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Via Online Submission to www.Regulations.gov

The Honorable Carole Johnson
Administrator
Health Resources & Services Administration
Department of Health & Human Services

RE: RIN 0906-AB28: 340B Drug Pricing Program; Administrative Dispute Resolution
HHS Docket No. HRSA–2021–000X

Dear Administrator Johnson:

On behalf of over 300 340B Covered Entities that have come together to form the Hall Render 340B Collaborative ("**Collaborative**"), we appreciate the opportunity to submit comments in response to the proposed revisions to the 340B Administrative Dispute Resolution ("**340B ADR**") rules ("**Proposed Rule**").[1]

The Collaborative's members are safety-net government or non-profit hospitals and grant-funded clinics that provide vital access to care for our nation's uninsured, underinsured, and impoverished communities. Consistent with Congressional intent in creating the 340B drug discount program ("**340B Program**"), statutory discounts on specified covered outpatient drugs ("**SCOD**" or "**340B Drugs**") ensure that Collaborative members and their patients are not "unprotected against manufacturer price increases."[2] Meanwhile, CMS and third-party payor reimbursement in the ordinary course for drugs that may have been acquired using a 340B Program discount ensures that Collaborative members can continue to reach more eligible patients and provide more comprehensive services, again consistent with Congressional intent.[3]

[1] 87 Fed. Reg. 73,516 (Nov. 30, 2022).

[2] H.R. Rep. 102-384(II), at 11.

[3] *See id.* at 12.

The 2020 promulgation of the current 340B ADR rule[4] ("**Current Rule**") was an important step toward stabilizing the 340B Program. As the Proposed Rule references,[5] beginning in 2020, an increasing number of drug manufacturers that voluntarily participate in the 340B Program have openly flouted the Department of Health & Human Services' ("**HHS**" or the "**Agency**") longstanding interpretation of the 340B statute by refusing to ship 340B-priced drugs to Covered Entities' contract pharmacies or by conditioning those shipments on Covered Entities' provision of claim-specific data to manufacturers or their for-profit vendor. When HHS affirmatively directed these manufacturers[6] to resume shipments of Covered Entity 340B-priced drugs to their contract pharmacies, they refused and instead sued HHS, arguing that the agency's actions were procedurally deficient and inconsistent with the plain language of the 340B statute. These suits appear to have resulted in HHS declining to exercise its statutory enforcement tools, which include the imposition of civil monetary penalties or termination of the pharmaceutical pricing agreements that enable Medicare Part B and Medicaid reimbursement for drug manufacturer's SCODs in exchange for making 340B pricing available to 340B Covered Entities.

Covered Entities have limited options for directly responding to manufacturers who refuse to offer required 340B pricing. In 2011, the U.S. Supreme Court determined that Covered Entities do not have standing to sue manufacturers for 340B Program violations.[7] Instead, the Court agreed with HHS' position that Congress intended for the 340B Program to be regulated through "centralized enforcement in the government."[8] Notably, the Supreme Court specifically identified the 340B ADR process as a legitimate means by which HHS can regulate the 340B Program.

In the face of perceived inadequate enforcement, Congress in 2010 amended the 340B statute and "directed HRSA to create a formal dispute resolution procedure," which would "make the new adjudicative framework the proper remedy for covered entities complaining of overcharges and other violations of the discounted pricing requirements and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA[.]"[9] Facing allegations by a Covered Entity that a manufacturer overcharged it for 340B Drugs, the Supreme Court recognized that Congress had already directed HHS to implement a robust, effective administrative pathway for such claims: the 340B ADR process. As described in detail below, HHS is not only authorized, but legally compelled, to interpret the 340B statute when adjudicating 340B ADR claims.

HHS should not interpret subsequent lower court decisions narrowing the Agency's ***rulemaking*** authority as foreclosing it from interpreting the 340B statute through the 340B ADR ***adjudication***

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[4] 85 Fed. Reg. 80,632 (December 14, 2020).

[5] 87 Fed. Reg. at 73,517-18 (incorrectly stating that these restrictions apply only to "certain covered entities").

[6] As of the date of this letter, HHS has sent enforcement letters to AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck, Novartis, Novo Nordisk, Sanofi, UCB, and United Therapeutics. HRSA Website, *Program Integrity* (available at https://www.hrsa.gov/opa/program-integrity**)** (last accessed Jan. 26, 2023).

[7] *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011).

[8] *Id.* at 119.

[9] *Id*. at 121-22.

process. Rulemaking and adjudication are fundamentally different means by which an agency can interpret a statute that it is responsible for administering. Where HHS has faced challenges in regulating the 340B Program, is has been common for manufacturers to allege in litigation that HHS lacks the authority to take the action they are challenging. For instance, in 2014, the D.C. District Court ruled that HHS exceeded its statutory authority when it issued its orphan drug rule.[10] Since the District Court found that HHS lacked broad "prophylactic non-adjudicatory rulemaking" authority regarding the 340B Program,[11] it was unnecessary for the District Court to consider whether it should afford any deference to HHS' interpretation of the statute. That is, since the Court found that HHS did not have the authority to promulgate the rule, that was the end of the matter. However, in reaching this conclusion, the District Court did not find that HHS lacks the authority to interpret the 340B statute through adjudication or other mechanisms.

Decisions that HHS makes through a robust 340B ADR process are far less likely to be overturned on the same grounds. Congress has clearly granted HHS the authority to decide Covered Entities' and manufacturers claims through a 340B ADR process, provided that the process is not inconsistent with both the Administrative Procedure Act ("**APA**") and the enabling section of the 340B statute.

The Proposed Rule, if finalized without material modification, would fall far short of the robust process intended by Congress as acknowledged by the Supreme Court. Although HHS may have faced practical challenges in implementing the Current Rule, we encourage HHS to rescind the Proposed Rule and, if necessary, propose a new rule that more directly addresses any perceived shortcomings in the current 340B ADR process and similarly affirms its position as an administrative adjudication through which HHS can interpret 340B Program requirements. By implementing a robust 340B ADR process, HHS will enable itself to issue decisions that are entitled to deference when reviewed by a Federal court. In the interim, HHS should proceed with adjudicating all pending 340B ADR claims under the current process since it appears to serve as the only current mechanism available for 340B Covered Entities to seek remedies for manufacturer noncompliance with 340B Program requirements.

