IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 3:21-CV-634

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S NEW COUNTS X-XII; REPLY IN SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT; AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Constitution

Legislative Materials

Other Authorities

As explained in HHS's pending dispositive motion, this dispute arose in mid-2020 when Sanofi and five other global drug makers abruptly upended the twenty-five year operation of the 340B Program by restricting access to discounted drugs by safety-net healthcare providers that rely on neighborhood pharmacies. Specifically, the manufacturers announced that no longer will they offer (or offer without manufacturer-imposed, extra-statutory restrictions) access to discounted drugs for certain statutorily defined healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies." Sanofi's policy demands that healthcare providers turn over HIPAA-protected information to a for-profit, third-party consultant's software platform, and *denies* "purchases by" these safety-net providers should they refuse. This policy has increased Sanofi's profits while dramatically curtailing much-needed funding for safety-net providers and forcing patients to pay more for medications or adjust their medication regimen.

After a thorough, months-long review of Sanofi's newly imposed contract-pharmacy restrictions, including assessment of thousands of complaints from safety-net providers, detailed analysis of real-world changes to Sanofi's discounted-sales volumes, review of correspondence from Sanofi and other manufacturers, and meetings with numerous stakeholders, the Health Resources and Services Administration has determined that Sanofi is flouting its obligation under Section 340B by overcharging covered entities for its drugs and conditioning access to discounted drugs on onerous demands for data to which Sanofi is not entitled. As shown herein, that conclusion is based on sound statutory interpretation and voluminous evidence; this Court should reject Sanofi's challenge to HRSA's violation finding and allow HRSA's enforcement of the statute to proceed. This Court should also grant summary judgment to HHS on Sanofi's challenge to the new ADR Rule.

BACKGROUND

A comprehensive explanation of the 340B Program's statutory and regulatory background, and the concerted actions by six pharmaceutical manufacturers that led to the current litigation, are set forth in HHS's Motion to Dismiss or, in the Alternative, for Summary Judgment at 3-12 ("HHS Mot."), ECF No. 62-1. Included herein is information relevant to the new agency action, HRSA's

May 17, 2021 violation letter issued to Sanofi and challenged in Sanofi's second amended complaint (hereinafter "Compl."), ECF No. 78.

Four months before the Advisory Opinion ("AO") challenged in this action was issued, and shortly after Sanofi and its peers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put manufacturers on notice that the agency was "considering whether [manufacturers' new contract-pharmacy] polic[ies] constitute[] a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *See* Violation Letter Administrative Record ("VLTR") at 7627, Adm. Pedley Letter to D. Asay, Aug. 26, 2020; *see also e.g.*, *id.* 7658. HRSA also disavowed the manufacturers' assertion that restrictions on 340B discounts "did not give rise to an enforceable violation of the 340B statute," and warned that the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* HRSA transparently explained that it "continues to examine" whether the manufacturers' restrictions "amount to attempts to circumvent" their statutory obligation "by inappropriately restricting access." *Id.* And HRSA was clear that, "[e]ven for those covered entities with in-house pharmacies," manufacturers' new policies "to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions." *Id.* 7659. Unfazed, Sanofi proceeded to implement its new contract-pharmacy restrictions.

HRSA's comprehensive review of Sanofi's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. *See* VLTR_9, D. Espinosa Letter ("Violation Letter"). That letter informed Sanofi that HRSA "has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 1. It relies on statutory text to determine that the requirement that Sanofi honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the

right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA directs Sanofi to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that civil monetary penalties (CMPs) may be imposed. *Id.* 2. Although the letter instructs Sanofi to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on Sanofi's willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS thus has not made any determination as to whether sanctions are warranted at all but, should Sanofi continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the violation letter does not rest upon—or even reference—the General Counsel's December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, VLTR_8048). Instead, the Violation Letter culminates the evaluative process pharmaceutical manufacturers were apprised of in August 2020, months before the AO was issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. Alongside the statute and its legislative history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other stakeholders, HRSA also gathered proof of the real-world implications of Sanofi's changes and the substantial harm to covered entities its restrictions have wrought.

The record contains *over six thousand pages* of complaints from covered entities. VLTR_110-6,806. Although that multitudinous evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's violation letter. Beverly Hospital's complaint alerted HRSA to the fact that

"manufacturer(s) [are] deliberately refusing [the] 340B Price" and explained that the restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] contract pharmacy" orders—the highest commercial rate.[1] *Id.* 1460-61. That complaint included a spreadsheet showing specific transactions where the 340B ceiling price[2] was denied and the hospital instead was subject to wholesale acquisition cost on Sanofi's medications of up to $1,516 per unit; that hospital's orders from October 2020 alone totaled $126,508 in lost 340B savings. *Id.* 1463. Another covered entity included a screenshot from its ordering system showing that, when it tried to reorder Lantus Solostar, one of Sanofi's drugs, all formulations of that medication were marked as "Ineligible" for purchase on its 340B account. *Id.* 1589. That community health center told HRSA that it "is forced to pay WAC for these products if purchased for a contract pharmacy" to handle dispensing to patients, and included another screenshot showing the non-340B pricing to which it was subject. *Id.* 1593, 1595.

Similarly, a county health service wrote to Sanofi requesting a refund after it "identified a 340B overcharge by Sanofi" and, "[a]fter a review of all 340B purchases," determined "a total of 8 packages were overcharged on 340B" for a total of "$3087.61 [in] overcharged products on 340B." *Id.* 3158-59. When Sanofi refused to refund the county, it documented the overcharge to HRSA. *Id.* 3157-59.

Blue Ridge Medical Center complained specifically that "Sanofi is blocking 340B prices for their drugs ordered by [the medical center] that are shipped to my contract pharmacies. *I am forced to pay WAC* [wholesale acquisition cost] for these products for my contract pharmacies." *Id.* 1603 (emphasis added). Lancaster Health Center notified the agency that Sanofi is "refusing to fulfill orders (for any of their manufactured products) placed by [the] covered entity and shipped to my contract pharmacies at 340B prices. *I am forced to pay WAC* for these products." *Id.* 3303 (emphasis added). Lancaster specified three separate drug formulations it had tried to order at 340B prices, but found that Sanofi was "refusing to ship my orders to my contract pharmacies." *Id.* 3302-03. The Chief

[1] A different complaint shows that the WAC for one of Sanofi's medications, Dupixent, was more than $3,000 per unit—significantly higher than the 340B ceiling price. *See* VLTR_6993.

[2] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record, along with other figures that would allow a reader easily to calculate the ceiling price for any particular drug. Sanofi cannot dispute, however, that the ceiling price for medications referenced in this discussion are often only a fraction of the WAC price.

Executive Officer of Windrose Health Network reported to HRSA in March 2021 that "Sanofi is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. *I am forced to pay WAC* for these products." *Id.* 6650 (emphasis added). That covered entity also included the drug formulations for which Sanofi had overcharged it by charging full price. *Id.* 6649. Countless complaints echo these concerns. *E.g.*, *id.* 139-40; 150-51; 282-83; 301-02; 321; 405-11 (attaching lengthy list of Sanofi drugs hospital was blocked from purchasing at 340B rate); 443-49 (same); 473-79 (same); 848-54; 1525-26; 1669-70 (confirming covered entity "forced to pay WAC" for Sanofi's products to have drugs shipped to contract pharmacies); 1674-75 (same); 3243 (same); 3263.

HRSA also relied on evidence regarding the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents a sizeable, rural area and a "medically underserved population," submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. VLTR_7255-56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "generate additional revenue" through the spread between the 340B-discount price and the price paid by or on behalf of some patients, as Congress intended,[3] and that it "reinvest[s] all 340B savings and revenue in services

[3] As explained in HHS's opening brief (3), Congress designed the program to allow covered entities to generate revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report). Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. As explained herein, this enables covered entities to reinvest in patient care and services.

that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[4] *Id.* Despite the critical importance of its contract-pharmacy network to both the provider and its patients, the covered entity documented that it "currently has no access to … Sanofi medications at 340B pricing to be dispensed through its contract pharmacies." *Id.* 7257.

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. VLTR_7260-61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to" its pharmacy partners, under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible … patients." *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261-62. The covered entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that Sanofi and its peers' restrictions have caused. *Id.* 7262-63. The administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270-75; 7277-83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295-98 (safety-net provider with high-poverty population expects to lose $6

[4] This covered entity also thoroughly rebutted manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest, predetermined fee to the pharmacy for its services, "as required by HRSA, [it] does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300-06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309-14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"; further documenting significant harm to patients, *id.* 7312); 7316-20; 7324-25 (explaining that covered entity "decided not to enroll" in Sanofi's data-sharing platform because of its "burdensome reporting" requirements and that manufacturers' restrictions are "put[ting] our patients' access to care at risk" and may cause reduction or elimination of much-needed services); 7331-33; 7347-50.

The record also evidences Sanofi's denial of 340B pricing even where a covered entity *was* relying on an in-house pharmacy—in direct contravention of the supposed "exceptions" to its contract-pharmacy restrictions. A federally funded provider in Michigan, filed a complaint with HRSA after finding it was "unable to purchase Sanofi Aventis products at the 340B ceiling price" for its "2 clinics *with outpatient pharmacies*." VLTR_3288 (emphasis added). That clinic reported that it instead was charged $410.42 for one of Sanofi's drugs—far above the applicable 340B price. *Id.* 3291. Although it is unclear whether Sanofi's denial of 340B pricing for an on-site pharmacy was inadvertent, it further underscores the havoc wrought by Sanofi's abrupt, marketplace-shifting restrictions.

