637–4258; or by email at *singerman.joel@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' Section of today's **Federal Register**, EPA is publishing a direct final Notice of Deletion (NOD) of the Site without a prior NOID because EPA views this as a noncontroversial revision and anticipates no adverse comment. EPA has explained its reasons for this deletion in the preamble to the direct final NOD. If EPA receives no adverse comment(s) on this deletion action, EPA will proceed with the deletion without further action on this NOID. If EPA receives adverse comment(s), EPA will withdraw the direct final NOD, and it will not take effect. EPA will, as appropriate, address all public comments in a subsequent final NOD based on this NOID. EPA will not institute a second comment period on this NOID. Any parties interested in commenting must do so at this time.

For additional information, see the direct final NOD, which is located in the ''Rules'' section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9675; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: August 2, 2016.

Judith A. Enck,

Regional Administrator, EPA Region.

[FR Doc. 2016–19142 Filed 8–11–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA90

340B Drug Pricing Program; Administrative Dispute Resolution

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

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 proposed rule will apply to all drug manufacturers and covered entities that participate in the 340B Program. The proposed rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution process.

DATES: Submit written comments on or before October 11, 2016.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AA90, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email: 340BNPRMADR@hrsa.gov.* Include 0906–AA90 in the subject line of the message.
- *Regular, express, or overnight mail:* CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

All submitted comments will be available to the public in their entirety. All comments received may be posted without change to *http://www.regulations.gov,* including any personally identifiable or confidential business information that is included in a comment.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, OPA, HSB HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. Accordingly, the Department of Health and Human Services (HHS or the Department) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the **FOR FURTHER INFORMATION CONTACT** field above for the name and contact information of the subject-matter expert involved in the development of this proposal. We will consider all written comments received during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA's Regulations Officer at: Room 13N82, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301–443–1785, to obtain this information in an accessible format. This is not a toll free telephone number.

Please visit *http://www.HHS.gov/regulations* for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

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 the HHS delegated the authority to operate section 340B of the PHSA to the Administrator of HRSA. Pursuant to this delegation of authority, HRSA established and administers the 340B Program. Operationally, the 340B Program is housed within HRSA's Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B of the PHSA instructs HHS to enter into pharmaceutical pricing agreements (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHSA if they participate in the Medicaid Drug Rebate Program. 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, which are based on quarterly pricing data reported by manufacturers to 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), hereinafter referred to as the ''Affordable Care Act,'' added section 340B(d)(3) of the PHSA, which requires the Secretary of HHS (or the Secretary) to promulgate a regulation establishing

and implementing a binding administrative dispute resolution (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 to ineligible patients or duplicate discounts. The 340B ADR process is not intended to be a trial-like proceeding governed by formal review of evidence and procedure. Rather, it is an administrative process that is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion. Historically, HHS has encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith. The ADR process as proposed in this rule 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 not been successful. In addition, covered entities and manufacturers should carefully evaluate whether the ADR process is appropriate for de minimis claims given the investment of the time and resources required of the parties involved.

In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) that requested comments on the development of an ADR process (75 FR 57233, September 20, 2010). The ANPRM specifically requested comments on: (1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act. HHS received 14 comments on the ANPRM. The comments received were considered in the development of this proposed rule.

HHS encourages all stakeholders to provide written comments on this NPRM. This proposed regulation, when finalized, will replace the 340B Program's guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers, which was published on December 12, 1996 (61 FR 65406).

II. Summary of the Proposed Regulations

The proposed revisions to 42 CFR part 10 are described according to the applicable section of the regulations. The United States District Court for the District of Columbia vacated the 340B Program Regulations at 42 CFR part 10 relating to Orphan Drugs (subpart C). (*PhRMA* v. *HHS, No. 13–01501 (D.D.C. May 23, 2014).* This NPRM proposes to add new definitions to § 10.3 and retitle and replace the language in subpart C as set forth below.

§ 10.3 Definitions.

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

Subpart C—Administrative Dispute Resolution

§ 10.20 340B Administrative Dispute Resolution Panel

(a) Members of the 340B ADR Panel.