We address in greater detail below our concerns regarding the Proposed Rule. In short, we believe that HHS should not finalize the Same or Similar Provision at 42 C.F.R. § 10.23(a). We further believe HHS should make revisions, some of them significant, to the balance of the Proposed Rule to ensure that the 340B ADR process is a robust adjudication process whose decisions will be upheld by Federal courts. Finally, we strongly urge HHS to abandon its proposal to transfer all pending 340B ADR claims to the new process when it is finalized.

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[10] *PhRMA v. HHS*, 43 F. Supp. 3d 28 (D.D.C. 2014).

[11] *Id.* at 42-43 (emphasis added).

HHS Should Not Finalize the Same or Similar Provision

HHS should not finalize its proposed revision to 42 C.F.R. § 10.23(a), restated below:

> *The 340B ADR Panel will conduct an initial review of the claims. If the 340B ADR Panel determines the specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending in Federal court, it will suspend review of the claim until such time the issue is no longer pending in Federal court.*

If finalized, this proposal (the "**Same or Similar Provision**") would frustrate HHS' ability to effectively administer the 340B Program, undercutting for indefinite periods of time its ability to adjudicate disputes in the manner directed by Congress and affirmed by the Supreme Court. As a result, it would unlawfully restrict HHS' authority to interpret the 340B statute and hold manufacturers and Covered Entities accountable for program violations, foreclose Covered Entities' and Manufacturers' ability to compel compliance with even well-established statutory obligations, and violate the 340B statute and fundamental principles of administrative law. It should be abandoned or, if not abandoned, fundamentally revised.

Congress Empowered and Compelled HHS to Interpret the 340B Statute through the 340B ADR Process

Although it is not stated in the Proposed Rule, the Same or Similar Provision suggests HHS may believe it lacks the statutory authority to interpret the 340B statute where an issue in controversy may exist.[12] That is, given adverse determinations in Federal court relative to its rulemaking authority, HHS may have concluded it should suspend its review of any claim if a Federal court is considering the same or a similar question. This interpretation should be rejected. Whatever its basis for the proposed Same or Similar regulation, this provision should be removed entirely from the Proposed Rule. Congress directed HHS to implement the 340B ADR process, and the only way to effectuate this intent would be to allow HHS to interpret the 340B statute.

It is true that Congress has not affirmatively granted HHS general rulemaking authority over any aspect of the 340B Program.[13] However, such authority is not necessary for HHS to implement a robust administrative adjudication process through which it interprets the 340B statute. It is well established that an agency's authority to issue prospective rules and its authority to adjudicate claims are not synonymous. That is, Congress can grant an agency adjudicatory authority that extends beyond its rulemaking authority.[14] Such is the case here. In short, Congress did not leave

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[12] *See, e.g.*, Mirga, 340B Report, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority* (Mar. 12, 2020) (available with a subscription at https://340breport.com/your-340b-report-for-thursday-march-eae/) (last accessed Jan. 24, 2023).

[13] *See PhRMA v. HHS*, *supra* n.6.

[14] *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 209 (1988) (overturning a retroactive rule promulgated by HHS because a statutory provision that permitted the Secretary to make "retroactive corrective adjustments" to hospitals' inpatient Medicare payments only authorized the Secretary to make such adjustments through "case-by-case adjudication").

a gap by requiring HHS to implement the 340B ADR process without granting it general rulemaking authority over the 340B Program. Rulemaking authority is not a legal precondition to a robust adjudication process.

When it updated the 340B statute in 2010, Congress directed HHS to not only "establish," but "implement" the 340B ADR process as a means of addressing allegations of overcharging, diversion, and duplicate discounts.[15] In doing so, it inherently granted HHS the authority to interpret the 340B statute as necessary to resolve claims brought through the 340B ADR process. Any other interpretation is illogical and absurd, because it would require Covered Entities to submit their claims to a decision-making body with such limited authority as to render it powerless to help them. Statutes must not be interpreted in a way that "defies rationality by rendering a statute nonsensical and superfluous."[16] Here, Congress directed HHS to create a 340B ADR process "for the **resolution** of claims by covered entities [and] manufacturers"[17] Resolving a statutory claim requires interpreting statutory language, just as reading this sentence requires interpreting the words in it. For the 340B ADR process to be not only effective, but rational, HHS must interpret the 340B statute. Rather than being rejected as acts unauthorized by Congress, interpretations that HHS reaches through the 340B ADR process will be reviewed by judges under the APA's deference jurisprudence.[18] If this were not the intent, it would be unnecessary for Congress to have specified that, by law, the 340B ADR process will result in a "final agency decision" reviewable by a court of competent jurisdiction.

It should be acknowledged that many of HHS' prior efforts to enforce the 340B statute have been stymied, often by aggressive manufacturer litigation. HHS' setbacks in those cases have stemmed from perceived procedural deficiencies in its decision-making processes. For instance, courts rejected the Office of General Counsel's 2020 Advisory Opinion and HHS' manufacturer-specific enforcement letters because, in their view, they were final agency actions that Congress did not authorize HHS to take. HHS is appealing those decisions, but even if they are upheld, it is unlikely that a court will foreclose HHS from interpreting the 340B statute through the Congressionally-mandated 340B ADR process. That is to say, HHS would be expected to suffer far fewer procedural setbacks if it issued its decisions interpreting the 340B statute using the procedure mandated by Congress. The Same or Similar Provision represents a *de facto* abandonment of this statutorily mandated procedure.

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[15] 42 U.S.C. § 256b(d)(3)(A).

[16] *Western Minn. Mun. Power Agency v. FERC*, 806 F.3d 588, 596 (D.C. Cir. 2015) (internal citations and alterations omitted).

[17] *Id.* at § 256b(d)(3)(A) (emphasis added).

[18] *Id*. at § 256b(d)(3)(C) providing that any ADR decision is a final determination under the APA that may be subsequently "invalidated by an order of a court of competent jurisdiction."

The Same or Similar Provision Would Lead to Procedurally Deficient, Reversible Delays in the 340B ADR Process

HHS should not finalize the Same or Similar Provision because it will inevitably lead to unlawful delays in implementing the 340B ADR process. Under standard administrative law principles, it is true that an agency's decision not to act is generally not reviewable by a court.

