

This rule is not expected to lead to the promulgation of a rule constituting a “regulatory action” under Executive Order 13771 because the final rule is fixing a procedural error from a prior rulemaking and does not impose burden on regulated entities. The addition of the phrase “allegedly committed by the patient” was not a logical outgrowth of the 2016 NPRM proposals, or of comments received thereon, and it was added in error to the regulatory text of section 2.63.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of “small entity”). HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least five percent of small entities experience an impact of more than three percent of revenue. HHS determines that this rule does not have a significant economic impact on a substantial number of small entities. The rule would merely correct an erroneous change made in 2017 to, and restore the pre-2017 language to, the longstanding provision in 42 CFR 2.63, in order to avoid a possible interpretation that could hamper or impede Federal enforcement efforts in the fight to address the opioid crisis, including investigations that involve disclosures of Part 2 program records authorized by court orders. As such, this final rule will have a de minimis, if any, impact on small entities.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 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 \$100,000,000 or more (adjusted annually for inflation) in any one year.” In 2019 that threshold level is approximately \$154 million. HHS does not expect the rule to exceed the threshold.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The change in this rulemaking would result in no new reporting burdens.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Drug abuse, Grant programs—health, Health records, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HHS amends 42 CFR part 2 as follows:

PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

- 1. The authority citation for Part 2 continues to read follows:

Authority: 42 U.S.C. 290dd–2.

Subpart E—Court Orders Authorizing Disclosure and Use

§ 2.63 [Amended]

- 2. Amend § 2.63(a)(2) by removing the phrase “allegedly committed by the patient”.

* * * * *

Dated: August 27, 2020.

Elinore F. McCance-Katz,
Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

Approved: September 30, 2020.

Alex M. Azar II,
Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AB26

340B Drug Pricing Program; Administrative Dispute Resolution Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Health Resources and Services Administration (HRSA) implements section 340B of the Public Health Service Act (PHSA), 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.

DATES: This final rule is effective January 13, 2021.

FOR FURTHER INFORMATION CONTACT: RADM Krista Pedley, Director, OPA, HRSA, 5600 Fishers Lane, Mail Stop 13N182, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992,” enacted section 340B of the PHSA entitled “Limitation on Prices of Drugs Purchased by Covered Entities,” which was codified at 42 U.S.C. 256b. The 340B Program permits 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) delegated the authority to establish and administer the 340B Program to the Administrator of HRSA. Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B(a)(1) of the PHSA 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 PHSA “[i]n order for payment to be available under section 1903(a) or under part B of title XVIII 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 defined 340B ceiling prices. Those prices are based on quarterly pricing reports that manufacturers must provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS).

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 PHSA, which requires the Secretary to promulgate regulations establishing and implementing a binding ADR process for certain disputes arising under the 340B Program. The purpose of the 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 PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts. The ADR process is an administrative process designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion. To resolve these disputes, a panel charged with resolving the dispute may find it necessary to resolve related issues such as whether someone is a “patient” or whether a pharmacy is part of a “covered entity.” Historically, HHS has encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith. The ADR process is not intended to replace these good faith efforts, but should be considered as a last resort in the event good faith efforts to resolve disputes have failed. In addition, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for minor claims given the investment of the time and resources required of the parties involved and the government.

In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) that requested comments on the development of an ADR process (75 FR 57233, Sept. 20, 2010). HHS received 14 comments. In 2016, HHS issued a Notice of Proposed Rulemaking (NPRM) and received 31 comments. The NPRM was removed from the HHS Regulatory Agenda in accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, titled “Regulatory Freeze Pending

Review,”¹ which had the effect of pausing action on the proposed rule. The Secretary, however, did not formally withdraw the NPRM, but rather left it open as a viable option. HHS considered the comments received on the NPRM in the development of this final rule. This final rule will replace the 340B Program’s guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers, which were published on December 12, 1996 (61 FR 65406). Finally, we note that in order to fairly, efficiently, and expeditiously resolve claims pursuant to the ADR process described in this final rule, the Secretary hereby delegates to each 340B ADR Panel, constituted from members of the 340B Administrative Dispute Resolution Board, the authority to make final agency decisions as set forth under 42 U.S.C. 256b(d)(3)(C) and codified in 42 CFR part 10, as amended by 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 amended to incorporate the ADR process, which is described below in conjunction with comments received to each such section.

General Comments

Comments received during the comment period addressed general issues. We have summarized those comments and have provided a response below.

Comment: Commenters recommend that, before HRSA develops the ADR process, HRSA should establish foundational guidance on key issues, as the conditions for creating such a process are not in place. Specifically, commenters suggest that HRSA reform its guidelines regarding manufacturer audits of covered entities as they are outdated and do not allow for a functioning ADR process; develop manufacturer refund procedures for cases where 340B ceiling prices change due to restated Medicaid rebate metrics; finalize the process for calculating 340B ceiling prices and imposing civil monetary penalties; and finalize the 340B mega-guidance.

Response: HHS finalized the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation on January 5, 2017 (82 FR 1211). That regulation addressed the

¹ See <https://www.whitehouse.gov/presidential-actions/memorandum-heads-executive-departments-agencies/>.

calculation of the 340B ceiling price, and imposition of CMPs on manufacturers who knowingly and intentionally overcharge a covered entity. Neither updated manufacturer audit guidelines nor the finalization of the 340B mega-guidance is needed to finalize the ADR process. The 340B statute empowers the 340B ADR Panel reviewing a claim, as set forth in this final rule, to determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts.

Comment: Several commenters urge HRSA to adopt those conventions for ascertaining deadlines that are commonly used by other administrative bodies and courts. Commenters suggested that HRSA should use calendar days for deadlines rather than business days as misunderstandings about correct deadlines and due dates can be avoided if HRSA were to adopt these commonly used conventions.

Response: HHS agrees with these comments. The ADR process will be governed, to the extent applicable, by the Federal Rules of Civil Procedure and Federal Rules of Evidence, unless the parties agree otherwise and the 340B ADR Panel concurs. Rule 6 of the Federal Rules of Civil Procedure sets out the rules for computing any time period specified in the Rules and that Rule will govern time computation under this regulation.

Comment: Commenters urge HRSA to clarify what would constitute a de minimis claim given the investment of time and resources required of the parties involved. Commenters argue that while the parties may be able to assess what would constitute a reasonable materiality threshold that would warrant pursuing the ADR process, having a standardized threshold could ensure a more uniform and judicious use of the ADR process. Commenters recommend that covered entities could use a threshold of 5 percent of total 340B savings for establishing a de minimis claim.

Response: HHS agrees that some disputes may be too small to warrant the expenditure necessary to conduct a hearing on the matter. Recognizing that petitioners can file jointly as warranted and that claims can be aggregated or consolidated, we do not believe that setting a jurisdictional threshold, where money damages are sought, should adversely affect any covered entity or manufacturer. We believe that an appropriate threshold for a claim or claims for money damages should be \$25,000; where equitable relief is sought, however, there will be no threshold for past damages provided

that the relief sought will be the equivalent of \$25,000 in the twelve months following the 340B ADR Panel's decision. HHS is finalizing the jurisdictional threshold for filing a claim in paragraph (b) of § 10.21.

Subpart C—Administrative Dispute Resolution

§ 10.20 Administrative Dispute Resolution Panel

In the proposed rule, HHS sought to establish a decision-making body to review and resolve claims in an unbiased and fair manner, ensure fairness and objectiveness by avoiding conflicts of interest, and set forth the duties of the panel. In this final rule, HHS is finalizing that proposal with some modifications. In this final rule, the Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of the General Counsel (OGC). Administrative Dispute Resolution Panels (340B ADR Panel) of three Board members shall be selected by the HRSA Administrator to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers. HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.

(a) Members of the 340B ADR Panel.

HHS proposed that HRSA select a 340B ADR Panel to include three members, chosen from a roster of eligible individuals, and one *ex-officio*, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA) to facilitate the review and resolution of claims within a reasonable timeframe. HHS is modifying that proposal. In this final rule, the HRSA Administrator is empowered to select and convene three-member 340B ADR Panels, constituted from the above-referenced Board, with one member from HRSA, CMS, and OGC with relevant expertise to review claims and make final agency decisions. HHS proposed that individuals serving on a 340B ADR Panel may be removed for cause. HHS is finalizing that proposal. In this final rule, if there is a conflict of interest, as described in paragraph (b), with respect to a claim, the 340B ADR

Panel member will be removed from the 340B ADR Panel and replaced by another individual from the Board.

