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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

[Docket No. 2021-0004]

RIN 0906-AB28

340B Drug Pricing Program; Administrative Dispute Resolution Regulation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Health Resources and Services Administration administers section 340B of the Public Health Service (PHS) Act, which is referred to as the "340B Drug Pricing Program" or the "340B Program." This final rule will apply to all drug manufacturers and covered entities that participate in the 340B Program. The final rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process. This final rule revises the 340B administrative dispute resolution process set forth in the Code of Federal Regulations.

DATES: This final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, HRSA, 5600 Fishers Lane, Mail Stop 08W12, Rockville, MD 20857; email: 340badr@hrsa.gov; telephone: 301-594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 340B of the PHS Act entitled "Limitation on Prices of Drugs Purchased by Covered Entities," was created under section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," and codified at 42 U.S.C. 256b. The 340B Program is intended to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible

patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). The Secretary of Health and Human Services (Secretary) has delegated the authority to administer the 340B Program to the HRSA Administrator, who has further delegated authority to the Office of Pharmacy Affairs (OPA), within HRSA, which oversees the 340B Program. Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing agreements (PPAs) with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act "[i]n order for payment to be available under section 1903(a) or under part B of title XVIII of the Social Security Act for covered outpatient drugs of a manufacturer." When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 340B ceiling prices are based on quarterly pricing reports that manufacturers must provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS) and are calculated and verified by HRSA.

Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), jointly referred to as the "Affordable Care Act," added section 340B(d)(3) to the PHS Act, which requires the Secretary to promulgate regulations establishing and implementing a binding 340B ADR process for certain disputes arising under the 340B Program. Under the 340B statute, the purpose of the 340B ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHS Act, that a covered entity has violated the prohibition on diversion or duplicate discounts.

The 340B ADR process is an *administrative* process designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion, as outlined in statute. This 340B ADR process is also designed to provide stakeholders the opportunity to have disputes evaluated in a timely, consistent, and fair and equitable manner.

Historically, HHS has encouraged manufacturers and covered entities to work with one another to attempt to resolve disputes in good faith. HHS recognizes that most disputes that occur between individual parties are resolved in a timely manner without HRSA's involvement. The 340B ADR process is not intended to replace these good faith efforts and should be considered only when good faith efforts to resolve disputes independently have been exhausted and failed.

In 2020, HHS issued a final rule ((85 FR 80632, Dec. 14, 2020) herein referred to as the 2020 final rule), which was codified at 42 CFR 10.20 through 10.24. HRSA began implementing the 2020 final rule when it became effective on January 13, 2021, by accepting claims through the 340B ADR process. HRSA encountered policy and operational challenges with implementation of the 2020 final rule and issued a notice of proposed rulemaking (NPRM) on November 30, 2022 (87 FR 73516), to propose a revision to the 340B ADR process.

HHS is issuing this final rule to revise the current ADR process by modifying the regulations issued under the 2020 final rule. As HHS has indicated in the 2022 NPRM, the 2020 final rule poses policy and operational challenges that are described in this section.

First, HHS is finalizing that the 340B ADR process be revised to be more accessible, administratively feasible and timely than the 2020 final rule. The 340B statute at section 340B(d)(3)(B)(ii) of the PHS Act, requires the establishment of deadlines and procedures that ensure that claims are resolved fairly, efficiently, and expeditiously. This ADR process should be an expeditious and less formal process for parties to resolve disputes than the 2020 final rule. An ADR process governed by the Federal Rules of Evidence (FRE) and Civil Procedure (FRCP), as envisioned in the 2020 final rule, does not advance these goals. For example, potential

petitioners, many of whom are safety net providers in under-resourced communities, may lack the resources to undertake ADR even if it would be in their best interest to do so. In addition, reliance on the FRE and FRCP could create unnecessary delays in what is intended to be a timely decision-making process. Finally, it is challenging to assign ADR Panel members with expertise in the FRE or FRCP. In implementing the 2020 final rule, HRSA received questions from stakeholders about the formality of the ADR process and the legal requirements under the FRCP for submitting a petition and accompanying documents, *e.g.,* whether the filings submitted must conform to the FRCP, which added to the complexity and difficulty of the ADR process.

HHS is finalizing an ADR process that is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion, as set forth in the 340B statute. HHS believes that for the ADR process to be workable, it needs to be accessible. HHS recognizes that many covered entities are small, community-based organizations with limited means. These covered entities may not have the financial resources to hire an attorney to navigate the complex FRCP and FRE requirements and engage in a lengthy, trial-like process, as envisioned in the 2020 final rule. The 340B statute does not compel such a process. The 2020 final rule also institutes a minimum threshold of $25,000 or where the equitable relief sought will likely have a value of more than $25,000 to be met before the petition could be filed. Given the smaller, community-based nature of many covered entities, HHS believes that flexibility should be maintained with respect to the amount of damages and is therefore not finalizing a minimum threshold for accessing the ADR process. However, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for minor or *de minimis* claims given the time and resource investment required of the parties involved. After deliberate consideration of these issues and review of the comments, HHS is finalizing rule provisions that create a more accessible process where stakeholders have equal access to the ADR process and can easily understand and participate in it without having legal expertise or expending significant resources.

Second, the 2020 final rule states that the Secretary of HHS shall establish a 340B ADR Board that consists of at least six members appointed by the Secretary with equal numbers from HRSA, CMS, and the HHS Office of the General Counsel (OGC). It also requires the HRSA Administrator to select three members from the ADR Board to form a 340B ADR Panel and that each 340B ADR Panel include one ex-officio, non-voting member (appointed by the Secretary) from OPA to assist the 340B ADR Panel. The 2020 final rule states that HRSA and CMS ADR Board members must have relevant expertise and experience in drug pricing or drug distribution and that the OGC ADR Board members must have expertise and experience in handling complex litigation. While the 340B Program is related to drug pricing and drug distribution, it is a distinct program that requires knowledge of the 340B statute and specific 340B Program operations. Few OGC, CMS, and HRSA employees (outside of OPA) have both the required expertise as well as the availability (in addition to their day-to-day responsibilities) to serve on such 340B ADR Panels.

Therefore, HHS is finalizing rule provisions requiring that 340B ADR Panel members should be subject matter experts from OPA to ensure Panel members have specific knowledge of the authorizing statute and the operational processes of the 340B Program (*e.g.,* registration and program integrity efforts) and the ability to dedicate a portion of their time to ADR Panel service. Moreover, decisions by subject matter experts from OPA are less likely to conflict with current 340B policy. All members on the 340B ADR Panel will undergo an additional screening prior to reviewing a specific claim to ensure that the 340B ADR Panel member was not involved in previous agency actions related to the claim (including previous 340B ADR Panel decisions).

Third, HHS is finalizing final rule provisions stating that prior to initiating the ADR process, parties must undertake good-faith efforts to resolve the disputed issues. Historically, HRSA has encouraged parties to work in good faith and covered entities, and manufacturers have not had significant numbers of disputes due to the success of these good-faith-resolution efforts. 340B Program administrative improvements have narrowed the areas where parties had,

in the past, disagreed over 340B Program issues. For example, HRSA released the pricing component of the 340B Office of Pharmacy Affairs Information System (340B OPAIS) in February 2019, which, for the first time, provided 340B ceiling prices to authorized covered entity users. OPAIS implementation has provided the necessary transparency to decrease disputes specific to the 340B ceiling price and its calculation. Outside of an issue involving some manufacturers placing restrictions on certain covered entities use of contract pharmacies, OPA has only received three covered entity overcharge complaints since making 340B ceiling prices available to covered entities through 340B OPAIS. Of additional note, prior to the 2020 final rule, stakeholders were able to utilize an informal dispute resolution process to resolve disputes between covered entities and manufacturers (61 FR 65406, Dec. 12, 1996) ("1996 guidelines"). There have been only four informal dispute resolution requests since the publication of the 1996 guidelines. Of the four informal dispute resolution requests received, two were terminated by HRSA due to non-participation by one of the parties, another was dismissed due to lack of sufficient evidence, and the last was terminated because the parties disputed each other's attempts of good faith resolution. The relatively small number may also be attributed to the parties' successful attempts to resolve issues in good faith. With this very small number of past informal disputes, the increased transparency in 340B pricing data, and HRSA's encouragement that parties work to resolve issues in good faith, HHS is finalizing final rule provisions that include an ADR process more closely aligned with the process that was established in the 1996 guidelines, and less trial-like and resource-intensive—for both the participants and HHS—than that established in the 2020 final rule.

Also, in the time since Congress enacted the 340B ADR statutory provision, HRSA implemented its extensive audit program in 2012, which ensures that participating covered entities and manufacturers can demonstrate compliance with all 340B Program requirements. On average, HRSA conducts 200 covered entity audits each fiscal year including child/associate sites and contract pharmacies associated with the covered entities, and issues findings in three

areas: eligibility, diversion, and duplicate discounts. These findings vary in terms of severity—from covered entities not having the correct information in the 340B OPAIS to the diversion of 340B drugs to individuals who are not patients of the covered entity. HRSA conducts approximately five manufacturer audits each year and makes findings related to manufacturers charging above the 340B statutorily required ceiling price and manufacturers not reporting the required 340B pricing data to HRSA. Since HRSA began auditing covered entities and manufacturers, HRSA has identified 340B compliance concerns that would have previously been disputed. In addition to the extensive audit program, HRSA has also developed a comprehensive program integrity strategy to ensure compliance among all stakeholders participating in the 340B Program. These activities include quarterly checks of 340B Program eligibility, a self-disclosure and allegation process, which involves communication between OPA and the stakeholders regarding the compliance issue, and spot checks of covered eligibility documentation including contracts with State and local governments and contract pharmacy agreements.

Further, manufacturers are required to audit a covered entity prior to filing an ADR claim pursuant to section 340B(d)(3)(B)(iv) of the PHS Act. Since November 2022, HRSA has received two final audit reports from the manufacturers. The infrequency of finalized manufacturer audit reports along with the requirement that manufacturers audit covered entities prior to filing an ADR claim suggests that the number of manufacturer ADR claims will be low.

HRSA's impartial facilitation of good faith resolution efforts have allowed parties to take advantage of opportunities for open communication to better understand each other's positions and come to an agreement, without need for formal intervention by HRSA (*e.g.,* through a HRSA targeted audit).