> There are, however, two limited instances where a party may rebut this presumption against reviewability. The first is if the agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities. The second is when an agency's decision not to undertake an enforcement action is based entirely on its interpretation of the statute.[19]

The Same or Similar Provision commits both of these errors. Congress, through the 340B statute, made HHS responsible for resolving claims by Covered Entities and manufacturers in accordance with "such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously[.]"[20] The Same or Similar Provision would cause HHS to abdicate to unrelated litigants and Federal courts its responsibility to resolve these claims. Under the Same or Similar Provision, rather than resolving cases according to its own deadlines and procedures, 340B ADR Panel would hold all action on a pending claim until unrelated litigants are satisfied with a Federal court's decision or no longer have funds to contest it. This is itself a "general policy that is so extreme as to amount to an abdication of" HHS' statutory responsibility to "resolve" claims as a procedural matter.

Congress also required that HHS "finally resolv[e]"[21] claims through "final agency decision[s]"[22] that are "binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction."[23] Congress thus contemplated that the 340B ADR process would fit into the standard APA framework under which an agency issues a decision and a reviewing court determines whether to uphold or reverse it through evolving, but well-established, deference jurisprudence. Courts defer to an agency's interpretation of a statute, with the level of deference depending on, among other factors, the agency's technical expertise with respect to the program at issue.[24] "However, while the agency enjoys deference in the area of its expertise—including its interpretation of the statutes it is tasked with enforcing—the agency's interpretation of judicial

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[19] *Public Citizen v. Federal Election Commission*, 347 F. Supp. 3d 51, 56 (emphasis supplied;. internal quotation marks and citations omitted).

[20] 42 U.S.C. § 256b(d)(3)(A).

[21] *Id.* at § 256b(d)(3)(B)(i)

[22] *Id.* at § 256b(d)(3)(C).

[23] *Id.*

[24] *See*, *e.g.*, *Amneal Pharmaceuticals LLC v. FDA*, 285 F. Supp. 3d 328, 340 (D.D.C. 2018).

precedent is entitled to no deference."[25] The Same or Similar Provision, if enacted, would cause HHS to abdicate its responsibility to interpret the 340B statute to the Federal courts, ultimately resulting in a decision that would be entitled to no deference from a reviewing court. Again, such a policy is so extreme as to amount to an abdication of HHS' Congressionally-mandated obligation to substantively interpret the 340B statute.

Finally, as explained above, the Same or Similar Provision appears to be rooted in a fundamental misunderstanding of HHS' authority under the 340B statute. As a result, any claimant whose claim is delayed under the Same or Similar Provision would be entitled seek a court order compelling HHS to review the claim because HHS's decision not to undertake the enforcement action—*i.e.*, reviewing the 340B ADR claim—based entirely on its incorrect interpretation of the 340B statute. This is directly contrary to HHS' stated purpose in issuing the Proposed Rule, *i.e.*, creating a process that does not require a claimant to hire a lawyer.[26]

The Same or Similar Provision Violates the 340B Statute and the Administrative Procedure Act.

The 340B statute requires the 340B ADR regulations to include "such deadlines and procedures as be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously[.]"[27] A related mandate is found in the APA, which requires that each federal agency shall "within a reasonable time…proceed to conclude a matter presented to it."[28] As drafted, the Same or Similar Provision violates both the 340B Statute and the APA because it would prohibit a 340B ADR Panel from resolving a claim for an indefinite period of time based solely on its determination that somewhere in the country, someone filed a Federal lawsuit that addresses an issue the same as or similar to one included in the claim. It is neither fair, efficient, expedient, nor permissible to force Covered Entities to wait for an indeterminate period of time for an ADR Panel to hear their claim when, by statute,[29] that claim will result in a decision that can be appealed to a Federal court under the APA. Then, and only then, would it be appropriate for a court to review that final determination. If by then a court's decision compelled a different determination than what was reached by an ADR Panel, then the court reviewing the Panel's decision is certainly capable of making that determination.

Furthermore, the Same or Similar Provision would provide no mechanism for a Covered Entity or manufacturer to contest a 340B ADR Panel's determination that it is compelled to suspend its review due to a pending Federal case. HHS intends for the 340B ADR process to be simple enough for a Covered Entity to handle without legal counsel. It is difficult to imagine a more inefficient

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[25] *Banner Heart Hosp. v. Burwell*, 201 F. Supp. 3d 131, 137 (D.D.C. 2016).

[26] 87 Fed. Reg. at 73,517 ("HHS is proposing a more accessible process where stakeholders have equal access to the ADR process and can easily understand and participate in it without expenditure of significant resources or legal expertise.")

[27] 42 U.S.C. § 256b(d)(3)(B)(iii).

[28] 5 U.S.C. § 555(b).

[29] 42 U.S.C. § 256b(d)(3)(C).

or inequitable process than one where the decision-maker tells the (unrepresented) claimant that their claim will not be reviewed until an indeterminate point in the future.

Questions Pertinent to Any Implementation of the Same or Similar Provision

If HHS does implement the Same or Similar Provision in some form, it should clearly and specifically identify the circumstances in which the Same or Similar Provision will be implicated. Included here as **Attachment 1** is a list of questions and concerns that are pertinent to this issue, and we request that HHS consider and respond to them as appropriate if it issues a final rule that includes any version of the Same or Similar Provision. In addition to the questions and concerns on **Attachment 1**, we have the following overarching concerns about the Same or Similar Provision.

Under the Same or Similar Provision, it is unclear whether a 340B ADR Panel has any discretion to review a claim if it determines that the same or a similar issue is pending in a Federal court. If HHS finalizes the Same or Similar Provision, it should reverse the presumption that a 340B ADR Panel will suspend its review of a claim if the Same or Similar Provision applies and instead permit the Panel to suspend review only if it determines that a suspension is warranted because a final material legal determination is imminent and no immediate or material harm will be done to an ADR claimant as a result of such suspension. The Same or Similar Provision should be revised to permit the parties to the claim to make their positions known to the Panel prior to the Panel rendering its decision. As a practical matter, though, if these standards were met it is highly unlikely that parties to an ADR action would not elect to stay the proceeding pending resolution of any litigation in controversy.