During its evaluation HRSA also gathered relevant evidence through meetings with stakeholders impacted by Sanofi and its cohort's restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. VLTR_7891-92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* The very next day, HRSA officials learned in another meeting that one pharmacy in

West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. In another listening session that same month, HRSA gathered evidence from tribal leaders in multiple states detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[p]atients are having to choose between buying food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894-97. Another tribe reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898. Yet another tribal leader implored HRSA "to take immediate action," pointing out that drug makers are "experiencing record-breaking profit" so it was "unacceptable for them to gauge [sic] small entities." *Id.*

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. VLTR_7957-63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided detailed information on how they use 340B savings to provide more-comprehensive serves for medically underserved and low-income patients, such as addiction treatment, oncology treatment, medication management, and outpatient behavioral health for children. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully one-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural hospitals are at even greater risk, since fully three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960-61. Of particular note, survey respondents expressly tied financial concerns to six manufacturers' (including Sanofi's) contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most

of which expect to lose *more than fifteen percent* of their annual 340B savings as a result of contract-pharmacy restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

Sanofi's overcharges are also reflected in aggregate statistics compiled at HRSA's request in an "attempt[] to quantify the loss of units sold and savings." VLTR_7936-47. That analysis showed a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only 2.9 million in January 2021. *Id.* 7936. "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* The statistics include graphs showing the stark, immediate impacts of Sanofi and its peers' refusal to honor 340B pricing. Figure one shows that, in October 2020 when Sanofi and two other manufacturers put in place their changes, 340B units sold took a nosedive from 9.4 million units to 5.1 million in just one month; WAC-priced units more than doubled at the same time.[5] *Id.* Figure two shows that covered entities' monthly 340B savings fell from $357 million in July 2020, just before restrictions were put in place, to $92 million in January 2021—representing annualized lost savings of $3.2 billion. *Id.* Figure three shows that, in January 2021, covered entities lost an estimated $234 million in that month *alone* and had lost an estimated $665 million in roughly four months of restrictions. *Id.* That analysis also shows the impact of Sanofi's specific changes, separated from other manufacturers; what it terms its "integrity initiative" caused 340B sales to plummet *in one month* from 2.04 million units to only .28 million units—that same month, WAC-priced units sold by Sanofi skyrocketed from negligible to .37 million units. *Id.* 7937. Stated plainly, in a one-month period the graph shows millions of units of Sanofi's drugs sold at above-ceiling prices to covered entities. The analysis also quantifies the fiscal impact of Sanofi's changes. Monthly savings to covered entities dropped from $54.2 million just before its "integrity initiative" to only about $5 million within two

[5] As the analysis explains, VLTR_7936, WAC-priced units do not fully reflect the loss of 340B-priced sales and thus underrepresent the impact of manufacturers' changes. This is because some sales will be lost entirely and because covered entities' third-party administrators will shift 340B-priced sales to other commercial purchasing accounts rather than pay the highly marked-up WAC price. For this reason, lost 340B sales is a better indicator of impact than increased WAC sales.

months. *Id.* 7939. By January 2021, Sanofi's restrictions represented an average lost savings to covered entities of $43.4 million monthly. *Id.* 7941.

HRSA also gathered evidence that Sanofi's data-collection demands are infeasible for covered entities (in addition to unauthorized by statute). Covered entities report that the so-called "integrity initiative" could increase the risk of unauthorized access to patients' health information and thereby expose covered entities to significant liability under various federal and state privacy laws, including HIPAA. VTLR_1545-46. The initiative may also contravene the terms of the covered entities' contract-pharmacy agreements. *Id.* 1547. Putting those legal concerns aside, Sanofi's initiative imposes undue administrative burden: Sanofi demands bi-weekly submission of data, which in some instances may require the submitter to organize or reformat the data they otherwise collect to prepare such a submission. *Id.* 1548. And even without undue burden, Sanofi is attempting to co-opt covered entities' resources to support data collection that could be used by private insurance to facilitate the reduction of reimbursement on claims involving 340B drugs, against the interests of covered entities and their patients. *Id.* 1544-45.[6] *See also id.* 7324-25 (informing HRSA of covered entity's decision not to enroll in Sanofi's data-collection system due, in part, to burden of producing data).

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Sanofi's "integrity initiative" and its real-world impact on the 340B Program. After evaluating this evidence, alongside Sanofi's communications to covered entities and to the agency explaining its initiative, *e.g.*, VLTR_7617, HRSA concluded that Sanofi is violating the 340B statute and issued its May 17, 2021 letter to that effect.

ARGUMENT

HRSA's 340B-violation letter is a new agency action that must be challenged and considered independently from previous agency decisions. Although Sanofi amended its complaint to challenge

[6] In this litigation, undersigned counsel also have learned that the software platform used by Sanofi to collect covered entities' data was designed and is administered by a third-party consultant who has been employed by a pharmaceutical-industry trade group to undermine the 340B program—and who also has submitted a purported *amicus curiae* brief. *See infra* § I.B.1. This further raises concerns about covered entities being forced to divulge patient and prescribing information to a third party.

the letter after this Court ordered it to do so, ECF No. 83, it continues inaccurately to allege that the violation letter "enforced against Sanofi the Advisory Opinion's new rule." Compl. ¶ 173. Not so: HRSA's Violation Letter is the culmination of a separate process begun *months* before the AO was issued and based on the statute itself along with copious evidence gathered through HRSA's investigative process. It also embodies a determination by a different entity—HRSA, the component charged with enforcing Congress's mandate—that Sanofi is overcharging covered entities and may face sanctions or expulsion from government-insurance programs. More importantly, whereas the AO opined generally on what the 340B statute requires, without purporting to analyze the legality of Sanofi's "integrity initiative," HRSA's violation letter concludes directly and for the first time that Sanofi's specific policy violates the statute. And the AO now has been withdrawn in its entirety, yet HRSA's enforcement of the statute continues unabated. The actual dispute between the parties—whether HRSA's violation finding is correct—must be decided on the basis of HRSA's reasoning in the violation letter and the administrative record supporting it. [7]

This distinction is elucidated by the fact that vacatur of the AO would not resolve the merits of HRSA's determination that Sanofi is overcharging covered entities. Indeed, Sanofi continues to seek declaratory relief that so fundamentally misportrays the agency's interpretation that granting it would have no bearing on HRSA's ongoing enforcement. Sanofi asks this Court to declare that the statute "does not require drug manufacturers to provide discounted covered outpatient drugs *to contract pharmacies*" and "does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs *to contract pharmacies*." Compl., Prayer for Relief ¶¶ 4-5 (emphasis added). As explained in HHS's opening brief, HRSA has *never* interpreted the statute to allow contract pharmacies to purchase 340B-discounted drugs, receive 340B discounts, or otherwise participate in the program (as opposed to covered entities), so Sanofi's requested declaration is meaningless.

[7] In its order denying Sanofi's request for an emergency stay, this Court wrote that, "[a]ccording to Defendants, the Advisory Opinion prohibits Plaintiff's integrity initiative." *See* ECF No. 83 ¶ 3. HHS respectfully wishes to clarify that the AO neither addressed nor specifically prohibited Sanofi's new policy; instead it contained a general interpretation of *the 340B statute's* requirements.

See HHS Mot. 14-15 (explaining that Sanofi relies on artful drafting to misframe the dispute). Neither HHS nor HRSA require Sanofi to sell any drugs to any pharmacies at any price.

But in its violation letter HRSA made the specific determination that Sanofi's policy violates the 340B statute, 42 U.S.C. § 256b(a)(1), and may warrant sanctions, including expulsion from Medicaid and Medicare Part B, because Sanofi is overcharging and refusing statutorily mandated discounts *to covered entities* using outside-dispensing channels. As demonstrated below, that conclusion is based on voluminous evidence and the best interpretation of the statute. This Court should grant summary judgment in favor of the agency on Sanofi's challenge to the violation letter and allow HRSA's enforcement action to proceed. The Court should also dismiss or grant summary judgment for HHS on Sanofi's numerous (but meritless) challenges to the ADR Rule.

I. THE COURT SHOULD ALLOW HRSA'S ENFORCEMENT OF THE 340B STATUTE TO PROCEED AGAINST SANOFI

A. HRSA Correctly Found That Sanofi Is Violating Its Statutory Obligation

HRSA's 340B violation letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of Sanofi's policy," including "an analysis of the complaints HRSA has received from covered entities." Violation Letter 1. The determination "that Sanofi's actions have resulted in overcharges and are in direct violation of the statute," *id.*, is not only consistent with HRSA's interpretation since 1996, *see* HHS Mot. 3-6, 19-23, but also relies directly on statutory text. *See* Violation Letter 1 (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Sanofi's adherence to the statutory scheme it opted into by executing a Pharmaceutical Pricing Agreement ("PPA") requiring Sanofi to ensure that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1). It also specifies that "[e]ach such agreement shall require … that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As HRSA explained, that straightforward obligation "is not qualified, restricted, or dependent on how the

covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. Compliance with its PPA also requires Sanofi to "ensure that the 340B ceiling price is available to all covered entities." *Id.*

HRSA further explained that Sanofi's restrictions run afoul of its obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because Sanofi's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." *Id.* (citing 42 C.F.R. § 10.11(b)(2)). HRSA's analysis rests on the statute itself and duly promulgated regulations issued through an express grant of rulemaking authority.

And HRSA plainly is correct in its statutory interpretation. In urging this Court to find that it can somehow fulfill its duty to honor "purchases by" covered entities while admitting that it now denies millions of dollars in purchases every month unless certain conditions are met, Compl. ¶ 177, Sanofi rips particular words from context and asks the Court to consider them in a vacuum. The statute does not, as Sanofi insists, "only require[] [] manufacturers" to "offer discounted drugs to covered entities," Sanofi Mot. 29, ECF No. 68-1, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access.

Since 1992 the statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). And as discussed *infra*, HRSA's early guidances issued in 1994 and 1996 were unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense the drugs (as did the 2010 guidance, which also was issued *before* Congress amended the statute to include the language

on which Sanofi relies). *E.g.*, ADVOP_370 (interpreting statute to *prohibit* manufacturers from denying purchases where the covered entity "directs the drug shipment to its contract pharmacy"). Read "as a whole," *United States v. Atlantic Research Corporation*, 551 U.S. 128, 135 (2007), as this Court must, 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to sell discounted drugs to covered entities.

The "offer" language on which Sanofi relies, added in 2010, codified an additional requirement that manufacturers cannot discriminate by prioritizing full-priced purchases over 340B purchases. *See* ADVOP_394, Clarification of Non-Discrimination Policy, May 23, 2012. That amendment in no way changed the substance of Sanofi's preexisting obligation. Crediting Sanofi's assertion that the statute's requirement that drugs "purchased by a covered entity" not exceed the ceiling price "*imposes no obligation on manufacturers*," Sanofi Mot. 30 (emphasis added), would lead to the bizarre and unsupportable conclusion that, from 1992 until 2010, manufacturers sold deeply discounted drugs to covered entities on a purely voluntary basis. That assertion is false and illogical; from the statute's enactment, pharmaceutical companies wishing to receive drug coverage through certain government health-insurance programs have been required by both the statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment.