Finally, HHS solicited specific comments on the proposed size and composition of the 340B ADR Panel, in particular whether the 340B ADR Panel should be comprised of a set number of voting members to maintain consistency and transparency across each claim that is reviewed, whether HHS should retain the flexibility to appoint a requisite number of voting members based on the complexity of the claim and other factors, and whether the 340B ADR Panel should include at least one OPA staff member as a voting member or whether the inclusion of an OPA staff member as an *ex-officio*, non-voting member would be sufficient to ensure adherence to 340B policies and procedures.

HHS received comments related to the composition of the 340B ADR Panel and after consideration of the comments received, HHS has determined that each 340B ADR Panel must include one attorney from OGC with complex litigation expertise, along with one member from HRSA and one member from CMS, each with drug pricing, drug distribution, and other relevant 340B expertise. A non-voting, *ex-officio* member from OPA will assist each three-member 340B ADR Panel.

Comment: Some commenters suggest that given that the 340B ADR Panel will likely review claims submitted by manufacturers that involve audits conducted of covered entities, the 340B ADR Panel members should also have demonstrated expertise or familiarity with the Government Audit Standards and expertise or familiarity with the 340B Program, in order to properly assess the quality of the audit conducted.

Response: HHS believes the requirements set forth in the final rule allow for 340B ADR Panels with a wide breadth of experience that will ensure an equitable review and fair outcome. In addition, each 340B ADR Panel will include a non-voting member of OPA who would bring additional 340B Program expertise to the ADR proceedings.

Comment: Several commenters support the 340B ADR Panel's composition as proposed, specifically with respect to limiting the 340B ADR Panel to three members to maintain consistency and transparency across each claim reviewed while asserting that a rotation of members will lead to conflicting decisions and inconsistency in dispute decisions. Some commenters recommend that the final rule establish a fixed pool of seven potential 340B

ADR Panel members who would serve on the pool for a defined term. In addition, the commenters explain that 340B ADR Panel members would not develop expertise in the details of 340B policies if they only occasionally served on the 340B ADR Panel.

Response: HHS disagrees that appointing a permanent board rather than alternating individuals is the best course. The United States Courts of Appeals operate in panels of three and intra-circuit splits are rare. We are concerned that a single permanent panel may be unable to fairly, efficiently, and expeditiously hear and resolve cases.

Comment: Commenters support the inclusion of at least one OPA staff member as an *ex-officio*, non-voting member to ensure adherence to 340B policies and procedures. However, other commenters argue that OPA staff cannot be impartial due to their day-to-day involvement with the 340B Program. These commenters argue that even a non-voting member would exercise too much influence over the voting members, particularly if the voting members serve only part-time on the 340B ADR Panel.

Response: HHS appreciates the comments outlining both support and concern with OPA's participation in the process. HHS believes that participation of an OPA staff member as a non-voting, *ex officio* member is beneficial to the 340B ADR Panel to allow for quick and efficient responses to questions regarding the 340B statute, regulations, and policy and that an OPA staff member would not exercise undue influence over the three voting members. The OPA staff member or members, as the case may be, will be appointed by the Secretary to serve as a non-voting, *ex officio* member or members. *See Federal Election Comm'n v. NRA Political Victory Fund*, 6 F.3d 821 (D.C. Cir. 1993), *cert. dismissed for want of jurisdiction*, 513 U.S. 88 (1994).

Comment: Commenters opposing OPA staff being involved or participating on the 340B ADR Panel suggest that HRSA designate HHS Administrative Law Judges (ALJs) to decide 340B disputes. They argue that ALJs would be in the best position to resolve 340B disputes as ALJs have training to decide administrative law issues correctly, and using an ALJ would ensure an objective evaluation of each dispute by separating the dispute resolution function from HRSA's day-to-day activities and duties.

Response: The involvement of an OPA staff member as a non-voting, *ex officio* has been addressed above. HHS disagrees that ALJ's are best positioned to resolve 340B disputes. The

Department's established cadre of ALJs to resolve disputes between the Department and private entities involving federal funds whether through grants, contracts, or under benefit programs such as Medicare. Here, the 340B ADR Panels are more akin to an arbitration panel focusing on complex commercial arrangements between private actors, where Federal funds may not be directly involved. In this final rule, HHS is establishing 340B ADR Panels, which are uniquely situated to handle the complexities of the 340B Program and related disputes.

Comment: Commenters recommend that the final rule include a provision that allows either party to object to a particular 340B ADR Panel member.

Response: HHS appreciates the comment but believes this is unnecessary as 340B ADR Panel members will be screened for conflicts of interest before reviewing a claim.

(b) Conflicts of interest.

To ensure fairness and objectiveness, HHS proposed that each 340B ADR Panel member be screened prior to reviewing a claim and not be allowed to conduct a review if any conflicts of interest exist. For example, the individual would not review a claim if he or she has a conflict of interest with respect to the parties involved in the claim or the subject matter of the claim. HHS proposed that individuals be screened for conflicts of interest in accordance with U.S. Office of Government Ethics policies and procedures applicable to Federal employees. Conflicts of interest may include the following: (1) Financial interest; (2) family or close relation to a party involved; and (3) current or former business or employment relation to a party. HHS received comments in support of the provision to review for conflicts of interest and is finalizing this section as proposed. Below is a summary of the comments received and HHS' responses.

Comment: Several commenters agree that the 340B ADR Panel members should have demonstrated expertise or familiarity with the 340B Program. These commenters also agree that the 340B ADR Panel members be screened for potential conflicts of interest. Commenters suggest that the final rule include flexibility to expand the 340B ADR Panel beyond the three members to ensure expeditious review of complex 340B claims.

Response: HHS appreciates the comments regarding the expansion of 340B ADR Panel members; however, it does not believe adding more members would expedite the review process.

(c) Duties of the 340B ADR Panel.

HHS proposed that once the 340B ADR Panel receives a claim, the 340B ADR Panel would consider all documentation provided by the parties and may request additional information or clarification from any party involved with the claim.

After further consideration, HHS has determined that a 340B ADR Panel reviewing a claim may consult with OPA subject matter experts regarding 340B program requirements, may entertain motions to dismiss pursuant to Rule 12 of the Federal Rules of Civil Procedure, may permit limited discovery, as necessary, may entertain motions for summary judgment (*see* Fed. R. Civ.P. 56), and may hold evidentiary hearings as necessary. The 340B ADR Panel's final agency decision must represent the decision of a majority of the 340B ADR Panel members, but need not be unanimous. The 340B ADR Panel's final agency decision shall be precedential and binding on the parties to the claim. HHS did not receive any comments related to the duties of the 340B ADR Panel. This final rule provides the 340B ADR Panel significant discretion in determining relevant material to consider and the manner to conduct its evaluation.

As with typical administrative hearings, the petitioner in an ADR proceeding would bear the burden of persuasion by a preponderance of the evidence. *See* Administrative Procedure Act, 5 U.S.C. 556(d) ("the proponent of a rule or order shall have the burden of proof."); *Director, OWCP v. Greenwich Collieries*, 512 U.S. 267 (1994).

§ 10.21 Claims

(a) Initiating an action. In the NPRM, HHS proposed deadlines and procedures for filing a claim in § 10.21(f). To address some redundancies, HHS is consolidating and finalizing the requirements for initiating an ADR action in a new paragraph (a) of § 10.21. Correspondingly, the comments received on the proposals in the NPRM regarding deadlines and procedures for filing a claim are addressed here in paragraph (a).

In the NPRM, HHS proposed that covered entities and manufacturers file a claim demonstrating that they satisfy certain threshold requirements and that the party filing a claim must send written notice to the opposing party regarding the claim within 3 business days of submitting the claim and the party must submit confirmation of the opposing party's receipt or acknowledgement of receipt. HHS also proposed that the written notice to the opposing party must include a summary of the documents submitted as part of

the claim. HHS proposed that information will be reviewed that is submitted as part of the claim to verify that the requirements for filing a claim have been met. The initiating party would then be contacted once the claim has been received and may request additional information before accepting a claim for review by the 340B ADR Panel. If HRSA requests additional information, the party filing the claim would have 20 business days of receipt of the request to respond. Claims would not move forward for review by the 340B ADR Panel if a party files a claim for any purpose other than those specified in the statute (*i.e.*, overcharging, duplicate discount, or diversion), or if the alleged violation occurred more than 3 years before the date of filing the claim.

