827	Excepted Quantity Provision Package.
828	Ground Only Hazardous Materials.
829	ID8000 Consumer Commodity Package.
830	Lighters Package.
831	LTD QTY Ground Package.
832	Small Quantity Provision Package.

ESCs Domestic & APO/FPO/DPO (Requesting Label From USPS APIs or WebTools) (Required)

The following is an ESC that must be provided if requesting a USPS created label from USPS APIs or WebTools for a shipment containing hazardous materials.

857	Hazardous Materials.

ESCs International (Required)

The following is a list of ESCs required for use in the mailers Shipping Service File, when tendering dangerous goods internationally with the Postal Service.

813	Class 7—Radioactive Materials Package.
820	Class 9—Lithium batteries, unmarked package.
826	Division 6.2 Hazardous Materials.

* * * * *

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–26072 Filed 11–25–22; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

[Docket No. 2021–0004]

RIN 0906–AB28

340B Drug Pricing Program; Administrative Dispute Resolution

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Health Resources and Services Administration implements section 340B of the Public Health Service (PHS) Act, which is referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' This notice of proposed rulemaking (NPRM) proposes to revise the current 340B administrative dispute resolution (ADR) final rule (Dec. 14, 2020) with a new process and solicits comment on the proposal.

DATES: Written comments and related material to this proposed rule must be received on or before January 30, 2023.

ADDRESSES: You may submit written comments electronically by the following method: *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions on the website for submitting comments. Include the HHS Docket No. ''HRSA–2021–000X'' in your comments. All comments received will be posted without change to *https://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

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

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Section 340B of the PHS Act entitled ''Limitation on Prices of Drugs Purchased by Covered Entities,'' was created under section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' and codified at 42 U.S.C. 256b. The 340B Program is intended to enable covered entities ''to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' H.R. Rep. No. 102–384(II), at 12 (1992). The Secretary of Health and Human Services (Secretary) delegated the authority to establish and administer the 340B Program to the HRSA Administrator. The Office of Pharmacy Affairs (OPA), within HRSA, oversees the 340B Program. Eligible covered entity types are defined in Section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing agreements (PPAs) with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act ''[i]n order for payment to be available under section 1903(a) or under part B of title XVIII of the Social Security Act for covered outpatient drugs of a manufacturer.'' When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 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 PHS Act, which requires the Secretary to promulgate regulations establishing and implementing a binding ADR process for certain disputes arising under the 340B Program. Under the 340B statute, 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 PHS Act, 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, as outlined in statute. The 340B ADR process should be reserved for the above-stated statutory areas where the 340B ADR Panel can apply 340B law and policy to the case-specific factual circumstances at issue in a dispute.

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

In 2010, HHS issued an advanced notice of proposed rulemaking 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 and received 30 non-duplicative comments. On December 14, 2020, HHS issued a final rule (85 FR 80632, Dec. 14, 2020, herein referred to as the 2020 final rule), which was codified at 42 CFR 10.20 through 10.24. HRSA began implementing the 2020 final rule when it became effective on January 13, 2021, by accepting claims and establishing the ADR process. However, as outlined in the *Justification for proposing to revise the ADR process established by the 2020 final rule* section below, HRSA has encountered policy and operational challenges with implementation of the 2020 final rule. Therefore, HHS is proposing to revise the ADR process set forth in the 2020 final rule and is soliciting comment on this new approach. HHS proposes that the ADR process set forth in this NPRM, if finalized, would revise the ADR process established by the 2020 final rule.

HHS proposes that upon finalization of this NPRM, any claims that are in process and have been submitted pursuant to the 2020 final rule would be automatically transferred to the new process under this proposed rule. HHS is soliciting comment on this proposal, including whether extensions should be granted for pending claims, or whether pending claims should instead be resubmitted by the party that filed the claim to OPA.

II. Discussion of Proposed Rule

Justification for Proposing To Revise the ADR Process Established by the 2020 Final Rule

HHS is soliciting comment on its proposal to revise the current ADR process by modifying the regulations issued under the 2020 final rule. The 2020 final rule poses policy and operational challenges that are described in this section. First, HHS is proposing that the 340B ADR process be revised to be more accessible, administratively feasible and timely. The 340B statute at section 340B(d)(3)(B)(ii) of the PHS Act, requires the establishment of deadlines and procedures that ensure that claims are resolved fairly, efficiently, and expeditiously. This ADR process should be a more expeditious and less formal process for parties to resolve disputes. An ADR process governed by the Federal Rules of Evidence (FRE) and Civil Procedure (FRCP), as envisioned in the 2020 final rule, does not advance these goals. For example, potential petitioners, many of whom are safety net providers in under-resourced communities, may lack the resources to access ADR even if it would be in their best interest to do so. In addition, reliance on the FRE and FRCP could create unnecessary delays in what is intended to be a timely decision-making process. Finally, it is challenging to assign ADR Panel members with expertise in the FRE or FRCP. In implementing the 2020 final rule, HRSA received questions from stakeholders about the formality of the ADR process and the legal requirements under the FRCP for submitting a petition and accompanying documents, *e.g.,* whether the filings submitted must conform to the FRCP, which added to the complexity and difficulty of the ADR process.

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

Second, the 2020 final rule states that the Secretary of HHS shall establish a 340B ADR Board that consists of at least six members appointed by the Secretary with equal numbers from HRSA, CMS, and the HHS Office of the General Counsel (OGC). It also requires the HRSA Administrator to select three members from the ADR Board to form a 340B ADR Panel and that each 340B ADR Panel include one ex-officio, non-voting member (appointed by the Secretary) from OPA to assist the 340B ADR Panel. The 2020 final rule states that HRSA and CMS ADR Board members must have relevant expertise and experience in drug pricing or drug distribution and that the OGC ADR Board members must have expertise and experience in handling complex litigation.

