwithstanding the implementation of the ADR Rule, effective January 13, 2021. Although the Court addresses the parties' substantive jurisdictional arguments, it ultimately denies the motion on the retroactivity ground raised by the parties in the Motion and related filings [ECF No. 646 pp. 12–15; ECF No. 670 pp. 18–21; ECF No. 674 pp. 3–5]. Even assuming Defendants are correct that Congress's creation of the 340B ADR Process divests district courts of subject matter jurisdiction to adjudicate the claims permitted in the 340B ADR Process—and even assuming that any such removal of jurisdiction would apply to the instant common law and state law claims—any such divestiture of jurisdiction would be triggered, at the very least, upon the effective date of the ADR Rule, which came after Gilead's initiation of this suit. Based on that retroactivity determination, Defendants' Motion is **DENIED**.

To start off, it is an open question whether the ADR Rule strips district courts of subject matter jurisdiction over claims of violations of the 340B requirements; the authorities on that point do not indicate a clear answer, although they suggest the answer is no.

In certain contexts, the Supreme Court has determined that statutory schemes "that channel certain claims to administrative agency adjudication first, followed by judicial review in a federal court," may strip district courts of subject matter jurisdiction. *Fort Bend*, 139 S. Ct. at 1851. The Court reviews some of those authorities here as a counterpoint to the 340B dispute resolution process and its associated statutory and regulatory language.

In *Elgin v. Dep't of Treasury*, for example, the Supreme Court found it "fairly discernible" from the "'elaborate' framework" of the Civil Service Reform Act of 1978 that Congress intended to preclude district court jurisdiction over the relevant claims, including even constitutional claims. 567 U.S. 1, 11–13 (2012) (quoting *United States v. Fausto*, 484 U.S. 439, 443 (1988)). Under that elaborate framework, set forth in statutory language governing appellate procedures and judicial review, litigants first may appeal relevant agency action to the Merit Systems Protection Board, *see* 5 U.S.C. § 7701, and then, if dissatisfied with the Board's final order or decision, may file an appeal in the United States Court of Appeals for the Federal Circuit, *see* 5 U.S.C. § 7703. That latter step generally requires the filing of a petition for judicial review within 60 days of the Board's notice of final order or decision. *See* 5 U.S.C. § 7703(b). Further, 5 U.S.C. § 7703 instructs the Federal Circuit to "hold unlawful and set aside any agency action, findings, or conclusions found to be[:] (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) obtained without procedures required by law, rule or regulation having been followed; or (3) unsupported by substantial evidence . . . ." 5 U.S.C. § 7703(c).

In *Thunder Basin Coal Co. v. Reich*, the Supreme Court similarly concluded that the statutory-review scheme in the Federal Mine Safety and Health Amendments Act of 1977 prevented district courts from exercising subject matter jurisdiction over relevant claims. 510 U.S. 200, 202–04 (1994). There, the statutory-review scheme established an independent Federal Mine Safety and Health Review Commission tasked with reviewing challenges to enforcement measures and whose decisions were subject to review by a federal court of appeals. Under 30 U.S.C. § 816(a), petitions for judicial review are required to be filed within 30 days of the issuance of mine commission's order, and federal courts of appeals are not to consider objections that have not been raised before the Commission absent extraordinary circumstances. In reaching its

conclusion, the Supreme Court relied heavily on the legislative history of the statutory-review scheme, including Congress's rejection of a proposal for *de novo* review by district courts of enforcement measures. *Thunder Basin*, 510 U.S. at 211, 216.

Finally, in *Weinberger v. Salfi*, after analyzing the Social Security Act and its provision setting forth requirements for judicial review, the Supreme Court concluded that the requirement that district courts review "*final* [agency] decisions . . . made *after a hearing*" divested district courts of jurisdiction in circumstances where those requirements were not met and could not be waived. 422 U.S. 749, 763–67 (1975) (emphases added) (citing 42 U.S.C. § 405(g)).

The statutory language at issue here, by contrast, does not bear the hallmarks of a jurisdiction-stripping framework in the manner suggested by Defendants. Congress directed the Secretary of HHS to promulgate regulations to "establish and implement an administrative process for the resolution of," among other things, "claims by manufacturers, after the conduct of audits[,] . . . of violations of [the duplicate discount prohibition or the drug resale prohibition], including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraph[] . . . (2)(B)."[7, 8] 42 U.S.C. § 256b(d)(3)(A). Congress then ordered the Secretary to establish a "decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by [C]overed [E]ntities." *Id.* § 256b(d)(B). That body,

[7] 42 U.S.C. § 256b(d)(2)(B) governs actions that may be taken to ensure Covered Entity compliance, including the imposition of sanctions, the establishment of a Covered Entity identification system, and creation of information and reporting guidelines.