HHS proposed that a determination will be made as to whether all requirements are met and provide written notice to all parties within 20 business days after receiving the claim and any subsequently requested information. If it is determined the claim includes all necessary documentation and meets the requirements for filing a claim, the claim would be forwarded to the 340B ADR Panel for review. Additional information would be provided on the 340B ADR process to all parties at that time, including contact information for requested follow-up communications and an approximate timeframe for the 340B ADR Panel's review.

HHS proposed that if the claim does not move forward for review by the 340B ADR Panel, written notice would be sent to the parties involved that includes the basis for the determination and would advise the party that they may revise and refile the claim if the party had new information to support the alleged statutory violation.

HHS is finalizing these filing requirements with some changes. Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA that satisfies all of the requirements set forth in this section. The parties may voluntarily submit additional information to substantiate a claim. In this final rule, HHS also clarifies that the party filing a claim must mail a copy of its petition, along with any attachments, to the General Counsel or other senior official (*e.g.*, Executive Director) opposing party or legal counsel for the opposing party, if applicable, at its principal place of business by certified mail, return receipt requested, within three days of filing the

claim with HRSA. HHS intends for the 340B ADR Panel to have wide latitude to define the proper course of conduct, scope of the process, and any additional instructions necessary or desirable for the ADR proceedings. HHS underscores that the 340B ADR Panel may in its sole judgment request additional information from the parties to ensure that it will be able to conduct a fair, efficient, and expeditious review of a claim. Our summary of the comments and responses follow.

Comment: Some commenters request that just as covered entities have advance notice of potential claims due to a prior audit, manufacturers should also know about a potential covered entity's claim so that the parties can make good faith efforts to resolve the claim. These commenters explain that such an early notification requirement for covered entities would reinforce HHS' efforts to limit the ADR process to disputes that cannot be resolved informally and would be consistent with the requirement suggested earlier in this letter that any claim (whether asserted by a manufacturer or covered entity) must be accompanied by documentation of prior good faith efforts to resolve the dispute. Advance notification of potential claims and the opportunity to resolve them are crucial. Accordingly, manufacturers should have the same advance notice of potential claims as covered entities that learn of such claims due to a prior audit.

Response: While HHS appreciates the comments regarding advance notification to manufacturers of claims, it does not agree with the assertion that a manufacturer audit constitutes notification of a manufacturer filing an ADR claim. If a manufacturer engages in ADR after an audit of a covered entity, the manufacturer must provide written notice. Further, HHS believes there is already a process in place for good faith negotiations between manufacturers and covered entities that occurs before filing an ADR claim.

Comment: When reviewing the sufficiency of a claim, HHS proposed that HRSA will decide whether a claim will move forward for review. Commenters request that HRSA include an additional safeguard clarifying that the individual or individuals who review the sufficiency of a claim should not be involved further in the process. The 340B ADR Panel should receive the claim (including any supporting documentation and response) as one complete package. That way, the 340B ADR Panel would be able to review the claim as a matter of first impression. The 340B ADR Panel could remain impartial, and would not be prejudiced

by any claims that are initially deemed inadequate or that are further refined through additional documentation.

Response: HHS disagrees that the 340B ADR Panel could not remain impartial or would be prejudiced by claims that are initially deemed inadequate or that are further refined through additional documentation. In any event, HHS anticipates that the 340B ADR Panel will receive a complete package with all of the supporting documentation that is submitted by the parties for ADR review and resolution.

(b) 340B ADR Panel's jurisdiction. In response to comments received as discussed above (General Comments), HHS is finalizing this new paragraph (b), which provides that the 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed \$25,000 or where the equitable relief sought will likely have a value of more than \$25,000 during the twelve-month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.

(c) Claims permitted.

Section 7102 of the Affordable Care Act added section 340B(d)(3) of the PHSA, which instructs the Secretary to establish and implement a binding ADR process to resolve certain 340B Program statutory violations. Section 340B(d)(3)(A) of the PHSA specifies that the ADR process is to be used to resolve: (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 PHSA, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHSA). This includes covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim. Each 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim in a fair, efficient, and expeditious manner.

Comment: Some commenters suggest that the proposed rule's requirement that permits claims by a manufacturer only after it has conducted an audit of

a covered entity pursuant to section 340B(a)(5)(c) of the PHSA is overly burdensome. These commenters claim that in addition to audits being costly and time-consuming, there are instances where an audit of a covered entity is not possible, but a legitimate basis for a dispute exists. For example, a covered entity may reasonably or unreasonably withhold audit information or behave in a manner that would make an audit ineffective.

Response: HHS disagrees that the process for conducting an audit of a covered entity is improperly burdensome. More important, HHS does not have the authority to waive this statutory requirement. Section 340B(d)(3)(B)(iv) of the PHSA states that the ADR process requires "that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity."

Comment: Some commenters recommend that HHS clarify that it is outside of the jurisdiction of the ADR process for a covered entity to pursue claims which challenge a manufacturer's Average Manufacturer Price (AMP) or best price (BP) calculations as a covered entity's claims are limited to the allegation that they were overcharged relative to the statutory 340B ceiling price as calculated using the manufacturer's current "as submitted" AMP and BP data.

Response: Section 340B(d)(3)(A) of the PHSA states, in part, that the ADR process is to resolve claims of alleged 340B overcharges. HHS believes that to do so, the 340B ADR Panel may find it necessary to assess whether the manufacturer's claimed "ceiling price" is in fact accurate. Even though a challenge to the claimed ceiling price is within the 340B ADR Panel's jurisdiction and any potential overcharges that may have resulted from an incorrect ceiling price, a challenge to a manufacturer's AMP or BP calculations is beyond the scope of this jurisdiction.

Comment: A few commenters recommend that HRSA consider allowing the parties the opportunity to voluntarily select mediation, as opposed to arbitration, as a mechanism for resolving disputes. Only after the attempt at mediation proves unsuccessful or if the parties do not agree to mediation, then the process should move to binding arbitration before the 340B ADR Panel.

Response: HHS appreciates the comments regarding the ability of the parties to select mediation as opposed to

arbitration. HHS notes that there is already an informal process in place for good faith negotiations between covered entities and manufacturers to attempt to resolve 340B disputes before pursuing ADR.

(d) Limitations of actions.

In the NPRM, HHS proposed that the covered entity and the manufacturer meet certain requirements for filing an ADR claim set forth in proposed paragraph (d). The proposed requirements would ensure that a claim of the type specified in section 340B(d)(3)(A) of the PHSA is the subject of the dispute.

The Department proposed that covered entities and manufacturers file a written claim, based on the facts available, or that should have been available, within 3 years of the date of the sale at issue in the alleged violation and that any claim not filed within 3 years would be time barred. The proposed requirement that a claim be filed within 3 years is consistent with the record retention expectations for the 340B Program and would ensure that covered entities and manufacturers have access to relevant records needed to review and respond to claims. The party filing the ADR claim would need to submit documents with each claim to verify that the alleged violation is not time barred. This proposed requirement would prevent a party from asserting a claim that is stale.

HHS also proposed that any file, document, or record associated with a claim be maintained by the covered entity or manufacturer until the 340B ADR Panel's final agency decision is issued unless the 340B ADR Panel provides otherwise. HHS received comments both agreeing with and questioning the timeframe proposed. HHS is finalizing this provision of the rule as proposed, with some modifications, to ensure consistency with requirements set forth in 340B PPAs setting record retention for 3 years for both manufacturers and covered entities. Below is a summary of the comments received and HHS' responses.

Comment: While many commenters agree with the effort to establish a timeframe by which the parties should file a claim, many disagree with the proposed 3-year requirement and suggest a period of at least 5 years. Certain commenters urge HHS to extend the document retention period to take into account the length of manufacturer audits and the time it may take to work with manufacturers on potential solutions (e.g., which could include beginning the 3-year period on the date that the required covered entity audit is concluded, or other similar solutions).

Other commenters urge HHS to adopt a different start date based on when a manufacturer restates the 340B ceiling price or when a covered entity discovers that the manufacturer should have restated the 340B ceiling price.

Response: HHS is changing the title of paragraph (d) to "Limitation of Actions" in this final rule. HHS appreciates comments regarding the requisite record retention period. HHS plans to finalize the 3-year period to be consistent with the PPA record retention requirements that apply to both covered entities and manufacturers. However, the three-year time limit would be subject to normal rules governing statutes of limitations that are not jurisdictional, including the doctrine of equitable tolling. See *United States v. Wong*, 575 U.S. 402, No. 13–1074 (2015); *United States v. June*, 575 U.S. 402, No. 13–1075 (2015).