If HHS finalizes the Same or Similar Provision, the regulation should require a 340B ADR Panel to consider whether the outcome of a claim will, as a matter of law, affect the outcome of the pending 340B ADR claim in determining whether the "issue" in the suit is "the same as or similar to" an issue in the pending 340B ADR claims.

Finally, we note that the Proposed Rule does not require the 340B ADR Panel to notify the parties to a claim that it has suspended its review under the Same or Similar Provision. Any version of the Same or Similar Provision should require that the 340B ADR Panel notify the parties of its decision to suspend review, detail in a written decision the basis for its determination, allow the parties to respond to this decision, and clarify that the decision to suspend review is appealable as a final agency action.[30]

In short, we believe that HHS should not finalize the Same or Similar Provision at 42 C.F.R. § 10.23(a) and, if it does finalize the Same or Similar Provision in some form, should consult with its legal counsel to consider and respond to the questions attached as **Attachment 1**.

[30] "[W]hen administrative inaction has precisely the same impact on the rights of the parties as denial of relief, an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief." *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970).

HHS Should Reinstate the Description of Claims Permitted at 42 C.F.R. § 10.21 in the Current Final ADR Rule to Affirmatively Include Constructive Overcharging

The 2020 ADR Current Rule[31] finalized as law a regulation that provides the ADR Panel has jurisdiction to hear "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price.[32] While the Proposed Rule does not take an alternative interpretation, its apparent silence on this issue could have unintended consequences, frustrating the ability of 340B Covered Entities to access the dispute resolution process consistent with Congressional intent.

The 340B Program statute provides that HHS shall "establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs[.]" The current regulatory language serves to affirmatively preclude manufacturers from attempting to circumvent the law by arguing that unless a Covered Entity affirmatively is charged above the 340B ceiling price for drugs purchased "under this section" then no ADR Panel claim could proceed. For example, a drug manufacturer could direct a wholesale drug distributor to simply refuse to set up a 340B Program pricing account to, in one view, prevent any "overcharge[s] for drugs purchased under" the 340B statute. However, it is clear that an overcharge would occur in both the Covered Entity facility and contract pharmacy setting since both would be forced to purchase drugs dispensed to 340B eligible patients at a higher wholesale acquisition cost ("**WAC**") or group purchasing organization ("**GPO**") price.

Since refusing to allow access to 340B pricing by act or omission results in increased costs to a 340B Covered Entity, reinserting this language would serve to preclude unnecessary ADR Panel adjudicatory efforts and limit the incentive for additional manufacturer efforts to refuse to allow access to 340B Program pricing in the first place.

Finally, we request that HHS further modify this language to add a clause clarifying that limitations on a Covered Entity's ability to purchase drugs include any setting where HHS has established that 340B Drugs may be delivered to eligible patients. This would serve to incorporate any future decisions made by a court (e.g., contract pharmacy) or HHS.

HHS Should Modify or Abandon Other Provisions of the Proposed Rule

Below is a detailed description of other provisions in the Proposed Rule that should be abandoned, modified, or clarified in a final rule. Unless otherwise stated, all references are to the version of the regulations that are included in the Proposed Rule.

- 42 C.F.R. § 10.3: Definitions

[31] 85 Fed. Reg. 80,632 (December 14, 2020).

[32] 42 C.F.R. § 10.21(c)(1).

- The definitions of "claim" and "consolidated claim" appear to be identical in the Current Rule and the Proposed Rule. We request a clarification as to whether HHS intended to make any change to the Current Rule.

- 42 C.F.R. § 10.20: 340B Administrative Dispute Resolution Panel

  - This section was revised to, among other things, remove language stating that the 340B ADR Panel is empowered to make "precedential" decisions. We recognize that the 340B statute does not specify that decisions reached through the 340B ADR process will be precedential, but basic administrative law principles provide for agency adjudication to have some policymaking, and therefore precedential, effect.[33] This is consistent with the fact that the Proposed Rule makes clear that ADR panel determinations will be considered a "final agency decision."[34]

  - In addition, the APA requires that "Each agency, in accordance with published rules…make available for public inspection in an electronic format…all final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases."[35] We request that HHS publicly post all orders made in the adjudication of claims before the 340B ADR Panel on the HRSA website. This would allow Covered Entities and manufacturers to understand HHS's lawful interpretation of the 340B statute and, if appropriate, adjust their conduct accordingly.

- 42 C.F.R. § 10.20(b)(2): Conflicts of Interest

  - HHS should reconsider the requirement that all members of the 340B ADR Panel undergo an "additional screening" to identify involvement in previous agency actions or provide more detail about the type of involvement that would preclude an eligible Office of Pharmacy Affairs ("**OPA**") employee from participating on a specific 340B ADR Panel. As a practical matter, since HHS subcontracts its audit fact finding process to a third party, front line audit staff will not be eligible to participate on the ADR Panel in the first place, which would seem to be the biggest concern implicated by this proposed requirement. Similarly, since HHS is proposing that CMS staff be removed from the ADR Panel roster, which we support, the most obvious conflicts of interest would be materially ameliorated.

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[33] *See*, *e.g.*, *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 765-66 (1969) ("Adjudicated cases may and do, of course, serve as vehicles for the formulation of agency policies, which are applied and announced therein. They generally provide a guide to action that the agency may be expected to take in future cases. Subject to the qualified role of stare decisis in the administrative process, they may serve as precedents. But this is far from saying, as the Solicitor General suggests, that commands, decisions, or policies announced in adjudication are 'rules' in the sense that they must, without more, be obeyed by the public.") (plurality) (*accord N.L.R.B. v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 293-94 (1974).

[34] Proposed Rule at § 10.24(e).

[35] 5 U.S.C. § 552(a)(2)(A).

It is unclear from the Proposed Rule what nexus is required between an OPA employee's prior work and an instant claim before the employee would be screened from participating in the claim. If an OPA employee would be screened from a claim brought by Covered Entity "A" against manufacturer "B" because the employee previously served on a Panel involving either A or B, we think this provision is unnecessary, likely disruptive, and subject to abuse by a participant claimant or respondent. We note that OPA had only 19 full-time employees as of 2022.[36] Although we support HHS' proposal that only OPA staff be eligible to be rostered as ADR Panel members because it encourages the development of 340B-specific expertise and core competencies, HHS could quickly run out of eligible staff if too broad a conflict of interest rule is finalized.