Fourth, the ADR process should be reserved for those disputes set forth in the statutory ADR provision (overcharge, diversion, or duplicate discount). For example, a manufacturer that audited a covered entity may report its findings of alleged duplicate discounts identified by specific purchasing patterns over a period of time. The covered entity may disagree with the

audit assessment of purchases. In this example, the matter would be best resolved through the ADR process as it involves an alleged duplicate discount violation.

This final rule aligns with the statutory provisions by outlining the specific types of claims that can be brought forth through the ADR process—claims for overcharge, diversion or duplicate discounts.

Fifth, HHS believes that there should be an opportunity for dissatisfied parties to seek reconsideration of the 340B ADR Panel's decision by HRSA. The 2020 final rule did not include such a process. This final rule establishes an appeals or reconsideration process option that would be made available to either party.

Therefore, based on these issues with the 2020 final rule, HHS is finalizing in this rule to (1) establish a more accessible ADR process that is reflective of an administrative process rather than a trial-like proceeding; (2) revise the structure of the 340B ADR Panel so that it is comprised of 340B Program subject-matter experts; (3) ensure that the parties have worked in good faith before proceeding through the ADR process; (4) more closely align the ADR process with the provisions set forth in the 340B statute (diversion, duplicate discounts, and overcharges); and (5) include a reconsideration process for parties dissatisfied with a 340B ADR Panel's decision.

HRSA received 112 non-duplicative comments and, after consideration of the comments received, HHS has developed this final rule.

II. Summary of Proposed Provisions and Analysis and Responses to Public Comments

Part 10 of title 42 of the Code of Federal Regulations has been revised to incorporate changes to the 340B ADR process, which is described below in conjunction with the comments received to each such section.

General Comments

Comments received during the comment period addressed general issues that were raised in the preamble of the NPRM. We have summarized these general comments and have provided a response below.

Comment: The 2020 final rule instituted a minimum threshold of $25,000 or where the equitable relief sought would likely have a value of more than $25,000 as an ADR petition prerequisite. In the NPRM, HHS did not propose a minimum threshold for accessing the 340B ADR process. Many covered entity comments favored eliminating the threshold and argued that the 340B ADR process would be more accessible and would help ensure all providers could seek relief through the 340B ADR process. Most manufacturer comments were against eliminating the minimum threshold and argued that *de minimis* claims and frivolous claims would be filed through the 340B ADR process.

Response: Many 340B covered entities are small, rural or health care providers in underserved areas. The 340B ADR process should be accessible and available to these and all other stakeholders regardless of their volume of purchases or sales, and that flexibility should be maintained with respect to the amount of damages demonstrated when filing a 340B ADR claim; therefore, HHS is finalizing this provision as proposed without a minimum threshold for accessing the 340B ADR process. As noted above, HHS recognizes that most disputes that occur between individual parties are resolved in a timely manner without HRSA's involvement. The 340B ADR process should be considered only when good faith efforts to resolve disputes have been exhausted and failed.

Comment: The 2020 final rule established the 340B ADR process as reliant on the Federal Rules of Civil Procedure (FRCP) and the Federal Rules of Evidence (FRE). These rules govern civil proceedings and the introduction of evidence at civil and criminal trials in Federal courts. In the NPRM, HHS proposed removing reliance on these rules as the statute does not compel reliance on the FRCP and FRE and many covered entities lack the expertise in these legal rules as well as the resources to hire outside counsel to navigate them. Conflicting

comments were received related to removal of reliance on the FRCP and FRE for the 340B ADR process. Some covered entity stakeholders appreciated the proposal to make the process more accessible and administrative rather than trial-like. Most manufacturer commenters raised concerns that HHS had not proposed an alternative procedural framework or evidentiary standards in the absence of the Federal Rules asserting that without standards, the ground rules would be subject to dispute in each case.

Response: HHS believes the new 340B ADR process will be a more accessible process, especially for covered entities with fewer resources, and will not require legal expertise during the claim resolution process. This approach will be more accessible to stakeholders and will use fewer stakeholder and government resources to resolve disputes. As such, this final rule sets up an accessible and comprehensible process without needing to invoke the more elaborate procedures available under the FRCP and FRE.

Comment: Some covered entity commenters approved of the proposal to automatically transfer claims under the 2020 final rule to the new process.

Other commenters disagreed that claims should be automatically transferred to the new process. These commenters specifically argued that HHS should proceed to handle the claims that are currently in the queue under the 2020 final rule as opposed to automatically transferring them to the new process. Further, one covered entity commenter generally stated that it was unclear whether HHS would be permitted under administrative law principles to transfer claims to the new process. The commenter suggested that such a transfer would conflict with the general principle that 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.

Most manufacturer commenters disagreed, arguing that all pending ADR claims should be dismissed upon issuance of a final rule, and claimants should be required to refile claims if they wished to initiate new ADR proceedings.

Response: After consideration of the comments received, HHS is finalizing this provision as proposed to provide for the automatic transfer of any pending claims to the new process. The decision to automatically transfer any claims that were submitted pursuant to the 2020 final rule and that are pending will minimize burden on all parties involved. For petitioners, it will mean that they do not have to resubmit claims under the new process. It will ensure the continuity of the 340B ADR process for the stakeholders involved in claims under the 2020 final rule, despite the new process as envisioned in this final rule.

In particular, we disagree that automatically transferring claims to the new process will run afoul of any administrative law principles. The general presumption that agencies apply the law in effect at the time a decision was made is of no moment here, because nothing in this final rule changes the substantive law governing disputes covered by the 340B ADR process. Transferring pending claims to the new process "takes away no substantive right but simply changes the tribunal that is to hear the case"; in such a situation, "[p]resent law normally governs." *Landgraf v. USI Film Prod.,* 511 U.S. 244, 274 (1994) (cleaned up). As the Supreme Court has explained, a law "govern[ing] the transfer of an action instituted prior to that statute's enactment" may "be applied in suits arising before their enactment without raising concerns about retroactivity." *Id.* at 275. "Because rules of procedure regulate secondary rather than primary conduct, the fact that a new procedural rule [is] instituted after the conduct giving rise to the suit does not make application of the rule at trial retroactive." *Id.*

This rule modifies procedural requirements for the 340B ADR process. It does not impair any rights possessed by parties when they acted, increase or affect their liability for past conduct, or impose new duties on the parties for already completed transactions. The changes in this final rule do not affect the substance of claims at issue for the ADR panel and accordingly could not be considered to have retroactive application that affects potential consequences understood by the parties when they began the 340B ADR process.

Claims that are automatically transferred will be first in the queue to be reviewed once this final rule becomes effective. Within a specified time period, HHS will allow petitioners of claims submitted under the 2020 final rule to submit additional information or revise their petition, as necessary, in support of their original claim. Petitioners will also be able to withdraw their pending claims. HRSA will work with affected parties to the extent that additional information is needed as part of the process outlined in this final rule. Details concerning this automatic transfer of claims will be provided to affected parties once this final rule becomes effective.

Comment: Many manufacturer commenters requested that HHS revise the 1996 manufacturer audit guidelines before it issues regulations on ADR. They stated that the guidelines are problematic because they impose onerous and unnecessary barriers on a manufacturer's ability to audit a covered entity for 340B compliance.

Response: Revisions to the 1996 manufacturer audit guidelines are outside the scope of this final rule. The requirement for a manufacturer to conduct an audit prior to initiating the 340B ADR process is a statutory requirement (section 340B(d)(3)(B)(iv) of the PHS Act). This rule is not meant to address how a manufacturer should conduct the audit – only that a manufacturer does conduct the audit prior to initiating the ADR process. Multiple manufacturers have utilized the 1996 manufacturer audit guidelines to conduct audits of covered entities. In the last 5 years, six have followed the guidelines to request audits of covered entities. During that same time frame, HRSA has not denied a request for a manufacturer audit of a covered entity, thereby, demonstrating the guidelines are not overly burdensome or present any barriers to a manufacturer's ability to perform an audit of a covered entity. Further, the guidelines present a clear and transparent process that may decrease burden on both parties with open dialogue and present an objective review of a covered entity's compliance.

Comment: Several manufacturer commenters raised that HHS has failed to establish procedures for manufacturers to issue refunds to covered entities for overcharges. They

explained that this is a prerequisite to the 340B ADR process in order for it to be fair, efficient, and expeditious. Relatedly, they stated that there is a need for HHS to address refund procedures that permit offsets of covered entity overpayments and underpayments to a manufacturer.

Response: Specific procedures for refunds are outside the scope of this final rule, as the authority for this final rule directly relates to the development of an administrative process for the resolution of claims as described in section 340B(d)(3) of the PHS Act.

Subpart A – General Provisions

Section 10.3 Definitions.

In the NPRM, HHS sought to add or revise the following definitions: "Administrative Dispute Resolution Panel (340B ADR Panel)," "340B Administrative Dispute Resolution Process," "claim," "consolidated claim," "joint claim," and "Office of Pharmacy Affairs." HHS did not receive substantive comments on this section, and we are finalizing this section as proposed. HHS received numerous comments on defining the types of claims that could be adjudicated through the 340B ADR process, and HHS addresses those comments in § 10.21.

Subpart C – Administrative Dispute Resolution

Section 10.20 340B Administrative Dispute Resolution Panel.

a) Members of the 340B ADR Panel.

The 2020 final rule states that the Secretary shall establish a 340B ADR Board consisting of at least six members appointed by the Secretary with equal numbers from HRSA, CMS, and the HHS OG C. It also requires the HRSA Administrator to select three members from the ADR Board to form a 340B ADR Panel and that each 340B ADR Panel include one ex-officio, non-voting member (appointed by the Secretary) from OPA to assist the 340B ADR Panel. HHS proposed to revise the composition of the 340B ADR Panel that would review and make decisions for claims filed by covered entities and manufacturers. In the NPRM, HHS proposed that the Secretary appoint a roster of no fewer than 10 eligible individuals (Roster) consisting of OPA staff to serve on the 340B ADR Panels. Under the proposed rule, the OPA Director, or

designee, selects at least three members for each 340B ADR Panel from the Roster of appointed staff; has the authority to remove an individual from the 340B ADR Panel and replace such individual; selects replacement members should a 340B Panel member be removed or resign; and screens for any potential conflicts of interests. After consideration of the comments received, HHS is finalizing this provision as proposed. HHS has addressed specific comments with respect to this section below.

Comment: Several covered entity commenters favored the proposal to have OPA staff serve as the 340B ADR Panel members, because the staff understand the intricacies of the 340B Program. They explained that the 340B Program is complex and it is important that individuals understand the complexities of the 340B Program to adjudicate these disputes in order to ensure a fair outcome. Some concerns were raised that the workload may be too much for a small OPA staff, and that an insufficient number of available panelists could lead to delayed decisions. Some covered entity commenters who favored OPA staff serving on 340B ADR Panels also recommended that other staff within HRSA could serve on 340B ADR Panels, such as staff working on programs with grantees that participate in the 340B Program.

Response: HHS agrees with the commenters that OPA staff should serve on 340B ADR Panels given their specialized knowledge and expertise of the 340B Program. Therefore, HHS is finalizing this provision as proposed. HHS also appreciates the commenters' concerns regarding the workload of OPA staff and the suggestion to include other HRSA staff that work with grantees participating in the 340B Program. However, as stated in the preamble of the proposed rule, OPA staff are subject matter experts and have years of experience with complex 340B matters involving covered entities and manufacturers. Given this expertise, HHS continues to believe that OPA staff are best suited to serve on 340B ADR Panels to ensure that the process is efficient and that claim reviews are handled in a timely fashion. This final rule limits 340B ADR Panel participation to OPA staff who have daily exposure to the complex issues facing both covered entities and manufacturers, to ensure there will be equitable, consistent, and fair 340B

ADR adjudications. In addition, the OPA Director is aware of the workload of each OPA staff member and will be able to appropriately assign 340B ADR Panel members taking into consideration existing workload demands and priorities.

Comment: Some manufacturer commenters opposed OPA staff serving on 340B ADR Panels. These commenters argued that all OPA staff are involved in audits of covered entities and manufacturers, and with at least 10 staff planned to be on the ADR Roster under the proposed rule, there may be too many conflicts of interests and, in turn, the possibility and perception of bias may arise. Moreover, manufacturers opposing this policy were concerned that, given OPA's regular and extensive involvement in the day-to-day administration of the 340B Program, it may be difficult for OPA staff to approach adjudications without the appearance that they may be predisposed to particular views on relevant issues. Some commenters suggested Administrative Law Judges be the adjudicators of the 340B ADR process because they have the professional background, legal training and independence needed to resolve claims in a fair, consistent, and well-reasoned manner.

Response: HHS continues to believe that a Panel of OPA staff members who are steeped in 340B knowledge and experience and who can provide a consistent application of 340B policies will ensure a more efficient ADR adjudication process. As such, HHS is finalizing this provision as proposed. OPA staff members work to provide oversight of the 340B Program without bias – working with both manufacturers and covered entities in a manner that is impartial to the stakeholders involved. In addition, staff members work toward the goal of ensuring the integrity of the 340B Program and they do so without prejudice toward particular stakeholders. Those serving as 340B ADR Panel members will be fair and make consistent decisions in a well-reasoned manner using the 340B statute, applicable regulations, policies, and guidance documents. OPA staff have demonstrated their ability to follow the principles of fairness, consistency, transparency of applicable statute, regulations, policies, and guidance in their performance of covered entity and manufacturer audits. The breadth of experience, which

we believe far outweighs any risks of perceived bias, among the OPA staff members serving on a 340B ADR Panel will ensure fairness, consistency, and transparency in ADR decisions. In addition, the OPA Director, in consultation with government ethics officials, will consider financial interest(s), current or former business or employment relationship(s), or other involvement of a prospective panel member or close family member who is either employed by or otherwise has a business relationship with an involved party, subsidiary of an involved party, or particular claim(s) expected to be presented to the prospective panel member.[1]

In addition, specialized legal knowledge or training is not necessary for 340B ADR Panel members to effectively function in their role as the 340B ADR process is an administrative process that is best served by having 340B subject matter experience rather than legal experience. HHS disagrees with the recommendation that Administrative Law Judges should be appointed as adjudicators of the 340B ADR process.

The 340B ADR process is different, as it is designed as a process to resolve disputes between covered entities and manufacturers and in this final rule, HHS is establishing 340B ADR Panels comprised of OPA staff, who are uniquely suited to handle the complexities of the 340B Program, given their day-to-day administration of the Program. Processes are well established to provide staff opportunity for continuous learning and training on program implementation and oversight. OPA staff also have distinct knowledge of the 340B statute, laws, and policies as they apply that subject matter expertise throughout the work that is conducted on a daily basis to oversee the program and therefore will be able to handle such disputes effectively and efficiently.

Comment: Some manufacturer commenters argued that the new proposed rule has the same Appointments Clause and structural constitutional defects as the 2020 final rule. They stated that there is no mechanism for review of a 340B ADR Panel decision by a principal officer, appointed by the President with Senate confirmation, before that decision becomes "final

[1] "Confidential Financial Disclosure Guide: OGE 450." U.S. Office of Government Ethics. October 2023.

agency decision."

Response: HHS disagrees. Under this final rule, the Secretary will appoint a roster of eligible individuals (Roster) consisting of staff within OPA to serve on a 340B ADR Panel. When a 340B ADR claim is presented, the OPA Director will select three members from the Roster to serve on a 340B ADR Panel to review claims and make final agency decisions that will be binding on the parties involved, unless invalidated by an order of a Federal court. As discussed further in § 10.20(c), the Secretary, who is appointed by the President and Senate-confirmed, has the authority to intervene in the 340B ADR process at any time, including the ability to remove any individual from the Roster of 340B ADR Panelists for any reason. The Secretary had inherent authority to take these same actions under the 2020 final rule, and the codified regulatory text now explicitly addresses this authority. Specifically, as outlined further below, any 340B Panel decision or reconsideration decision regarding a 340B ADR Panel's decision will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision.

b) Conflicts of interest.

In the NPRM, HHS proposed that the OPA Director would ensure that each 340B ADR Panel member is screened prior to reviewing a claim and that there are no conflicts of interest between the parties involved in the dispute and the 340B ADR Panel member. The conflict-of-interest review includes financial interest(s), current or former business or employment relationship(s), or other involvement of a prospective panel member or close family member who is either employed by or otherwise has a business relationship with an involved party, subsidiary of an involved party, or particular claim(s) expected to be presented to the prospective panel member. Under the proposed rule, members of the 340B ADR Panel will also undergo additional screening prior to reviewing a specific claim to ensure that the 340B ADR Panel member was not involved in the previous agency action, including previous 340B ADR Panel decisions,

concerning the specific issue in the claim. HHS received several comments on this provision, which are summarized below. After a review and analysis of the comments, HHS is clarifying the additional conflict of interest screening as discussed in more detail below.

Comment: Both manufacturer and covered entity commenters agreed that HHS should evaluate conflicts of interest with regard to a 340B ADR Panel member; however, they recommended that the parties should have the ability to make objections to a proposed panelist. Some commenters mentioned the small size of the OPA staff may make having too broad of screening for conflict of interest, such as having worked on an audit, difficult to fill a panel with subject matter experts. Commenters also requested the policies and procedures for screening panel members be publicly outlined.

Response: HHS will inform the parties involved in the ADR of Panel members for that specific claim. The OPA Director has full knowledge of a Panel member's workload and will select Panel members for each claim, which will also be based on the OPA Director's awareness of any potential conflicts of an OPA staff member, including financial interest conflicts, current or former business relationships or other involvement. We believe that the process sufficiently addresses the need to screen for conflicts and allowing the parties to object to proposed panelists or the specific policies or procedures for screening panel members would unduly lengthen the 340B ADR process. To the extent a conflict arises regarding an assigned panelist, the OPA Director is authorized to make changes to the panel composition. The commenters also raised concern about whether the additional conflict of interest screenings would make it difficult to fill 340B ADR Panel positions, given the small staff within OPA. In order to make this process fair, efficient and transparent, HHS is retaining the policy that a conflict of interest screening will be conducted on all 340B ADR Panel members to ensure there is no conflict of interest with respect to financial conflicts or current/former business relationships or other involvement of a prospective panel member or close family member who is either employed by or otherwise has a business relationship with an involved party, subsidiary of an involved party in an 340B ADR

claim. However, based on the comments received, HHS is clarifying that the additional screening in § 10.20(b)(2) will be conducted to ensure that a 340B ADR Panel member was not directly involved in a decision concerning the specific issue of the ADR claim as it relates to the specific covered entity or manufacturer involved, including previous 340B ADR Panel decisions. This clarification responds to the concerns of the commenters and balances the fact that 340B ADR Panel members will be selected from a relatively small staff. Indirect or tangential involvement in matters affecting a specific covered entity or manufacturer will not be considered a conflict of interest.

To the extent that any significant conflict issue is raised outside of those specifically addressed in § 10.20(b), the OPA Director or the Secretary still have the discretion to remove a 340B ADR Panel member (as addressed in §10.20(a) and (c) of this final rule, respectively).

c) Secretarial removal power.

The NPRM proposed to codify in regulatory text the Secretary's authority to remove any individual from the Roster of 340B ADR Panelists for any reason, including from any 340B ADR Panel to which the individual has already been assigned. After a review of the comments received, HHS is modifying this provision by clarifying the Secretary's role in the 340B ADR process.

To respond to commenter requests for transparency, HHS commits to publishing these policies and procedures for screening panel members on a HRSA public-facing website within 120 calendar days of the publication of this final rule and, likewise, in the event that these policies and procedures are modified, HHS commits to publishing these policies and procedures for screening panel members on a HRSA public-facing website within 120 calendar days of such modification.

Comment: Many manufacturers argued that while the preamble to the proposed rule suggests that the Secretary would have the inherent authority to review and reverse or alter the 340B ADR Panel's decision, it was not explicitly included in the proposed regulatory text.

Further, they stated that the Secretary does not exercise sufficient control over ADR panelist decisions.

Response: There are no restrictions on the Secretary's oversight or supervision over the 340B ADR process. The Secretary has the authority to intervene in the 340B ADR process at any time, has the authority to remove Panel members from the Roster, and has the authority to review, reverse, or alter any decision made by the 340B ADR Panel or any reconsideration decision made by the HRSA Administrator as outlined in § 10.24. In consideration of the comments received, HHS is modifying this provision to make explicit that the Secretary has the authority to review, alter, reverse, or uphold any 340B ADR Panel or reconsideration decision. Specifically, as outlined further below, any 340B Panel decision or reconsideration decision regarding a 340B ADR Panel's decision will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision. If the Secretary reviews and reverses, alters, or upholds any 340B ADR Panel or reconsideration decision, the Secretary's decision will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court.

d) Duties of the 340B ADR Panel.

The proposed rule outlined the duties of the 340B ADR Panel, which included:

1) reviewing and evaluating claims, including consolidated and joint claims, and documents and information submitted by covered entities and manufacturers;

2) reviewing and possibly requesting additional documentation, information, or clarification of an issue from any or all parties to make a decision;

3) evaluating claims based on information received, unless, at the 340B ADR Panel's discretion, the nature of the claim necessitates that a meeting with the parties be held;

4) consulting with other Federal agencies while reviewing the claim, at the 340B ADR Panel's discretion; and

5) making decisions on each claim.

There were no substantial comments received on this provision; therefore, HHS is finalizing the provision as proposed.

Section 10.21 Claims.

a) Claims permitted.

In accordance with section 340B(d)(3) of the PHS Act, 340B ADR claims may include: 1) claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug; and 2) claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHS Act, that the covered entity has violated section 340B(a)(5)(A) of the PHS Act, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHS Act, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity. The NPRM proposed that all claims must be specific to the parties identified in the claims. Based on the comments received, HHS is finalizing this provision as proposed. HHS has also decided to provide an illustrative but not exhaustive list of examples of the types of overcharges, diversion, and duplicate discount claims that may be eligible for the 340B ADR process.

Comment: Several covered entity commenters argued that manufacturers should not be allowed to bring claims related to a covered entity's eligibility and suggested that manufacturers cannot pursue claims alleging Medicaid managed care duplicate discount violations. These commenters believe that these types of claims are outside those permitted under the ADR statute.

Response: Generally, HHS agrees with the exclusion of claims regarding covered entity eligibility but disagrees with the commenters on claims related to duplicate discounts in Medicaid managed care. This final rule aligns claims to those expressly set forth in section 340B(d)(3) of the PHS Act: 1) claims by covered entities that they have been overcharged by manufacturers for drugs purchased under this section and 2) claims by manufacturers, after a manufacturer has conducted an audit of a covered entity, as authorized by section 340B(a)(5)(C)

of the PHS Act, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHS Act). As duplicate discounts can occur with drugs subject to rebates under both Medicaid fee-for-service and Medicaid managed care, HHS declines to exclude Medicaid managed care claims from the 340B ADR process. In addition, although the eligibility of a covered entity is generally outside of the scope of the 340B ADR process; if resolution of a diversion claim depends in whole or in part on whether a claimant is an eligible covered entity, then that claim may proceed through the 340B ADR process, given that the 340B statute permits claims for overcharges, diversion, and duplicate discounts. In this final rule, the role of the 340B ADR Panel is to independently review and apply the 340B statute and applicable regulations, policies, and guidance documents to the case-specific factual circumstances at issue in an overcharge, diversion, or duplicate discount dispute.

Comment: Some covered entity commenters urged HHS to reinstate language from the 2020 final rule to make clear that covered entities may bring an overcharge claim in situations in which a manufacturer has limited the covered entity's ability to purchase a covered outpatient drug at or below the 340B ceiling price.

Response: HHS agrees and has modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price.

Comment: Some covered entity commenters recommended that the final rule include a definition for the term "overcharge," to mean an attempt to collect a price in excess of the 340B price for a covered outpatient drug, any attempt to cause a drug wholesaler to decline to offer 340B pricing on a covered outpatient drug to a covered entity, and any refusal by a manufacturer to sell a covered outpatient drug at 340B pricing.

Response: When an overcharge claim is presented before a 340B ADR Panel, the Panel will follow the 340B statute, relevant case law, all applicable regulations, and consider 340B policies and guidance documents when evaluating 340B ADR claims. One example of an overcharge

claim in the 340B ADR process would be a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price. We do not believe that an explicit definition of the term "overcharge" is needed in light of the process discussed above for addressing an overcharge claim.

Comment: Many manufacturer commenters objected to the lack of an explicit definition in the proposal for the terms "patient" or "diversion." They explained that covered entities are prohibited from selling or otherwise transferring drugs purchased under the 340B Program to a person who is not a patient of the entity in accordance with section 340B(a)(5)(B) of the PHS Act. These commenters believe that HRSA should revise and clarify its current guidance (61 FR 55156 (Oct. 24, 1996)), to strengthen administration of the 340B Program, including the 340B ADR process and the parties' ability to work together to resolve disputes in good faith as proposed in § 10.21(b).

Response: Revision of the 1996 patient definition guidance is outside the scope of this rule. When a diversion claim is presented before a 340B ADR Panel, the Panel will follow the 340B statute and all applicable regulations, and consider 340B policies and guidance documents when evaluating 340B ADR claims. Examples of a diversion claim that may be submitted (after a manufacturer has conducted an audit of a covered entity), include but are not limited to: 1) transferring of covered outpatient drugs to a patient where there was no record of the individual's health care or no provider relationship or 2) transferring covered outpatient drugs to an individual who is an inpatient. Similarly, examples of a duplicate discount claim include but are not limited to: 1) if it is found after an audit of a covered entity that the covered entity billed Medicaid without the site being listed on the Medicaid Exclusion File and the manufacturer paid a State rebate or 2) if it is found after an audit of a covered entity that the manufacturer paid a State rebate and the covered entity had incomplete or inaccurate information on the Medicaid Exclusion File.

b) Requirements for filing a claim.

As proposed in the NPRM, a covered entity or manufacturer must file a 340B ADR claim in writing to OPA within 3 years of the date of the alleged violation. HHS also proposed that any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision. Before filing a claim, each stakeholder must provide appropriate documentation, including documentation of communication with the opposing party to resolve the matter in good faith. In the case of a covered entity, the covered entity must provide documentation to support that it has been overcharged by a manufacturer, in addition to any other documentation requested by OPA. Covered entities are not permitted to file a claim against multiple manufacturers. A manufacturer must provide documents that show it audited the covered entity and that are sufficient to support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts, in addition to any other documentation as may be requested by OPA. HHS received several comments on these provisions and considered them carefully. For the reasons detailed below, HHS is finalizing these provisions as proposed.

Comment: Some covered entities commenters requested clarification that the 3-year records limitation period begins on the date of sale or payment at issue except when the manufacturer issues a restatement of the average manufacturer price (AMP), best price, customary prompt pay discounts, nominal prices, or other data that affects the 340B ceiling prices. Some of these commenters recommended that HHS include an undue hardship exemption to the 3-year limitation on claims to benefit small rural covered entities. They explain that small rural providers may submit ADR claims without outside counsel. Further, they state that alongside other challenges that a covered entity could be facing, pulling together the needed documentation to file a claim could be burdensome for covered entities.

Some manufacturer commenters expressed that because of the manufacturer audit requirement, which may take significant time to complete, the final rule should “toll” the 3-year

period for manufacturer ADR claims from the point when a manufacturer first seeks to conduct an audit until the audit concludes with the completion of the audit report.

Response: While HHS believes that the 3-year limit is sufficient, there may be times when the initial reviewer will account for extenuating circumstances. For example, the timeline for manufacturer audits of covered entities depends on a variety factors, which may affect when they are finalized. Another example is when data affecting the 340B ceiling price are revised, such as where AMP or best price are corrected or restated, an alleged violation would have not occurred until the data were revised. These examples are not exhaustive but illustrate situations that may warrant flexibilities. In addition, under the current ADR process, the 3-year time period has proved to be sufficient for the parties. Noting these flexibilities, HHS is finalizing the provision as proposed.

Comment: Most commenters were generally supportive of the proposal that documentation of "good faith" efforts is required before a party can initiate a claim through the 340B ADR process. However, some manufacturer commenters believe that HHS should specify the types of documents required to evidence "good faith", including, but not limited to, documentation demonstrating that the covered entity has contacted the manufacturer about the potential issue and has given the manufacturer sufficient notice of a potential claim before initiating 340B ADR process.

Some covered entity commenters recommend that HHS remove the "good faith" requirement before filing a claim. Specifically, they argue that the act of overcharging a covered entity could not be an act of good faith and engaging with the manufacturer would be futile and cause unnecessary delay. These commenters argue that a "good faith effort" prerequisite to filing a claim requires the agency to make difficult determinations regarding whether an attempt at resolution was made in "good faith."

Response: After consideration of the comments received, HHS is finalizing this provision as proposed. Given the resources required to pursue an ADR claim, HHS encourages

covered entities and manufacturers to work in good faith to resolve disputes. Good faith attempts include for example, at least one instance of written documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim. The requirement to engage in good faith efforts may resolve disputes before the need to file a petition in many cases. In addition, HHS has historically encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith, and most disputes have been resolved in a timely manner without needing HRSA's involvement. Also, the 340B ADR process is not intended to replace these good faith efforts and should be considered only when good faith efforts to resolve disputes have been exhausted and failed.

Good faith efforts and documentation can include communication between parties to obtain clarifications or to provide explanations that may not be readily apparent and may provide perspective to either party that may help mitigate concerns. For example, HRSA currently has a process in place when a covered entity is unable to obtain a 340B price from a manufacturer. In this case, HRSA can facilitate good faith efforts between the parties, and oftentimes help them resolve disputes, which typically are as a result of an error or misunderstanding.

Comment: Some manufacturer commenters encouraged HHS to protect the proprietary and confidential components of all parties' information throughout the 340B ADR process. They explained that for the 340B ADR process to work efficiently, parties need assurances that the proprietary and confidential information that they disclose will not be made publicly available.

Response: HHS will work to protect the proprietary and confidential information of the parties to the maximum extent that it is able to pursuant to current law.

c) Combining claims.

The NPRM proposed that two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug. The NPRM also provided that an association or organization may file on behalf of one or more covered entities representing their

interests pertaining to overcharging by a single manufacturer for the same drug(s). The proposed rule provided specific parameters for covered entities filing joint claims and for associations/organizations filing claims on behalf of one or more covered entities, including that each covered entity meets the requirements for filing the ADR claim and that there is documentation of each covered entity's consent.

The NPRM also proposes that a manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the consolidated claim, meets the requirements for filing a claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources. The statutory authority for implementing the 340B ADR process does not address consolidated claims on behalf of manufacturers by associations or organizations representing their interests. After a careful review and consideration of the comments received, HHS is finalizing this provision as proposed.

Comment: Many covered entities commenters indicated that the NPRM improperly limits claims brought by associations and organizations representing covered entities to only those covered entities that consent to the claim being asserted on their behalf. These commenters argued that the criteria for inclusion in an organizational claim in the 340B statute is merely membership in the organization. Representation by associations, regardless of whether the entity consents, allows covered entities to access the process more easily. They argued that requiring consent from each member of an organization introduces unnecessary resource and time burden – and could significantly delay the filing of claims that are sometimes time sensitive.

Response: An ADR claim could substantively affect a covered entity's ability to recover for 340B overcharges, as well as a covered entity's relationship with a manufacturer. However, after consideration of the comments, HHS, will permit associations or organizations filing a claim on behalf of its members to submit an attestation, rather than submitting signatures from

each individual covered entity, that they have confirmed that all of the individual covered entities have agreed to be part of the ADR claim.

As part of the initial review of the claim, OPA will review the attestation statement submitted by the organization or association. If attestation documentation is missing, OPA will follow-up to obtain the attestation.

Comment: A few manufacturer commenters requested that HHS prohibit covered entities or manufacturers from asserting any individual claim that overlaps with a consolidated claim or joint claim. Commenters also urged HHS to clarify that the requirement for a joint claim by covered entities must involve the "same drug or drugs," which would mean that the alleged overcharges must involve substantially the same national drug code (NDC) and quarters.

Response: As part of the initial claim review, OPA will evaluate whether an individual claim would overlap with a consolidated claim or joint claim. If an overlap exists, OPA will contact the parties involved and request that they resolve the discrepancy. In addition, the review will also ensure that the alleged overcharge involves the same NDCs for joint claims.

Comment: Several manufacturer commenters argued that HHS should recognize manufacturers' ability to pursue claims through a trade association or agent of their choice. The statute required HHS to allow the combining of claims and permit claims to be brought on behalf of covered entities by associations or organizations – however, commenters assert that the statute does not preclude HHS from extending this ability to manufacturers. Commenters also argued that few manufacturers will utilize the 340B ADR process due to the onerous requirements of the 2020 final rule and the audit requirement placed on them. They explained that this requirement would further preclude manufacturers from accessing the 340B ADR process by requiring them to wait several years for each manufacturer to audit a covered entity before bringing a consolidated claim.

Response: Section 340B(d)(3)(B) of the PHS Act permits associations to file joint ADR claims on behalf of covered entities; however, it does not include similar language for

associations to file consolidated claims filed on behalf of manufacturers. In addition, due to the requirement that a manufacturer must first audit a covered entity before submitting an ADR claim, it would be difficult to have each manufacturer of the association or organization conduct an audit of a covered entity before filing a claim. Therefore, HHS is finalizing this provision as proposed. Regarding the commenter's argument about the audit requirements, HHS does not have the authority to waive this statutory requirement. Section 340B(d)(3)(B)(iv) of the PHSA requires that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating the 340B ADR process against a covered entity.

d) Deadlines and procedures for filing a claim.

The proposed rule set forth the deadlines and procedures for filing a claim, including that OPA would conduct an initial review to determine whether the claim meets certain requirements as set forth by the statute and regulations. HHS proposed that OPA staff reviewing the initial claim review may not be appointed to serve on the 340B ADR Panel reviewing the specific claim. Additionally, under the proposed rule, OPA could request additional information of the initiating party and the party would have 20 business days from the receipt of the request to respond and if the party does not respond (or request and receive an extension to respond during that time period), the claim would not move forward to the 340B ADR Panel for review. The proposed rule also indicates that a written response would be sent to the initiating party once the claim is complete and OPA would send that verification of completion to the opposing party with instructions regarding the 340B ADR process, including timelines and information on how to submit their response as outlined in § 10.21(e). Once OPA receives the opposing party's response, OPA would notify both parties, either advising that the claim would move forward for the 340B ADR Panel for review or that OPA determined the claim did not meet the requirements as set forth in § 10.21(b) and the reasons why. HHS proposed that for any claim that did not proceed to review by the 340B ADR Panel, the claim could be revised and refiled if there were new information to support the alleged statutory violation and the claim meets the criteria set

forth in the statute and the regulation. HHS received several comments related to this provision and is finalizing this provision as proposed.

Comment: Several commenters suggested that HHS clarify that OPA's initial review of the claim is limited to determining whether the claim meets all the information requirements to file a claim and does not involve a factual or legal review of the claim. They state that at this stage, OPA should only be requesting additional information to satisfy the filing requirements. The determination as to whether a claim is substantiated should be reserved exclusively for the 340B ADR Panel.

Response: During the initial claim review, OPA will review a claim only for completeness, and not make any determinations whether a claim is substantiated. That determination will be reserved for the 340B ADR Panel.

e) Responding to a submitted claim.

When responding to a submitted claim, the NPRM proposed that the opposing party would have 30 business days to submit a written response to OPA upon receipt of notification that the claim is deemed complete. The proposed rule indicated that the opposing party may request an extension of the initial 30 business days to respond. Once the opposing party's response is received, OPA would provide a copy to the initiating party as indicated in § 10.21(d). The proposed rule also explained that if the opposing party's response was not received or the party elects not to participate in the 340B ADR process, OPA would notify both parties that the claim has proceeded to 340B ADR Panel review, and the 340B ADR Panel will render its decision after review of the information submitted in the claim. HHS carefully considered the comments received, which are summarized below, and is finalizing the provision as proposed.

Comment: Some commenters suggested that HHS adopt a timeframe of 60 calendar days (with the possibility of extensions) for opposing parties to respond to claims. These commenters are concerned with the proposal to allow 340B ADR Panels to draw an adverse inference if the opposing party does not respond. They argued the proposed rule does not contain any standard

that would ensure that adverse inferences are drawn against a party only in narrow circumstances. Finally, commenters noted that the final rule should recognize that an "adverse inference" is an extraordinary sanction, and there should be clear standards for when such a sanction is appropriate.

Response: HHS is revising this rule to remove references to adverse inferences, but otherwise finalizing this rule as proposed. Consistent with the statutory goals of efficiency, fairness and timeliness, we believe a response in 30 days is an adequate amount of time. However, HHS recognizes that there may be instances that require time beyond the stated deadlines, such as availability of key personnel. Depending on the circumstances presented, the 340B ADR Panel may exercise its discretion in granting additional time if warranted.

In addition, if a non-responsive party fails to respond before the deadline, the 340B ADR Panel will render its decision based on the information available to it during the adjudication process. If a party chooses not to respond, the 340B ADR Panel will move forward with its decision and there is a possibility that the decision may not be in favor of the non-responsive party.

Section 10.22 Covered entity information and document requests.

Under the proposed rule and in accordance with section 340B(d)(3)(B)(iii) of the PHS Act, covered entities may discover or obtain information and documents from manufacturers and third parties relevant to a claim that the covered entity has been overcharged by a manufacturer. The NPRM proposed that the covered entity submit a written request within 20 business days of the receipt from OPA that the claim was forwarded to the 340B ADR Panel for review. The NPRM proposed that such covered entity document requests be facilitated by the 340B ADR Panel, including a review of the information/document request and notifying the covered entity if the request is not reasonable, not relevant or beyond the scope of the claim, and would permit the covered entity to resubmit a revised request if necessary.

The manufacturer (and any affiliated third-party agents of the manufacturer – wholesalers

or other third parties) must respond to the request within 20 business days of receiving the request. The manufacturer must fully respond, in writing, to an information/document request from the 340B ADR Panel by the response deadline. An extension will be granted by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request. The NPRM proposed that if a manufacturer fails to fully respond to an information request, the 340B ADR Panel shall draw an adverse inference and proceed with the facts that the 340B ADR Panel has determined have been established in the proceeding.

Many commenters recommended changes to the proposed provision allowing parties to request and receive information during the 340B ADR process, including allowing a manufacturer to submit an information request – which was not contemplated by the statute. HHS carefully reviewed the comments received, which are summarized below, and is finalizing this provision as proposed.

Comment: Commenters argued HHS should establish a process for manufacturers to directly request additional information from covered entities during an ADR proceeding. These commenters requested that HHS extend the timeframe for manufacturers to respond to additional information and document requests from 20 business days to 60 calendar days (with the possibility of reasonable extensions).

Response: Section 340B(d)(3)(B)(iii) of the PHS Act requires a process whereby a covered entity may discover or obtain information and documents from manufacturers and third parties relevant to a claim that the covered entity has been overcharged by a manufacturer. The statute does not have a similar provision for manufacturers and manufacturers have the ability to gather needed information through the audits they are required to conduct prior to filing ADR claims. As such, the provision will be finalized as proposed.

In addition, HHS believes a response from manufacturers for additional information and document requests in 20 business days is an adequate amount of time. Any such additional time will unduly delay the 340B ADR process and run counter to the goals of fairness, efficiency, and

timeliness. This final rule also contains a provision through which manufacturers may request an extension of this deadline.

Section 10.23 340B ADR Panel decision process.

Aligned with section 340B(d)(3)(B)(ii) of the PHS Act, HHS has sought to ensure that the 340B ADR decision process would ensure that its review and decision of the claim is conducted in a fair, efficient, and expeditious manner. HHS proposed that the 340B ADR Panel would conduct an initial review of the claim to determine if 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. If this determination is made, the 340B ADR Panel would suspend review of the claim until such time as the issue is no longer pending in Federal court. If no such issue exists, the proposed rule explained that the 340B ADR Panel would review the documents submitted by the parties and determine if there is adequate support to conclude that an overcharge, diversion, or a duplicate discount has occurred in the specific case at issue. As discussed in more detail below and after consideration of the comments received on this proposal, HHS is removing this proposed provision from this final rule to allow claims on issues pending in Federal court to proceed through the 340B ADR process.

In addition, the NPRM proposed that the 340B ADR Panel would prepare a decision that would represent the determination of a majority of the 340B ADR Panel members' findings and include an explanation regarding each finding. Once the letter has been transmitted to the OPA Director and the parties involved, either party may request that the HRSA Administrator reconsider the 340B ADR Panel decision or the HRSA Administrator may decide to initiate a reconsideration without such a request as outlined in § 10.24. Under the NPRM, after 20 business days of the issuance of the 340B ADR Panel decision, there is no request for reconsideration from either party and the HRSA Administrator has not initiated a reconsideration, the 340B ADR Panel's decision letter will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a

Federal court. The NPRM proposed that the OPA Director would then determine any necessary corrective action or consider whether to take enforcement action, and the form of that action, based on the final agency decision. Based on comments received and as discussed in detail below, HHS is modifying this proposal in this final rule by including a timeframe by which the 340B ADR Panel decisions will be issued to ensure that 340B ADR claims are resolved in a timely manner. Finally, HHS will address the OPA Director's role in making determinations for corrective action in future guidance and other clarifications as discussed below.

Comment: The NPRM proposed that if the ADR Panel determines that a specific issue in a claim is the same as, or similar to an issue pending in Federal court, the ADR Panel would suspend review of the claim until such time the issue is no longer pending in Federal court. The NPRM expressly solicited comments from stakeholders on this issue and HHS received significant comments. Some commenters favor suspending claims until they are resolved in Federal court as it would limit the risk of using limited ADR resources on complex legal questions that would also be considered by the courts. Without a suspension of claims, they argue there could be a risk that the ADR Panel decision would be superseded by a Federal court ruling.

In contrast, other commenters strongly oppose the proposal and argue why the provision should not be finalized. In general, the commenters raised the following arguments:

- Commenters opposing the policy expressed that an issue relevant to an ADR proceeding may be pending in several district courts and the court decisions may diverge and not achieve a final consistent resolution on the issue. They stated it is unclear how an ADR Panel would decide after the rulings and whether the ruling would be based on the outcome of the Federal court decision, and if so, which court decision would control in the case of conflicts.
- Commenters also argued that Congress created the 340B ADR process since covered entities have limited options for bringing legal claims against manufacturers. They

asserted that suspending claims is a divergence from the statute, as the statute vests the ADR Panel with authority to issue final agency decisions that are binding on the parties involved through adjudication of 340B disputes. They argued that the provision violates the 340B statute and the Administrative Procedure Act (APA) as it prevents the 340B ADR Panel from resolving a claim for an indefinite period of time based solely on the determination that a Federal lawsuit is addressing an issue that is the same or similar to the one included in an ADR claim.

- Commenters also expressed that the NPRM did not include rules that would govern the 340B ADR Panel's determination that it would not review a claim nor is there any mechanism for a covered entity or manufacturer to contest a 340B ADR Panel's determination to suspend review.
- Commenters cited the 2011 U.S. Supreme Court ruling in *Astra* (*Astra USA, Inc. v. Santa Clara County,* 563 U.S. 110 (2011)) that determined that covered entities do not have a cause of action to sue manufacturers for 340B violations, but noted that covered entities do have the option of pursuing recourse through the 340B ADR process.
- Finally, commenters opposing the policy explain that the suspension of the 340B ADR Panel review may lead a 340B ADR Panel to defer to a Federal court's decision on a 340B compliance issue, thereby abrogating the 340B ADR Panel's duty to interpret 340B statutory requirements. These commenters stated that this is contradictory to the role of the 340B ADR Panel envisioned by the NPRM, which is to independently review and apply 340B law and policy to the case-specific factual circumstances at issue.

Response: After review of the comments received, HHS is removing the provision at § 10.23 in the NPRM that would suspend review of ADR claims if the issue is the same as or similar to an issue that is pending in Federal court. By allowing claims that are the same as or

similar to those pending in Federal court to move through the 340B ADR process, HHS is proceeding consistent with the *Astra* decision and meeting its statutory mandate to establish and implement a 340B ADR process including the establishment of such deadlines and procedures to ensure that claims involving certain 340B disputes are resolved fairly, efficiently, and expeditiously. Therefore, this final rule will remove the proposed § 10.23(a) and revise § 10.23(b) to allow for a claim to proceed through the 340B ADR process, regardless of whether it is the same as or similar to one that is pending in Federal court.

Comment: Many commenters argued that HHS should impose a timeframe for ADR Panel decisions to ensure that 340B ADR claims are resolved in a timely manner. Some suggested 45, 90, 120, or 180 days. Some explained that 120 days is longer than the 90-day timeframe that Medicare administrative law judges are subject to for Medicare claims appeals and would be a sufficient amount of time. Commenters assert that HHS should clarify that if an ADR panel has not issued a decision within 120 days, a claimant should be able to bypass the 340B ADR process and proceed to Federal court. Most commenters agreed that the decision should be rendered no later than within one year.

Response: Based on the comments received, HHS is clarifying that the expectation is that the 340B ADR Panel will make a decision on a claim within one year of receiving the claim for review. However, HHS recognizes that this general timeframe may not be suitable in every situation, as there may be complexities that warrant additional time beyond the one year timeframe. Additional time may be necessary, for example, if a claim is submitted and the 340B ADR Panel requires additional material, must determine whether there are overlapping claims, must determine whether a covered entity consented to an organizational claim, or seeks to consult with, as appropriate or necessary, other staff within OPA, other HHS offices, other Federal agencies, or with outside parties. Depending on the complexity of the issue, this timeframe may exceed the one year timeframe set forth in this final rule.

HHS does not believe it possible to list out every possible exception in this final rule as

there may be situations that are beyond the control of the 340B ADR Panel and cannot be anticipated or predicted in this final rule; however, these examples serve to illustrate circumstances when it may take longer than one year for a 340B ADR Panel to render a decision. In any event, HHS does not believe that many claims that are submitted under this final rule will take longer than a year to resolve. As such, HHS is clarifying that the expectation is the 340B ADR Panel decisions will be issued within a one year time period; however, the 340B ADR Panel will inform the parties, no later than 1 year from the date a claim is deemed complete, if the forthcoming decision will exceed that one year timeframe and provide an explanation as to why the decision on the claim will exceed one year.

Comment: Many commenters requested there be the option for an in-person hearing before the 340B ADR Panel, if requested by either party. The commenters explain that ADR claims may often involve factual questions and the 340B ADR Panel may benefit from the "adversarial input" of the parties involved.

Response: The NPRM did not contemplate in-person hearings as part of the 340B ADR process, as HHS proposed a process that would be more accessible than the 2020 final rule, by making it more expeditious and less trial-like for all parties to resolve disputes. HHS believes adding in-person hearings to the process could be arduous, could create disadvantages to under-resourced parties, and could create unnecessary delays. For example, smaller or rural covered entities, including those with limited resources, could have significant difficulties complying with such a requirement compared to larger and better resourced parties.

Comment: Some commenters appreciated HHS' proposed removal of language indicating that 340B ADR Panel decisions are precedential. They argued that the 2020 final rule gave the 340B ADR Panel the ability to set and change policy on fundamental program issues, such as who qualifies as a 340B-eligbile patient—and they argued that such language was inconsistent with the 340B statute, which does not support making 340B ADR Panel decisions precedential.

Conversely, other commenters disagreed and believed that ADR decisions should be

precedential because, otherwise, it would be difficult to adequately assess the viability of a claim prior to submitting it to the 340B ADR Panel. They explained that by ensuring that decisions are precedential, it would impact how well entities are able to evaluate whether the 340B ADR process is appropriate for a given claim based on the time and resource investment required of the parties involved.

Response: Section 340B(d)(3)(C) of the PHS Act states that the administrative resolution of a claim shall constitute final agency decision and will be binding on the parties involved, unless invalidated by an order of a court of competent jurisdiction. The 340B statute does not expressly state that the 340B ADR Panel decision or a subsequent reconsideration decision be precedential. As set forth in §§ 10.21 and 10.23, the 340B ADR Panel will follow the 340B statute, regulations, and all policies governing the 340B Program when reviewing and evaluating 340B ADR claims and HHS is finalizing as proposed.

Comment: Most commenters urged wider transparency and requested that HHS publish 340B ADR Panel decisions on HRSA's website and require 340B ADR Panel decisions to include the 340B ADR Panel's factual and legal conclusions, including the HRSA policy on which the decision is based. They reasoned that this would ensure ADR decisions are consistent with current 340B policies and that 340B stakeholders are able to understand and apply HRSA's rule and compliance expectations.

Response: HHS values and supports transparency in the outcome of any 340B ADR Panel decision.. For HRSA audits of covered entities and manufactuers, HRSA publishes its audit findings in summary format as full audit reports may include proprietary and/or sensitive business information (for example, under the statute, 340B ceiling prices themselves cannot be publicly disclosed). Consistent with this approach, HRSA will publish 340B ADR final agency decisions on a HRSA public-facing website within 120 calendar days of issuance.

Comment: Some commenters suggest that HHS revise this section to require the 340B ADR Panel or OPA to inform the parties of their reconsideration rights when the 340B ADR

Panel's decision is communicated to the parties.

Response: HHS agrees and is finalizing this rule to include a provision that would ensure that parties are informed of their reconsideration rights at the time the 340B ADR Panel's decision is communicated to the parties.

Comment: HHS received several comments recommending that HHS revise this section to require manufacturers or covered entities to repay the other party within a specified time-period (e.g., 60 days) of the date 340B ADR Panel's decision letter or the HRSA Administrator's reconsideration decision.

Response: The NPRM explained that once the parties have been notified of the final agency decision and no request for reconsideration has been made in accordance with § 10.24, the OPA Director will consider whether to take enforcement action to ensure corrective action to the extent allowed under the 340B statute. For example, based on the final agency decision, the OPA Director may require a covered entity to repay an affected manufacturer in a timely manner. In addition, in the case of a 340B ADR Panel decision involving an overcharge, the OPA Director may require that the manufacturer refund or issue a credit to the impacted covered entity. Such an enforcement decision may include the time frame and manner of such remedies.

Section 10.24 340B ADR Panel decision reconsideration process.

The NPRM proposed a process for either party to initiate a reconsideration request within 20 business days of the date of the 340B ADR Panel's decision letter. The HRSA Administrator, or their designee, may initiate the process without such a request. The NPRM also proposed that a reconsideration process may only be granted when a party demonstrates that the 340B ADR Panel decision may have been inaccurate or flawed. As proposed, the reconsideration process would involve the HRSA Administrator, or designee, reviewing the record and the 340B ADR Panel's decision, and either issuing a revised decision to be effective 20 business days from issuance or declining to issue a revised decision. Finally, the NPRM proposed that the reconsideration decision or the 340B ADR Panel decision (in the event of a declination) will

serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court. The proposed rule indicates that the OPA Director will determine any necessary corrective action, or consider whether to take enforcement action, and the form of any such action, based on the final agency decision. There were several comments received on the reconsideration process, and HHS is finalizing this provision with some clarifications as discussed below.

Comment: The majority of comments received support a reconsideration process by the HRSA Administrator. Some suggest that HHS clarify the timeline for a reconsideration decision.

Response: HHS appreciates the comments received in support of a reconsideration process conducted by the HRSA Administrator. Regarding a timeline for the HRSA Administrator's reconsideration and after review of the comments, the HRSA Administrator will make efforts to issue a reconsideration decision within 180 calendar days from the initiation of the reconsideration process. HHS is finalizing, as proposed, that if a reconsideration decision is rendered, the reconsideration decision, unless altered or reversed (after review) by the Secretary, will serve as the final agency decision and will be binding on the parties involved in the dispute, unless invalidated by an order of a Federal court.

Comment: Some commenters recommend that HHS lengthen the amount of time for parties to request a reconsideration. The NPRM contemplates that a request for reconsideration must be made within 20 business days of the date of the 340B ADR Panel's decision letter. Commenters urged HHS to revise this timeline to either 30 or 60 business days to allow for more time to (1) determine that they believe the reconsideration is necessary and (2) file the request in a timely manner.

Response: HHS agrees with the commenters and is finalizing § 10.24(b) to lengthen the time that a request for reconsideration can be made from the proposed 20 business days to 30 business days. This will allow a requestor additional time to obtain consent in the case of a joint or consolidated claim for a reconsideration request as indicated in § 10.24(b)(3). In the event that

no request for reconsideration is received by either party after the 30-day period, the 340B ADR Panel decision or any such alteration or reversal by the Secretary (after review) will serve as the final agency decision and will be binding on the parties involved in the dispute, unless invalidated by an order of a Federal court.

Comment: Some commenters request that HHS clarify that new facts or information may not be submitted as part of the reconsideration process. They argue that new legal or policy arguments may be warranted in light of the 340B ADR Panel's decision and should not be prohibited.

Response: HHS has clarified in §10.24 to state that no new "facts," information, or legal or policy arguments may be submitted as part of the reconsideration process in order to remain consistent with the content reviewed by the 340B ADR Panel in reaching their decision.

Comment: Several commenters request that HHS remove the proposed provision at § 10.24(b)(3), which would require that in the case of joint or consolidated claims, the requestor for reconsideration submit documentation showing consent to the reconsideration process, including signatures of the individuals representing each covered entity or manufacturer. They state that it is unclear why consent should be required for a reconsideration request when the covered entity or manufacturer previously consented to joint/consolidated representation as part of the 340B ADR process as outlined in § 10.21(c).

Response: After consideration of the comments, HHS will permit associations or organizations filing a claim on behalf of its members to submit an attestation that they have confirmed that all covered entities have agreed to be part of the reconsideration process. Also, as discussed above, HHS is modifying the proposal to lengthen the time for a party to initiate a reconsideration request from 20 business days to 30 business days.

Comment: A few commenters recommended that HHS clarify the HRSA Administrator's standard of review used when analyzing the 340B ADR Panel's decision and further clarify that the 340B ADR Panel's decision is held in abeyance until the HRSA

Administrator issues a decision on reconsideration.

Response: The standard that the HRSA Administrator will use in reviewing any reconsideration request will be the same for each request. The HRSA Administrator will review the record, including the 340B ADR Panel decision, and determine whether there was an error in the 340B ADR Panel's decision, including any deviation from policy, guidance or statute. HHS has made this clear in this final rule. HHS will also clarify in § 10.24 that in the event of a reconsideration request, the 340B ADR Panel's decision is held in abeyance until the HRSA Administrator modifies or sustains the 340B ADR Panel's decision. Any such reconsideration decision letter will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court.

Section 10.25 Severability.

In this final rule, we adopt modifications to 42 CFR part 10 that support a unified scheme for review of 340B ADR claims. While the unity and comprehensiveness of this scheme maximizes its utility, we clarify that its constituent elements operate independently of each other. Were a provision of this regulation stayed or invalidated by a reviewing court, the provisions that remain in effect would continue to provide a process for review of 340B claims. For example, this final rule contains a number of requirements to be fulfilled prior to review by the 340 ADR Panel, such as providing evidence of good faith efforts and evidence that each covered entity consents to the combining of the claims for a joint claim. To the extent that these provisions were no longer in effect, the remainder of the final rule could still function without these provisions.

To best serve these purposes, we have addressed severability in the regulations to make clear that the provisions of 42 CFR part 10 are designed to operate independently of each other and to convey the Department's intent that the potential invalidity of one provision or any of its subparts should not affect the remainder of the provisions.

III. Regulatory Impact Analysis

A. Regulatory Impact Analysis

HHS has examined the effects of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (UMRA; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999). HHS did not receive any substantive comments on this section of the proposed rule and is therefore finalizing this section as proposed.

B. Overall Impact

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and promoting flexibility.

Under E.O. 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the E.O. and review by OMB. *See* 58 FR 51735 (Oct. 4, 1993). Section 1(b) of E.O. 14094 amended sec. 3(f) of E.O. 12866 to define a "significant regulatory action" as an action that is likely to result in a rule that may: 1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product) or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; 2) create a serious inconsistency or otherwise

interfere with an action taken or planned by another agency; 3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or 4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the E.O. *See* 88 FR 21879 (Apr. 11, 2023). OIRA has determined that this final rule is a significant regulatory action, although not a significant regulatory action under sec. 3(f)(1) of E.O. 12866. Accordingly, OMB has reviewed this final rule.

This final rule would modify the framework for HHS to resolve certain disputed claims regarding manufacturers overcharging covered entities and disputed claims of diversion and duplicate discounts by covered entities audited by manufacturers under the 340B Program. HHS does not anticipate the modification of the 340B ADR process to result in significant economic impact. Because this rule only updates an existing process, there is no additional economic impact. In addition, the parties involved already have the information that will reported through the 340B ADR process; therefore, we do not anticipate any additional impact. This is also consistent with a similar determination in the 2020 final rule that "HHS does not anticipate the introduction of an ADR process to result in significant economic impacts." Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act (5 U.S.C. 801 et seq.), OIRA has determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2).

C. The Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601 et seq.) and the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), which amended the RFA, requires HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of this rule on small entities and analyze regulatory options that could lessen the impact of this rule. HHS will use a RFA threshold of at least a 3 percent impact

on at least 5 percent of small entities.

This final rule's requirements would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 700 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of this final rule on the industry as a whole, the data necessary to project the impact of changes on specific manufacturers or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program. This final rule would also affect health care providers. For purposes of the RFA, HHS considers all health care providers to be small entities either by virtue of meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $8 million to $41.5 million. As of April 1, 2023, 14,134 covered entities participate in the 340B Program.

This final rule would modify the ADR mechanism for reviewing claims by manufacturers that covered entities have violated certain statutory obligations and claims by covered entities alleging overcharges for 340B covered outpatient drugs by manufacturers. This 340B ADR process would require submission of documents that manufacturers and covered entities are already required to maintain as part of their participation in the 340B Program. HHS expects that this documentation would be readily available prior to submitting a claim. Therefore, the collection of this information would not result in an economic impact or create additional administrative burden on these businesses.

By design of this final rule, the 340B ADR process will resolve claims in a fair, efficient, and expeditious manner in accordance with section 340B(d)(3)(B)(ii) of the PHS Act. This final rule provides an option to join or consolidate claims by similar situated entities, and covered entities may have claims asserted on their behalf by associations or organizations which could

reduce costs. HHS has determined, and the Secretary certifies, that this final rule would not have a significant economic impact on a substantial number of small health care providers or a significant impact on the operations of a substantial number of small manufacturers; therefore, HHS is not preparing an analysis of impact for the purposes of the RFA. HHS estimates that the economic impact on the less than 5 percent of small entities and small manufacturers participating in the 340B Program would be minimal and less than a 3 percent economic burden and therefore does not meet the RFA threshold of 3 percent.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 UMRA requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2023, that threshold is approximately $177 million. HHS does not expect this rule to exceed the threshold.

E. Executive Order 13132 - Federalism

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have federalism implications. This final rule would not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." The final rule would also not adversely affect the following family elements: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

F. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This final rule would not impact the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. Because the 340B ADR process provides the mechanism and procedures for an administrative action or investigation involving an agency against specific individuals or entities, pursuant to 44 U.S.C. 3518(c), the 340B ADR process is exempt from Paperwork Reduction Act requirements. In addition, participants in the 340B Program are already required to maintain the necessary records to submit an ADR claim.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B Drug Pricing Program.

Dated: April 12, 2024.

Xavier Becerra,

Secretary,

*Department of Health and Human Services***.**

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR part 10 as follows:

PART 10 - 340B DRUG PRICING PROGRAM

1. The authority citation for part 10 continues to read as follows:

Authority: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b) (PHSA), as amended.

2. Amend §10.3 by:

a. Removing the definition for *Administrative Dispute Resolution (ADR) Process* and dding the definition *340B Administrative Dispute Resolution (ADR) process* in its place;

b. Revising the definitions for *Administrative Dispute Resolution Panel (340B ADR Panel)*, *Claim*, *Consolidated claim*, and *Joint claim*; and

c. Adding in alphabetical order the definition for *Office of Pharmacy Affairs (OPA)*.

The revisions and additions read as follows:

§ 10.3 Definitions.

* * * * *

340B Administrative Dispute Resolution (ADR) process means a process used to resolve the following types of claims, including any issues that assist the 340B ADR Panel in resolving such claims:

(1) Claims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers; and

(2) Claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity (pursuant to section 340B(a)(5)(C) of the Public Health Service Act (PHS Act)), that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Health Resources and Services Administration's Office of Pharmacy Affairs that reviews and makes decisions for claims filed through the 340B ADR process.

* * * * *

Claim means a written allegation filed by or on behalf of a covered entity or by a manufacturer for resolution under the 340B ADR process.

* * * * *

Consolidated claim means a claim resulting from combining multiple manufacturers' claims against the same covered entity.

* * * * *

Joint claim means a claim resulting from combining multiple covered entities' claims (or claims from their membership organizations or associations) against the same manufacturer for the same drug or drugs.

* * * * *

Office of Pharmacy Affairs (OPA) means the office, or any successor office assigned to administer the 340B Program, within the Health Resources and Services Administration, or any successor agency, that oversees the 340B Program.

* * * * *

3. Revise subpart C to read as follows:

Subpart C - Administrative Dispute Resolution

Sec.

Subpart C - Administrative Dispute Resolution

§ 10.20 340B Administrative Dispute Resolution Panel.

The Secretary shall appoint a roster of eligible individuals (Roster) consisting of staff within OPA, to serve on a 340B ADR Panel, as defined in § 10.3. The OPA Director, or the OPA Director's designee, shall select at least three members from the Roster to form a 340B ADR Panel to review and make decisions regarding one or more claims filed by covered entities or manufacturers.

(a) *Members of the 340B ADR Panel.* (1) The OPA Director shall:

(i) Select at least three members for each 340B ADR Panel from the Roster of appointed staff;

(ii) Have the authority to remove an individual from the 340B ADR Panel and replace such individual; and

(iii) Select replacement 340B ADR Panel members should an individual resign from the panel or otherwise be unable to complete their duties.

(2) No member of the 340B ADR Panel may have a conflict of interest, as set forth in paragraph (b) of this section.

(b) *Conflicts of interest.* (1) All members appointed by the Secretary to the Roster of individuals eligible to be selected for a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. In determining whether a conflict exists, the OPA Director, in consultation with government ethics officials, will consider financial interest(s), current or former business or employment relationship(s), or other involvement of a prospective panel member or close family member who is either employed by or otherwise has a business relationship with an involved party, subsidiary of an involved party, or particular claim(s) expected to be presented to the prospective panel member.

(2) All members of the 340B ADR Panel will undergo an additional screening prior to reviewing a specific claim to ensure that the 340B ADR Panel member was not directly involved in a decision concerning the specific issue of the ADR claim as it relates to the specific covered entity or manufacturer involved, including previous 340B ADR Panel decisions.

(c) *Secretarial authority in the 340B ADR process.* The Secretary may remove any individual from the Roster of 340B ADR Panelists for any reason, including from any 340B ADR Panel to which the individual has already been assigned. The Secretary has the authority to review and reverse, alter, or uphold any 340B ADR Panel or reconsideration decision as outlined in §§ 10.23 and 10.24. Any such decision of the Secretary will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a

Federal court.

(d) *Duties of the 340B ADR Panel.* The 340B ADR Panel will:

(1) Review and evaluate claims, including consolidated and joint claims, and documents and information submitted by (or on behalf of) covered entities and manufacturers;

(2) Review and may request additional documentation, information, or clarification of an issue from any or all parties to make a decision (if the 340B ADR Panel finds that a party has failed to respond or fully respond to an information request, the 340B ADR Panel may proceed with facts that the 340B ADR Panel determines have been established in the proceeding);

(3) Evaluate claims based on information received, unless, at the 340B ADR Panel's discretion, the nature of the claim necessitates that a meeting with the parties be held;

(4) At its discretion, consult with others, including staff within OPA, other HHS offices, and other Federal agencies while reviewing a claim; and

(5) Make decisions on each claim.

§ 10.21 Claims.

(a) *Claims permitted.* All claims must be specific to the parties identified in the claims and are limited to the following:

(1) Claims 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; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHS Act, that the covered entity has violated section 340B(a)(5)(A) of the PHS Act, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHS Act, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity.

(b) *Requirements for filing a claim.* (1) Absent extenuating circumstances, a covered entity or manufacturer must file a claim under this section in writing to OPA within 3 years of

the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision.

(2) A covered entity filing a claim described in paragraph (a)(1) of this section must provide the basis, including all available supporting documentation, for its belief that it has been overcharged by a manufacturer, in addition to any other documentation as may be requested by OPA. A covered entity claim against multiple manufacturers is not permitted.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts, in addition to any other documentation as may be requested by OPA.

(4) A covered entity or manufacturer filing a claim must provide documentation of good faith efforts, including for example, documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim.

(c) *Combining claims.* (1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity consents to the jointly filed claim and meets the filing requirements.

(i) For covered entity joint claims, the claim must list each covered entity, its 340B ID and include documentation as described in paragraph (b) of this section, which demonstrates that each covered entity meets all of the requirements for filing the ADR claim.

(ii) For covered entity joint claims, a letter requesting the combining of claims must accompany the claim at the time of filing and must document that each covered entity consents to the combining of the claims, including signatures of individuals representing each covered entity and a point of contact for each covered entity.

(2) An association or organization may file on behalf of one or more covered entities representing their interests if:

(i) Each covered entity is a member of the association or the organization representing it and each covered entity meets the requirements for filing a claim;

(ii) The joint claim filed by the association or organization must assert overcharging by a single manufacturer for the same drug(s); and

(iii) The claim includes a letter from the association or organization attesting that each covered entity agrees to the organization or association asserting a claim on its behalf, including a point of contact for each covered entity.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the consolidated claim, meets the requirements for filing a claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources. Consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests are not permitted.

(d) *Deadlines and procedures for filing a claim.* (1) Covered entities and manufacturers must file claims in writing with OPA, in the manner set forth by OPA.

(2) OPA will conduct an initial review of all information submitted by the party filing the claim and will make a determination as to whether the requirements in paragraph (b) of this section are met. The OPA staff conducting the initial review of a claim may not be appointed to serve on the 340B ADR Panel reviewing that specific claim.

(3) Additional information to substantiate a claim may be submitted by the initiating party and may be requested by OPA. If additional information is requested, the initiating party will have 20 business days from the receipt of OPA's request to respond. If the initiating party does not respond to a request for additional information within the specified time frame or request and receive an extension, the claim will not move forward to the 340B ADR Panel for review.

(4) OPA will provide written notification to the initiating party that the claim is complete. Once the claim is complete, OPA will also provide written notification to the opposing party that the claim was submitted. This written notification will provide a copy of the initiating party's claim, and additional instructions regarding the 340B ADR process, including timelines and information on how to submit their response in accordance with the procedures for responding to a claim as outlined in paragraph (e) of this section.

(5) If OPA finds that the claim meets the requirements described in paragraph (b) of this section, and once OPA receives the opposing party's response in accordance with the procedures outlined in paragraph (e) of this section, additional written notification will be sent to both parties advising that the claim will be forwarded to the 340B ADR Panel for review.

(6) If OPA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both parties stating the reasons that the claim did not move forward.

(7) For any claim that does not move forward for review by the 340B ADR Panel, the claim may be revised and refiled if there is new information to support the alleged statutory violation and the claim meets the criteria set forth in this section.

(e) *Responding to a submitted claim.* (1) Upon receipt of notification by OPA that a claim is deemed complete and has met the requirements in paragraph (b) of this section, the opposing party in alleged violation will have 30 business days to submit a written response to OPA.

(2) A party may submit a request for an extension of the initial 30 business days response period and OPA will make a determination to approve or disapprove such request and notify both parties.

(3) OPA will provide a copy of the opposing party's response to the initiating party and will notify both parties that the claim has moved forward for review by the 340B ADR Panel.

(4) If an opposing party does not respond or elects not to participate in the 340B ADR process, OPA will notify both parties that the claim has moved forward for review by the 340B

ADR Panel and the 340B ADR Panel will render its decision after review of the information submitted in the claim.

§ 10.22 Covered entity information and document requests.

(a) To request information necessary to support its claim from an opposing party, a covered entity must submit a written request for additional information or documents to the 340B ADR Panel within 20 business days of the receipt from OPA that the claim was forwarded to the 340B ADR Panel for review. The 340B ADR Panel will review the information/document request and notify the covered entity if the request is not reasonable, not relevant or beyond the scope of the claim, and will permit the covered entity to resubmit a revised request if necessary.

(b) The 340B ADR Panel will transmit the covered entity's information/document request to the manufacturer who must respond to the request within 20 business days of receipt of the request.

(c) The manufacturer must fully respond, in writing, to an information/document request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities.

(2) If a manufacturer anticipates that it will not be able to respond to the information/document request by the deadline, it can request one extension by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request.

(3) A request to extend the deadline must include the reason why the specific deadline is not feasible and must outline the proposed timeline for fully responding to the information/document request.

(4) The 340B ADR Panel may approve or disapprove the request for an extension of time and will notify all parties in writing of its decision.

(5) If the 340B ADR Panel finds that a manufacturer has failed to fully respond to an

information/document request, the 340B ADR Panel will proceed with the facts that the 340B ADR Panel has determined have been established in the proceeding.

(6) If a manufacturer believes an information request to a covered entity is necessary for the 340B ADR Panel's review, it may make a request to the 340B ADR Panel to make the request to the covered entity.

§ 10.23 340B ADR Panel decision process.

(a) The 340B ADR Panel will conduct a review of the claims. The 340B ADR Panel will review all documents gathered during the 340B ADR process to determine if a violation as described in § 10.21(a)(1) or (2) has occurred.

(b) The 340B ADR Panel will prepare a decision letter based on its review. The 340B ADR Panel's decision letter will be completed within one year of receiving a complete claim for review, except to the extent that there are situations beyond the control of the 340B ADR Panel that may affect the ability to issue a decision on a claim within one year. If the issuance of a 340B ADR Panel decision will exceed one year, the 340B ADR Panel must provide notice to the parties involved. The 340B ADR Panel decision letter will represent the determination of a majority of the 340B ADR Panel members' findings regarding the claim and include an explanation regarding each finding. The 340B ADR Panel will transmit its decision letter to all parties and to the OPA Director.

(c) The 340B ADR Panel decision letter will inform the parties involved of their rights for reconsideration as described in § 10.24. Either party may request reconsideration of the 340B ADR Panel decision or the Health Resources and Service Administration (HRSA) Administrator may decide to initiate a reconsideration without such a request. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court. The 340B ADR Panel's decision letter will be effective 30 business days from issuance and serve as the final agency decision unless:

(1) Within 30 business days of issuance, reconsideration occurs under § 10.24; or

(2) Within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision.

(d) The OPA Director will determine any necessary corrective action or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.24 340B ADR Panel decision reconsideration process.

(a) Either party may initiate a reconsideration request, or the HRSA Administrator may decide to initiate the process without such a request. In the event of a reconsideration request, the 340B ADR Panel's decision is held in abeyance until such time the HRSA Administrator makes a reconsideration decision of the 340B ADR Panel decision (or in the event of a declination). A reconsideration decision will affirm or supersede a 340B ADR Panel decision.

(b) The request for a reconsideration of the 340B ADR Panel's decision must be made to the HRSA Administrator within 30 business days of the date of the 340B ADR Panel's decision letter.

(1) The request for reconsideration must include a copy of the 340B ADR Panel decision letter, and documentation indicating why a reconsideration is warranted.

(2) New facts, information, legal arguments, or policy arguments may not be submitted as part of the reconsideration process in order to remain consistent with the facts that were reviewed by the 340B ADR Panel in determining their decision.

(3) In the case of joint or consolidated claims, the reconsideration request must include an attestation confirming that all of the entities have agreed to be part of the reconsideration process.

(c) The standard for review of the reconsideration request by the HRSA Administrator, or their designee, will include a review of the record, including the 340B ADR Panel decision, and a determination of whether there was an error in the 340B ADR Panel's decision. The HRSA Administrator, or designee, may consult with other HHS officials, as necessary.

(d) The HRSA Administrator, or their designee, will make a determination based on the reconsideration request by either issuing a revised decision or declining to issue a revised decision.

(e) The reconsideration decision letter will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court.

(f) The OPA Director will determine any necessary corrective action, or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.25 Severability.

If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof.

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