While the 340B Program is related to drug pricing and drug distribution, it is a distinct program that requires knowledge of the 340B statute and specific 340B Program operations. Therefore, HHS is proposing that the 340B ADR Panel members should have specific knowledge of the authorizing statute and the operational processes of the 340B Program (*e.g.,* registration and program integrity efforts). Consequently, HHS is proposing an ADR process and Panel in which 340B subject matter experts from OPA will resolve matters that proceed through the ADR process. Moreover, decisions by subject matter experts from OPA are less likely to conflict with current 340B policy. All members on the 340B ADR Panel will undergo an additional screening prior to reviewing a specific claim to ensure that the 340B ADR Panel member was not involved in previous agency actions (including previous 340B ADR Panel decisions) concerning the specific issue of the ADR claim as it relates to the specific covered entity or manufacturer involved.

Third, this NPRM proposes that prior to initiating the ADR process, parties must undertake good-faith efforts to resolve the disputed issues. Historically, HRSA has encouraged parties to work in good faith and covered entities and manufacturers have not had significant numbers of disputes due to the success of these good-faith-resolution efforts.

Other 340B Program administrative improvements have narrowed the areas where parties had, in the past, disagreed over 340B Program issues. For example, HRSA released the pricing component of the 340B Office of Pharmacy Affairs Information System (340B OPAIS) in February 2019, which, for the first time, provided 340B ceiling prices to authorized covered entity users. Implementation of that system has provided the necessary transparency to decrease disputes specific to the 340B ceiling price and its calculation. Outside of an issue involving some

manufacturers placing restrictions on certain covered entities use of contract pharmacies, OPA has only received three covered entity overcharge complaints since making 340B ceiling prices available to covered entities through 340B OPAIS.

Of additional note, prior to the 2020 final rule, stakeholders were able to utilize an informal dispute resolution process to resolve disputes between covered entities and manufacturers (61 FR 65406, Dec. 12, 1996) (''1996 guidelines''). There have been only four informal dispute resolution requests since the publication of the 1996 guidelines. Of the four informal dispute resolution requests received, two were terminated by HRSA due to non-participation by one of the parties, another was dismissed due to lack of sufficient evidence, and the last was terminated because the parties disputed each other's attempts of good faith resolution. The relatively small number may also be attributed to the parties' successful attempts to resolve issues in good faith. With this very small number of past informal disputes, the increased transparency in 340B pricing data, and HRSA's encouragement that parties work to resolve issues in good faith, HHS is proposing an ADR process more closely aligned with the process that was established in the 1996 guidelines, and less trial-like and resource-intensive—for both the participants and HHS—than that established in the 2020 final rule.

Also, in the time since Congress enacted the 340B ADR statutory provision, HRSA implemented its extensive audit program in 2012, which ensures that participating covered entities and manufacturers are able to demonstrate compliance with all 340B Program requirements. On average, HRSA conducts 200 covered entity audits each fiscal year including child/associate sites and contract pharmacies associated with the covered entities, and issues findings in three areas: eligibility, diversion, and duplicate discounts. These findings vary in terms of severity—from covered entities not having the correct information in the 340B OPAIS to the diversion of 340B drugs to individuals who are not patients of the covered entity. HRSA conducts approximately five manufacturer audits each year and makes findings related to manufacturers charging above the 340B statutorily required ceiling price and manufacturers not reporting the required 340B pricing data to HRSA. All audit results are posted in summary form on the 340B Program website.[1] Since the establishment of HRSA audits of covered entities and manufacturers, HRSA has been able to identify 340B compliance concerns that would have previously been disputed. In addition to the extensive audit program, HRSA has also developed a comprehensive program integrity strategy to ensure compliance among all stakeholders participating in the 340B Program. These activities include quarterly checks of 340B Program eligibility, a self-disclosure and allegation process which involves communication between OPA and the stakeholders regarding the compliance issue, and spot checks of supporting eligibility documentation including contracts with state and local governments and contract pharmacy agreements.

Further, manufacturers are required to audit a covered entity prior to filing an ADR claim pursuant to section 340B(d)(3)(B)(iv) of the PHS Act. Over the last 3 years, two manufacturers have requested to audit covered entities. In both instances, HRSA approved the audits and received final audit reports from the manufacturers. The historical infrequency of manufacturer audit requests along with the requirement that manufacturers audit covered entities prior to filing an ADR claim suggests that the number of manufacturer ADR claims will be low, but HHS welcomes comment on its assessment.

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

Fourth, the ADR process should be reserved for those disputes set forth in the statutory ADR provision (overcharge, diversion, or duplicate discount). For example, a manufacturer that audited a covered entity may report its findings of alleged duplicate discounts identified by specific purchasing patterns over a period of time. The covered entity may disagree with the audit assessment of purchases. In this example, the matter would be best resolved through the ADR process as it involves an alleged duplicate discount violation.

This NPRM aligns with the statutory provisions by outlining the specific types of claims that can be brought forth through the ADR process—claims for overcharge, diversion or duplicate discounts. HHS is soliciting comment on whether there may be appropriate claims limitations to ensure that ADR is limited to the specific statutory areas (diversion, duplicate discounts and overcharges).