We are unaware of any other HHS-related precedent for this standard. If, for example, CMS were to implement a similar standard for its PRRB hearings it would quickly become practically impossible to administer the Medicare program. In fact, familiarity with particular 340B-related issues should be a goal that sought by the ADR Panel. This provision could have the opposite effect and oddly penalize development of subject matter expertise.

- 42 C.F.R. § 10.21: Claims
    - (a): Claims Permitted
        - HHS should remove the language stating that "all claims must be specific to the parties identified in the claims". A claimant already bears the burden of demonstrating that they have been harmed by the action described in their claim. This new language is presumably meant to further limit the types of claims that may be brought, but the Proposed Rule does not provide either the parties or the OPA employees initially reviewing the submission with any standard by which they may determine that their claim is "specific to the parties identified in the claims". Furthermore, the 340B statute does not authorize HHS to limit the types of permissible claims within the 340B ADR process. To the extent that HHS intends this language to prohibit a Covered Entity from bringing a claim against a broadly applicable manufacturer policy, we strongly object and refer to the above discussion regarding HHS's power and obligation to interpret the 340B statute though the 340B ADR process. The 340B Program statute is clear what subject matter may be disputed through the ADR process and this provision would impermissibly serve to restrict that authority.
    - (b): Requirements for Filing a Claim

[36] *See* HRSA Fiscal Year 2023 Congressional Budget Justification, at 371 (available at https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf) (last accessed Jan. 24, 2023).

- HHS should remove the language in paragraph 2 that requires a Covered Entity to provide "all available supporting documentation" with its claim. This is not a statutory requirement, and a Covered Entity bringing a claim already bears the burden of persuasion regarding its claim. Surplus regulatory language such as this could form the basis of a manufacturer's APA challenge if it is later determined that the Covered Entity did not include with its claim some document that could bear on the Panel's ultimate decision. Alternatively, language requiring that a Covered Entity must reasonably offer proof of a claim would afford the ADR panel the ability to compel the production of evidence without a standard that creates the potential for abuse by a participating manufacturer or its affiliated affinity organizations.

- HHS should clarify within paragraph 2 what constitutes a "manufacturer" and permit a Covered Entity to bring claims against multiple drug companies if it is evident that the companies are under common control. HHS should further clarify that a "manufacturer" is not determined by the labeler code as recorded on the 340B Office of Pharmacy Affairs Information System ("**OPAIS**"). Consolidation and corporate restructuring within the pharmaceutical industry and manufacturers' internal business decisions have led to single entities controlling a number of different labelers. As of January 16, 2023, there were 884 unique, active labeler codes on OPAIS, but only 442 unique contact names for those manufacturers. If a Covered Entity has suffered harm because a single entity with multiple labeler codes has overcharged it, it should not be required to file multiple 340B ADR claims.

- HHS should eliminate Section 4 which would require a covered entity or manufacturer filing a claim to "provide documentation of good faith efforts, including evidence of communication with the opposing party to resolve the matter in good faith prior to filing a claim." This is apparently intended to create an additional jurisdictional requirement for claims that may be brought through the 340B ADR process. Although current guidance encourages parties to engage in good-faith discussions, this guidance does not have the force of law, and HHS does not have the authority to limit the scope of claims that it is required to adjudicate under the 340B statute. In addition, this requirement would violate principles of fairness as demonstrated in the Federal Rules of Evidence because it could require the parties to disclose information exchanged in settlement discussions.[37] If a court could not admit these communications into evidence, HHS should not obligate parties to disclose them.

[37] Fed. R. Ev. 408.

- (c): Combining Claims
  - HHS should clarify that, in the case of a combined joint claim, the failure by any Covered Entity or organization representing Covered Entities to submit the required documentation does not invalidate the whole claim. Instead, the Covered Entity that does not have appropriate documentation should be removed from the group, and the claim should otherwise proceed.
- (d): Deadlines and Procedures for Filing a Claim
  - HHS should revise this section to clarify that OPA's initial review of a claim is limited to determining whether, on its face, a claim includes all the information required to file a claim. The OPA employees performing the initial review should not be authorized to consider the factual or legal sufficiency of the claim. Paragraph 3 should be revised to clarify that OPA may request additional information to satisfy the filing requirements because, as currently drafted, paragraph 3 implies that OPA will review the claim to determine if the claimant's allegations are "substantiate[d]". The determination as to whether a claim is substantiated should be reserved exclusively for the assigned 340B ADR Panel.
  - HHS should revise paragraph 7 to eliminate the bar on refiling a claim unless the claimant produces "new information to support the alleged statutory violation". As currently drafted, paragraph 7 amounts to an automatic grant of default judgment, with prejudice, against a filing party. This is inequitable and does not advance the purposes of the 340B Program. Paragraph 7 is harsher than the analogous rule under the Federal Rules of Civil Procedure, which permits (but does not compel) a court to grant a defendant's motion to dismiss for a plaintiff's failure to prosecute a claim.[38] If enacted in its current form, paragraph 7 would, by default, deprive Covered Entities of their exclusive means of seeking redress from a manufacturer, potentially even before the manufacturer even knows that the claim was filed against it.
  - HHS should clarify that a decision not to advance a claim under this section is a final agency decision under 42 U.S.C. § 256b(d)(3)(C).
- (e): Responding to a Submitted Claim
  - HHS should revise paragraph 4 to remove "or elects not to participate in the 340B ADR process". Participating in the 340B ADR process is compulsory for Covered Entities and manufacturers, and HHS's regulations should not imply otherwise.

[38] Fed R. Civ. P. 41(b).

- HHS should permit a claimant to reply to the respondent's submission. This is standard practice in judicial proceedings and is an equitable means of ensuring that a decision-maker has the ability to consider relevant information and arguments. It would be reasonable for HHS to limit the scope of the respondent's information to the issues identified by the claimant, and to likewise limit the scope of the claimant's reply to the information and arguments raised by the respondent.

- 42 C.F.R. § 10.22: Covered Entity Information and Document Requests

  - HHS should revise this section to contemplate that a Covered Entity may submit an information/document request at the same time that it submits its claim. This would allow a Covered Entity to proactively address potential gaps in its claim and allow for the efficient administration of the 340B ADR process by ensuring that the Covered Entity's information/document request is transmitted to the manufacturer, either together with the claim or shortly thereafter if the request needs to be reviewed by the assigned 340B ADR Panel. 42 C.F.R. §§ 10.21(d)(4) and 10.21(d)(5) imply that a 340B ADR Panel will not be assigned until a respondent's information is received, and HHS should revise them to provide that a 340B ADR Panel will be provisionally assigned if the Covered Entity submits an information/document request with its claim.

  - HHS should consider the potential interaction between 42 C.F.R. §§ 10.21(d)(4), 10.21(d)(5), and the Covered Entity's window for submitting an information/ document request under paragraph (a) of this section. Paragraph (a) requires the Covered Entity to submit its information/document request within 20 days of "receipt from OPA that the claim <u>was forwarded</u> to the 340B ADR Panel for review." (emphasis added) Paragraph 10.21(d)(5) only requires that OPA notify the parties that "the claim <u>will be forwarded</u> to the 340B ADR Panel for review" (emphasis added). The difference between these sections is the future tense "will be forwarded" versus the past tense "was forwarded". HHS should resolve this discrepancy in the final rule. In doing so, HHS should consider our prior recommendation which would allow a Covered Entity to submit an information/document request at the same time as it submits its claim. This would be the preferrable approach if HHS anticipates that a material amount of time will elapse between OPA determining that the claim is complete and assigning a 340B ADR Panel to hear the assigned claim. Otherwise, if the 340B ADR Panel will be assigned months or years later, Covered Entity personnel will have to spend time and energy reacquainting themselves with the claim in order to submit an effective information/document request. In the alternative, HHS should affirmatively state that OPA is required to notify the parties when it forwards a claim to the 340B ADR Panel and to provide appropriate contact information for the Panel or its administrative representative (in court, a clerk).

  - HHS should revise paragraph (b)(5) to require the 340B ADR Panel to draw an adverse inference against a manufacturer that fails to respond to an

information/document request. Under paragraph (a), the 340B ADR Panel will already have determined that the Covered Entity's information/document request is reasonable, relevant, and within scope of the claim. The manufacturer's total failure to respond to a reasonable, relevant, and in-scope request should cause the Panel to assume that the information that the manufacturer could, but did not, produce would be beneficial to the Covered Entity.

- HHS should consider revising paragraph (b)(5) to permit the 340B ADR Panel to draw an adverse inference against a manufacturer that fails to fully respond, or fails to explain its lack of a full response, to an information/document request. While manufacturers should not be obligated to produce records that do not exist, the 340B ADR Panel should be empowered to draw adverse inferences if a manufacturer cannot supply a good reason why it cannot fully respond to a reasonable, relevant, and in-scope information/document request.

- If the manufacturer provides materials pursuant to an information/document request, the claimant should be afforded an opportunity to review the materials and submit a filing stating its position as to whether and how the materials support or undermine its claim.

- 42 C.F.R. § 10.23: 340B ADR Panel Decision Process

  - As noted above, we strongly object to paragraph (a). HHS should not finalize this portion of the Proposed Rule.

  - HHS should revise paragraph (c) to require that the 340B ADR Panel issue an order that has enforceable consequences for a manufacturer that is found to have overcharged the Covered Entity and for a Covered Entity that is found to have engaged in duplicate discounts or diversion. The 340B statute specifically requires that the 340B ADR regulations "includ[e] appropriate procedures for the provision of remedies and enforcement of determinations pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B)."[39] Paragraph (1)(B) requires HHS to "establish[] procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including…[o]versight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, [including] in exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." The 340B ADR Panel is equipped to determine when such an overcharge has occurred. Paragraph (2)(B) specifically incorporates language from elsewhere in the 340B statute that requires Covered Entities to repay manufacturers "in an amount equal to the reduction in the price of the drug".[40] To avoid uncertainty and potential claims under the APA, HHS should update this paragraph to specifically

[39] 42 U.S.C. § 256b(d)(3)(A)

[40] *Id.* § 256b(a)(5)(A).

authorize each 340B ADR Panel to order manufacturers and Covered Entities to pay the amounts specified under 42 U.S.C. §§ 256b(d)(1)(B), 256b(d)(2)(B), and (by reference) 256b(a)(5)(A).

- HHS should revise this paragraph to require that a manufacturer or Covered Entity that is ordered to repay the other party must pay within sixty (60) days of the date of the 340B ADR Panel's decision letter or, if HRSA Administrator reconsiders the decision, within sixty (60) days of the date of the reconsideration decision.

- 42 U.S.C. § 256b(d)(2)(B)(v)(I) and (II) permit HHS to impose enhanced sanctions against a Covered Entity if it determines that the Covered Entity engaged in knowing and intentional or systematic and egregious behavior. HHS should revise paragraph (c) to require the 340B ADR Panel to: (i) inform the Covered Entity that it is considering issuing a decision that would find that that the Covered Entity's conduct was knowing and intentional or systemic and egregious; and (ii) provide the Covered Entity an opportunity to respond prior to the issuance of such a decision.

- 42 U.S.C. § 256b(d)(1)(B)(vi) authorizes HHS to impose civil monetary penalties on a manufacturer that knowingly and intentionally overcharges a Covered Entity. The Secretary has delegated the authority to impose sanctions under 42 U.S.C. § 256b(d)(1)(B) to the Office of Inspector General ("**OIG**").[41] HHS should specify in this paragraph that the 340B ADR Panel is authorized to recommend that the OPA Director refer a manufacturer to OIG for investigation. Unless the Secretary revises the delegation of authority referred to above, HHS should revise this paragraph to clearly state that the 340B ADR Panel is not authorized to determine whether a manufacturer's conduct was knowing and intentional and that any statement to the contrary in a Panel decision is not binding and of no force or effect. This would counteract manufacturers' likely arguments on appeal that such a Panel lacked the authority to make such a determination in its decision.

- HHS should revise this paragraph to require the 340B ADR Panel or OPA to inform the parties of their reconsideration rights under 42 C.F.R. § 10.24 when the 340B ADR Panel's decision is communicated to the parties.

- 42 C.F.R. § 10.24: 340B ADR Panel Decision Reconsideration Process

  - HHS should revise paragraph (b) to extend the period to request a reconsideration from 20 business days to 60 days. HHS should also clarify that the reconsideration request must be submitted within 60 days of the date <u>that the party receives</u> the 340B ADR Panel's decision letter. This time frame is consistent with analogous CMS reconsideration processes (e.g., FI/MAC, QIC).