Sanofi's claim that "HRSA enforced against Sanofi the Advisory Opinion[]" and thus is acting "contrary to law and in excess of statutory authority," Compl. ¶¶ 165, 167, fails. The Violation Letter does not "enforce[]" the AO, but instead relies on the statute itself and the fact that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." Violation Letter 1. HRSA could not have begun a review of whether various manufacturers' actions violated *the statute* back in August 2020, VLTR_7627, 7658, were there no basis for such a determination before the General Counsel opined in December. HRSA's determination rests on its own investigation and did not even derive from the same administrative process as the AO.

Sanofi again distorts the agency's interpretation as requiring it to allow for-profit pharmacies "to acquire 340B-priced drugs." Compl. ¶ 10; *see also* Sanofi Mot. 19 (claiming that HHS interprets statute to "legally obligate[] drug manufacturers to provide 340B-priced drugs to contract pharmacies"). Once again, the violation letter does not require Sanofi to provide discounts to *any* pharmacies whatsoever—only to resume selling 340B-priced drugs to eligible covered entities, regardless how they dispense medications to needy patients.

Legislative history forecloses Sanofi's reading, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Sanofi's interpretation. *See* S. Rep. No. 102-259, at 1-2 (1992) (proposing to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity) (emphasis added). Rather than codify that plain requirement that a covered entity *itself* dispense the drugs, either in-house or on-site—indeed, precisely the constraint Sanofi urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity. Congress legislates against the backdrop of real-world facts and surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy, and reliance on outside pharmacies was commonplace. 61 Fed. Reg. 43,550. It defies reason to suggest that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. The fact that Congress specifically chose to remove any restriction on how covered entities dispense medications forecloses Sanofi's attempt to read those restrictions back into the statutory scheme.

Sanofi's attempt to sanitize its restrictions by downplaying their real-world impact is unavailing. Sanofi claims that, under its "integrity initiative, covered entities have no obligation to provide the requested claims data" because, if they decline, "Sanofi continues to offer its drugs at 340B prices *for shipment to the covered entity's own facilities*; the entity simply may not order discounted

drugs *for shipment to contract pharmacies*." Compl. ¶ 48 (emphasis added). This assertion ignores the fact that these are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, employees legally able to dispense drugs, appropriate storage space to keep and safeguard medications, software to bill insurers, etc., that would allow them to take delivery of, and dispense, pharmaceuticals. As has been explained in this litigation, the majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are not entitled to handle their own dispensing or even to *take delivery* of Sanofi's medications. And even for those that do, as explained *supra*, Background, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site. Were it as simple as Sanofi portrays for covered entities to access the program through direct, in-house dispensing, sales of discounted medications would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra* 9-10. While these practical realities demonstrate that Sanofi's offer to ship its drugs to each provider's physical location often is meaningless in practice, the critical point is that nowhere does the statute authorize Sanofi to make 340B-discounted drug sales contingent on a provider operating a pharmacy and accepting drugs on-site. Nor does the statute permit Sanofi to deny any discounted-drug orders by any covered entities, regardless whether the covered entity specifies that its purchase should be shipped to an outside dispenser (and certainly not based on a refusal to turn over voluminous patient and prescribing data to which Sanofi has *no* statutory entitlement).

Nor has HRSA ever suggested that it lacked authority to enforce the 340B statute's requirements, *contra* Sanofi Mot. 46. Sanofi rips from context statements in which a HRSA official acknowledged that the agency is limited to enforcing requirements that derive *from the statute* because Congress has not granted the agency explicit authority to promulgate rules having the force and effect of law in some instances. HRSA's statements only confirm (accurately) that *guidance* is unenforceable. But that does not mean HRSA now is relying on guidance rather than the statute and manufacturer

PPAs (which are enforceable) to determine that Sanofi is out of compliance.

In its complaint and motion Sanofi insists, without evidentiary support, that under its policy "when [Sanofi] declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not 'overcharged'—indeed, it typically is not charged at all." Compl. ¶ 177. This wishful thinking is flatly belied by the administrative record. As detailed *supra* 3-10, it is covered entities that place and *are charged for* orders of Sanofi's drugs that are shipped to, and dispensed by, neighborhood pharmacies. Whether or not some covered entities are foregoing certain 340B purchases altogether (a result that also is unlawful, when caused by Sanofi's refusal of discounts), Sanofi is simply incorrect that its restrictions result in only pharmacies paying commercial pricing; the administrative record is replete with examples of covered entities being subject to commercial rates due to Sanofi's denial of 340B pricing.

Sanofi ignores additional historic evidence to maintain that HHS has had "a longstanding position that manufacturers *are* permitted to impose certain conditions, such as reasonable data-collection requests," on their provision of discounted drugs. Sanofi Mot. 45 (citing 59 Fed. Reg. 25,112, 25,114). Precisely the opposite is true. Nearly thirty years ago—and not long after the statute's enactment—HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. 25,110-01, 25,112-14 (1994). In arguing otherwise, Sanofi points to a single response confirming that a manufacturer may "require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain and account) if this is a usual business practice of the manufacturers." *Id.* But permitting a manufacturer to perform the ministerial task of collecting "standard information" such as that needed "to set up … an account" is a far cry from blessing policies by which manufacturers, like Sanofi, *deny purchases by covered entities* unless non-statutory data demands are met. Indeed, the 1994 guidance prohibits such moves: "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions (e.g., minimum purchase

amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and—most pertinent here—drug companies are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.* 25,113-14. HRSA may not yet have conceived in 1994 of the *precise* data demands Sanofi now seeks to impose through its so-called "integrity initiative," but the agency made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill orders placed by covered entities—not even "require[ments] to sign agreements assuring manufacturers of their compliance with section 340B provisions." *Id.* There is no support for Sanofi's position that HHS previously has approved of manufacturer-imposed conditions.[8]

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. Contrary to Sanofi's insistence that its obligation to "offer" discounted drugs first was imposed through the 2010 amendments, the 1994 guidance interpreted the statute to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." *Id.* at 25,113. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to their patients through outside pharmacies, so too are 340B purchasers.

[8] Sanofi's focus on "conditions" on sales is a distraction; HRSA now has found that Sanofi's contract-pharmacy restrictions are *overcharging* covered entities by denying discounted purchases and forcing safety-net providers to pay commercial rates.

Id. It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

Moreover, Sanofi's assertion that, even if the statute permits covered entities to use multiple contract pharmacies (it does), that Sanofi's data-collection demands "are designed to aid compliance with the statute's other provisions and are reasonable," Compl. ¶ 11, is unavailing. As discussed above, nothing in the statute allows a manufacturer to place conditions on its fulfillment of its statutory obligation, HRSA long ago interpreted the statute to forbid it, and Sanofi's policy has the effect of *denying* sales to covered entities, so it matters not whether Sanofi thinks its conditions are "reasonable." But even were that the proper inquiry, Sanofi's demands are not as reasonable as it portrays. The federal government long has made efforts to *reduce* the burden on participants in federal programs, including from data-collection demands, and Sanofi's restrictions would contravene that attempt by requiring covered entities to collect data, in cooperation with their contract pharmacy, reformat it, and submit it on a biweekly basis to an as-yet untested system (with unknown privacy protections). This burden to provide claims-level data would fall on the safety-net community that provides care for the most vulnerable patient populations on already-thin margins. And the provision of information to *commercial* payors, to which Sanofi repeatedly analogizes, arises from contracts between covered entities and those payors to facilitate reimbursement—unlike Sanofi's program, which requires additional effort and time by the provider's staff. Plus, since other drug manufacturers do not require covered entities to expend the labor to format and submit detailed prescribing data every other week in order to realize their right to discounted medications, allowing Sanofi to do so would disincentivize providers from relying on Sanofi's drugs, thus improperly shifting discounted sales from its drugs to those of other companies. Regardless, Sanofi cannot prevail on its challenge by portraying its restrictions as reasonable because, as evidenced throughout the administrative record, Sanofi *is overcharging* them by forcing providers to pay WAC prices unless they accede to Sanofi's demands.

HRSA agrees with Sanofi that the statute does not allow contract pharmacies to participate in the 340B Program, and that Sanofi has no obligation to sell discounted drugs to pharmacies. But HRSA's review of the evidence has demonstrated that Sanofi is denying sales *to covered entities* when

those providers dispense drugs through neighborhood pharmacies (forcing those providers to either forego needed medications for their patients or pay commercial prices). Sanofi also is making extra-statutory demands that covered entities disgorge data to which Sanofi has no entitlement, that burdens covered entities, and that could place covered entities at risk of significant liability under privacy laws should a data breach occur. Sanofi remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to flout its statutory obligation.

B. The *Astra* Opinion does not compel a different conclusion.

The district court's recent decision in *AstraZeneca Pharmaceuticals LP v. Becerra* does not answer the statutory question before this Court—whether HRSA correctly found that Sanofi is overcharging covered entities—indeed, the Violation Letter was not even before that Court. No. 21-27-LPS, ECF No. 78 (June 16, 2021) (*Astra* op.). On the contrary, the *Astra* court made plain that its "role" in that opinion was "to decide only the narrow question[]" whether "the position outlined in the [AO] [is] compelled by the unambiguous text of the 340B statute." *Id.* at 1. Answering that question, the court found the AO to be "legally flawed" because its "analysis is not the sole reasonable interpretation of the statute." *Id.* at 17, 2. Far from setting forth a position *contrary* to law, however, the court confirmed that "HHS's current interpretation of the statute is permissible." *Id.* at 19. Thus not only did the *Astra* court have neither any claims regarding HRSA's Violation Letter nor the administrative record before it, the Court expressly found that the General Counsel's view regarding manufacturers' obligations represents a permissible reading, albeit not an unambiguous one.[9]

[9] HRSA respectfully contends that the relevant inquiry is not whether "the Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies," *Astra* op. 12. HRSA had no reason to be so explicit regarding manufacturers' obligations vis-à-vis *multiple* neighborhood pharmacies because HRSA repeatedly was clear that manufacturers cannot refuse covered entities sales based on dispensing mechanism or other manufacturer-imposed restrictions (and until mid-2020 manufacturers universally complied). Plus, HRSA's stance is not that drug makers must "provide" drugs to contract pharmacies, but that they must honor the ceiling price when selling to covered entities, regardless of the "ship to" location on the *covered entities'* invoice. Moreover, the briefing before the *Astra* court did not include the *1994 guidance*, *supra* 19-20, which interpreted the statute to require that "manufacturers *must offer* covered outpatient drugs at or below the section 340B discount prices" while confirming that use of contract pharmacies is a customary, common business practice, and that manufacturers are

Although HHS disagrees that there is ambiguity regarding whether manufacturers can deny 340B-priced drugs to covered entities based on the dispensing mechanism or delivery location chosen by the purchaser, even if this Court agrees that the statute is ambiguous, HRSA's letter is based on the best reading of the statute and HRSA's decades of expertise administering the statute and thus is entitled to deference. Moreover, the HRSA letter does not purport to rest on unambiguous statutory text (nor do the arguments presented herein depend on any lack of ambiguity), so HRSA's rationale would not suffer from the same "flaw" identified by the *Astra* court. As demonstrated *supra* § I.A, HRSA's conclusion that Sanofi is overcharging covered entities by refusing discounted-drug orders and imposing unlawful, extra-statutory conditions is well-grounded on statutory text, historic evidence of the agency's interpretation, and material in the administrative record, even if this Court agrees with the *Astra* opinion's finding of ambiguity.

To the extent this Court finds ambiguity in the 340B statute, it should afford a high level of deference to HRSA's interpretation of the statute under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The Third Circuit conceptualizes the *Skidmore* framework "as a sliding-scale test in which the level of weight afforded to an interpretation" varies based on several considered factors, all of which militate here in favor of deference to HRSA's Violation Letter. *Hagans v. Comm'n of Soc. Sec.*, 694 F.3d 287, 304

---

prohibited from placing limitations on such transactions. 59 Fed. Reg. 25,113, 25,111. Regardless whether HRSA's allowance for the number of contract pharmacies *a covered entity may engage* has changed over time, each of these historic guidances consistently explained that, *e.g.*, "the statute directs the manufacturer to sell the drug at the discounted price" regardless whether "a covered entity us[es] contract pharmacy services [when it] requests to purchase a covered drug." 61 Fed. Reg. at 43,549. Stated differently, the agency had no cause to opine in the *Astra* court's precise formulation because the broader obligation to honor 340B purchases without manufacturer-imposed restrictions encompasses the more-explicit requirement. HRSA respectfully contends that, properly viewed as the obligation to provide discounts to covered entities without non-statutory restrictions, its "interpretation of manufacturers' obligations" does not "shift[] every time that HHS changes its guidance with respect to covered entities' rights." *Astra* op. 14. But even if this Court disagreed that the agency's position has been consistent, HRSA's interpretation of the statute still would be the best interpretation for all the reasons set forth *supra* § I.A.

(3d. Cir. 2012). HRSA's interpretation is consistent "with its prior positions," *id.* at 304, was explained in the exercise of the "agency's specialized experience overseeing the complex" 340B program, *Hayes v. Harvey*, 903 F.3d 32, 47 (3d. 2018), and is "reasonable given the language and purpose" of the statute, *Sec'y U.S. Dep't of Labor v. Am. Future Systs., Inc.*, 873 F.3d 420, 428 (3d. Cir. 2017).

The *Astra* court's other observations do not undermine HRSA's conclusions in the Violation Letter. True, as the court found, 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Astra* op. 18. But as explained above, that matters not because Congress considered *and explicitly removed* a provision from the statute that would have limited 340B purchases to drugs dispensed in-house or on-site at a covered entity;[10] this, coupled with the fact that 95% of covered entities at the time of enactment did not have an in-house pharmacy, makes it unlikely that Congress created a novel social-safety-net program that the majority of beneficiaries had no means to access in practice.[11] Similarly, the fact that § 256b(a)(1) is directed to the Secretary of HHS, requiring him to enter agreements obligating manufacturers to honor covered-entity purchases, *discussed Astra* op. 18, does not displace HRSA's finding because HRSA is acting

[10] The *Astra* court wrote that Congress considered including this restriction when it "added the 'must offer' requirement to the statute in 2010." *See Astra* op. 21. In actuality, Congress considered restricting covered entities to in-house or on-site dispensing *when the statute was enacted in 1992*. Rather than "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies," *id.*, Congress's *removal* nearly three decades ago of any restriction on delivery site or dispensing mechanism can best be interpreted as evidence that it knew how to—but chose not to—restrict safety-net providers' access to the discount scheme.

[11] HRSA respectfully disagrees with the *Astra* court's statement that "[t]he statute's total omission of contract pharmacies renders it ambiguous *with respect to the central issue in this case*," op. 19. The central issue in that case (and this) is not the role of contract pharmacies under 340B, but the obligation of manufacturers to honor purchases by covered entities. Similarly, that court's statement that "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication," *id.* 20, is inapposite to HRSA's conclusion. HRSA is not including contract pharmacies as a "type of covered entity" nor allowing pharmacies to participate in 340B. Congressional silence strongly supports HRSA's conclusion: At time of enactment (and now) the overwhelming majority of healthcare providers relied on outside pharmacies to serve their patients. Had Congress intended to *exempt* covered entities from the usual business practice of the day (and require them to undertake the expense and effort to dispense medications in-house) surely it would have said so explicitly. Finally, Congress's addition in 2010 of the non-discrimination requirement shows it intended covered entities to be treated on par with commercial purchasers—who plainly *are* permitted to serve patients through outside dispensers.

(through delegation from the Secretary) to enforce against Sanofi the requirement in the statute and its PPA to provide discounts to safety-net providers. In other words, the Violation Letter is HRSA's effort to effectuate the command to the Secretary in § 256b(a)(1), and there is no question that the statute instructs the Secretary to ensure covered entities are not charged more than the ceiling price.

Because the *Astra* Opinion was limited to the narrow ground of finding the AO erred in concluding its interpretation was compelled by unambiguous statutory text, and the court explicitly found that "HHS's current interpretation of the statute is permissible," id. 22, *Astra* does not undermine HRSA's determination that Sanofi is violating the statute.

C. HRSA's Violation Letter Is a Reasonable Interpretation of the 340B Statute, and Is Both Substantively and Procedurally Compliant with the APA.

1. HRSA's determination that Sanofi is flouting its statutory obligation is neither arbitrary nor capricious.

HRSA reasonably explained its conclusion that Sanofi is violating its statutory obligation in the Violation Letter, and properly grounded its determination in the text of Section 340B. Agency action is not arbitrary and capricious under § 706(2)(A) of the APA if the agency "has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Judicial review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U. S. 29, 43 (1983)). And a court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). Here, Sanofi makes a number of attempts to pick apart HRSA's reasoning—none of which are persuasive—and the Court should reject Sanofi's effort to undermine HRSA's enforcement of the 340B statute.

Running throughout all of Sanofi's allegations is the mischaracterization that HRSA is requiring drug manufacturers to "provide 340B-priced drugs to contract pharmacies." Compl. ¶ 173, *see also e.g., id.* ¶ 175 (alleging that HRSA determined that "contract pharmacies" are "entitled to 340B-priced drugs"). In reality, drug manufactures must provide discounted drugs to covered entities,

though covered entities are permitted to use contract pharmacies to distribute drugs to their patients. While unsupported by the allegations of Sanofi's complaint, Sanofi's theory appears to rely on assertions made in the *amicus curiae* brief of Aaron Vandervelde, a self-styled "nationally recognized expert on the 340B program." ECF No. 69-2 at 1, 14-21.[12] Though Mr. Vandervelde attacks the predominant replenishment model, even he admits that orders under the replenishment model are made "on behalf" of the covered entity. *Id.* at 14. The fact is that, even under the replenishment model, manufacturers are still selling drugs to covered entities, and thus must do so at the discounted 340B price. *See* Decl. of Krista M. Pedley ("Pedley Decl.") ¶ 10, attached here as Exhibit 2 (explaining that, under the replenishment model, "the covered entity is the legal purchaser and authorizes the order").[13]

Generally speaking, under the replenishment model, a covered-entity patient who is 340B eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. *Id.* ¶ 3; *see also e.g.*, VLTR_7323 (declaration of covered entity CEO explaining that "contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used"); VLTR_7257 (same). The model works in three main steps. First, a contract pharmacy

[12] Mr. Vandervelde acquired his purported "expertise" by serving as an industry consultant for PhRMA, the same trade organization to which Sanofi belongs. Vandervelde *curriculum vitae*, *available at* https://media.thinkbrg.com/wpcontent/uploads/2020/06/27145336/Vandervelde_Aaron_CV.pdf (last visited June 15, 2021). Mr. Vandervelde prepared for PhRMA a lengthy publication on "abuse" of 340B by contract pharmacies, Aaron Vandervelde, et al., *For-Profit Pharmacy Participation in the 340B Program* (October 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf, and has even developed and sold the very software platform Sanofi is using to impose contract-pharmacy restrictions. *See* Email from J. Garner to K. Talmor (May 7, 2021 12:07:47 PM), attached here as Exhibit 1. Aside from constituting impermissible extra-record evidence, Mr. Vandervelde has a *financial* stake in Sanofi's ability to continue its data-collection demands (and a client relationship with PhRMA), thus rendering his views a particularly inappropriate basis for Sanofi's claims.

[13] While Sanofi's arbitrary-and-capricious claim should be decided on the basis of the administrative record, RADM Pedley submits her declaration in response to the Vandervelde amicus brief, to the extent Sanofi relies on any extra-record facts therein. Pedley Decl. ¶ 2.

dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient was eligible for 340B product. Pedley Decl. ¶¶ 5-6. The software is operated under the oversight of the covered entity, and HRSA audits the process by taking a sample of drugs dispensed and requiring the covered entity to show "each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient." *Id.* ¶ 6. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *Id.* ¶¶ 7-8; *see also e.g.*, VLTR_7317 (covered entity CEO explaining "virtual inventory" system where "each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the covered entity] places an order via our 340B wholesaler to replenish the contract pharmacies' stock"). Importantly, the replenishment order is placed on a covered entity's 340B account and the covered entity is billed for that order. Pedley Decl. ¶ 9. If any dispute (including instances of non-payment) about the invoice arises, it is the covered entity that is responsible—not the contract pharmacy—which merely serves as the "ship to" address on the invoice. *Id.* During this process, "the covered entity is the legal purchaser and authorized the order." *Id.* ¶ 10; *see also, e.g.* VLTR_7296 (declaration of covered entity CEO explaining that it purchases "drugs at 340B pricing … and direct[s] those drugs to be shipped to our contract pharmacies on a replenishment basis," during which time the covered entity "maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies"); VLTR_7279 (same). Indeed, the covered entity should be aware of all replenishment orders and "the order is often approved by the covered entity prior to submission to the wholesale/distributor to ensure accuracy." Pedley Decl. ¶ 10. Finally, the "replenished" drug is shipped to the contract pharmacy, where it becomes neutral inventory "and may be dispensed to any subsequent patient." ¶ 11.