Covered Entity Claims

In the NPRM, HHS proposed that to be eligible for the ADR process, each claim filed by a covered entity must include documents sufficient to demonstrate a covered entity's claim that it has been overcharged by a manufacturer, along with any such documentation as may be requested to evaluate the veracity of the claim. Such documentation may include: (1) A 340B purchasing account invoice which shows the purchase price by national drug code (NDC), less any taxes and fees; (2) the 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim; and (3) documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging. HHS believes that these documents are readily available to a covered entity through the usual course of business and should not be overly burdensome to produce. HHS, however, recognizes that in some cases, a covered entity or manufacturer may not have access to all needed documentation. HHS may also request that a party in need of information provide it with a written summary of attempts to work in good faith to resolve issues with the other party. In cases where documents are essential to a case, but not in the possession of one party and are not provided voluntarily by the other party, the 340B ADR Panel may request the documents and ensure that they become a part of the administrative record and that in most cases, summary judgment would not be entertained where there are outstanding documents in the possession of the party seeking summary judgment but not in the possession of the other party. HHS

received comments recommending additional instructions on how to file claims and the type of information requested, which are addressed below. HHS clarifies in this final rule that notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a covered entity filing a claim described in paragraph (c)(1) of this section must provide documents sufficient to demonstrate in its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by the 340B ADR Panel.

Comment: Some commenters recommend that HHS should separate covered entity documentation requirements for the different types of illustrative overcharge claims: (1) Claims that the initial purchase price of a drug purchased by the covered entity exceeded the ceiling price at that time; and (2) claims that the purchase price of a drug should have been adjusted downward later and a refund should have been issued at a specified later point in time, but was not issued within the time period required under HRSA's yet-to-be-developed refund procedure.

Response: HHS disagrees and believes the documentation requirements set forth in this final rule will provide, in most cases, the necessary information to ascertain the type of overcharge a covered entity is alleging in its claim. Where that is not the case, the petitioner would be entitled to limited discovery, in the case of a covered entity, or an opportunity to make an information request to the 340B ADR Panel, in the case of a manufacturer.

Comment: Commenters object to the requirement that covered entities would need to submit 340B ceiling price information when initiating a claim. According to those commenters, the proposed rule did not consider that covered entities do not have access to 340B ceiling prices, and this information is central to proving that a manufacturer overcharged for a drug. These commenters suggest that HRSA fast-track the development of the ceiling price system that would ensure a level playing field in the ADR process.

Response: HHS has acted to ensure that covered entities have access to the 340B ceiling price, through its launch of the pricing component of the 340B Office of Pharmacy Affairs Information System in January 2019. Every active covered entity has access to the pricing component of 340B OPAIS and can view the prices of all active National Drug Codes (NDC) in the 340B Program. A covered entity's authorizing official and primary contact have secure access through an account and two-factor

authentication. A manufacturer's authorizing official and primary contact also have access to this secure, online system to view the prices of their company's NDCs.

Manufacturer Claims

In the NPRM, HHS proposed that, to be eligible for the 340B ADR process, each manufacturer claim must include documents sufficient to demonstrate that a covered entity has violated the prohibition on diversion or duplicate discount. After receiving such a claim, HRSA may request the following documentation for an initial screening of the claim: (1) A final audit report to indicate that the manufacturer audited the covered entity for compliance with the prohibition on diversion (section 340B(a)(5)(B) of the PHSA) or duplicate discounts (section 340B(a)(5)(A) of the PHSA), and (2) the covered entity's written response to the manufacturer's audit finding(s). HRSA may also request that the manufacturer submit a written summary of attempts to work in good faith to resolve the claim with the covered entity. In this final rule, HHS clarifies that it is the 340B ADR Panel that is reviewing a claim that is responsible for making a request for documents or other information from a party, and not HRSA. We further note that notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a manufacturer filing a claim under paragraph (c)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion or duplicate discount, along with any such documentation as may be requested by the 340B ADR Panel.

Comment: Commenters express concern that the causes of actions for manufacturers to file a claim are limited to two instances (diversion and duplicate discounts) and recommend that they be broadened to include other legitimate claims, particularly for other unforeseen examples that may emerge. The commenters recommend an inclusion of "catch-all" language that would allow the 340B ADR Panel to accept other legitimate claims, such as a dispute of the covered entity's eligibility that led the manufacturer to grant the 340B ceiling price, or a dispute concerning the dollar amount attributable to a violation.

Response: HHS agrees that in adjudicating claims of duplicate discounts and diversion, it may be necessary for a 340B ADR Panel to address issues such as covered entity eligibility in making its decisions. HHS is clarifying in this final rule that a 340B ADR Panel's review of diversion and

duplicate discounts may include a review of issues such as whether an individual does not qualify as a patient for 340B Program purposes and claims that a covered entity is not eligible for the 340B Program. These issues, although they may appear ancillary, would be entertained because they may determine the outcome of any claim by the manufacturer that the covered entity has engaged in diversion.

Comment: Commenters recommend that HHS exclude specific types of allegations involving duplicate discounts, including the following: (1) The allegation involves duplicate discounts on claims submitted to Medicaid managed care organizations (MCOs); (2) the covered entity incorrectly elected Medicaid carve-out status on the OPA database or failed to include state-mandated modifiers on its claims, but the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity; and (3) a covered entity has correctly listed its carve-in status on the OPA database and has included state-mandated modifiers on its claims, or otherwise followed state requirements to identify 340B drugs, but the state Medicaid agency claimed rebates on the 340B drugs purchased by the covered entity nonetheless.

Response: HHS appreciates these comments, and 340B ADR Panels will consider the first and third types of claims listed above as section 340B(d)(3)(B) of the PHSA states that the decision-making body or official shall be responsible for considering manufacturer duplicate discount claims (violations of section 340B(a)(5)(A) of the PHSA). 340B ADR Panels will not consider claims where the covered entity incorrectly elected Medicaid carve-out status on the OPA database or failed to include state-mandated modifiers on its claims, but the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity, as manufacturers would have not demonstrated that the drugs at issue were subject to duplicate discounts under the Medicaid Drug Rebate and the 340B Programs.

(e) Combining claims.

In the NPRM, HHS proposed that, if requested, covered entities or manufacturers may be permitted to combine their individual claims. Section 340B(d)(3)(B)(vi) of the PHSA permits "multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding . . ." HHS proposed that for joint claims, the claim must list each covered entity and include

documentation or information from each covered entity demonstrating that the covered entity meets all of the requirements for filing a claim with HHS and that a letter requesting consolidation of claims must also accompany the claim and must document that each covered entity consents to the consolidation of the claims.

Pursuant to section 340B(d)(3)(B)(vi) of the PHSA, joint claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, HHS proposed that the covered entities must be members of the association or the organization representing them and that each covered entity must meet the requirements listed in paragraph (d) for filing a claim. The proposed joint claim must assert overcharging by the same manufacturer for the same drug(s), and the organization or association will be responsible for filing the claim. HHS also proposed requiring that a letter requesting consolidation of claims must accompany the claim and must document that each covered entity consents to the organization or association asserting a claim on its behalf.

Similarly, at the request of two or more manufacturers, section 340B(d)(3)(B)(v) of the PHSA permits the consolidation of claims brought by more than one manufacturer against the same covered entity if consolidation is appropriate and consistent with the statutory goals of fairness and economy of resources. HHS proposed that the claim must list each manufacturer and include documentation or information from each manufacturer demonstrating that the manufacturer meets the requirements listed in paragraph (d) for filing a claim. HHS also proposed that a letter requesting consolidation of claims must be submitted with the claim and must document that each manufacturer consents to the consolidation of the claims. The statutory authority for implementing the 340B ADR process does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests. Therefore, HHS did not propose this option in the NPRM.