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

The proposed 340B ADR Panel will ensure an unbiased and fair review of the claims, and reduce the individual burden associated with having a single decision-making official who is solely responsible for reviewing and resolving claims. The proposed 340B ADR Panel will include three members, chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of OPA to facilitate the review and resolution of claims within a reasonable time frame. The proposed roster of eligible individuals will be comprised of Federal employees (*e.g.,* employees of CMS or the U.S. Department of Veterans Affairs) with demonstrated expertise or familiarity with the 340B Program. The ADR panel will not be compensated.

HHS proposes that for each filed claim that is reviewed, HSB will review the qualifications of individuals on the 340B ADR Panel roster and select those with expertise or familiarity with the appropriate aspects of the 340B Program. HHS also proposes that individuals serving on a 340B ADR Panel may be removed for cause. 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 subsection (b), with respect to that claim, the Panel member will be removed from the Panel and replaced by another individual from the 340B ADR Panel roster.

HHS is soliciting 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 is sufficient to ensure adherence to 340B policies and procedures.

(b) Conflicts of interest.

To ensure fairness and objectiveness, HHS proposes that each 340B ADR Panel member be screened prior to reviewing a claim and not 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 proposes 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. The specific procedures for screening members of the panel prior to their service on the 340B ADR Panel will be detailed in future guidance.

(c) Duties of the 340B ADR Panel.

In subsection (c), HHS proposes that once the 340B ADR Panel receives the claim, the 340B ADR Panel will consider all documentation provided by the parties and may request additional information or clarification from any party involved with the claim. HHS also proposes that the 340B ADR Panel review claims in a session closed to the parties involved, including any associations or organizations, or legal counsel representing the parties.

In this subsection, HHS also proposes that the 340B ADR Panel may consult with subject matter experts within OPA regarding 340B program requirements while reviewing a claim. The 340B ADR Panel will provide a final decision only with respect to the claim. HHS proposes that the 340B ADR Panel's final decision must represent the decision of a majority of the Panel members but need not be unanimous.

§ 10.21 Claims

(a) 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).

(b) Requirements for filing a claim.

In subsection (b), HHS proposes that the covered entity and the 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 PHSA is the subject of the dispute.

The Department is proposing that covered entities and manufacturers file a written claim, based on the facts available, to HSB within 3 years of the date of the sale (or payment) at issue in the alleged 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 will ensure that covered entities and manufacturers have access to relevant records needed to review and respond to claims. This proposal ensures documents must be submitted with each claim to verify that the alleged violation is not time barred. This proposed requirement will prevent a party from asserting a claim that is stale. HHS requests public comment concerning the 3 year limitation on claims submission.

HHS is also proposing that once a claim is submitted and the opposing party has been notified of the claim, any file, document, or record associated with a claim be maintained by the covered entity and/or manufacturer until the 340B ADR Panel's final agency decision is issued.

Covered Entity Claims

In section 10.21(b)(2), HHS proposes 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 by HSB 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, however HHS requests public comment on the feasibility or producing the documentation as proposed. HHS may also request that the covered entity provide it with a written summary of attempts to work in good faith to resolve the instance of overcharging with the manufacturer at issue.

Pursuant to section 340B(d)(1)(B) of the PHSA, HHS is developing a system to verify the ceiling price of a 340B drug and allow covered entities to access and verify the ceiling price. Until such system is developed, HHS has access to ceiling price data and will ensure that the 340B ADR panel will also have access as they evaluate any particular claim. Covered entities will be able to access ceiling price information through this system, which may lessen the burden in submitting the information accompanying a claim.

Manufacturer Claims

In section 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 demonstrate 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 HSB to evaluate the veracity of the claim. Such documentation may include: (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 PHSA) and/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). HHS 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.

(c) Consolidation of claims.

In subsection (c), HHS proposes that, if requested, covered entities or manufacturers may be permitted to consolidate 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 proposes that for consolidated claims, the claim must list each covered entity and include documentation and/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 claim.

Pursuant to section 340B(d)(3)(B)(vi) of the PHSA, consolidated claims are also permitted on behalf of covered entities by associations or organizations representing their interests. Therefore, HHS proposes 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 subsection (b) for filing a claim with HSB. The proposed consolidated 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 proposes 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 consistent with the statutory goals of fairness and economy of resources. This NPRM proposes that the claim must list each manufacturer and include documentation and/or information from each manufacturer demonstrating that the manufacturer meets the

requirements listed in subsection (b) for filing a claim with HSB. 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. 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.