[8] 42 U.S.C. § 256b(d)(3)(A) also directs HHS to promulgate regulations to "establish and implement an administrative process" for the resolution of certain claims by Covered Entities against manufacturers. However, because the claims in this action are being brought by a manufacturer against Covered Entities (and others), this Order focuses on the language governing such claims.

as further specified in § 256b, is directed to establish procedures to resolve claims, including through discovery, mandated audits prior to commencing administrative proceedings, and consolidation of claims before the ADR panel—ultimately yielding final administrative agency as described by Congress as follows: "[t]he administrative resolution of a claim or claims under the regulations . . . 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." *Id.* §§ 256b(d)(3)(B)(i)–(vi), 256b(d)(3)(C). This statutory language shows Congress's intent to establish an agency adjudication process to resolve claims of violations of the duplicate discount and drug resale prohibitions by Covered Entities. But it does not—by its text—speak to displacing or limiting district courts of their authority to entertain such claims, at least not in the manner typically required to strip or reduce a court's subject matter jurisdiction. It does not, for instance, set forth specific requirements for judicial review or limitations on the arguments that courts may consider. Instead, the statutory language of 42 U.S.C. § 256b references judicial review only in passing, and the overall scheme to which it belongs does not provide any further insight on the matter.

Even the regulations governing the 340B process do not themselves bespeak HHS's exclusive jurisdiction over initial adjudication of 340B-type claims. Under the ADR framework, "[a]ny covered entity or manufacturer may initiate an action . . . against a manufacturer or covered entity . . . by filing a written petition for relief" that satisfies federal pleading requirements, 42 C.F.R. § 10.21(a); the ADR Panel "shall have jurisdiction to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000" during the year after the final agency decision, 42 C.F.R. § 10.21(b); and ADR Panel decisions are binding "unless invalidated by an order of a court of competent jurisdiction," 42 C.F.R. § 10.24(d). Yet missing from the regulatory language is any clear statement purporting

to imbue the ADR Panel with exclusive jurisdiction in the first instance over the identified claims or to strip district courts of subject matter jurisdiction. *See* 42 C.F.R. §§ 10.20–10.24. It bears noting that HHS expressly acknowledged, in one of its responses to the public comments, that "[t]he form of judicial review for 340B ADR panel decisions is beyond the scope of this final rule." 85 Fed. Reg. 80632-01. Thus, zooming out, the Court is left with the following: (1) a relatively open-ended congressional instruction for HHS to establish an agency review process subject to judicial review; (2) HHS' ADR Rule, which primarily outlines how the review process operates as an internal matter; (3) the absence of any statutory or regulatory language discussing judicial review in depth; and (4) HHS' representation that the form of judicial review is beyond the scope of the ADR Rule.

Even if the ADR Rule *did* include clear language stripping district courts of subject matter jurisdiction, this Court still would need to consider whether Counts I–VIII are wholly collateral to the ADR Rule and outside of HHS' specialized expertise. Reasonable minds could differ as to those issues. There is also a related concern, still undeveloped, of the ramifications of adopting Defendants' jurisdictional position as relate to a potentially large swath of interwoven common law and state statutory claims that happen to involve elements of the 340B Program's duplicate discount and drug resale prohibitions [*see* ECF No. 1 ¶ 178 (alleging that the clinic defendants illegally bought back dispensed medication); ECF No. 1 ¶ 302 (alleging that the clinic defendants' employees falsely represented themselves to be MAP applicants on phone calls with Gilead agents); ECF No. 1 ¶¶ 315, 325 (alleging that Defendants forged the signatures of prescribers and recruits); ECF No. 1 ¶ 352 (alleging that Defendants violated Florida law by offering kickbacks to enrollees, writing false prescriptions, and dispensing medication without a proper prescription)].

In any case, having reviewed the matter to some extent, the Court need not resolve the question of whether Congress intended to strip district courts of jurisdiction over Counts I–VIII. This is because any possible limitation on this Court's jurisdiction as a result of promulgation of the 340B ADR Rule would not govern this case, which was filed before the January 13, 2021 effective date of the rule. As stated, "[r]etroactivity is not favored in the law," *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988), and the inclusion of an effective date in a provision indicates that the provision is not meant to be applied retroactively, *Sierra Club v. Tennessee Valley Auth.*, 430 F.3d 1337, 1351 (11th Cir. 2005); *Hargress v. Soc. Sec. Admin., Comm'r*, 883 F.3d 1302, 1308 (11th Cir. 2018); *Landgraf v. USI Film Prod.*, 511 U.S. 244, 275 (1994) ("A new rule concerning the filing of complaints would not govern an action in which the complaint had already been properly filed under the old regime . . . ."). The ADR Rule specifies that it became "effective January 13, 2021," 85 Fed. Reg. 80632-01, over two months after this action was initiated, and there is no provision indicating that the ADR Rule was meant to be applied retroactively. As such, the cited authorities counsel heavily against applying the ADR Rule retroactively, and Defendants' attempts to argue otherwise [ECF No. 646 pp. 12–15; ECF No. 674 pp. 3–5] fall considerably short of overcoming that presumption.

CONCLUSION

Accordingly, it is hereby **ORDERED AND ADJUDGED** as follows:

1. The United Health Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction [ECF No. 646] is **DENIED**.
2. Pursuant to the Court's Order [ECF No. 689], a Second Amended Scheduling Order will be entered separately.

DONE AND ORDERED in Chambers at Fort Pierce, Florida, this 10th day of February 2022.

AILEEN M. CANNON
UNITED STATES DISTRICT JUDGE

cc: counsel of record