With regard to the consolidation of claims by manufacturers against a covered entity, HHS sought specific comment on the grounds under which consolidation would be consistent with the statutory goals of fairness and economy of resources, as required by section 340B(d)(3)(B)(v) of the PHSA. In addition, while HHS proposed, as required by the 340B statute, an ADR

process that allows manufacturers to consolidate claims against a covered entity, we recognized the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS, therefore, sought comment on how manufacturers requesting a consolidated claim against a covered entity could satisfy the audit requirement. HHS received comments regarding the combining of claims for both manufacturers and covered entities. Both covered entities and manufacturers request the same drugs and alleged violations be present when making a request for combining claims and entering into the dispute process. HHS is finalizing this section as proposed as it did not receive specific comments on how to address the operational challenges set forth in the proposed rule and believes the process proposed to be sound, fair, and equitable to both parties. However, it should be noted that consolidation of claims by manufacturers against a single covered entity, or joint claims by multiple covered entities against one manufacturer shall be governed by this section guided by the relevant Rules of the Federal Rules of Civil Procedure (Rules), including Rules that contemplate multiple petitioners. Additionally, joinder, consolidation, and other third-party practice not referenced in this subsection (e) shall be governed by the Rules, as relevant, unless the parties and 340B ADR Panel agree otherwise. Below is a summary of the comments received and HHS' responses.

Comment: For consolidated manufacturer claims, commenters request that HHS should add a requirement that: (1) All manufacturers assert covered entity duplicate discount violations, diversion violations, or both arising out of the same policy or practice by the covered entity; and (2) all manufacturers assert these violations during the same time period. HHS must also recognize manufacturers' right to pursue claims (consolidated or otherwise) through a trade association or other agent of their choice.

Response: HHS disagrees. HHS believes that the above proposal would unnecessarily limit the scope of claims that could be brought against a covered entity, when the 340B statute provides only that the claim be based on a duplicate discount or diversion. The statutory ADR provisions allow 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. Therefore, HHS will not alter the final

rule to permit joint claims by associations representing manufacturers.

Comment: While the proposed rule outlines that covered entities must submit a letter requesting consolidation of claims, some commenters suggest that HHS further require covered entities to provide proof of consent of an organization or association asserting a claim on the covered entities' behalf. These commenters argue that the proposed rule implies that a covered entity would have to request and be granted permission in order to combine claims, which is not consistent with the statute.

Response: Section 340B(d)(3)(vi) allows for the combining of claims by a covered entities and does require proof of consent. HHS has outlined a process for resolving 340B disputes and has given the 340B ADR Panels wide latitude to establish the proper course of conduct and scope of the process including any additional deadlines, procedures, or instructions that may be necessary or desirable for a fair, efficient, and expeditious ADR proceeding.

Comment: Commenters recommend that HHS clarify that multiple covered entities may combine claims as long as they have in common an overcharge allegation relating to at least one of the same NDCs. For example, if one covered entity alleges overcharges against a manufacturer for three NDCs and another covered entity alleges overcharges against the same manufacturer for two out of three of those NDCs (potentially because the second covered entity only purchased two of the three drugs), these commenters suggest that covered entities should be permitted to combine their claims.

Response: Section 10.21(e) allows for the combining of covered entities' overcharge claims against the same manufacturer for the same drug or drugs. The 340B statute does not require that joint claims contain overcharge claims for the identical set of NDCs. Section 340B(d)(3)(B)(vi) states that "multiple covered entities . . . (may) jointly assert claims of claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding[.]"

(f) Responding to a submitted claim.

In the NPRM, HHS proposed that once the parties have been notified that the claim has met the filing requirements (subsection (b) of the NPRM) and will move forward for review by the 340B ADR Panel, the opposing party will have 20 business days to submit a written response to the

allegation to the 340B ADR Panel. The 340B ADR Panel may make subsequent requests for information regarding the claim as needed, and will consider any additional information provided by the named parties involved. However, if an opposing party does not respond to the ADR Panel's request for information or otherwise elects not to participate in the 340B ADR process, the 340B ADR Panel will issue its decision on the claim based on the information submitted in the claim. Commenters raised concerns regarding the lack of detail as it relates to timeframes and recommends set timeframes.

After consideration of the comments received, HHS is finalizing this section with some changes. In this final rule, HHS is extending the timeframe for responding to a claim. After an initiating party (or Petitioner) has received notification from HRSA that its claim will move forward to a 340B ADR Panel for review, the opposing party (or Respondent) will have 30 days to submit a written response to the 340B ADR Panel that may be of the type authorized by Rules 12, 13, or 56 of the Federal Rules of Civil Procedure. The 340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information that it may request. If the opposing party does not respond to the claim from the Petitioner, the 340B ADR Panel may enter a final agency decision by default in favor of the Petitioner. HHS believes that in a proceeding for damages, the Petitioner must still introduce evidence sufficient to support its claim for damages even though the merits have been resolved through default.

Comment: Several commenters raise concerns about the proposed rule's lack of detail regarding the timeframes for the 340B ADR Panel. They suggest that to better ensure predictability of the ADR process, HRSA should establish discreet timeframes for each of the steps in the ADR process for which HRSA is responsible. They explain that identifying these timeframes in the final rule will improve transparency of the process for all parties involved.

Response: HHS disagrees with the assertion that detailed timeframes must be established at this juncture for each step in the ADR process. Flexibility is needed as each dispute will be evaluated on its merits and the documents presented, and some disputes may take longer than others based on the level of complexity. The 340B ADR Panel is empowered to utilize the deadlines set forth in the

Federal Rules of Civil Procedure as necessary.

Comment: Some commenters recommend that HRSA change the period to respond to claims to 60 days as opposed to 20 business days, with potential extensions if needed. These commenters urge HRSA to provide more flexibility, especially as those involved in the process may not have had adequate prior notice of the subject of the claim. The commenters claim that the proposed 20 business day response time frame does not provide manufacturers sufficient time to review the data underlying a claim, assess the factual or legal questions raised by the claim, and prepare a response.

Response: HHS recognizes that there will be instances that require time beyond the stated deadlines. HHS has included in the final rule a provision that the “340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information.”

§ 10.22 Information requests

Pursuant to section 340B(d)(3)(B)(iii) of the PHSA, regulations promulgated by the Secretary for the 340B ADR process will establish procedures by which a covered entity may discover and obtain information and documents from manufacturers and third parties as may be relevant to a claim that the manufacturer has overcharged the covered entity. The NPRM proposed that such covered entity information requests be facilitated by the 340B ADR Panel. HHS proposed that a covered entity must submit a written request for information to the 340B ADR Panel no later than 20 business days after the entity was notified that the claim would move forward for the 340B ADR Panel’s review. The 340B ADR Panel will review the information/document request to ensure that it is reasonable and within the scope of the asserted claim. The 340B ADR Panel will notify the covered entity in writing if its request is deemed as such and permit the covered entity to submit a revised information/document request, if it is not.

In this section, HHS proposed that the 340B ADR Panel will consider relevant factors, such as the scope of the information/document request, whether there are consolidated claims, or the involvement of one or more third parties in distributing drugs on behalf of the manufacturer and that once reviewed, the 340B ADR Panel will submit the information/document request to the

manufacturer, which must respond within 20 business days.

HHS also proposed that the manufacturer must fully respond in writing to the information request and submit its response to the 340B ADR Panel by the stated deadline and that the manufacturer is responsible for obtaining relevant information/documents from wholesalers or other third parties that may facilitate sales or distribution of its drugs to covered entities. HHS proposed that if a manufacturer anticipates it will not be able to fully respond by the deadline, the manufacturer may request one extension in writing within 15 business days. The extension request that is submitted to the 340B ADR Panel must include any available information, the reason why the deadline is not feasible, and outline a proposed timeline for fully responding to the information request. The 340B ADR Panel will review the extension request and notify both the manufacturer and the covered entity in writing as to whether the request for an extension is granted and the date of the new deadline. If a manufacturer does not respond to a request for information, HHS proposed that the 340B ADR Panel will issue its decision on the claim based on the information submitted in the submitted claim package. Many of the commenters recommended changes to the ability of parties to request and receive information during the course of the ADR proceedings including allowing a manufacturer to submit an information request, which was not addressed in the NPRM.

HHS has decided to broaden the scope of this section to include information requests from the 340B ADR Panel. To provide further guidance to the parties involved, HHS has also decided that covered entities’ discovery shall be governed by the Federal Rules of Civil Procedure. While HHS limited the scope of these information requests to covered entities in the NPRM, consistent with the limited discovery requirements of the statute pertaining to covered entities, this final rule allows the 340B ADR Panel to request additional information from a party if deemed necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously. This leaves open the possibility that a drug manufacturer could petition the 340B ADR Panel to request further information from a covered entity. If the 340B ADR Panel determines that such a request would enhance its deliberations, the 340B ADR Panel could make the request to the covered entity. Based on comments received, HHS has also added (c) to this

section to address actions the 340B ADR Panel may take if a party fails to fully respond to the information request.