HHS is also proposing as part of the ADR process that if the ADR Panel determines that a specific issue in a claim is the same as or similar to an issue that is pending in Federal court, the ADR Panel will suspend review of the claim until such time the issue is no longer pending in Federal court. HHS welcomes comments on its proposal to suspend ADR review of claims that involve issues pending in Federal court.

Fifth, HHS believes that there should be an opportunity for dissatisfied parties to seek reconsideration of the 340B ADR Panel's decision by HRSA. Several comments received on the 2016 NPRM requested an appeals process be made available to all parties. This NPRM proposes an appeals or reconsideration process option that would be made available to either party. Under the 2020 final rule and under this proposal, the Secretary has the inherent authority to review and reverse or alter the 340B ADR Panel's decision. Discretionary review by the Secretary would similarly apply to any reconsideration decision upon finalization of this NPRM. The final agency decision will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court.

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

III. Summary of the Proposed Regulations

The proposed revisions to 42 CFR part 10 are described according to the applicable section of the regulations. This NPRM proposes to add and revise the definitions of ''Administrative Dispute Resolution Panel (340B ADR Panel),'' ''Administrative Dispute

[1] See: *https://www.hrsa.gov/opa/program-integrity/index.html.*

Resolution Process,'' ''claim,'' ''consolidated claim,'' ''joint claim,'' and ''Office of Pharmacy Affairs'' at § 10.3 as set forth below. HHS proposes to revise the language in subpart C as set forth below.

Section 10.3 Definitions

HHS is proposing to add and revise the following definitions: ''Administrative Dispute Resolution Panel (340B ADR Panel),'' ''Administrative Dispute Resolution Process,'' ''claim,'' ''consolidated claim,'' ''joint claim,'' and ''Office of Pharmacy Affairs.''

Subpart C—Administrative Dispute Resolution

Section 10.20 340B Administrative Dispute Resolution Panel

(a) Members of the 340B ADR Panel

As required by section 340B(d)(3)(B)(i) of the PHS Act, regulations promulgated by the Secretary shall designate or establish a decision-making official or body within HHS to review and make a decision for claims filed by covered entities and manufacturers. HHS proposes to revise the composition of the decision-making body (referred to as the ''340B ADR Panel'' or ''Panel'') that will review and resolve such claims.

In this section, HHS is proposing that the Secretary appoint a roster of eligible individuals (Roster), consisting of OPA staff, to serve on the 340B ADR Panels. The Roster will include no less than 10 staff from OPA. The OPA Director, or designee, shall select at least three members from the Roster to form a 340B ADR Panel to facilitate the review and resolution of an ADR claim. The OPA Director would have the authority to ensure that the Panel is operating in accordance with this proposed rule, including through the selection of the Panel members and the removal of Panel members for reasons including but not limited to conflicts of interest as described in paragraph (b) or pursuant to instructions from the Secretary in accordance with the Secretary's authority to remove 340B ADR Panel or Roster members at will.

Subject matter experts in the 340B Program are best suited to resolve issues for covered entity and manufacturer claims, in a manner similar to the process that OPA uses when it conducts program compliance audits of covered entities and manufacturers. OPA staff are knowledgeable of 340B Program operations and oversight. They have years of subject matter expertise on the complex matters that may arise as part of dispute resolution. OPA also has experience in conducting audits and has a robust audit program of both covered entities and manufacturers that focuses on many of the challenges facing stakeholders in implementing 340B Program policy. OPA has already instituted processes to help parties resolve issues (many of which are resolved in good faith or are errors/misunderstandings). For example, the 340B Program has existing processes and reporting when a covered entity asserts a 340B price is unavailable. OPA has the capability and experience to initiate a dialogue between covered entities and manufacturers to resolve such matters and has done so successfully on many occasions. OPA's access to appropriate stakeholder contact information and awareness of 340B drug distribution plans have facilitated resolutions to certain drug product access concerns. These examples illustrate that OPA has the requisite expertise to administer and staff the 340B ADR Panels to ensure alignment, consistency, and transparency in ADR decisions, and understands the impact of these decisions on the 340B Program as a whole, and the 340B Program audits, as well as other program integrity initiatives.

HHS is soliciting specific comments on the proposed size and composition of the 340B ADR Panel, including the proposal to maintain the 340B ADR Panel within OPA or whether staff from other components of HRSA or HHS more generally should serve as members of the Panel.

(b) Conflicts of Interest

The ADR process assists covered entities and manufacturers in resolving disputes specifically related to overcharging, duplicate discounts, or diversion as outlined in section 340B(d)(3) of the PHS Act. Neither HHS, HRSA, nor OPA are parties to the ADR process, but rather help facilitate the process between covered entities and manufacturers. HHS is proposing that OPA staff serve on the 340B ADR Panel to review and make decisions on claims that are brought forth through the ADR process. HHS is also proposing that the OPA Director will ensure that each 340B ADR Panel member is screened prior to reviewing a claim and that there are no conflicts of interest between the parties involved in the dispute and the 340B ADR Panel member. As background, HRSA employs an ongoing, rigorous ethics clearance process for OPA staff to ensure that there are no conflicts of interest between staff and 340B stakeholders. OPA employees undergo an annual ethics clearance process in accordance with the U.S. Office of Government Ethics policies applicable to Federal employees. As part of this annual clearance, OPA staff are assessed in the following areas: if they have a (1) financial interest in a covered entity or a manufacturer participating in the 340B Program; (2) family or close relation who is either employed by or otherwise involved with a covered entity or a manufacturer participating in the 340B Program; (3) current or former business or employment relationship to a covered entity or manufacturer participating in the Program. If a potential conflict arises, OPA staff must immediately inform their supervisors and disclose any potential issues. In this case, depending on the circumstances, the staff member may be removed from the ADR Panel. However, to ensure fairness and objectivity in the ADR process, this NPRM proposes that each OPA 340B ADR Panel member also undergo additional screening prior to reviewing a specific claim and will not be allowed to review the claim if any conflicts of interest exist. In addition, this NPRM proposes that dedicated OPA staff members will have specific ADR duties as part of their job functions, including being part of the 340B ADR Panel that makes decisions on an ADR claim.