At no point during this process are the 340B drugs "purchased by" the contract pharmacy. The drugs are simply delivered to contract pharmacies after being purchased by covered entities to replenish the pharmacy's stock of drugs that were distributed to 340B-eligible patients. Thus, contrary to Sanofi's allegation, the replenishment model does not foreclose HRSA's determination that Sanofi's policy resulted in overcharges to covered entities. *See* Compl. ¶ 177. As explained above, the

manufacturer or wholesaler is still *charging the covered entity* for the price of the 340B-eligible drug under the replenishment model. Since the commercial price charged often is much higher than the 340B ceiling price, *see infra* for examples, this provides a reasonable basis for HRSA's conclusion that Sanofi is overcharging covered entities in violation of the 340B statute. Moreover, even if Sanofi's contention that no covered entity was "charged" for 340B-eligible drugs was always true, Sanofi would still be overcharging covered entities by not allowing covered entities to reap the benefits of the 340B statute at all. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25, 110, 25,113 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Here, though, and contrary to Sanofi's allegation that HRSA failed to support its "determination that Sanofi's integrity initiative has resulted in overcharges" with any evidence, *see* Compl. ¶ 178, the administrative record is replete with evidence that covered entities were, in fact, forced to pay higher prices as a result of Sanofi's policy. Indeed there are numerous complaints by covered entities that explicitly state: "Sanofi is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. I am forced to pay [the wholesale acquisition cost] for these products for my contract pharmacies." *See, e.g.*, VLTR_151 (Adelante Healthcare); VLTR_283 (Alcona Citizens for Health); VLTR_1198 (Aspire Health Center); VLTR_1603 (Blue Ridge Medical Center); VLTR_1679 (Central FL Health Center); VLTR_1806 (Cherry Street Services); VLTR_1886 (Christ Community Health Services Augusta, Inc.); VLTR_1904 (Clinicas De Salud De Pueblo, Inc.); VLTR_2052 (Compass Health Inc.); VLTR_2263 (El Rio Health); VLTR_2333 (Family Medical Center of Michigan, Inc.); VLTR_2934 (HealthNet Inc.); VLTR_6595 (Maricopa County Special Health Care District DBA Valleywise Health); VLTR_4357 (MHC Health Care); VLTR_4702 (North Country HealthCare, Inc.); VLTR_4829 (Penobcot Community Health Care); VLTR_5037 (South Central Missouri Community Health Center);

VLTR_5052 (Salina Health Education Foundation); VLTR_5127 (Santa Barbara County Health Care); VLTR_5312 (Tandem Health). Multiple complaints go even further, and identify screenshots or detail specific transactions in which a covered entity had to pay a wholesale acquisition price for Sanofi drugs that resulted in significant lost savings to the covered entity. *See e.g.*, VLTR_1468 (including multiple Sanofi drugs in monthly loss of over $70,000); VLTR_1595-99.

While the administrative record clearly "identifies" a "covered entity that Sanofi has … overcharged" and "transaction[s]" in which Sanofi has done so, *see* Compl. ¶ 178, the record also reflects Sanofi's overcharges in aggregate statistics. In October 2020, for example, when Sanofi stopped offering 340B pricing on drugs shipped to contract pharmacies, the number of 340B-priced units of Sanofi drugs sold through contract pharmacies plummeted from 2.04 million to .28 million and the number of WAC-priced units rose from under .01 million to .37 million. *See* VLTR_7937. This constituted $40.8 million in average lost savings by covered entities on Sanofi products in October 2020 alone. *See* VLTR_7940. The trends continued in the subsequent three months, constituting average lost savings on Sanofi products of over $40 million each month. *See id.* These statistics represent thousands of transactions in which Sanofi's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices, which further supports HRSA's determination that Sanofi has, in fact, overcharged covered entities.

In addition to Sanofi's new arguments with respect to the Violation Letter, Sanofi attempts to recast several of its other arguments as reasons to declare the Violation Letter arbitrary and capricious. These attempts are unpersuasive. For example, Sanofi argues that, because the AO is supposedly arbitrary and capricious, "HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also arbitrary and capricious." Compl. ¶ 174. But as explained *supra* § IV.A, the AO did not amount to a "new rule" and, in any event, is entirely separate from HRSA's Violation Letter that speaks to the legality of Sanofi's particular restrictions. *Id.* Thus the merits of the AO have no relevance to the Court's inquiry with respect to the Violation Letter.

Regardless, the Violation Letter is not "inconsistent" with the AO, as Sanofi claims. *See* Compl. ¶ 175. At the threshold, the AO did not conclude that "contract pharmacies are entitled to 340B-

priced drugs because they act as agents of covered entities." *Id.* To the contrary, the AO specifically concluded that "*covered entities*," not *contract pharmacies*, "are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price." VLTR_8055. And, rather than requiring manufacturers to offer 340B discounts to contract pharmacies, the AO reiterated that the statute requires manufacturers to "offer" discounted drugs to covered entities, "even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* The AO's reference to an agency relationship was merely an example used to illustrate the reality that contract pharmacy arrangements do not constitute unlawful diversion. VLTR_ 8053. In any case, the Violation Letter is consistent with the AO's conclusions. The Violation Letter explicitly states that the 340B statute does not "grant[]" Sanofi "the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities," and that the statute does not permit the imposition of any conditions, such as "the production of claims data," independent of "how the covered entity chooses to distribute" the drugs. VLTR_9. Thus, the gravamen of both the AO and the Violation Letter is that manufacturers, including Sanofi, have a statutory obligation to provide discounted drugs even if covered entities use contract pharmacies to aid in distribution, and that Sanofi's attempts to undermine this statutory reality are inconsistent with the law.

Finally, Sanofi also incorrectly characterizes prior HRSA guidance related to the 340B program in reiterating its argument that the Violation Letter is "inconsistent … with prior guidance permitting manufacturers to impose certain conditions … such as agreement to the manufacturer's normal business policies and the collection of standard information." *See* Compl. ¶ 176. As explained above, the agency long ago forbid manufacturers from conditioning discounted-drug sales on manufacturer-imposed conditions. *See supra* § I.A.

The Violation Letter represents HRSA's reasonable consideration of relevant issues and reasonably explains the agency's decision. It thus is not arbitrary and capricious.

2. The APA's notice-and-comment requirement is inapplicable to HRSA's 340B violation letter.

Sanofi claims that HRSA's 340B-violation letter should be set aside, 5 U.S.C. § 706(2)(D), because it "enforce[s] … the Advisory Opinion," which (Sanofi contends) HHS issued in violation of the notice-and-comment procedures set forth in 5 U.S.C. § 553(b)(3)(A). Compl. ¶¶ 181–83. This procedural challenge to the violation letter is wholly derivative of Sanofi's procedural challenge to the AO and fails because the letter does not "enforce" the AO (and because the AO is withdrawn). And as Sanofi appears to concede, a letter merely informing a regulated entity that it has violated a statute administered by the agency is not subject to the APA's notice-and-comment requirement. *See, e.g.*, *Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 122–25 (D.D.C. 2014).

II. THE ADMINISTRATIVE-DISPUTE RESOLUTION MECHANISM MANDATED BY CONGRESS WAS LAWFULLY ESTABLISHED

A. *ARTHREX* CONFIRMS THAT ADR BOARD MEMBERS ARE LAWFULLY APPOINTED INFERIOR OFFICERS

This past week the Supreme Court issued additional guidance on the appointment of adjudicatory officers, holding that administrative judges operating under statutory restrictions on *both* review of their decisions *and* removal from their office exceeded the power that properly may be vested in inferior officers. *United States v. Arthrex, Inc.*, 594 U.S. __ , slip op. 19-1434, 2021 WL 2519433 (June 21, 2021). *Arthrex* concerned Administrative Patent Judges (APJs) appointed by the Secretary of Commerce and empowered, when assigned to three-judge panels, to hear challenges to previously issued patents in an adversarial proceeding "which resembles civil litigation in many respects." *Id.* 1, 3-4. Although a dissatisfied litigant could request rehearing by a panel, under the statutory scheme "[n]either the Secretary nor Director," the supervising principal officer, "had the authority to review [APJs'] decisions or to remove them at will"; the APJs' decisions were final for the Executive Branch and could be appealed only to the Court of Appeals for the Federal Circuit. *Id.* at 4-6. The Court determined that this novel structure, where "Congress has assigned APJs 'significant authority' in adjudicating the public rights of private parties[] while also insulating their decisions from review and their offices from removal," was inconsistent with the Appointments Clause. *Id.* at 19.

As a remedy, the Court concluded that the will of Congress could best be effectuated in that particular scheme by severing the statutory restriction on review of APJs' decisions by the Director, rather than the statutory restriction on removal from office at will. "In every respect save the insulation of their decisions from review within the Executive Branch, APJs appear to be inferior officers—an understanding consistent with their appointment" by a Head of Department, the Court concluded, so the most-sound result was to render the statute "unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the [APJs] on his own." *Id.* at 21-22. It mattered not that no formal mechanism for appeal to the Director would then exist, because vesting the Director with the discretionary power to review APJs' decisions "would follow the almost-universal model of adjudication in the Executive Branch." *Id.* "To be clear, the Director need not review every decision," because "[w]hat matters is that the Director *have the discretion to review* decisions rendered by APJs." *Id.* at 23 (emphasis added).