Comment: Some commenters recommend that a covered entity should be afforded an opportunity to review the manufacturer’s response before crafting and submitting its request for additional information. Once the covered entity has seen the manufacturer’s position, it can better tailor its information request to the dispute, and request only those documents it needs to pursue its overcharge claim. HHS should allow covered entities 30 calendar days from the date on which it receives the manufacturer’s response to submit an information request.

Response: The 340B ADR Panel is given wide latitude to determine the proper course of conduct in an ADR proceeding and may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings including instructions pertaining to submission of additional information.

Comment: Some commenters recommend that HHS allow manufacturers to submit information requests regarding disputes just as covered entities can. They argue that manufacturers must have the right to submit information requests in the event that they are unable to obtain all relevant information during an audit or new information relevant to the dispute arises.

Response: Section 340B(d)(3)(B)(iii) of the PHSA expressly authorizes covered entities to “discover and obtain such information and documents from manufacturers” as may be relevant to their filed claims. As the statute does not provide similar authorization for manufacturer document requests, HHS declines to alter the final rule in this area. However, to the extent that a manufacturer believes an information request to a covered entity is necessary for the 340B ADR Panel’s deliberations, it may petition the 340B ADR Panel to make the request to the covered entity.

Comment: The proposed rule allows 340B covered entities to request information relevant to their claim from manufacturers and third parties; however, commenters argue that the proposed rule does not hold a manufacturer accountable for actually producing the requested information. These commenters recommend that if a manufacturer fails to comply with the information request, the 340B ADR panel should rely on the information contained in the original submitted claim and issue a finding in favor of the covered entity due to lack of

information obtained from the manufacturer.

Response: HHS agrees. Section 10.22(c) has been added to address sanction for failure to respond or failure to respond fully to an information request.

Comment: Some commenters urge HHS to consider that the filing party should be required to share with the responding party all of the documents it has filed with HRSA to ensure that the ADR process benefits from the full and open exchange of information. These commenters explain that full disclosure of the filing documents also might prevent some parties from seeking judicial review of 340B ADR Panel final agency decisions. A party dissatisfied with a 340B ADR Panel final agency decision might be more prone to seek judicial review if it has not had the opportunity to review the evidence on which the 340B ADR Panel relied.

Response: HHS agrees. Section 10.22(b) allows the 340B ADR Panel to take into account the possibility that a manufacturer would need additional information in order to respond appropriately to the dispute in question. While it is expected that a manufacturer would have all the information needed through its audit of a covered entity, this section would allow the 340B ADR Panel to make an information request of any party and to share that information with the opposing party if necessary for the fair, efficient, and expeditious conduct of the ADR proceeding.

§ 10.23 Conduct of the ADR proceeding

HHS has added this section to address comments received regarding the needs of the parties as it relates to the conduct of these proceedings. HHS recognizes there are instances, sometimes beyond the control of the parties that warrant flexibility in how it conducts the proceedings and that may warrant additional instructions. This new section will allow for ADR proceedings to take place in the most fair, efficient, and expeditious manner, which could include video conference, in-person, or through other means. It will also allow the 340B ADR Panel discretion in admitting evidence and testimony during the course of a proceeding as well as provide the 340B ADR Panel with the additional flexibility to provide instructions during the proceeding in order to achieve a fair, efficient, and expeditious review. HHS has also decided that unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Civil Procedure (https://www.uscourts.gov/sites/default/files/federal_rules_of_civil_procedure_-_dec_1_2019_0.pdf)

and the Federal Rules of Evidence (https://www.uscourts.gov/sites/default/files/federal_rules_of_evidence_-_dec_1_2019_0.pdf), to the extent applicable, shall apply to proceedings. HHS has summarized and responded to comments received below.

Comment: Some commenters recommend HHS provide the parties with the opportunity to present evidence live in front of the 340B ADR Panel. The commenters explain that relying exclusively on a paper record could potentially lengthen the ADR process if the documents were interpreted differently by the parties and further clarification were needed before proceeding. A live process could allow for questions arising from paper records to be answered efficiently. These commenters explain that by enabling parties to present evidence and respond to questions from the 340B ADR Panel orally, HHS can provide a forum where information is shared among affected parties.

Response: HHS agrees that there may be instances where portions of the ADR may need to be conducted by telephone or video conference, or through other means. Therefore, HHS has clarified the means by which the process may be conducted in this final rule.

Comment: Several commenters suggest that HHS detail in the final rule how it plans to establish safeguards and protections to ensure that proprietary information submitted on behalf of either party is kept confidential by the 340B ADR Panel in order to minimize risk of harm.

Response: HHS appreciates the suggestion on addressing safeguards to ensure confidentiality and minimize disclosure risk. HHS believes adequate safeguards are in place to ensure that confidential, proprietary information is not disclosed.

§ 10.24 Final agency decision

In the NPRM, HHS proposed that the 340B ADR Panel would review the documents submitted by the parties to determine if there is adequate support to conclude that a violation occurred. HHS proposed a process whereby the 340B ADR Panel's draft agency decision letter would be sent to all parties, and the parties involved would have 20 business days to respond to the 340B ADR Panel. HHS sought specific comments on this process and whether this proposed process would facilitate or hinder the fair, efficient, and timely resolution of claims.

HHS also proposed that once the parties have reviewed and submitted comments in response to the draft agency decision letter, the 340B ADR

Panel would prepare and submit its final agency decision letter to all parties in the dispute. In issuing a final agency decision letter, the 340B ADR Panel will be operating under an express, written delegation of authority from the Secretary of HHS to make such final agency decisions. This Regulation constitutes that *ex officio* delegation. The final agency decision made by the 340B ADR Panel would conclude the administrative resolution process; however, HHS proposed that the final agency decision letter also be submitted to HRSA to provide remedies and enforcement of determinations through mechanisms and sanctions as described section 340B(d)(1)(B) or (d)(2)(B), as appropriate.

HHS proposed that the 340B ADR Panel's final agency decision letter would be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction, acting under Section 10 of the Administrative Procedure Act (5 U.S.C. 706), and in accordance with section 340B(d)(3)(C) of the PHSA. HHS is finalizing the rule as proposed with modifications. First, in this final rule, HHS is replacing "HSB" with "HRSA Administrator," in order to elevate the responsibilities conducted under the ADR process. Second, this final rule adds section 10.24(d), which states the final agency decision will be precedential and binding on the parties. Lastly, given that HHS has added procedural protections and more clearly defined the ADR process, HHS does not feel that it is necessary to provide the parties an opportunity to respond to a draft agency decision.

Comment: Commenters explain that the proposed rule does not incorporate an appeals process and recommend that an appeals process be made available to all parties. These commenters also suggest that HHS publish all findings and decisions by the 340B ADR Panel to enable all parties to be informed and more compliant. These commenters suggest that publication of the ADR's decisions will also prevent inconsistent decisions and unsupported rulings.

Response: HHS agrees, as these ADR decisions will be precedential. Therefore, HHS will ensure that the final agency decisions are publically available (e.g., by publication on the HRSA website). HHS does not believe that an appeals process is necessary given that an aggrieved party has a right to seek judicial review under section 10 of the Administrative Procedure Act (5 U.S.C. 706).

Comment: When deciding disputes, some commenters suggest that the 340B ADR Panel use a "preponderance of the

evidence” standard. Once the 340B ADR Panel reaches its decision, HHS should mandate the issuance of a summary that includes a transparent analysis of the reasons for the decision, without disclosing any proprietary or otherwise confidential information. HHS should also recognize that the 340B ADR Panel decision is binding on the parties involved in the dispute (unless otherwise overturned by a court acting pursuant to the Administrative Procedure Act), but is not binding on third parties.

Response: HHS agrees, as the final agency decisions will be precedential and binding on the named parties in the dispute. As such, HHS will ensure that all final agency decisions are publically available. HHS also agrees that the 340B ADR Panel use a “preponderance of the evidence” standard when making its determinations and has adjusted the final rule accordingly in section § 10.24(a).

Comment: Commenters suggest that HHS clarify that it will not impose sanctions on a party as a result of a 340B ADR Panel decision until the party has been given an opportunity to complete corrective action with respect to the 340B ADR Panel’s findings.

Response: Section 340B(d)(3)(A) includes a requirement that the ADR process include the “appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B) (of 340B(d))” Therefore, when appropriate, the 340B ADR Panel may make recommendations to HRSA for sanctions, including referrals to the HHS Office of Inspector General for its consideration of civil monetary penalties, as appropriate. Whether sanctions or remedial action is appropriate will be dependent on the type of violation that occurred.