The staff with ADR duties in their job functions will also be screened prior to being assigned to a 340B ADR Panel to ensure that they have not been involved in prior 340B Program oversight work related to the parties involved, including previous 340B ADR Panel decisions concerning the ADR claim as it relates to the specific covered entity or manufacturer involved. For example, if an OPA staff member were involved in reviewing or approving an audit work plan for a specific manufacturer that is part of an ADR claim, then that staff member would not serve on that 340B ADR Panel. This would not, however, preclude an OPA staff member from serving on the 340B ADR Panel when the covered entities or manufacturers were parties in a prior ADR decision. HHS solicits comments on this aspect of the proposed process and will consider other proposals to ensure that the 340B ADR Panel members are fair and objective.

In addition, HHS proposes that OPA staff members serving on a 340B ADR Panel may be removed by the OPA Director for reasons including but not limited to conflicts of interest. For example, if it is determined prior to or during the course of a Panel member's review of a claim that there is a conflict of interest, as described in paragraph (b), with respect to that claim, the Panel member would be removed from the

Panel and replaced by another OPA staff member from the Roster of eligible individuals.

(c) Secretarial Removal Power

The Secretary retains the authority to remove an individual from the Roster of persons appointed to sit on a 340B ADR Panel at any time, such that the individual may no longer serve on any 340B ADR Panel. In addition to the ability to remove an individual from the Roster, the Secretary may also remove a panelist from a particular 340B ADR Panel at any time.

(d) Duties of the 340B ADR Panel

HHS is proposing that the role of the 340B ADR Panel is to independently review and apply 340B law and policy to the case-specific factual circumstances at issue in an overcharge, diversion, or duplicate discount dispute. In this proposed rule, once OPA determines a claim meets the requirements set forth in § 10.21(b) and forwards the claim to the 340B ADR Panel, the Panel will review and evaluate all documentation submitted by the party initiating the claim. The 340B ADR Panel may request additional information or clarification from any party involved in the claim during the review and evaluation process. The 340B ADR Panel will also facilitate the review of covered entity requests for information and documents from manufacturers and third parties as outlined in § 10.22 of this proposed rule. If the 340B ADR Panel finds that either party does not fully respond to a request for information or documents from OPA or the 340B ADR Panel, HHS proposes that the 340B ADR Panel may draw an adverse inference and make a decision on the claim based on the information submitted in the claim package that moved forward for review.

HHS also proposes that the 340B ADR Panel would conduct a review of the documents submitted by the parties and evaluate claims based on the information received (including from any associations or organizations, or legal counsel representing the parties) unless, at the 340B ADR Panel's discretion, the nature of the claim necessitates that a meeting with the parties be held. In addition, the 340B ADR Panel may consult with, as appropriate or necessary, other staff within OPA, other HHS offices, other Federal agencies, or with outside parties to the extent additional information is needed.

The 340B ADR Panel will issue a decision on the claim in accordance with § 10.23. HHS proposes that the 340B ADR Panel's decision must represent the decision of a majority of the Panel members.

Section 10.21 Claims

(a) Claims Permitted

Section 7102 of the Affordable Care Act added section 340B(d)(3) to the PHS Act. It instructs the Secretary to establish and implement a binding ADR process to resolve certain claims of 340B Program statutory violations. Section 340B(d)(3)(A) of the PHS Act 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 PHS Act, that a covered entity has violated the prohibitions against duplicate discounts and diversion (sections 340B(a)(5)(A) and (B) of the PHS Act). This NPRM proposes aligning claims to those outlined in the 340B statute and is also proposing that the harm alleged (overcharge, diversion, duplicate discount) be specific to the parties identified in the claim. HHS believes that the role of the 340B ADR Panel is to independently review and apply 340B law and policy to the case-specific factual circumstances at issue in an overcharge, diversion, or duplicate discount dispute. OPA will review each claim to ensure the claim meets the filing requirements set forth in the rule and as outlined in § 10.21(b) prior to forwarding the claim to the 340B ADR Panel.

(b) Requirements for Filing a Claim

HHS proposes that a covered entity and a manufacturer meet certain requirements for filing a claim. These proposed requirements will ensure that a claim of the type specified in section 340B(d)(3)(A) of the PHS Act is the subject of the dispute.

The claims will be submitted through a secure electronic mechanism to safeguard confidential and proprietary information. HHS will provide additional detail as to the mechanism for submitting claims in future sub-regulatory guidance.

HHS is proposing that covered entities and manufacturers file a written claim, based on the facts available, to OPA within 3 years of the alleged specified violation and that any claim not filed within 3 years shall 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. This proposal would ensure that documents are submitted with each claim to verify that the alleged violation is not time barred. HHS requests public comment concerning the 3-year limitation on claims submission. HHS is proposing that while there is no minimum threshold to submit a claim through the ADR process, parties should carefully consider whether the ADR process is appropriate for de minimis claims given the time, resources, and investment needed to undertake ADR.