[41] 82 Fed. Reg. 1356 (Jan 5, 2017).

- HHS should revise paragraph (b)(2) to clarify that new fact information may not be submitted as part of the reconsideration process. New legal or policy arguments may be warranted in light of the 340B ADR Panel's decision and should not be prohibited.

- HHS should eliminate paragraph (b)(3). Since a party has only 20 business days to submit its reconsideration request and since the Covered Entities/manufacturers represented in a joint or combined claim already consented to joint/combined representation, it is unclear why that consent should not be effective for a reconsideration request. If the intent of the Proposed Rule is to create a simpler, less trial-like proceeding, then imposing additional filing requirements such as this undermine that goal.

- As drafted, paragraph (c) does not distinguish between: (a) a dissatisfied party's right to initiate the reconsideration process; (b) the burden of proof upon reconsideration; and (c) the standard of review which the HRSA Administrator would apply when analyzing the 340B ADR Panel's decision. HHS should revise paragraph (c) to state that a dissatisfied party has a right to request a reconsideration and that once a reconsideration request has been submitted, the 340B ADR Panel's decision is inoperative until the HRSA Administrator issues a decision on reconsideration. It is common in HHS and other agency adjudication processes to provide a dissatisfied party with a reconsideration or first-level appeal right.[42] In addition, clarifying the reconsideration process and suspending the effectiveness of the 340B ADR Panel's decision until any reconsideration process is complete, HHS would clarify when a dissatisfied party has a right to judicial review under the APA.[43]

- HHS should move language related to the burden of proof (requiring the requesting party to "demonstrate") and standard of review ("that the 340B ADR Panel decision [was] inaccurate or flawed") from paragraph (c) to paragraph (d) or (e), as appropriate.

- HHS should revise paragraph (e) to require the HRSA Administrator to affirmatively act on each reconsideration request by either: (a) affirming the 340B ADR Panel's decision; or (b) issuing a revised decision that supersedes the 340B ADR Panel's decision. This is important because to avail itself of its right to judicial review under the APA, a party generally must demonstrate that it has exhausted its administrative remedies. If the party does not have a right to reconsideration, or if it is possible that the HRSA Administrator would simply

[42] *See*, *e.g.*, 42 C.F.R. § 405.1811 (providing a Medicare provider with a right to a contractor hearing if it is dissatisfied with the contractor's determination for the provider's cost reporting period); *see also* 42 C.F.R. § 1003.1500 (providing a right to a hearing for any party upon whom OIG proposes to impose a civil monetary penalty).

[43] *See* 5 U.S.C. § 704; *see also Darby v. Cisneros*, 509 U.S. 137, 147 (1993) (holding that § 704 "explicitly requires exhaustion of all intra-agency appeals *mandated* either by statute or agency rule; it would be inconsistent with the plain language of [§ 704] for courts to require litigants to exhaust optional appeals as well." (emphasis added)).

"declin[e] to issue a revised decision," it may be difficult for the party to prove that it has exhausted its remedies. HHS should make appropriate revisions to paragraph (f) to account for any revisions to paragraph (e).

- HHS should revise paragraph (e) to eliminate the portion stating that the revised decision would be effective 20 business days from issuance. In the alternative, HHS should explain why it is necessary or advisable to delay the effectiveness of the revised decision when no similar timeline applies to the 340B ADR Panel's decision. Delaying the effective date of a revised decision could delay an aggrieved party's ability to seek judicial review, or at least increase costs while the party consulted its attorneys to determine whether it has a right to bring a suit under the APA before the 20-day effective date.

HHS Should Not Finalize Its Proposal to Transfer Existing 340B ADR Claims to the New Process

In the Preamble to the Proposed Rule, HHS indicates that it intends to automatically transfer "any claims that are in process and have been submitted pursuant to the 2020 final rule" to the new process.[44] HHS should not finalize this proposal and instead proceed promptly to handling the claims that are currently in the queue. Although the Current Rule may be cumbersome, it is the law, and Covered Entities and their representatives have relied on it to pursue manufacturers for overcharges. As explained above, both the 340B statute and the APA require that HHS implement the 340B ADR process efficiently. Moreover, it is unclear whether HHS would be permitted under administrative law principles to transfer pending cases to the new process. "[I]n general, agencies must apply the law in effect at the time a decision is made, even when that law has changed during the course of a proceeding."[45]

Given the lack of publicly available information about pending 340B ADR claims and HHS's characterization of the Current Rule as complex and difficult to implement,[46] it would be reasonable to assume that HHS does not intend to process any pending claims until the Proposed Rule is finalized. Covered Entities simply cannot wait for HHS to consider all stakeholders' comments, develop responses or revisions, obtain required Executive reviews, publish the Final Rule, then wait at least another 60 days for the rule to go into effect before HHS will even consider their claims.

Additional Comments on Issues Identified by HHS

In the Proposed Rule, HHS is soliciting comments "on whether there may be appropriate claims limitations to ensure that ADR is limited to the specific statutory areas" identified in the 340B Program statute. As proposed, 42 C.F.R. § 10.21(a) appropriately references the subject matter

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[44] 87 Fed. Reg. at 73,517.

[45] *Aacon Auto Transport, Inc. v. ICC*, 792 F.2d 1156 (D.C. Cir. 1986), *accord Algeria I, Inc. v. FCC*, 905 F.2d 471 (D.C. Cir. 1990) (holding that this rule applies where an agency changes its regulations while a matter is pending).

[46] *See* 87 Fed. Reg. at 73,517.

jurisdiction limitations detailed by Congress. We have repeatedly seen manufacturers engage in creative mechanisms to circumvent 340B Program requirements and affirmative guidance and requests issued by HHS, HRSA, and OPA. Since any ADR Panel decision would be a final agency determination appealable to a federal court, parties that believe jurisdictional authority was exceeded would retain a remedy to ensure statutory authority is appropriately applied. To do otherwise could inadvertently limit the ADR Panel's jurisdictional authority which could jeopardize the enforceability of any ADR Panel final rule.

We would be happy to discuss any of these concerns at your convenience.

Very Truly Yours,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C.