With regard to the consolidation of claims by manufacturers against a covered entity, HHS is seeking 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 is proposing, as required by the 340B statute, an ADR process that allows manufacturers to consolidate claims against a covered entity, we recognize the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS is, therefore, seeking comment on how manufacturers requesting a consolidated claim against a covered entity can satisfy the audit requirement.

(d) Deadlines and procedures for filing a claim.

In subsection (d), HHS proposes that covered entities and manufacturers file a claim with HSB demonstrating that they satisfy the requirements described in subsection (b) 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 within 3 business days. HHS also proposes that the written notice to the opposing party must include a summary of the documents submitted as part of the claim.

HHS proposes that HSB will review the information submitted as part of the claim to verify that the requirements for filing a claim have been met. HSB would contact the initiating party once the claim has been received and may request additional information before accepting a claim for review by the 340B ADR Panel. If additional information is requested, the party filing the claim will have 20 business days of receipt of the request to respond. Claims will not move forward for review by the 340B ADR Panel if the initiating party does not respond to the request for additional information or 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 proposes that HSB will make a determination 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, which will be transmitted via both hard copy and email. If HSB determines the claim includes all necessary documentation and meets the requirements for filing a claim, the claim will be forwarded to the 340B ADR Panel for review. HSB would provide additional information 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 proposes that if the claim does not move forward for review by the ADR Panel, written notice will be sent by HSB to the parties involved that includes 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.

In subsection (e), HHS proposes that once the parties have been notified by HSB that the claim has met the requirements in subsection (b) 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 and the party who filed the claim. Subsequent requests for information regarding the claim would be made by the 340B ADR Panel as needed, and the 340B ADR Panel will consider any additional information that was provided by the parties involved. However, if an opposing party does not respond to a request for information from HSB or the 340B ADR Panel or otherwise elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim.

§ 10.22 Covered entity 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 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 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 by HSB that the claim would move forward for the 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 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 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 proposes 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 from HSB or the 340B ADR Panel, HHS proposes that the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim package that moved forward for review.

§ 10.23 Final agency decision

In § 10.23, HHS proposes that the 340B ADR Panel review the documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in subsection (a)(1) or (2) of § 10.21 has occurred. The 340B ADR Panel will prepare a draft agency decision letter, which includes the 340B ADR Panel's findings and conclusions regarding the alleged violation. HHS is proposing a process whereby the 340B ADR Panel's draft agency decision letter will be sent to all parties, and the parties involved will have 20 business days to respond to the 340 ADR Panel. HHS is seeking specific comments on this process and whether this proposed process will facilitate or hinder the fair, efficient, and timely resolution of claims.

HHS also proposes that once the parties have reviewed and submitted comments to the draft agency decision letter, the 340B ADR Panel will prepare and submit its final agency decision letter to all parties in the dispute, which may incorporate rebuttals from the parties that were considered by the 340B ADR Panel to help inform the final agency decision. The final agency decision made by 340B ADR Panel will conclude the administrative resolution process; however, HHS proposes that the final agency decision letter also be submitted to HSB to take enforcement action or apply sanctions, as appropriate. For example, if the 340B ADR Panel makes a decision that a covered entity has violated the prohibition against diversion, HSB may require, as a sanction, that the covered entity repay the affected manufacturer. If the 340B ADR Panel makes a decision that a manufacturer overcharged a covered entity, HSB may require, as a sanction, that the manufacturer refund or issue a credit to the affected covered entity. In both cases, HSB will work with the party in violation on any remedy and corrective action.

HHS proposes that the 340B ADR Panel's final agency decision letter will be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction in accordance with section 340B(d)(3)(C) of the PHSA. HHS may, at its sole discretion, publish a summary of the claims that have gone through the 340B ADR process on the HRSA Web site, including the names of the parties and the nature of the 340B ADR Panel's findings (*e.g.,* overcharging, duplicate discount, or diversion). HHS will consider issuing future subregulatory guidance on this topic as necessary.

III. 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).

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 proposed rule is not likely to have economic impacts 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 proposed 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 administrative dispute resolution process to result in significant economic impacts.