HHS is also proposing that all files, documents, or records associated with the specified claim that are the subject of the dispute must be maintained by the covered entity and/or manufacturer until the final agency decision is issued.

Covered Entity Claims

In § 10.21(b)(2), HHS proposes that to be eligible for the ADR process, each claim filed by a covered entity must provide the basis for the covered entity's belief that it has been overcharged by a manufacturer, along with any such documentation as may be requested by OPA to evaluate the accuracy of the claim. Such documentation may include, but is not limited to: (1) a 340B purchasing account invoice which shows the purchase price by national drug code, 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; (3) documentation by the manufacturer or wholesaler of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of alleged overcharging; (4) documentation and correspondence with HRSA regarding the alleged overcharge, including price unavailability forms or other correspondence; and (5) an estimate of monetary damages. HHS believes that these documents are readily available to a covered entity in the usual course of business and should not be overly burdensome to produce; however, HHS requests comment on the feasibility of producing the documentation as proposed. HHS is also proposing to require the covered entity, at the time of filing, to provide OPA with a written summary of attempts to work in good faith to resolve the instance of overcharging with the manufacturer at issue. An example of documented good faith efforts could include attempts to enter into discussion to resolve disputes or communication records between the covered entity and the manufacturer. HHS is seeking comment on what other types of documentation would indicate

good faith effort and whether a threshold for attempts at communication should be established.

Manufacturer Claims

In § 10.21(b)(3), HHS proposes that to be eligible for the 340B ADR process, each claim filed by a manufacturer must include documents sufficient to support a manufacturer's claim that a covered entity has violated the prohibition on diversion and/or duplicate discount, along with any such documentation as may be requested by OPA to evaluate the accuracy of the claim. Such documentation shall include but is not limited to: (1) a final audit report which indicates that the manufacturer audited the covered entity for compliance with the prohibition on diversion (section 340B(a)(5)(B) of the PHS Act) and/or duplicate discounts (section 340B(a)(5)(A) of the PHS Act); (2) any communication with the State Medicaid agency indicating rebates claimed (for duplicate discount violations only); (3) the covered entity's written response to the manufacturer's audit finding(s); and (4) an estimate of monetary damages. HHS is proposing to require the manufacturer, at the time of filing, to submit a written summary of attempts to work in good faith to resolve the claim with the covered entity. An example of documented good faith efforts could include attempts to enter into discussion to resolve disputes prior to an audit of a covered entity, along with attempts as part of the covered entity response to any findings. It could also include evidence of communication between the covered entity and the manufacturer. HHS is seeking comments on what other types of evidence would constitute the parties working in good faith and whether a threshold for attempts at communication should be established.

(c) Combining Claims

HHS proposes that, if requested, covered entities or manufacturers may be permitted to combine individual claims. Section 340B(d)(3)(B)(vi) of the PHS Act permits ''multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding...'' For covered entity joint claims, HHS proposes that the claim must list each covered entity and its 340B IDs and include documentation as described in paragraph (b)(2) and/or information from each individual covered entity demonstrating that each covered entity meets all of the requirements for filing an ADR claim. Additionally, a letter requesting the combining of claims must also accompany the claim at the time of filing and must document that each covered entity consents to the combination of the claim, including signatures of the individuals representing each covered entity.

Pursuant to section 340B(d)(3)(B)(vi) of the PHS Act, joint claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, this NPRM proposes that the covered entities represented in the claim must be members of the association or the organization representing them and that each individual covered entity listed in the claim must meet the requirements listed in paragraph (b) for filing a claim with OPA.

The proposed joint claim must assert overcharging by a single manufacturer for the same drug(s), and the organization or association will be responsible for filing the claim. HHS also proposes requiring that a letter requesting the combining of claims must accompany the claim and must include documentation that each covered entity consents to the organization or association asserting a claim on its behalf, including signatures of individuals representing each covered entity and a point of contact for the covered entity. HHS is also proposing that covered entities will not be permitted to file claims against multiple manufacturers in a single ADR proceeding. In other words, covered entities are only permitted to file a claim (individual or joint) against a single manufacturer for the same drug(s) in a single ADR proceeding.

Section 340B(d)(3)(B)(v) of the PHS Act permits the consolidation of claims brought by more than one manufacturer against the same covered entity if consolidation is consistent with the statutory goals of fairness and economy of resources. This NPRM proposes that the claim must list each manufacturer and include documentation as described in paragraph (b)(3), and/or information from each manufacturer demonstrating that each individual manufacturer meets the requirements listed in paragraph (b) for filing an ADR claim. HHS also proposes 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, including signatures of the individuals representing the manufacturers and a single point of contact for the claim being filed on behalf of the consolidated group. 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 is not proposing this option in this NPRM.

As required by the 340B statute, HHS is proposing an ADR process that allows more than one manufacturer to consolidate claims against the same covered entity. With regard to the consolidation of claims by manufacturers against the same covered entity, HHS is proposing that the 340B ADR Panel will determine whether such consolidation is appropriate and consistent with the goals of fairness and economy of resources.

(d) Deadlines and Procedures for Filing a Claim

HHS proposes that covered entities and manufacturers can file a claim with OPA, or any successor office assigned to administer the 340B Program, demonstrating that they satisfy the requirements described in paragraph (b). The OPA staff conducting the initial review of a claim will not be appointed to serve on a 340B ADR Panel reviewing that specific claim. OPA will contact the initiating party once the claim has been received. OPA will conduct an initial review of the claim and may request additional information. If additional information is requested, the initiating party filing the claim will have 20 business days from receipt of the request to respond. If the initiating party does not respond to the request for additional information within the time period specified or request an extension, the claim will not move forward to the 340B ADR Panel for review. OPA will determine whether a claim will be forwarded to the 340B ADR Panel for review in accordance with paragraph (b). In the event that a claim does not move forward for review, HHS is proposing that all parties listed on the claim will receive information from HRSA regarding the reason(s) why the claim did not move forward.

OPA will review all information submitted as part of the claim to verify that the requirements for filing a claim have been met and will provide written notification to the initiating party that the claim is complete. HHS is proposing that once the claim is deemed complete, OPA will also provide written notification to the opposing party that the claim was submitted to OPA and that they will have 30 business days to provide OPA with a response. This written notification will be provided to the opposing party before the claim moves forward to the 340B ADR Panel. As part of this written notification, OPA will provide a copy of the claim and additional instructions regarding the

ADR process, including timelines and information on how to submit their response as described in paragraph (e). At such time, OPA will also notify the initiating party that their claim is deemed complete and meets the requirements of paragraph (b).

In addition, HHS proposes that the claim will be forwarded to the 340B ADR Panel for review after OPA receives the opposing party's response. OPA would provide additional information on the 340B ADR process to both the initiating and opposing parties at that time, including contact information for requested follow-up communications.

HHS proposes that if the claim does not move forward for review by the 340B ADR Panel, OPA will send written notice to both parties briefly stating the basis for the decision and will advise the party that they may revise and refile the claim if the party has new information to support the alleged statutory violation.

(e) Responding to a Submitted Claim

HHS proposes that once the parties have been notified by OPA that the claim has met the requirements in paragraph (b) and the claim does not otherwise prevent OPA from moving it forward to the 340B ADR Panel for review as described in paragraph (d), the opposing party will have 30 business days to submit a written response to the allegation to OPA. The opposing party may submit a request for an extension of the initial 30 days and OPA will make a determination to approve or disapprove such request and notify both parties. Once the opposing party's response has been received, OPA will provide a copy to the initiating party and will notify both parties that the claim has moved forward for review by the 340B ADR Panel. If the opposing party does not provide a response or otherwise elects not to participate in the 340B ADR process, OPA will forward the information included as part of the initiating party's claim and the 340B ADR Panel will render its decision after review of the information submitted in the initial claim. Subsequent requests for information regarding the claim would be made by the 340B ADR Panel as appropriate, and the 340B ADR Panel will consider the information gathered during the ADR process and may request additional information from the parties.

Section 10.22 Covered Entity Information and Document Requests

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

In this section, HHS proposes 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 proposes that the manufacturer must fully respond in writing to the information/document 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 with which it contracts for sales or distribution of its drugs to covered entities. HHS proposes that if a manufacturer anticipates it will not be able to respond fully 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 or documents, the reason why the deadline is not feasible, and outline a proposed timeline for fully responding to the information/document 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 any.

HHS proposes that if the 340B ADR Panel finds that a manufacturer has failed to respond or fully respond to a covered entity information/document request, the 340B ADR Panel may draw an adverse inference, and proceed with facts that have already been established in the proceeding. Such adverse inference could include holding facts to have been established in the proceeding or precluding a party from contesting a particular issue. HHS invites specific comment on this issue.

Section 10.23 340B ADR Panel Decision Process

In § 10.23, HHS proposes that the 340B ADR Panel will conduct an initial review of the claim to determine if the specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending Federal court. If this determination is made, the 340B ADR Panel will suspend review of the claim until such time the issue is no longer pending in Federal court.

If suspending review of the claim is not appropriate, the 340B ADR Panel would review the documents submitted by the parties and determine if there is adequate support to conclude that an overcharge, diversion, or a duplicate discount has occurred in the specific case at issue. In alignment with the statute at section 340B(d)(3)(B)(ii) of the PHS Act, the 340B ADR Panel will seek to ensure that its review and decision of the claim is conducted in a fair, efficient and expeditious manner. The timeline for the review is wholly dependent on the complexity of each claim submitted through the ADR Process.

After review of the claim, the 340B ADR Panel would prepare a decision letter, which includes the 340B ADR Panel's findings regarding the alleged violation. HHS is proposing that the 340B ADR Panel's decision letter be submitted to all parties in the dispute and the OPA Director. HHS is also proposing, as described in § 10.24, that either party may, within 20 business days of the receipt of the 340B ADR Panel's decision letter, initiate a reconsideration of the 340B ADR Panel's decision. While the 340B ADR Panel decision would conclude the 340B ADR Panel process, either party may, at its sole discretion, request reconsideration as described in § 10.24.

If HRSA does not receive a reconsideration request from either party within 20 business days of the issuance of the 340B ADR Panel's decision letter, or the HRSA Administrator has not initiated a reconsideration request as described in § 10.24, the 340B ADR Panel's decision will serve as the final agency decision

letter and will be binding upon the parties involved in the dispute, unless invalidated by order of a Federal court. The 340B ADR Panel decision would bind only the specific parties to the dispute. In addition, in accordance with section 340B(d)(3)(C) of the PHS Act, any dissatisfied party may also seek judicial review of the final agency decision.

Once the parties involved have been notified of the final agency decision, the OPA Director will consider whether to take enforcement action or ensure corrective action, to the extent allowed under the 340B statute. For example, if the 340B ADR Panel finds that a covered entity has violated the prohibition against diversion, the OPA Director may require, as a sanction, that the covered entity repay the affected manufacturer. If the 340B ADR Panel finds that a manufacturer overcharged a covered entity, the OPA Director may require as a sanction that the manufacturer refund or issue a credit to the affected covered entity.

Section 10.24 340B ADR Panel Decision Reconsideration Process

HHS is proposing that after a decision has been issued by a 340B ADR Panel, if either the initiating party or the opposing party is dissatisfied with the decision, they may request administrative reconsideration of the claim if the requirements for obtaining a reconsideration are met. The HRSA Administrator also has the discretion to initiate a reconsideration if no request is received by the parties. HHS is proposing that the reconsideration be conducted by the HRSA Administrator, or designee, as their review will be independent of the 340B ADR Panel's decision.

HHS is proposing that the party requesting a reconsideration must submit its request in writing to both the other party involved in the claim and to the HRSA Administrator within 20 business days of receiving the 340B ADR Panel's decision. The request for reconsideration must include a copy of the 340B ADR Panel's decision letter, and the burden lies with the party filing the reconsideration to submit written documentation indicating why a reconsideration is warranted. New information may not be submitted as part of the reconsideration process in order to remain consistent with the facts that were reviewed by the 340B ADR Panel in determining the final agency decision. HHS proposes that parties be entitled to reconsideration of their claim upon demonstration that the 340B ADR Panel decision may have been inaccurate or flawed. HHS invites comments on its proposal regarding the scope of the reconsideration process.

HHS is proposing that the HRSA Administrator review the 340B ADR Panel decision, consult with HHS personnel, as necessary, and review any information indicating that a reconsideration is warranted based on inaccurate or flawed information.

Under the NPRM, the HRSA Administrator makes a determination of a reconsideration by issuing a decision that provides the basis for the new determination or dismissing the reconsideration. The HRSA Administrator will review the reconsideration in a fair, efficient, and expeditious manner; however, the timeline for making a decision can vary due to the complexity of each case. HRSA will work with the parties involved to ensure that they are updated about the process. The HRSA Administrator's reconsideration decision would be considered the final agency decision.

IV. Statutory and Regulatory Requirements

A. Regulatory Impact Analysis

HHS has examined the effects of this proposed 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).

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and promoting flexibility. 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 one 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 must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB).

This NPRM is not likely to have an economic impact of $100 million or more in any one year; therefore, it has not been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. This NPRM would modify the framework for HHS to resolve certain disputed claims regarding manufacturers overcharging covered entities and disputed claims of diversion and duplicate discounts by covered entities audited by manufacturers under the 340B Program. HHS does not anticipate the modification of the ADR process to result in significant economic impact. This is consistent with a similar determination in the 2020 final rule that ''HHS does not anticipate the introduction of an ADR process to result in significant economic impacts.''

C. The Regulatory Flexibility Act

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, HHS 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 a RFA threshold of at least a three percent impact on at least five percent of small entities.

This NPRM proposes requirements that would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees.

Approximately 700 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of this NPRM 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. This NPRM 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 million to $35.5 million. As of April 1, 2022, 13,730 covered entities participate in the 340B Program.

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

HHS believes the proposed ADR process would provide a less burdensome option for resolving claims that would be more streamlined and less trial-like in nature than the 2020 final rule. This NPRM provides an option to join or consolidate claims by similar situated entities, and covered entities may have claims asserted on their behalf by associations or organizations which could reduce costs. HHS has determined, and the Secretary certifies, that this NPRM would not have a significant economic impact on a substantial number of small health care providers or a significant impact on the operations of a substantial number of small manufacturers; therefore, HHS is not preparing an analysis of impact for the purposes of the RFA. HHS estimates that the economic impact on the less than 5 percent of small entities and small manufacturers participating in the 340B Program would be minimal and less than a 3 percent economic burden and therefore does not meet the RFA threshold of 3 percent. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers and small health care providers.

D. Unfunded Mandates Reform Act of 1995

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 2021, that threshold is approximately $158 million. HHS does not expect this NPRM to exceed the threshold.

E. Executive Order 13132—Federalism

HHS has reviewed this NPRM in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This proposed 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 NPRM, if implemented, 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. HHS invites additional comments on the impact of this proposed rule in this area.

F. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This proposed rule would not impact the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. HHS believes that the 340B ADR process is exempt from 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). In addition, participants in the 340B Program are already required to maintain the necessary records to submit an ADR claim. Comments are welcome on the accuracy of this statement.

Dated: November 21, 2022.

Xavier Becerra,

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 proposes to amend 42 CFR part 10 as follows:

PART 10—340B DRUG PRICING PROGRAM

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

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

■ 2. Amend § 10.3 by revising the definitions for *Administrative Dispute Resolution (ADR) Process, Administrative Dispute Resolution Panel (340B ADR Panel), Claim, Consolidated claim,* and *Joint claim* and adding the definition for *Office of Pharmacy Affairs (OPA),* in alphabetical order, 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 such claims:

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

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

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Health Resources and Services Administration's Office of Pharmacy Affairs that reviews and makes decisions for claims 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' claims (or claims from their membership organizations' or associations') against the same manufacturer for the same drug or drugs.

* * * * *

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

* * * * *

■ 3. Revise subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.

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

§ 10.20 340B Administrative Dispute Resolution Panel.

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

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

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

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

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

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

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

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

(c) *Secretarial removal power.* The Secretary may remove any individual from the Roster of 340B ADR Panelists for any reason, including from any 340B ADR Panel to which the individual has already been assigned.

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

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

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

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

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

(5) Make decisions on each claim.

§ 10.21 Claims.

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

(1) Claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug; and

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

(b) *Requirements for filing a claim.* (1) A covered entity or manufacturer must file a claim under this section in writing to OPA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision.

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

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

(4) A covered entity or manufacturer filing a claim must provide documentation of good faith efforts, including evidence of communication with the opposing party to resolve the matter in good faith prior to filing a claim.

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

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

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

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

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

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

(iii) A letter requesting the combining of claims must accompany the claim and must include documentation evidencing that each covered entity consents to the organization or association asserting a claim on its behalf, including signatures of individuals representing each covered entity and a point of contact for each covered entity.

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

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

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

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

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

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

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

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

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

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

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

(4) If an opposing party does not respond or elects not to participate in the 340B ADR process, OPA will notify both parties that the claim has moved forward for review by the 340B ADR Panel and the 340B ADR Panel will render its decision after review of the information submitted in the claim.

§ 10.22 Covered entity information and document requests.

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

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

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

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

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

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

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

(5) If the 340B ADR Panel finds that a manufacturer has failed to respond or fully respond to an information/document request, the 340B ADR Panel may draw an adverse inference and proceed with the facts that the 340B ADR Panel has determined have been established in the proceeding.

§ 10.23 340B ADR Panel decision process.

(a) The 340B ADR Panel will conduct an initial review of the claims. If the 340B ADR Panel determines the specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending in Federal court,

it will suspend review of the claim until such time the issue is no longer pending in Federal court.

(b) If no issues are identified in the initial review of the claim under paragraph (a) of this section, the 340B ADR Panel will review all documents gathered during the ADR Process to determine if a violation as described in § 10.21(a)(1) or (2) has occurred.

(c) The 340B ADR Panel will prepare a decision letter based on its review. The 340B ADR Panel decision letter will represent the determination of a majority of the 340B ADR Panel members' findings regarding the claim and include an explanation regarding each finding. The 340B ADR Panel will transmit its decision letter to all parties and to the OPA Director.

(d) Either party may request reconsideration of the 340B ADR Panel decision or the Health Resources and Service Administration (HRSA) Administrator may decide to initiate a reconsideration without such a request as described in § 10.24. If the HRSA Administrator does not initiate the reconsideration process without a request from the parties, or if HRSA does not receive a reconsideration request from either party within 20 business days of the issuance of the 340B ADR Panel's decision letter, as described in § 10.24, the 340B ADR Panel's decision letter will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court.

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

§ 10.24 340B ADR Panel decision reconsideration process.

(a) Either party may initiate a reconsideration request, or the HRSA Administrator may decide to initiate the process without such a request.

(b) The request for a reconsideration of the 340B ADR Panel's decision must be made to the HRSA Administrator within 20 business days of the date of the 340B ADR Panel's decision letter.

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

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

(3) In the case of joint or consolidated claims, the requester must submit documentation showing consent to the reconsideration process, including signatures of the individuals representing each covered entity or manufacturer as described in § 10.21(c).

(c) The reconsideration process may be granted when a party demonstrates that the 340B ADR Panel decision may have been inaccurate or flawed.

(d) The HRSA Administrator, or their designee, will review the record, including the 340B ADR Panel decision, and consult with HHS officials, as necessary.

(e) The HRSA Administrator will make a determination based on the reconsideration request by either issuing a revised decision to be effective 20 business days from issuance or declining to issue a revised decision.

(f) Such reconsideration decision or the 340B ADR Panel decision (in the event of a declination) will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court.

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

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Chapter XII

[Docket No. TSA–2022–0001]

RIN 1652–AA74

Enhancing Surface Cyber Risk Management

AGENCY: Transportation Security Administration, DHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Transportation Security Administration (TSA) is seeking input regarding ways to strengthen cybersecurity and resiliency in the pipeline and rail (including freight, passenger, and transit rail) sectors. This advance notice of proposed rulemaking (ANPRM) offers an opportunity for interested individuals and organizations, particularly owner/operators of higher-risk pipeline and rail operations, to help TSA develop a comprehensive and forward-looking approach to cybersecurity requirements. TSA is also interested in input from the industry associations representing these owners/operators, third-party cybersecurity subject matter experts, and insurers and underwriters for cybersecurity risks for these transportation sectors. Although TSA will review and consider all comments submitted, we are specifically interested in responses to the questions posed in this ANPRM. Input received in response to this ANPRM will assist TSA in better understanding how the pipeline and rail sectors implement cyber risk management (CRM) in their operations and will support us in achieving objectives related to the enhancement of pipeline and rail cybersecurity.

DATES: Submit comments by January 17, 2023.

ADDRESSES: You may submit comments, identified by the TSA docket number to this rulemaking, to the Federal Docket Management System (FDMS), a government-wide, electronic docket management system. To avoid duplication, please use only one of the following methods:

- *Electronic Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. The Department of Transportation (DOT), which maintains and processes TSA's official regulatory dockets, will scan the submission and post it to FDMS. Comments must be postmarked by the date indicated above.
- *Fax:* (202) 493–2251.

See the **SUPPLEMENTARY INFORMATION** section for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT:

For program questions: Victor Parker, Surface Division, Policy, Plans, and Engagement, TSA–28, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6002; telephone (571) 227–1039; email: *VettingPolicy@tsa.dhs.gov.*

For legal questions: David Kasminoff (TSA, Senior Counsel, Regulations and Security Standards) at telephone (571) 227–3583, or email to *VettingPolicy@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

TSA invites interested persons to participate in this ANPRM by submitting written comments, including relevant data. We also invite comments