Todd A. Nova
James Junger

ATTACHMENT 1

- Will the Same or Similar Provision apply to a Covered Entity's claim that a manufacturer has overcharged it by refusing to ship 340B Drugs to its contract pharmacies because manufacturers have sued HHS in multiple Federal courts over its interpretation of the statute?

    - Will the Same or Similar Provision continue to apply if those cases are ultimately remanded to HHS for further consideration?[47]

    - Will the Same or Similar Provision continue to apply if, upon remand, a District Court retains jurisdiction over the case to ensure that its orders are appropriately enforced?

    - Will the Same or Similar Provision continue to apply if certain district court cases are stayed pending resolution of one or more cases if the Supreme Court grants certiorari with a decision requiring remand to a lower court for further proceedings on administrative grounds?

- What standards will the 340B ADR Panel apply when identifying the "specific issue that would be brought forth in a claim"?

    - Will the 340B ADR Panel consider only the claimant's or respondent's description of the issue in making this determination?

    - May members of the 340B ADR Panel apply their knowledge and expertise to recharacterize the issue?

- What objective standards will the 340B ADR Panel apply when determining if an issue is "the same or similar to" the issue brought forth in a claim in order to allow for a valid, reviewable final agency determination to be issued?

    - Assume that a Covered Entity "A" has filed a 340B ADR claim alleging that manufacturer "Z" overcharged it for 340B Drugs. If the HHS Office of Inspector General imposed a civil monetary penalty on a different manufacturer "Y" for overcharging Covered Entities in violation of 42 C.F.R. § 10.11(a) and Y challenged the determination under the Administrative Procedure Act, will the 340B ADR Panel be required to suspend its review of A's claim? Under what circumstances would the 340B ADR Panel not be required to suspend its review?

    - The Supreme Court decided in *Astra USA, Inc. v. Santa Clara County* that Covered Entities do not have the right to sue manufacturers under the 340B statute. Will the 340B ADR Panel be required to suspend its review of a claim involving Covered

[47] *See AstraZeneca Pharmaceuticals LP v. Becerra*, Order of Feb. 16, 2022 (D. Del. Case No. 21-cv-27-LPS Docket No. 113).

Entity "A" and manufacturer "Z" if, notwithstanding the *Astra* decision, a different Covered Entity "B" sued a different manufacturer "Y" for overcharging it in the same way as A alleges Z overcharged it, even if it is likely that B's claim will not survive a motion to dismiss?

- What objective standards will the 340B ADR Panel apply when determining whether an issue is "pending in Federal court" and "no longer pending in Federal court"?

    - Assume that Manufacturer Z has brought a claim against Covered Entity A after an audit revealed that Covered Entity failed to record an NPI on the Medicaid Exclusion File. Would the assigned 340B ADR Panel be required to suspend its review of Z's claim if it identified a case in any of the following procedural postures? If the 340B ADR Panel would be required to suspend its review of Z's claim in some cases but not in others, what is the reasoning behind that distinction? We note that the hypothetical case below is illustrating the way in which a claim could reasonably be expected to be handled under the Administrative Procedure Act and is not meant to describe any particular case, party, or agency. We are unaware of any pending case that has facts similar to those described below.

        - HHS issues a decision that Covered Entity B knowingly and intentionally violated the prohibition on duplicate discounts by carving-in for Medicaid fee-for-service claims at contract pharmacies owned by the same health system. B has a right to challenge the decision as a final agency action under the APA but has not filed a case under the APA.

        - Covered Entity B (now the Plaintiff) has filed a Complaint against HHS (Government) under the Administrative Procedure Act, and it has served the Government with the Complaint. No other action has been taken on the case.

        - Government has filed a Motion to Dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that the Complaint fails to state a claim for which relief may be granted.

        - Court has granted Government's 12(b)(6) motion but dismissed the Complaint without prejudice so the Plaintiff may cure defects in the Complaint and re-file.

        - Plaintiff has re-filed its Complaint, curing the defects that led the Court to grant the Government's Motion to Dismiss.

        - Government has filed a second Motion to Dismiss.

        - The Court has denied the Government's Motion to Dismiss.

- The parties have entered into a confidential settlement agreement after the Plaintiff survived the Government's second Motion to Dismiss.

- The parties have entered into a publicly available settlement agreement after the Plaintiff survived the Government's second Motion to Dismiss. The case has terminated, but the Court never ruled on the substance of the Plaintiff's argument.

- There is no settlement agreement. Instead, the parties have filed Motions for Summary Judgment.

- The Court has granted the Plaintiff's Motion for Summary Judgment, finding that the Government's interpretation of the 340B statute is not compelled by the language of the statute and resolving the ambiguity in favor of the Plaintiff. The Court vacates the Government's decision with respect to the Plaintiff, and the Government does not appeal. However, the Government does not acquiesce to the Court's decision outside of the Federal Circuit where the District Court is located. As a result, it continues to apply the statutory interpretation that has been overruled by one Federal court.

- The Court has granted the Plaintiff's Motion for Summary Judgment and determines that the process the Government used to reach its initial decision was arbitrary and capricious, but its interpretation of the law is not foreclosed by the language of the statute. The Court remands the issue back to the Government for further proceedings during which the Government could reach the same conclusion using a more robust process.

- The Court has granted the Plaintiff's Motion for Summary Judgment and determines that the Government's interpretation of the law is foreclosed by the language of the statute.

- The Government has filed a Notice of Appeal in the District Court.

- The parties have fully briefed the issue before the Court of Appeals but have not held oral arguments.

- The parties have held oral arguments and await a decision from the Court of Appeals.

- The Court of Appeals has issued a decision in the Government's favor and has remanded to the District Court for further proceedings consistent with its opinion.

- The Plaintiff has petitioned the U.S. Supreme Court for a writ of certiorari.

- The U.S. Supreme Court has granted the writ of certiorari and has scheduled the case for argument in its next session.

- The U.S. Supreme Court has issued a decision in the Government's favor and has remanded the case to the Court of Appeals for further proceedings consistent with its opinion.

- The Court of Appeals has remanded the case to the District Court for further proceedings.

- The District Court has received the remanded case from the Court of Appeals but has not issued a final order.

- The District Court issues a final order requiring the Plaintiff to pay the amount identified in the Government's initial order, plus interest.