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 an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

The proposed 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 proposed 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 proposed 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 million to $35.5 million. As of July 1, 2016, over 12,000 covered entities participate in the 340B Program, which represent safety-net healthcare providers across the country.

The proposed rule introduces an administrative mechanism to review claims by manufacturers that covered entities have violated certain statutory obligations and claims by covered entities that 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 proposed administrative dispute resolution process will provide a cost-efficient option for resolving claims that would otherwise remain unresolved or require litigation. The proposed 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 we are not preparing an analysis of impact 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. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers and small health care providers.

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 2014, that threshold level was approximately $155 million. HHS does not expect this proposed rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule 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.'' The proposals in this notice of proposed rulemaking, 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 from affected stakeholders.

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. This proposed rule will not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program. Based on current experience with the informal ADR process offered by the 340B Program, there have only been four requests for informal dispute resolution since the inception of the Program. Of the four dispute resolution requests, 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 the existence of any attempt of good faith resolution. The relatively small number is attributed to the success of parties' attempts to resolve issues in good faith. Due to this very small number of informal dispute resolution requests, there has been very limited experience to date with dispute resolution record keeping. Changes proposed in this rulemaking would not result in significant reporting or recordkeeping burden. Comments are welcome on the accuracy of this statement.

Dated: May 24, 2016.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: June 7, 2016.

Sylvia M. Burwell,

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 is revised 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 definitions for ''Administrative Dispute Resolution (ADR) process'','' Administrative Dispute Resolution Panel (340B ADR Panel)'', ''Claim'', and ''Consolidated claim'' to read as follows:

§ 10.3 Definitions.

* * * * *

Administrative Dispute Resolution (ADR) process means a process used to resolve claims by covered entities that may have been overcharged for 340B drugs purchased by manufacturers, and claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity, 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 reviews and makes a binding decision for claims brought under the ADR Process.

* * * * *

Claim means an allegation made by or on behalf of a covered entity or by a manufacturer for purposes of the ADR Process.

Consolidated claim means the submittal of joint claims by covered entities (or their membership organization or association) or manufacturers to the 340B ADR Panel asserting the same allegation against the same party.

* * * * *

■ 3. Revise subpart C to read as follows:

Subpart C—Administrative Dispute Resolution

Sec.

10.20 Administrative Dispute Resolution Panel.
10.21 Claims.
10.22 Covered entity information requests.
10.23 Final agency decision.

§ 10.20 Administrative Dispute Resolution Panel.

The Secretary shall establish a decision-making body known as the Administrative Dispute Resolution Panel (340B ADR Panel) to review and make a binding final agency decision

regarding claims filed by covered entities and manufacturers.

(a) *Members of the 340B ADR Panel.* (1) The Health Resources and Services Administration (HRSA) shall:

(A) Select three voting members of the 340B ADR Panel from a roster of eligible individuals and one ex-officio, non-voting member from the staff of HRSA's Office of Pharmacy Affairs (OPA);

(B) Alternate the individuals on the 340B ADR Panel for each claim;

(C) Remove an individual from the 340B ADR Panel for cause; and

(D) Appoint replacement members should an individual be unable to complete his or her duties.

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

(b) *Conflicts of interest.* All members of the 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 the 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:

(1) Review and evaluate documents or 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 decision;

(3) Evaluate a claim in a separate session from the parties involved;

(4) Consult with OPA regarding any inquiries or concerns while reviewing a claim; and

(5) Make a final agency decision on each claim that will be communicated to HRSA for appropriate enforcement.

§ 10.21 Claims.

(a) *Claims permitted.* The ADR process is limited to the following:

(1) Claims by a covered entity that it has been overcharged, as defined in § 10.11(b), 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 PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHSA, 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 for administrative dispute resolution in writing to 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 a dispute must be maintained by the covered entity and manufacturer until the final agency decision letter is issued by the 340B ADR Panel.

(2) A covered entity filing a claim described in paragraph (a)(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 HRSA.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to demonstrate its 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 HRSA.

(c) *Consolidation of 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, and meets the minimum requirements, including submission of the required documentation, described in paragraph (b) 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 (b) 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 jointly filed claim, meets the requirements described in paragraph (b) 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 resources. The 340B ADR Panel will not permit joint claims filed on behalf of manufacturers by associations or organizations representing their interests.