Arthrex confirms that the ADR Rule challenged here is consistent with the Appointments Clause. The statutory scheme at issue here (which Sanofi does *not* challenge, as opposed to the Rule promulgated under it) contains no restraint whatsoever on the Secretary's ability to direct and supervise the ADR Board through review of panel decisions or removal from office at will. To be sure, the statute directs the Secretary to "establish a decision-making official or decision-making body … to be responsible for reviewing and finally resolving claims." 42 U.S.C. § 256b(d)(3)(B)(i). But that language instructs the Secretary *to delegate* authority to issue final agency actions reviewable in district court; it does not resemble the language at issue in *Arthrex*, where "Congress unambiguously specified" in *prohibitory* terms that the Director could not alter a decision. *See* slip op. at 10; *see also* 35 U.S.C. § 6(c) (specifying that "[o]nly the … Board may grant rehearings"); *Arthrex* at 12 (confirming § 6(c) represents "a statutory prohibition on review"). Here, the absence of any statutory constraint on

discretionary review by the Secretary of final decisions of his subordinates makes the ADR Rule analogous to the *Arthrex* Court's statutory *fix*—not the initial constitutional *violation.*[14]

Under the ADR Rule, the Secretary freely may exercise discretionary review of panel decisions; it matters not that no formal mechanism for appeal to the Secretary is set forth in the regulation. Indeed, the *Arthrex* Court confirmed that an express grant of power to direct and review the decisions of subordinates is unnecessary, so long as no *restriction* on that power is found in the statutory scheme. Notably for the present case, not only was there no need for express statutory authorization for the Director's review of APJs' decisions, the Court also made clear that the Director need not promulgate regulations establishing a formal mechanism to facilitate his review. Simply severing the statutory prohibition on review of APJs' decisions "does not result in an incomplete or unworkable statutory scheme," since "[w]hat matters is that the Director have the discretion to review decisions rendered by APJs." *Arthrex*, slip op. at 21, 23; *see also id.* at 15 ("For the most part, Congress left the structure of administrative adjudication up to agency heads, who prescribed internal procedures (and thus exercised direction and control) as they saw fit."); *id.* (confirming "authority to review" "decisions of [] subordinates despite congressional silence on the matter"). This principle was well established even before *Arthrex*; "[a]s a general proposition of administrative law, the head of an administrative agency has the power to review and revise the acts of subordinates where … the powers in question are vested in the subordinate under the supervision and direction of the superior." *Morrow v. Clayton*, 326 F.2d 36, 45-46 (10th Cir. 1963). *Accord Chevron Oil Co. v. Andrus*, 588 F.2d 1383, 1387-88 (5th Cir. 1979) (confirming officer who delegates authority does not divest himself of the power to exercise that authority to review and overrule subordinate absent express restriction in delegation). Because Congress has placed no restrictions on the Secretary's authority to review ADR panel decisions, ADR Board members serve as properly appointed inferior officers. Sanofi's argument (made without statutory support) that ADR panel decisions bind even "the Secretary himself" and "cannot be

[14] Even if this Court concluded that the statute was unclear as to whether it preserves the Secretary's authority to review Board decisions, principles of constitutional avoidance counsel in favor of construing the statute to allow for review.

reversed by the Secretary," Sanofi Mot. 62-63, fails as a matter of law because neither the statute nor the Rule purport to prohibit the Secretary from overturning a panel decision with which he disagrees.

But there is more: Not only may the Secretary review ADR decisions, he also may freely remove ADR Board members at will. In arguing otherwise in its brief, Sanofi does not (and cannot) point to any constraint on the Secretary's ability to remove *Board* members and instead focuses myopically on the *panels* to which members are assigned. Sanofi Mot. 60-68 (focusing exclusively on whether "ADR panelists are principal officers"). That shift in focus is unavailing; the Appointments Clause, U.S. Constitution art. II, § 2, cl. 2, concerns the *appointment* of federal officers—not the interim *assignments* on which those officers are tasked to work. Just as Article III is concerned with the manner in which judges are appointed and removed (through Senate confirmation and impeachment)—not their selection or deselection from particular cases or appellate panels during their judicial tenure—so, too, the Article II analysis turns on the manner in which ADR *Board* members, as officers, are appointed and can be removed—not the individual panel assignments for which they later are selected.

Sanofi claims that "the government cites no authority for th[e] proposition" that removal from the Board, not a panel, is relevant for constitutional purposes. Sanofi Mot. 67. That is incorrect on its face; each and every Article II case cited in the government's opening brief, HHS Mot. 32-39, concerned the question whether an officer can be removed from an appointment, not when (or by whom) that officer can be re-assigned from any particular task during his tenure. That is unsurprising, since this dispute arises under the Appointments Clause, not an "assignments clause." Moreover, this straightforward principle was on display in *Arthrex*, where the Supreme Court confirmed that the Director's ability to "reassign[] an APJ to a different task going forward" was not the relevant consideration since, according to the statute, the APJs could only be "remov[ed] from federal service entirely" for cause. Slip op. at 12. In other words, it is removal from one's office—not reassignment from the task at hand—that has constitutional significance. Under the ADR Rule, a federal employee becomes an officer when s/he receives an *appointment* by the Secretary to the ADR Board, not when s/he is selected from that Board by the HRSA Administrator to hear any particular petition. Sanofi's argument that removal must be considered "in the only context in which ADR panelists exercise any

authority—their service on ADR panels"—is akin to arguing that federal appellate judges must be impeached by the Senate before being removed from a panel assignment, since judges enjoy constitutional removal protection yet they, too, exercise their authority in the context of particular disputes. Similarly, Sanofi's claim that the removal power "belongs to the individual that appointed the ADR panelists: the HRSA Administrator," Sanofi Mot. 67, is nonsensical because the HRSA Administrator only assigns Board members to particular disputes *after* they have been appointed as federal officers by the Secretary. Clearly it is removal from one's appointment—not one's interim assignment—that matters for constitutional purposes.

Sanofi's removal arguments fail even as applied correctly to the ADR Board. Neither the Rule nor the statute contain any restraint on the Secretary's ability to remove ADR Board members, thus demonstrating that this "powerful tool for control," *Edmond v. United States*, 520 U.S. 651, 664 (1997), remains fully with the Secretary. The Secretary's partial delegation of authority to the HRSA Administrator to share in this task, by re-assigning a panel member when cause is shown, is a sensible delegation without constitutional significance.[15]

Because there are no "statutory restrictions on the [Secretary] that insulate the decisions of [ADR Board members] from his direction and supervision," *Arthrex*, slip op. at 23, Board members receive a proper appointment under the ADR Rule. Board members also may be removed *from their appointment* at-will by the Secretary at any time, further demonstrating their status as inferior officers.

B. CONGRESS PROPERLY VESTED ADJUDICATION OF STATUTORILY CREATED 340B RIGHTS BEFORE THE AGENCY

Sanofi's Article III challenge is equally wrong on the law. Sanofi spills significant ink insisting that the alleged remedial powers granted to the Board render it unconstitutional, Sanofi Mot. 68-72, while ignoring the caselaw and examples set forth in the government's brief demonstrating that, far from an infringement on the judiciary, the powers granted to the ADR Board are commonplace

[15] Even if the Court considered the circumstances for re-assignment of panel members, rather than removal from the Board (an approach not supported by caselaw), the Rule contains *no* constraint on the Secretary's ability to re-assign panels. On the contrary, the Rule merely authorizes the HRSA Administrator to re-assign panelists in more-limited circumstances where cause is shown.

features of modern administrative law. HHS Mot. 39-41. HHS disagrees with Sanofi regarding the scope of the Board's remedial powers, but even if Sanofi is correct that panels may purport to issue injunctive relief (which, as explained in the government's opening brief, would resemble a cease-and-desist demand to comply with statutory requirements, not a judicial-style order backed by contempt power) or a damages calculation, that *still* would pose no Article III problem. *See id.* 41 (explaining that many agencies have the power to order equitable relief and damages, including findings of violation, restitution, and fines, subject to judicial review under the APA, just like ADR panel rulings).

Sanofi's private-rights argument rests on inapposite caselaw and ineffective attempts to distinguish relevant authorities. Article III challenges arise in two distinct settings: challenges arising in *bankruptcy courts* typically concern the ability of those Article I bodies, serving as adjuncts of district courts, to adjudicate common-law counterclaims and similar matters that arise with some relationship to the bankrupt estate. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 56 (1989) ("fraudulent conveyance actions by bankruptcy trustees … are quintessentially suits at common law that … resemble state-law contract claims" and "therefore appear matters of private rather than public right"); *Stern v. Marshall*, 564 U.S. 462, 487 (2011) ("No 'public right' exception" permitted bankruptcy court to adjudicate "state common law counterclaim" for tortious interference); *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 71 (1982) (adjudication of "the right to recover contract damages" under state law "obviously is not" a public right and thus belongs in Article III court). In other words, Article III challenges to the jurisdiction of bankruptcy courts involve private rights because traditional, common-law *claims* (or those closely resembling them, and created by statute) are at stake. By contrast, Article III challenges arising before *administrative agencies* often involve the adjudication of entirely *new* rights, created by Congress through statute as part of a comprehensive regulatory scheme. *See Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 593-94 (1985). In such cases, Congress need not even create a remedy in the courts at all, so it "may set the terms of adjudicating" that right, including by assigning adjudication in another branch of government. *Stern*, 564 U.S. at 489 (citation omitted). And it matters not that the dispute may arise between private parties, or affect some interest in money or property. It is the nature of the claim asserted that renders it capable of non-judicial adjudication. *See*

HHS Mot. 41-46 (providing thorough analysis of public-rights caselaw and demonstrating that ADR Board adjudicates only statutory rights created by Congress).

Sanofi ignores the proper test for determining when *statutory* rights may be adjudicated outside Article III. Sanofi Mot. 72. For example, Sanofi emphasizes that "the claim at issue in *Granfinanciera* was created by federal statute but nevertheless involved a private right," Sanofi Mot. 76, and asserts that this proves that "new rights" under a federal regulatory scheme still must be adjudicated in Article III courts. Not so: *Granfinanciera* involved a private right because the statutory cause of action effectively supplanted and resembled a pre-existing common-law action. 492 U.S. at 53-56 (analogizing statutory claim to state-law contract dispute). And the *Granfinanciera* Court emphasized that "[t]he crucial question" in determining whether public rights are at issue is whether it "involv[es] statutory rights that are integral parts of a public regulatory scheme and whose adjudication Congress has assigned to an administrative agency or specialized court of equity." *Id.* at 54, 55 n.10. That precisely describes the comprehensive 340B drug-discount program, and the novel claims for "overcharging," "diversion," and "duplicate discounting" that arise under it. *See also Stern*, 564 U.S. at 490-91 (public rights are "cases in which the *claim at issue* derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority") (emphasis added). Sanofi's dismissal of *Union Carbide*, 473 U.S. at 584, ignores the Supreme Court's discussion and approval of *various* agency adjudicative schemes which "determine liabilities of individuals" to one another yet are able, consistent with constitutional constraints, to adjudicate "claims between individuals." 473 U.S. at 587, 589. *Union Carbide* does not stand for the proposition that any pre-existing property rights must be extinguished by a statute before claims may fall within the public-rights exception. *Contra* Sanofi Mot. 75-76. [16]

Sanofi's continued insistence that the claims heard by ADR panels—that a manufacturer has charged a covered entity more than the ceiling price for pharmaceuticals, or that a covered entity

[16] The fact that patent "infringement cases today must be tried to a jury, as their predecessors were more than two centuries ago," *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996) (Sanofi Mot. 76), is irrelevant since patent infringement rights are not integral to a federal regulatory scheme.

unlawfully has diverted or claimed duplicate discounts for 340B drugs—would have been "tried by the courts at Westminster in 1789," is absurd, as there clearly is no historic precedent for these disputes. Sanofi Mot. 72 (quoting *Stern*, 564 U.S. at 484). Congress created these rights from whole cloth so it is no infringement on the judiciary for initial adjudication to occur outside the third branch.[17]

Were Sanofi correct that the claims brought by covered entities against it are "the subject of a suit at the common law" that even *could* be heard, in the first instance, by Article III courts, *id.* 73 (citing *Den. ex dem. Murray v. Hoboken Land & Improvement Co.,* 59 U.S. (18 How.) 272, 284 (1855)), then the Supreme Court wrongly decided *Astra v. Santa Clara County*, 563 U.S. 110, 121-22 (2011) (holding covered entities may not litigate 340B claims for overcharging in federal court). Sanofi's contention that "covered entities' claims against manufacturers in ADR proceedings are effectively state-law contract claims," Sanofi Mot. 74, is precisely the theory rejected by the high court. *Astra*, 563 U.S. at 118 (rejecting attempt by covered entities to sue to enforce manufacturer PPAs because it would "render[] meaningless" "[t]he absence of a private right [of action] to enforce the statutory ceiling-price obligations"). Were Sanofi correct that covered entities' claims cannot be adjudicated before the agency, the result—in light of the holding that those same claims cannot be heard in federal court—would be that claims for 340B violations cannot be heard in *any* forum, thus negating the will of Congress to create a remedy for claims of "overcharging." That untenable result should be rejected.

C. HHS Fully Complied With Notice And Comment In Promulgating The ADR Rule

All parties agree that "[t]he [APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures."

[17] Sanofi asserts that the government "misunderstands the nature of the rights at issue" because, "[a]lthough Section 340B creates covered entities' entitlement to drug discounts, it is *Sanofi's* private rights that are at stake." Sanofi Mot. 75. Sanofi is wrong. The private/public rights inquiry focuses on the *claim* being adjudicated and whether it is "an integral part of a public regulatory scheme, assigned to an administrative agency," *Beard v. Braunstein*, 914 F.2d 434, 441 (3rd Cir. 1990), not whether property changes hands through the disposition. ADR panels simply do not, as Sanofi claims, determine "Sanofi's underlying private rights to hold and alienate property on terms of its choosing," Sanofi Mot. 75. Besides, Sanofi absolutely has the "voluntary choice," *id.* 77, to opt out of participation in Medicaid and Medicare Part B and charge whatever it wants for its drugs. But it cannot profit from these lucrative government programs while shirking its complementary statutory obligations.

See, e.g., *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978). Here, to follow the APA's procedures, the agency need only have published a notice of proposed rulemaking that included "either the terms or substance of the proposed rule or a description of the subjects and issues involved," 5 U.S.C. § 553(b)(3), and then "give[n] interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). HHS has complied with these requirements. Yet, while accusing HHS of "impos[ing] upon agencies specific procedural requirements that have no basis in the APA," Sanofi Mot. 59, Sanofi endorses the one opinion of a district court in another case that does just that. In *Eli Lilly & Co. v. Cochran*, No. 1:21-CV-81, 2021 WL 981350 (S.D. Ind. Mar. 16, 2021) the court essentially imposed a new (and highly subjective) procedural requirement on agencies not found in the APA—that agencies must publish a new NPRM and re-do the notice and comment process if the totality of the circumstances would lead a reasonable observer to view the original NPRM as withdrawn. In addition to creating a new rule that improperly inhibits an agency's statutorily delegated rulemaking authority, this "totality-of-the-circumstances" test, created in the first instance by the *Lilly* court, is incompatible with existing law setting forth the procedures for review of agency action.

Courts review the decision to terminate rulemaking as final agency action under the APA. *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 846 (D.C. Cir. 1983); *see also* HHS Mot. 47-48. Accordingly, the APA requires the agency to provide "an explanation [for terminating a rulemaking] that will enable the court to evaluate its rationale at the time of the decision." *Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 44 (D.C. Cir. 2004). Because the need for a statement explaining the reasons for withdrawal stems from the APA itself, *see Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990) (characterizing 5 U.S.C. § 706(2)(A) as imposing "a general 'procedural' requirement of sorts by mandating that an agency take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision"), HHS's position does indeed have a "basis in the APA" and is far from "nonsensical," *see* Sanofi Mot. 59 n.22. Thus, it is no surprise that not only have other courts reviewed the termination of rulemaking on the basis of a withdrawal notice published in the Federal Register, *see Int'l Union,*

United Mine Workers, 358 F.3d at 42 (acknowledging withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety*, 710 F.2d at 844 (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same), but HHS's usual practice is to publish a notice of withdrawal in the Federal Register. *See, e.g.*, 78 Fed. Reg. 12,702-01 (Feb. 25, 2013); 79 Fed. Reg. 19,848-01 (Apr. 10, 2014); 83 Fed. Reg. 60,804-01 (Nov. 27, 2018); 84 Fed. Reg. 37,821-01 (Aug. 2, 2019).

Even if this Court were to adopt the *Lilly* Court's newly-created and extra-statutory totality of the circumstances test (and it should not), the facts on which Sanofi relies, Sanofi Mot. 58, would not have led a reasonable observer to believe the ADR Rule had been withdrawn. First, listing or delisting of rulemaking on the Unified Agenda is not presumed to provide notice of a proposed rulemaking to regulated parties of agency action. Though the Unified Agenda exists to provide "uniform reporting of data on regulatory and deregulatory activities under development" in the Executive Branch, *About the Unified Agenda*, REGINFO.GOV,[18] listing a rulemaking on the Unified Agenda does not satisfy statutory requirements to provide notice of rulemaking, 5 U.S.C. § 553(b), or establish presumptive notice of regulation required for enforcement, *cf.* 44 U.S.C. § 1507. Accordingly, de-listing a rulemaking from the regulatory agenda is not sufficient to withdraw that rulemaking for the purposes of the APA. The Unified Agenda is simply an administrative tool to assist the Executive Branch in the organization and exercise of its regulatory authority. For the same reasons, the existence of a different RIN is legally insignificant. RINs are administrative tags created by the Office of Information and Regulatory Affairs, not the agency, and cannot properly be interpreted as a sign of the agency's intent with respect to rulemaking. *See* How to Use the Unified Agenda, Reginfo.gov.[19]

Second, the statements by an unnamed HRSA official in a news publication are far from a clear and direct statement of withdrawal that the public would expect if a rulemaking were terminated. Sanofi relies on the *Lilly* Court's citation to a news report quoting a HRSA official as stating that the agency "had no plans to create a binding ADR process" and "does not plan to move forward on issuing a regulation," Sanofi Mot. 58, but nowhere does Sanofi allege that the official actually

[18] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp.
[19] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.myjsp#rin.

purported to withdraw the existing NPRM. More importantly, Sanofi does not cite, and HHS has not found, caselaw supporting the notion that a public statement from an individual official without decisionmaking authority can provide any evidence as to whether a rulemaking has been withdrawn.

In a final attempt to invalidate the procedurally proper ADR Rule, Sanofi argues that the ADR Rule violates the APA because it is not a logical outgrowth of the 2016 NPRM. HHS addressed this claim at length in their motion, *see* HHS Mot. 49-50, and Sanofi fails to contest or meaningfully engage with a single argument raised therein. At bottom, the NPRM gave Sanofi adequate notice of the topics covered by the ADR Rule, and thus, Sanofi's logical outgrowth claim fails as a matter of law. *See Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 249 (3d. Cir. 2010).

D. THE ADR RULE IS NOT ARBITRARY, CAPRICIOUS, OR CONTRARY TO LAW

Sanofi identifies no sound basis on which to set aside the ADR Rule under 5 U.S.C. § 706(2).

First, Sanofi maintains that HHS has no statutory authority to award monetary or equitable relief through the ADR process. *See* Sanofi Mot. 77–78. But § 256b(d)(3)(A) explicitly authorizes the Secretary to create "procedures for the provision of remedies and enforcement of determinations made pursuant to [the ADR] process through [the] mechanisms and sanctions described" under subsections (d)(1)(B) and (d)(2)(B). These provisions identify both monetary and equitable remedies for 340B violations—*e.g.*, the issuance of refunds for overcharges, the imposition of civil monetary penalties, and removal from the 340B Program. *See* 42 U.S.C. § 256b(d)(1)(B)(ii), (vi); *id.* § 256b(d)(2)(B)(v). Thus, the authority delegated to HRSA under the ADR Rule to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities" falls squarely within the Secretary's statutory authority. *See* 42 C.F.R. § 10.24(e); 85 Fed. Reg. 80,642.

Second, Sanofi attempts to draw a distinction between HHS's statutory authority to resolve ADR "claims by covered entities that they have been overcharged for drugs," *see* 42 U.S.C. § 256b(d)(3)(A), and a panel's authority under the ADR Rule to decide, in resolving an overcharge claim, whether a drug maker has unlawfully denied a covered entity the "ability to purchase covered outpatient drugs at or below the 340B ceiling price," 42 C.F.R. § 10.21(c)(1). But this is a distinction

without any apparent difference. Where a drug maker denies a covered entity the ability to purchase 340B drugs at discounted prices, the covered entity is being offered those drugs at a price in excess of the applicable ceiling price, which is, by definition, an "overcharge." Sanofi nevertheless suggests that, to bring an overcharge claim, a covered entity must point to a "specific transaction[]" in which it purchased a drug above the applicable ceiling price. This fabricated requirement not only has no basis in the statute, it would leave covered entities who are *unable* to purchase 340B drugs at facially unlawful prices without any remedy. *See, e.g.*, VLTR_005827 (covered entity deterred from purchasing 340B drugs because the drug maker was denying the 340B price for covered outpatient drugs). "Congress cannot have intended this bizarre result." *See Caron v. United States*, 524 U.S. 308, 315 (1998).

Third, Sanofi argues that certain "industry changes" occurred in the years preceding promulgation of the final ADR Rule, and that HHS should have taken these changes into account. Sanofi Mot. 79. Sanofi points specifically to an increase in the use of contract pharmacies by covered entities, evidence of compliance issues in the 340B Program, and various drug makers' extra-statutory restrictions on purchases made by covered entities with contract-pharmacy arrangements. *Id.* But HHS had no obligation to consider these purported "changes" within the industry, because they have no relevance to HHS's development of a dispute-resolution mechanism under 42 U.S.C. § 256b(d)(3), and Sanofi offers no argument to the contrary. *See NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d 182, 190 (3d Cir. 2006) ("Reversal is appropriate *only* where the administrative action is irrational or not based on *relevant* factors.").[20]

CONCLUSION

Because each of Sanofi's claims is meritless, the Court should dismiss each count or, in the alternative, grant summary judgment for HHS.

[20] By offering no response to HHS's arguments, *see* HHS Mot. 51–53, Sanofi has abandoned its claims that the agency acted arbitrarily and capriciously by (i) not responding to comments regarding HRSA's audit guidelines, (ii) not considering PhRMA's petition for rulemaking, and (iii) not adequately explaining the design of the ADR process. *See Yucis v. Sears Outlet Stores, LLC*, No. CV 18-15842, 2019 WL 2511536, at *4 n.4 (D.N.J. June 18, 2019).

Dated: June 24, 2021

Respectfully submitted,

BRIAN NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Kate Talmor
KATE TALMOR
RACHAEL WESTMORELAND
JODY LOWENSTEIN
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20005
(202) 305-5267
kate.talmor@usdoj.gov
Attorneys for Defendants

Exhibit 1

From: Jekka Garner
To: Talmor, Kate (CIV)
Subject: Re: [EXT] RE: Consent to File Amicus
Date: Friday, May 07, 2021 12:07:47 PM

Hi Kate,

Mr. Vandervelde provided the below information:

- For clarification, we do have a client relationship with Sanofi as they license BRG's 340B ESP platform technology. I have made this clear in the amicus brief.
- With regards to Pharmaceutical Research and Manufacturers of America, BRG does policy analysis work for PhRMA but is not engaged with PhRMA related to any active litigation.

Please let me know if any further information is required. Thank you.

Best,
Jekka

Jekka Garner | Associate General Counsel

BRG
1800 M Street NW Second Floor | Washington, DC 20036
O 202.480.2700 | M 910.770.0317
JGarner@thinkbrg.com | thinkbrg.com

From: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Sent: Friday, May 7, 2021 11:26 AM
To: Jekka Garner <JGarner@thinkbrg.com>
Subject: RE: [EXT] RE: Consent to File Amicus

Hi Jekka, Thank you for the information. Your email below mentions that Mr. Vandervelde does not have a client relationship with respect to either Eli Lilly or Sanofi; can you please advise as to whether Mr. Vandervelde has a client relationship with the Pharmaceutical Research and Manufacturers of America?

Thank you,

Kate Talmor

From: Jekka Garner <JGarner@thinkbrg.com>
Sent: Wednesday, May 5, 2021 4:56 PM
To: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Subject: Re: [EXT] RE: Consent to File Amicus

Hi Kate,

Thank you for the prompt response. Mr. Vandervelde would like to file next Monday.

Best,
Jekka

Jekka Garner | Associate General Counsel

BRG
1800 M Street NW Second Floor | Washington, DC 20036
O 202.480.2700 | M 910.770.0317
JGarner@thinkbrg.com | thinkbrg.com

From: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Sent: Wednesday, May 5, 2021 2:12 PM
To: Jekka Garner <JGarner@thinkbrg.com>
Subject: [EXT] RE: Consent to File Amicus

Ms. Garner,

When do you propose to file your amicus brief?

Kate

From: Jekka Garner <JGarner@thinkbrg.com>
Sent: Wednesday, May 5, 2021 2:10 PM
To: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Subject: Consent to File Amicus

Dear Ms. Talmor,

My name is Jekka Garner, Associate General Counsel at Berkeley Research Group (BRG), and I am writing to seek your consent to file an amicus brief in the cases set forth below. Aaron Vandervelde, a managing director at BRG and nationally recognized expert on the 340B program, has authored the

brief with the goal of providing background information to the court on how contract pharmacy operations work and the downstream operational challenges that arise through these arrangements. Mr. Vandervelde has no client relationship with respect to either litigation matter and the parties listed have consented to the filings in the respective cases.

- Eli Lilly and Company and Lilly USA, LLC, Civil Action No. 1:21-cv-81 in the Southern District of Indiana
- Sanofi-Aventis U.S. LLC, Civil Action No. 3:21-cv-634 in New Jersey District Court

Please let me know if I should reach out to a different attorney to seek this consent. Thank you for your assistance and I look forward to your response.

Best,
Jekka

Jekka Garner | Associate General Counsel

BRG
1800 M Street NW Second Floor | Washington, DC 20036
O 202.480.2700 | M 910.770.0317
JGarner@thinkbrg.com | thinkbrg.com

Exhibit Two

DECLARATION OF KRISTA M. PEDLEY

I, Krista M. Pedley, declare as follows pursuant to 28 U.S.C. § 1746:

1. I currently serve as Director of the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), United States Department of Health and Human Services (HHS). OPA is the component within HRSA with primary responsibility for the day-to-day administration of the 340B Program. I have worked at OPA since 2007 and served as Director since 2010. In my role at OPA, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies.

2. I submit this Declaration to respond to certain factual representations that I understand have been made by drug manufacturers and a consultant for the pharmaceutical industry, Aaron Vandervelde, in litigation involving the issue of contract-pharmacy use. Specifically, Mr. Vandervelde has submitted amicus briefs in various cases that describes the "replenishment model" used in some contract-pharmacy arrangements. *See* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind. May 12, 2021), Dkt. 92-1 at 13-14; *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del. Apr. 16, 2021), Dkt. 46; *Sanofi-Aventis U.S., LLC v. HHS et al.*, 21-cv-634 (D.N.J. May 13, 2021), Dkt. 71-2. The drug manufacturers, in reliance on Mr. Vandervelde's brief, have also made assertions about how contract-pharmacy arrangements work. *See* Tr. of May 27, 2021 Hrg., *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del.), 10:6-14:6; Tr. of May 27, 2021 Hrg., *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind.), 20:9-15, 22:21-25, 67:8-14.

3. The following paragraphs describe my understanding of how, in general, contract-pharmacy arrangements work under the replenishment model. Of course, contract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy. But at its most basic level, under the replenishment model, to the extent that

an individual is determined to have been a 340B patient of the covered entity, the contract pharmacy's drug inventory is "replenished" with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed.

4. As an initial matter, for all contract-pharmacy arrangements (replenishment or otherwise), a covered entity may establish a relationship directly with a pharmacy, or it may elect to employ a third-party vendor or administrator (TPA) to facilitate data-capture and reporting in the administration of a covered entity's contract-pharmacy program. In the former situation, the covered entity sends data feeds about its patients' 340B eligibility directly to the contract pharmacy; in the latter, it sends that data to the TPA.

5. The replenishment model proceeds in three steps. First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from "e-prescribing," whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy's own inventory.

6. Various 340B-tailored software programs exist to evaluate each dispense. That software compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product. The software operates under the oversight of the covered entity, in that each 340B-eligible dispense is recorded and reported to the covered entity. And HRSA audits this process: we obtain a random sample of the drugs dispensed, and the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient. Each year, HRSA audits approximately 200 covered entities, along with any of the covered entities' contract-pharmacy arrangements.

7. Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity's 340B account with the relevant wholesaler. The replenishment order has to be an exact 11-digit match under the National Drug Code (NDC) system for the product that was identified by the software. (The NDC for a product identifies (1) the product's labeler, *i.e.* manufacturer or distributor; (2) the identity of the product, *i.e.* strength, dosage form, and formulation of the drug; and (3) the product's package size and type.)

8. The trigger for a replacement order will not usually be a single dispense. Rather, the TPA and/or contract pharmacy will "accumulate" 340B-eligible dispenses of a specific 11-digit NDC product towards a pre-set package size. So, for example, a package may be 270 tablets of Amoxicillin, which means that it would take 3 dispenses of the 90-tablet bottles to accumulate one package and lead to submission of a replenishment order. Covered entities are provided accumulation reports where they can track each accumulation to a specific patient/dispense.

9. As noted, the replenishment order will be placed on a covered entity's 340B account with the relevant wholesaler. The 340B account is in the covered entity's name and reflects its financial payment information. That 340B account reflects a "bill to" address and "ship to" address. The covered entity is reflected as the "bill to" party; the contract pharmacy (or sometimes, its warehouse) is reflected as the "ship to" address. The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. And so, the covered entity pays for and purchases the drug at the 340B discount price from the wholesaler. If the wholesaler's invoice is not paid, it will seek to collect payment from the covered entity directly—not the contract pharmacy.

10. While it is true that the logistics of placing the replenishment order can vary—for example, sometimes the covered entity places the order, sometimes the contract pharmacy orders it as a purchasing agent of the covered entity, sometimes the order is submitted by the TPA—HRSA

understands that the covered entity is the legal purchaser and authorizes the order. If the replenishment order is sent on behalf of the covered entity, the entity should be aware of the replenishment order; indeed, the order is often approved by the covered entity prior to submission to the wholesaler/distributor to ensure accuracy.

11. Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes "neutral inventory," and may be dispensed to any subsequent patient.

12. When utilizing a replenishment model, covered entities must ensure that appropriate safeguards are in place at the contract pharmacy to ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients. The covered entity must have systems in place to be able to demonstrate that the covered entity is properly accounting for 340B purchases in a replenishment system. HRSA ensures that is the case through the audits mentioned above (¶ 6).

13. OPA maintains the 340B Office of Pharmacy Affairs Information System (OPAIS), a database that assists in the functioning of the 340B Program. When registering on OPAIS, a covered entity must list its contract pharmacy(ies), and that listing must reflect a bill-to/ship-to arrangement. Thus, OPAIS clearly shows that the covered entity, as the bill-to party, is the party that purchases the 340B drugs.

Executed on June 16, 2021, in Frederick, MD.

Krista M. Pedley -S

Digitally signed by Krista M. Pedley -S
Date: 2021.06.16 12:41:17 -04'00'

Krista M. Pedley, PharmD, MS
RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health and Human Services