

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Chapter I**

**340B Drug Pricing Program Administrative Dispute Resolution Process**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking and request for comments.

**SUMMARY:** Section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992” enacted Section 340B of the Public Health Service Act (PHSA). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. Section 7102 of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) requires the Secretary of Health and Human Services (HHS) to promulgate regulations to establish and implement an administrative dispute resolution process for the 340B Drug Pricing Program (340B Program). (PHSA Section 340B(a)(5)(D) advises the Secretary on the sanctions available should a covered entity be found to be in violation of (a)(5)(A) or (a)(5)(B). The ANPRM does not currently refer to HRSA’s plan on how it will resolve any decision made through the new Administrative Dispute Resolution Process and the sanctions in current law). These regulations will address a number of issues that have the potential to impact stakeholders. Accordingly, the Health Resources and Services Administration is issuing an advance notice of proposed rulemaking (ANPRM) to solicit public comment on multiple issues regarding implementation of these regulations. These comments will be used, as appropriate, to help draft a proposed rule that will be published in the **Federal Register** for public comments.

**DATES:** Submit electronic or written comments by November 19, 2010.

**ADDRESSES:** Comments in response to this ANPRM should be marked “Comments on Administrative Dispute Resolution Process” and sent to Ms. Dorcas Ann Taylor, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857. Comments may also be e-mailed to: [opadrp@hrsa.gov](mailto:opadrp@hrsa.gov)

**FOR FURTHER INFORMATION CONTACT:** CDR Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Services Bureau (HSB), Health Resources Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Affordable Care Act introduces a number of changes to the 340B Program. The Affordable Care Act creates several new categories of eligibility for participation and provides a number of tools for improvement in compliance by manufacturers and covered entities. Among the tools is the creation of an administrative dispute resolution process for the resolution of claims by covered entities and manufacturers. Section 7102(a) of the Affordable Care Act requires the HHS Secretary to establish and implement an administrative process through regulations for resolution of (1) claims by covered entities that they have been overcharged for drugs purchased through the 340B Program; and (2) claims by manufacturers, after the conduct of audit as authorized by section 340B(a)(5)(C) of the PHSA, of violations of the prohibition of duplicate discounts or rebates and/or the prohibition on resale of drugs purchased under the 340B Program. As amended by the Affordable Care Act, section 340B(d)(3)(B) of the PHSA requires the Secretary to promulgate regulations that shall:

(i) Designate or establish a decision making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) Establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) Establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer’s product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) Require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) Permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) Include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

The 340B Program creates relationships between not only drug manufacturers and covered entities, but also involves, among others, wholesalers, group purchasing organizations, pharmacies, and state Medicaid agencies. Any change to the 340B Program has the potential to alter these relationships. The regulations mandated by the Affordable Care Act will be the first regulations for the 340B Program. Prior to enactment of the Affordable Care Act, the Health Resources and Services Administration (HRSA) did not have a required administrative dispute resolution process. The creation of a required administrative dispute resolution process presents a number of issues in the context of the 340B Program that have the potential to affect a large number of interrelated entities. Given these issues, HRSA is issuing this ANPRM to gather comments prior to committing to a particular regulatory path.

The use of audits and dispute resolution in the 340B program has limited precedent. On December 12, 1996, the Secretary of HHS published the Manufacturer Audit Guidelines and Dispute Resolution Process for the 340B Program (61 FR 65406). That notice provided auditing guidelines to permit the manufacturer of a covered outpatient drug to audit the records of a covered entity directly pertaining to the covered entity’s compliance with the requirements of section 340B(a)(5)(A) and (B) of the PHSA as to drugs purchased from the manufacturer. Section 340B(a)(5)(C) of the PHSA states

the Secretary shall establish guidelines relating to the number, scope and duration of the audits and these audits must be conducted in accordance with guidelines established by the Secretary. Further, the notice provided guidelines for disputes that may arise between covered entities and participating manufacturers regarding implementation of the provisions of section 340B. To resolve these disputes in an expeditious manner, HRSA developed a voluntary dispute resolution process.

## II. Request for Comments

The purpose of this document is to obtain information and public comment on how to efficiently and effectively implement the requirements to create an administrative dispute resolution process for the 340B Program authorized by Section 7102 of the Affordable Care Act. Although HRSA has identified several issues and areas where HRSA believes comment would be particularly helpful, comments may be submitted on any issues directly relevant to the implementation of the specified requirements.

Areas for which HRSA is expressly seeking comment include: (1) Administrative Procedures; (2) Existing Models; (3) Threshold Requirements; (4) Hearings; (5) Decision-making Official or Body; (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 Resolutions with Other Provisions in the Affordable Care Act.

### (1) Administrative Procedures

HRSA is seeking general comments regarding the administrative procedures associated with alternative dispute resolution. Systems must be put in place that address how and when to initiate the dispute resolution process, what level of evidence must be presented, who can be a party to a dispute, how dispute resolution requests will be processed, timelines, what type of notice is required for proposed determinations, and what involvement and notice should be given third parties and the public.

### (2) Existing Models

HRSA is seeking comments regarding what aspects of other existing models for administrative dispute resolution can be adapted to the 340B Program. HRSA is aware of several examples of administrative dispute resolution both

within and outside of the Department. Certain aspects of these other processes can provide useful insight as HRSA implements the 340B Program administrative dispute resolution authority.

One of the most useful existing models is the current dispute resolution guidelines for the 340B Program outlined at 61 FR 65406 (Dec. 12, 1996) (can also be found on the OPA Web site at <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR12121996.htm>). The current dispute resolution guidelines contain a voluntary process for the resolution of disputes between manufacturers and covered entities concerning compliance with the 340B Program. The current guidelines outline the types of disputes covered; steps the parties must take before bringing a dispute; the review process; and the assessment of penalties. While the current process has been underutilized (because it was a voluntary process), it does address many issues specific to creating a dispute resolution process for the 340B Program. HRSA would be interested in receiving comments about what aspects of the current process could be adapted for the new administrative dispute resolution process.

### (3) Threshold Requirements

HRSA is contemplating using a standard for bringing claims analogous to that utilized under the current informal dispute resolution guidelines (61 FR 65406). These guidelines state: "The party requesting the review may not rely only upon allegations but is required to set forth specific facts showing that there is a genuine and substantial issue of material fact in dispute that requires a review. The request for review shall include a clear description of the dispute, shall identify all the issues in the dispute, and shall contain a full statement of the party's position with respect to such issue(s) and the pertinent facts and reasons in support of the party's position. In addition to the required statement, the party shall provide copies of any documents supporting its claim and evidence that a good faith effort was made to resolve the dispute."

Generally, HRSA would expect that the party initiating the dispute to make a showing that it has more than mere allegations and to also demonstrate that it has made a good faith effort to settle the dispute before involving the Department. In the case of covered entities, the dispute must involve a claim of manufacturer overcharge. HRSA may consider claims of overcharge to include direct and indirect evidence of a violation, such as

cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program. In the case of manufacturers, the dispute must involve a claim of a violation of subsections 340B(a)(5)(A) or (a)(5)(B) of the PHSA. Manufacturers' claims can only be brought after the conduct of audits as authorized by subsection (a)(5)(C). Therefore, HRSA would expect that manufacturers would present direct evidence of a covered entity's alleged violations of either 340B(a)(5)(A) or (a)(5)(B).

HRSA is seeking comments on the feasibility of applying this construct to the new statutorily created administrative dispute resolution process.

### (4) Hearings

HRSA expects that the alternative dispute resolution process would involve some type of hearing. The hearing could be either conducted through an exchange of documents, in-person, or by web access. HRSA is inviting comments on the manner in which such a hearing should be structured. HRSA is considering a large number of issues involved in creating a fair and efficient hearing process, including, but not limited to: Ex parte contacts; rehearing conferences; subpoenas; form, filing and service of papers; motions; sanctions; burden of proof; evidence; and post-hearing briefs.

### (5) Decision-making Official or Body

HRSA expects to designate or establish a decision-making official or body from within the Department. HRSA welcomes comments as to whether the same or different decision-makers should decide the sufficiency to state a claim and to make a final determination on a claim. HRSA also invites comments on whether the decision-making official or body should be within HRSA, within OPA, or come from other parts of the Department.

### (6) Appropriate Appeals Procedures

HRSA expects to establish an appeals process applicable to a final administrative determination rendered by the decision-making body or official. In addition to comments regarding existing models and the applicability of the Administrative Procedures Act, HRSA is requesting public comment on the procedures related to this new 340B dispute resolution process.

### (7) Deadlines

HRSA invites comments on whether claims should be time barred and the standards applicable for maximum

timeframes to bring a claim. HRSA invites comments on deadlines for responses to submissions by the participants, the government and deciding body or official and the consequences of failure to meet a particular deadline.

#### (8) *Discovery Procedures*

HRSA is requesting input on the process used for discovery of information from participating manufacturers and covered entities. HRSA will need to determine the scope of documents (information, reports, answers, records, accounts, papers, documentary evidence, etc.) and interrogatories eligible for discovery. HRSA will also need to determine under what circumstances (irrelevancy, privileged information, unduly burdensome, etc.) protective orders should be utilized. Procedures to ensure the confidentiality of information discovered will also need to be developed. Finally, a determination will need to be made as to the power to compel discovery from third parties given that OPA has limited direct regulatory authority through the 340B Program over entities and individuals outside of 340B participating drug manufacturers and covered entities.

#### (9) *Manufacturer Audits*

The administrative dispute resolution requirements of the Affordable Care Act set forth that manufacturers must conduct an audit of a covered entity prior to bringing a claim. HRSA currently has guidelines regarding the requirements for initiating an audit (61 FR 65406). However, over the history of the 340B Program manufacturers have rarely utilized the process in the guidelines to conduct an audit. HRSA invites comments on whether it is appropriate or necessary to modify the guidelines concerning audits prior to implementing the administrative dispute resolution regulation or whether the current final guidelines are sufficient.

#### (10) *Consolidation of Manufacturer Claims*

HRSA is required to create a process for consideration of whether requests by a manufacturer or manufacturers to consolidate claims by more than one manufacturer against the same covered entity are "appropriate and consistent with the goals of fairness and economy of resources." HRSA seeks comments on how to create this process, the evidence to be considered, timing of requests to join in a consolidated claim, and the interests to be weighed.

#### (11) *Covered Entity Consolidation of Claims*

Similar to the consolidation of manufacturer claims, HRSA is required to create a process for consideration of requests for consolidation of particular covered entity claims. HRSA invites comment on whether the standard for manufacturers and covered entities should differ and whether there should be a presumption of allowing such consolidation of claims absent a finding that consolidation would be inconsistent with the goals of fairness and economy of resources.

#### (12) *Claims by Organizations Representing Covered Entities*

The legislation provides for claims by organizations representing entities. HRSA is interested in input on when a third party can bring claims on behalf of member covered entities in the context of a binding formal dispute resolution process and how to ensure that the group in fact represents the interests of the covered entities. In order to ensure that such organizations actually represent the interests of covered entities, HRSA is contemplating that prior to seeking to file a claim on behalf of covered entities, such groups must have a signed agreement with the covered entities. The agreement would indicate that the organization is authorized to bring a claim on behalf of the covered entities; the precise nature of the claim; that the covered entities agree to participate in good faith and abide by discovery procedures; and that the covered entities agree to be bound by any decision of the decision-making official or body. HRSA contemplates a decision-making official or body having the authority to not allow claims that would result in unfairness or a substantial waste of resources.

#### (13) *Integration of Dispute Resolutions With Other Provisions in the Affordable Care Act*

In addition to the compliance tools already available to HRSA, such as audits and alternative dispute resolution, the Affordable Care Act provides HRSA with many additional tools to monitor compliance. These additional tools include establishing procedures to verify the accuracy of ceiling prices; creating processes for manufacturers to refund overcharges; selective auditing of manufacturers; annual recertification of covered entities; and providing access to ceiling price information. The use of the new administrative dispute resolution authority must be used in conjunction with these other compliance tools to

ensure its most effective use. HRSA invites comments concerning the relationship between administrative dispute resolution and other oversight mechanisms.

While these thirteen areas were identified for comment, we welcome comments on any other issues that stakeholders believe are key to implementing an effective alternate dispute resolution process.

Dated: September 14, 2010.

**Mary K. Wakefield,**  
Administrator.

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 635

[Docket No. 100825390-0431-01]

RIN 0648-BA17

#### Atlantic Highly Migratory Species; Atlantic Shark Management Measures

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Advance notice of proposed rulemaking; request for comments.

**SUMMARY:** NMFS issues this advance notice of proposed rulemaking (ANPR) to provide background information and request public comment on potential adjustments to the regulations governing the U.S. Atlantic shark fishery to address several specific issues currently affecting management of the shark fishery and to identify specific goals for management of fishery in the future. NMFS is requesting public comment regarding the potential implementation of changes to the quota and/or permit structure that are currently in place for the Atlantic shark fishery. NMFS is also requesting comments on the implementation of programs such as catch shares, limited access privilege programs (LAPPs), individual fishing quotas (IFQs), and/or sectors for the Atlantic shark fishery.

**DATES:** Written comments regarding the issues in this ANPR must be received no later than 5 p.m. on January 14, 2011.

Public meetings to obtain additional comments on the items discussed in this ANPR will be held in September, October, November, and December 2010. Please see the **SUPPLEMENTARY INFORMATION** section of this ANPR for specific dates, times, and locations.