Comment: A few commenters were concerned that the proposed rule does not address how HRSA will enforce the findings of the 340B ADR panel or any underlying manufacturer audit. These commenters explain that the NPRM does not address if, or how, HRSA will go about enforcing the findings of the 340B ADR Panel or the underlying manufacturer audits. For example, if the 340B ADR Panel’s final agency decision requires covered entities to make any applicable repayments to manufacturers, timeframes should be established around such payment and, at a minimum, HRSA should permit affected manufacturers to withhold future discounts until HRSA, the manufacturer, and the covered entity

have resolved the findings noted in the manufacturer’s audits.

Response: Wide varieties of covered entities participate in the 340B Program, from small, rural health care facilities to large academic medical centers. HHS expects that the 340B ADR Panel will review violations ranging from minor and inadvertent to systematic and intentional. Given the wide variety of 340B Program participants and varying types of violations, HHS believes that the form of enforcement should be left open to permit HHS maximum flexibility in determining what is appropriate given the specific facts of each situation.

Comment: Some commenters urge HRSA to incorporate a timeframe for the issuance of 340B ADR Panel’s final agency decisions. They recommend that the final agency decision should be issued 30 business days from the date when the submission of all requested information is complete and in complex cases, the process should be extended 15 business days, so that the final agency decision would be issued within 45 business days. The commenters argue that this approach would be consistent with Medicare where the deadline for initial determination decisions is 45 days and for redetermination decisions is 60 days.

Response: HHS disagrees. The 340B ADR Panel has been given wide latitude to determine the scope of the process and should not be held to a timeframe that does not allow for thorough and thoughtful consideration of all materials presented.

Comment: Some commenters state that the ADR process should be governed by the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* They explain that a reviewing court should be authorized to hold unlawful and set aside ADR Panel decisions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or unsupported by substantial evidence. The commenters request that HRSA clarify that the APA will apply to the ADR Process, including judicial review.

Response: The form of judicial review for 340B ADR Panel decisions is beyond the scope of this final rule.

Comment: Commenters support the proposal that HRSA has the sole authority to enforce the 340B ADR Panel’s decision. The commenters explain that the 340B ADR Panel may not fully appreciate HRSA’s historical enforcement practices, and the NPRM will ensure that HRSA retains responsibility for compliance with 340B statutory requirements.

Response: While HHS appreciates the support of HRSA having sole enforcement authority, this final rule contemplates and allows HRSA to take appropriate action, which could include enforcement action or referral to another HHS Operating Division or to another Federal agency. For example, if the 340B ADR Panel’s final agency decision is that an overcharge did occur, HRSA could recommend the OIG review the overcharge to determine if it was knowing and intentional and should be assessed a civil monetary penalty.

Comment: Commenters express concern that HRSA should not use its enforcement authority to transform a 340B ADR Panel decision into a broad 340B policy decision. The commenters explain that enforcement should be limited to the parties to the ADR proceeding. 340B ADR Panel decisions should not have general applicability.

Response: As set forth in section 10.23(b)(2), 340B ADR Panel decisions will be final agency decisions, binding on the parties, and precedential.

III. 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 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, 13563, and 13771

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, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy,

productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB).

HHS does not believe that this final rule will have an economic impact of \$100 million or more in any 1 year, and is therefore not designated as an “economically significant” final rule under section 3(f)(1) of Executive Order 12866. This rule creates a framework for the Department 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 introduction of an ADR process to result in significant economic impacts.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is not expected to be an E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require 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, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a three percent impact on at least five percent of small entities.

The rule 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 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of the final rule on the industry as a whole, the data necessary to project changes for 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. The 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 \$7.5 million to \$38.5 million. Currently, in 2020., 12,500 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country.

The final rule introduces an ADR mechanism to review manufacturer claims that covered entities have violated certain statutory obligations and covered entities claims that they have been overcharged for covered outpatient drugs by manufacturers. The documentation required as part of this administrative process are 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 sufficiently 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.

HHS believes the ADR process will provide a cost-effective option for resolving claims that would otherwise remain unresolved or prompt litigation. The final rule provides an option to 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 will 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, it is not preparing an impact analysis for the purposes of the RFA. HHS estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 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 2020, that threshold is approximately \$156 million. HHS does not expect this rule to exceed the \$156 million threshold.

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 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.” This rule would 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.

Paperwork Reduction Act

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. Given the small number of requests for the informal dispute resolution process, HHS asserted in the proposed rule that the ADR process would not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. HHS solicited comments on the accuracy of this statement. No comments were received challenging the accuracy of this statement. Moreover, HHS believes that the 340B ADR Process is exempt from

the Paperwork Reduction Act requirements as it 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).

Dated: November 25, 2020.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Dated: December 9, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 10

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

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), as amended.

■ 2. Amend § 10.3 by adding in alphabetical order definitions for “Administrative Dispute Resolution (ADR) Process”, “Administrative Dispute Resolution Panel (340B ADR Panel)”, “Claim”, “Consolidated claim”, and “Joint claim” to read as follows:

§ 10.3 Definitions.

* * * * *

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 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 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 Department that, acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision for a claim brought under the ADR Process.

* * * * *

Claim means a written allegation filed by or on behalf of a covered entity or by a manufacturer for resolution under the 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’ (or their membership organizations’ or associations’) claims against the same manufacturer for the same drug or drugs.

* * * * *

■ 2. Add subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.

10.20 Administrative Dispute Resolution Panel.

10.21 Claims.

10.22 Information requests.

10.23 Conduct of the ADR proceeding.

10.24 Final agency decision.

§ 10.20 Administrative Dispute Resolution Panel.

The Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the Office of the General Counsel (OGC) from which Administrative Dispute Resolution Panels (340B ADR Panel) of three members shall be selected by the HRSA Administrator (to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, and to make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers). There shall also be one ex-officio, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA). HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.

(a) *Members of the 340B ADR Panel.*

(1) For each case, the HRSA Administrator shall:

(i) Select from the Board three voting members, one from each of the three HHS operating or staff divisions involved (*i.e.*, CMS, HRSA, OGC) to form a 340B ADR Panel.

(ii) Remove an individual from a 340B ADR Panel for cause; and

(iii) Appoint replacement members from the Board should an individual be unable to complete his or her duties on a 340B ADR Panel.

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

(b) *Conflicts of interest.* All individuals who serve on a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. Conflicts of interest may include:

(1) Financial interest in a party involved, a subsidiary of a party involved, or in the claim before a 340B ADR Panel;

(2) Family or close relation to a party involved; and

(3) Current or former business or employment relation to a party.

(c) *Duties of the 340B ADR Panel.* The 340B ADR Panel will adjudicate each claim using the procedures described §§ 10.21, 10.22, 10.23, and 10.24.

(1) Review and evaluate documents and other information submitted by covered entities and manufacturers;

(2) Request additional information or clarification of an issue from any or all parties to make a final agency decision;

(3) When necessary, evaluate a claim in a separate session from the parties involved;

(4) Consult with OPA and the parties, as appropriate and necessary, regarding any inquiries or concerns while reviewing a claim; and

(5) Issue a final agency decision on each claim and submit the written decision to the parties, and to HRSA for appropriate action.

§ 10.21 Claims.

(a) *Initiating an action.* Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA and mailing a copy of the petition with any attachments to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim. The petition should satisfy the pleading requirements of Rules 8, 10, and 11 of the Federal Rules of Civil Procedure, including setting forth the factual basis for invoking the 340B ADR Panel’s jurisdiction. A claim must include all of the requirements in paragraph (d) of this section. Additional information to substantiate a claim may be submitted.

(b) *340B ADR Panel’s jurisdiction.* The 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed

\$25,000 or where the equitable relief sought will likely have a value of more than \$25,000 during the twelve-month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.

(c) *Claims permitted.* The ADR process is 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 PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA regarding the duplicate discount prohibition, or section 340B(a)(5)(B) of the PHSA regarding the diversion prohibition, including claims that an individual does not qualify as a patient for 340B Program purposes and claims that a covered entity is not eligible for the 340B Program.

(d) *Limitation of actions.* (1) A covered entity or manufacturer must file a written claim for administrative dispute resolution with HRSA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of the ADR process must be maintained by the covered entity and manufacturer until the final agency decision is issued by the 340B ADR Panel.

(2) Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a covered entity filing a claim described in paragraph (c)(1) of this section must provide documents sufficient to demonstrate its claim that it has been overcharged by a manufacturer, along with any such other documentation as may be requested by the 340B ADR Panel.

(3) Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a manufacturer filing a claim under paragraph (c)(2) of this section must provide documents sufficient to demonstrate its claim that a covered entity has violated the prohibition on diversion or duplicate discount, along with any such documentation as may be requested by the 340B ADR Panel.

(e) *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 that could file a claim against the manufacturer consents to the jointly filed claim, including submission of the required

documentation, described in paragraph (d) of this section.

(2) An association or organization may file claims of overcharges by the same manufacturer for the same drug or drugs on behalf of multiple covered entities if each covered entity represented could file a claim against the manufacturer, is a member of the association or organization, meets the requirements described in paragraph (d) of this section, including submission of the required documentation, and each covered entity has agreed to representation by the association or organization on its behalf.

(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 filing of the consolidated claim, meets the requirements described in paragraph (d) of this section for that claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of sources. The 340B ADR Panel will not permit consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests.

(4) Joinder, consolidation, and other third-party practice not referenced in this paragraph (e) shall be governed by the Federal Rules of Civil Procedure, as relevant, unless the parties and 340B ADR Panel agree otherwise.

(f) *Responding to a submitted claim.* Upon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56. The 340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information. If an opposing party does not respond to the petition, the 340B ADR Panel may enter a final agency decision by default in favor of the Petitioner. In a proceeding for damages, the Petitioner must still introduce evidence sufficient to support its claim for damages even though the merits have been resolved through default.

§ 10.22 Information requests.

(a) *Discovery.* The 340B ADR Panel may permit a covered entity limited discovery to obtain such information and documents as may be relevant to demonstrate the merits of a claim. Such discovery shall be governed, to the

extent applicable, by the Federal Rules of Civil Procedure.

(b) 340B ADR Panel information requests. Taking into account any party's request for further information, the 340B ADR Panel may request additional information from either party.

(c) *Failure to respond to information requests.* 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 take the following actions, including:

(1) Holding facts to have been established in the proceeding;

(2) Precluding a party from presenting or contesting a particular issue;

(3) Excluding evidence; or

(4) Judgment in the proceeding or dismissal of proceeding.

§ 10.23 Conduct of the ADR proceeding.

(a) The 340B ADR Panel will determine, in its own discretion, the most efficient and practical form of the ADR proceeding. Unless the matter is resolved through a motion to dismiss or summary judgment under Rule 56, the 340B ADR Panel shall conduct an evidentiary hearing when there are material facts in dispute. The ADR proceeding may be conducted by video conference, in-person, or through other means.

(b) The 340B ADR Panel will determine the proper course of conduct in an ADR proceeding. Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Civil Procedure, to the extent applicable, shall govern the proceedings.

(c) Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Evidence shall apply to the proceedings.

(d) The 340B ADR Panel may issue additional instructions or guidance as may be necessary or desirable governing the conduct of ADR proceedings.

§ 10.24 Final agency decision.

(a) The 340B ADR Panel will review the evidence submitted by the parties and determine if the preponderance of the evidence supports the conclusion that a violation as described in § 10.21(c)(1) or (2) has occurred.

(b) The 340B ADR Panel will prepare an agency decision based on its review and evaluation of the evidence submitted by the parties, including documents provided as required in § 10.21(d), information requests in support of a claim, and responses to a claim.

(c) The agency decision will represent the decision of a majority of the 340B

ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(d) The agency decision constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction.

(e) The 340B ADR Panel will submit the final agency decision to all parties, and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 26

RIN No. 2105-AE92

Disadvantaged Business Enterprise Program; Inflationary Adjustment

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The United States Department of Transportation (DOT) is amending the small business size limit under its Disadvantaged Business Enterprise (DBE) program, also known as the gross receipts cap, to ensure that small businesses may continue to participate in the Department's DBE program after taking inflation into account. This final rule provides an inflation adjustment to the size limit on small businesses participating in the DBE program and implements a statutory change to the size standard pursuant to the Federal Aviation Administration (FAA) Authorization Act of 2018.

DATES: This rule is effective January 13, 2021.

FOR FURTHER INFORMATION CONTACT: Chris Cialeo, Office of the General Counsel (C-10), U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366-8789, christopher.cialeo@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The DBE program for DOT-assisted contracts is a statutory program intended to ensure nondiscriminatory contracting opportunities for small business concerns owned and controlled by socially and economically disadvantaged individuals in the Department's highway, mass transit, and

airport financial assistance programs. The statutory provision governing the DBE program in the highway and mass transit financial assistance programs is section 1101(b) of the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114-94, Dec. 4, 2015), and the statutory provision governing the DBE program as it relates to airport financial assistance programs is 49 U.S.C. 47113.

Under the Department's existing rules, to qualify as an eligible DBE firm, a firm's average annual gross receipts over the preceding three fiscal years cannot exceed a DOT-specific gross receipts cap. On April 2, 2007, in response to direction in the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59, August 10, 2005) to adjust this gross receipts cap annually for inflation, the Department published a final rule adjusting the gross receipts cap for its DBE program in 49 CFR part 26 from \$19,570,000 to \$20,410,000 (72 FR 15614). On April 3, 2009, the Department published another final rule adjusting the gross receipts cap for its DBE program from \$20,410,000 to \$22,410,000 (74 FR 15222). The Moving Ahead for Progress in the 21st Century (MAP-21) Act (Pub. L. 112-141, July 6, 2012) maintained the \$22,410,000 gross receipts cap amount set by the April 2009 final rule. On October 2, 2014, the Department issued a final rule that increased the gross receipts cap to \$23,980,000 (79 FR 59565). In 2015, The FAST Act maintained the \$23,980,000 gross receipts cap set by the October 2014 rule. Section 1101(b)(2)(A)(ii) of the FAST Act reaffirms the Secretary of Transportation's requirement to adjust this amount annually for inflation. Accordingly, this final rule adjusts the gross receipts cap for inflation by increasing the gross receipts cap applicable to firms for purposes of Federal Highway Administration (FHWA)—and Federal Transit Administration (FTA)—assisted work to \$26,290,000.

The Federal Aviation Administration (FAA) Reauthorization Act of 2018 (Pub. L. 115-254) removed the gross receipts cap for purposes of eligibility for FAA-assisted work. Therefore, the revised rule reflects that the gross receipts cap does not apply for purposes of determining a firm's eligibility for FAA-assisted work.

II. Business Size Standards for the DBE Program

To make an inflation adjustment to the gross receipts figures, DOT uses the Department of Commerce's price index for State and local consumption

expenditures (gross output of general government). The Bureau of Economic Analysis at the Department of Commerce prepares constant dollar estimates of State and local government purchases of goods and services by deflating current dollar estimates by suitable price indexes. These indexes include purchases of durable and non-durable goods, and other services. Using these price deflators enables the Department to adjust dollar figures for inflation from past years.

The current inflation rate on purchases by State and local governments is calculated by dividing the price deflator for the fourth quarter of 2019 (116.030) by 2015's fourth quarter price deflator (105.829). See Bureau of Economic Analysis Table 3.10.4, Price Indexes for Government Consumption Expenditures and General Government Gross Output (January 30, 2020). The result of the calculation is 1.09639, which represents an inflation rate of 10.9639% from the fourth quarter of 2015. Multiplying the FAST Act's \$23,980,000 standard for disadvantaged business enterprises in DOT financial assistance programs by 1.09639 equals \$26,291,465, which will be rounded off to the nearest \$10,000 is \$26,290,000. Therefore, if a firm's gross receipts averaged over the firm's previous three fiscal years exceeds \$26,290,000, it exceeds the small business size limit for participation in FHWA and FTA-assisted work under the Department's DBE program. The Department will adjust this amount for inflation on an annual basis. In subsequent years, the revised amount will be published on the Departmental Office of Civil Rights' website.

Regulatory Analyses and Notices

Under the Administrative Procedure Act (5 U.S.C. 553(b)(B)), an agency may waive notice and comment procedures if it finds good cause that such procedures are impracticable, unnecessary, or contrary to the public interest. The Department finds that notice and comment for this rule is unnecessary because it only relates to ministerial updates of business size standards and gross receipts caps to account for inflation, which does not change the standards or caps in real dollar terms. Accordingly, the Department finds good cause under 5 U.S.C. 553(b)(B) to waive notice and opportunity for public comment.