(d) *Deadlines and procedures for filing a claim.* (1) Covered entities and manufacturers must file claims in writing to HRSA. A claim must include all of the requirements in paragraph (b) of this section. Additional information to substantiate a claim may be submitted.

(2) The party filing the claim must notify the opposing party in writing within 3 business days of the date the claim was filed and must provide documentation of such notification to HRSA. The written notice to the opposing party must include a summary of the documents submitted as part of the claim.

(3) HRSA will review all information submitted by the party filing the claim and will make a determination 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.

(A) *Claims that move forward for review.* If HRSA finds that the party filing the claim submitted all required documentation and thereby meets the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity advising that the claim will be forwarded to the 340B ADR Panel for review.

(B) *Claims that do not move forward for review.* If HRSA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both the manufacturer and covered entity detailing the reasons that the claim did not move forward. A claim will not move forward for review by the 340B ADR Panel if the claim does not meet the requirements in paragraph (b) of this section. That same claim may only be resubmitted if new information is presented to support the alleged statutory violation.

(e) *Responding to a submitted claim.* Upon receipt of notification that a claim will move forward to the 340B ADR Panel for review, the party in alleged violation will have 20 business days to submit a written response to the 340B ADR Panel. If an opposing party does not respond to a request for information from HRSA or the 340B ADR Panel, or elects not to participate in the 340B ADR process, the 340B ADR Panel will make a decision on the claim based on the information submitted in the claim. The 340B ADR Panel will consider any additional information that was provided by the parties involved.

§ 10.22 Covered entity information requests.

(a) A covered entity must submit a written request for additional information necessary to support its claim to the 340B ADR Panel within 20 business days of the claim acceptance date. The 340B ADR Panel will review the information request and notify the covered entity if the information request is beyond the scope of the claim and will permit the covered entity to resubmit a revised information request if necessary.

(b) The 340B ADR Panel will submit the covered entity's information 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 request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information 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 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 current deadline is not feasible and must outline the proposed timeline for fully responding to the information 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.

§ 10.23 Final agency decision.

(a) The 340B ADR Panel will review documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in paragraph (a)(1) or (2) of § 10.21 has occurred.

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

(2) The draft agency decision letter will be sent to all parties and will include the 340B ADR Panel's preliminary findings regarding the alleged violation.

(3) All parties will have 20 business days to respond to the 340B ADR Panel's draft agency decision letter.

(b) The 340B ADR Panel will review the responses of all parties in producing the final agency decision letter.

(1) The final agency decision letter will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(2) The 340B ADR Panel will submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action.

[FR Doc. 2016–18969 Filed 8–11–16; 8:45 am]

BILLING CODE 4165–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 97

[WT Docket No. 16–239; FCC 16–96]

Amateur Radio Service Rules To Permit Greater Flexibility in Data Communications

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on proposed amendments regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as the baud rate) applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

DATES: Submit comments on or before October 11, 2016, and reply comments are due on or before November 10, 2016.

ADDRESSES: You may submit comments, identified by WT Docket No. 16–239, by any of the following methods:

- *Federal Communications Commission's Web site: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

FOR FURTHER INFORMATION CONTACT: Scot Stone, *Scot.Stone@fcc.gov,* Wireless Telecommunications Bureau, (202) 418–0638, or TTY (202) 418–7233.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), adopted July 27, 2016 and released July 28, 2016. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. This document will also be available via ECFS at *http://fjallfoss.fcc.gov/ecfs/.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

I. Introduction

1. In the *NPRM,* we propose, in response to a petition for rulemaking filed by the AmericanRadio Relay League, Inc. (ARRL), to amend part 97 of the Commission's rules regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as baud rate)—the rate at which the carrier waveform amplitude, frequency, and/or phase is varied to transmit information—applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

II. Background

2. The limitations on radioteletype (RTTY) and data transmissions below 450 MHz vary depending on the frequency band, and on whether the digital code used to encode the signal being transmitted is one of the codes specified in section 97.309(a) of the Commission's rules—Baudot, AMTOR, and ASCII (the ''specified digital codes''). Section 97.307(f) limits the symbol rate for the specified digital codes, and the bandwidth for unspecified digital codes, as follows: