October 11, 2016

Capt. Krista Pedley
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Dear Capt. Pedley:

On behalf of the thousands of providers enrolled in the 340B federal drug discount program, the undersigned organizations respectfully submit this letter in response to the Notice of Proposed Rulemaking published in the Federal Register on August 12, 2016 (Proposed Rule). The Proposed Rule, *340B Drug Pricing Program; Administrative Dispute Resolution Proposed Rule*, 81 Fed. Reg. 53,381 (Aug. 12, 2016) (RIN 0906-AA90), establishes the Alternative Dispute Resolution (ADR) process (ADR Process) described in the 340B statute. We generally applaud HRSA’s efforts in implementing the ADR Process, and offer these comments to assist the agency in ensuring that the ADR Process will be conducted fairly, efficiently, and expeditiously.

I. General Comments on Deadlines

Before addressing specific aspects of the Proposed Rule, we would like to comment more generally on the deadlines that HRSA has proposed for the ADR Process. We have identified several steps in the ADR Process that have no deadlines. We feel strongly that deadlines should be established for these steps, and, towards that end, we recommend several specific deadlines. Our recommendations are summarized in the chart below. We also offer two suggestions on how to establish and extend ADR-related deadlines.

First, we urge HRSA to adopt conventions for deadlines that are commonly used by other administrative bodies and courts: 1) use calendar days to count deadlines rather than business days; 2) not include the day of the act or event from which the time period begins, but include the last day, in the count of days; 3) if the last day of the time period is a Saturday, Sunday or Federal legal holiday, or a day in which the reviewing agency was not able to conduct business due to extraordinary circumstances beyond its control, the deadline becomes the next business day. Misunderstandings about correct deadlines and due dates can be avoided if HRSA adopts these well recognized and commonly used conventions.

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Second, HRSA should create a process for parties to request extensions of deadlines. The ADR Process must accommodate a wide range of covered entity types and manufacturers, and each case will be unique. We anticipate that covered entities and manufacturers will require flexibility with the ADR deadlines. We therefore propose that HRSA adopt for all ADR deadlines the standards for extensions reflected in proposed § 10.22(c)(2)–(4). Any party could submit a written request to HRSA or the ADR Panel (depending on which entity has authority for that procedure) to extend a deadline, with details explaining why the deadline is not feasible and proposing an alternative. HRSA or the ADR Panel could approve or disapprove the requested extension in writing. Any subsequent deadline affected by an approved extension would also be extended by a corresponding time period. A covered entity or manufacturer would not be permitted to request an extension to file the original claim.

We have summarized below the timeline for the ADR Process based on the Proposed Rule, and we also include our proposed changes and additions to the timeline. We discuss our proposed deadlines in more detail later in these comments.

<table>
<thead>
<tr>
<th>Event</th>
<th>Proposed Rule</th>
<th>340B Organizations’ Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claimant files claim. Proposed 42 C.F.R. § 10.21(b)(1).</td>
<td>Within 3 years of alleged violation.</td>
<td>For covered entity claims related to restatements of the 340B ceiling price, the three-year period should start when the manufacturer restates the ceiling price or a covered entity discovers that the manufacturer should have restated the ceiling price.</td>
</tr>
<tr>
<td>Claimant notifies other party of claims and notifies HRSA of service to the other party. Proposed 42 C.F.R. § 10.21(d)(2).</td>
<td>3 business days after the claim is filed.</td>
<td>Change to 3 calendar days.</td>
</tr>
<tr>
<td>HRSA notifies both parties whether requirements for filing a claim are met. Proposed 42 C.F.R. § 10.21(d)(3).</td>
<td>20 business days after HRSA receives the claim and any “subsequently requested information.”</td>
<td>Change to 30 calendar days.</td>
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<thead>
<tr>
<th>Event</th>
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</tr>
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<tbody>
<tr>
<td>HRSA notifies both parties of the identities of the ADR Panel members</td>
<td>No deadline.</td>
<td>Concurrent with notice from HRSA that the requirements for filing a claim are met.</td>
</tr>
<tr>
<td>Parties may object to ADR Panel member(s). (Not currently in the Proposed Rule.)</td>
<td></td>
<td>20 calendar days from the date that HRSA notifies the parties of the identities of the ADR Panel members.</td>
</tr>
<tr>
<td>Party opposing claimant responds. Proposed 42 C.F.R. § 10.21(e).</td>
<td>20 business days after “receipt of notification that a claim will move forward to the 340B ADR Panel for review.”</td>
<td>Change to 45 calendar days.</td>
</tr>
<tr>
<td>Covered entity submits written request for additional information. Proposed 42 C.F.R. § 10.22(a).</td>
<td>20 business days after “claim acceptance date.”</td>
<td>Change to 30 calendar days.</td>
</tr>
<tr>
<td>ADR Panel reviews any request for information from a covered entity and notifies the covered entity if the request is beyond the scope of the claim. The covered entity may submit an amended request if the original request was outside the scope of the claim. Proposed 42 C.F.R. § 10.22(a).</td>
<td>No deadline.</td>
<td>30 calendar days.</td>
</tr>
<tr>
<td>1. Manufacturer responds to the request for information. Proposed 42 C.F.R. § 10.22(b); OR 2. Manufacturer requests one extension, which outlines a timeline for fully responding. Proposed 42 C.F.R. § 10.22(c)(2).</td>
<td>1. 20 business days after ADR Panel submits the covered entity’s request for information to the manufacturer. 2. 15 business days after ADR Panel submits the covered entity’s request for information to the manufacturer.</td>
<td>1. Change to 30 calendar days. 2. Change to 21 calendar days.</td>
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<tr>
<td>Event</td>
<td>Proposed Rule</td>
<td>340B Organizations’ Proposal</td>
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</tr>
<tr>
<td>ADR Panel approves or disapproves manufacturer’s extension request. Proposed 42 C.F.R. § 10.22(c)(4).</td>
<td>No deadline.</td>
<td>7 calendar days.</td>
</tr>
<tr>
<td>Covered entity’s brief in response to information received from the manufacturer. (Not currently in the Proposed Rule.)</td>
<td></td>
<td>60 calendar days from receipt of the information.</td>
</tr>
<tr>
<td>Manufacturer’s responsive brief regarding the information furnished to the covered entity. (Not currently in the Proposed Rule.)</td>
<td></td>
<td>30 calendar days from receipt of the covered entity’s brief.</td>
</tr>
<tr>
<td>Covered entity’s reply brief regarding the information received from the manufacturer. (Not currently in the Proposed Rule.)</td>
<td></td>
<td>14 calendar days from receipt of the manufacturer’s brief.</td>
</tr>
<tr>
<td>ADR Panel issues draft agency decision. Proposed 42 C.F.R. § 10.23(a)(1).</td>
<td>No deadline.</td>
<td>120 calendar days from: 1. The covered entity’s response to a manufacturer’s claim; or 2. The conclusion of briefing if the claim is brought by a covered entity.</td>
</tr>
<tr>
<td>Both parties submit a response to the draft decision. Proposed 42 C.F.R. § 10.23(a)(3).</td>
<td>20 business days after issuance of ADR Panel draft decision.</td>
<td>Change to 30 calendar days.</td>
</tr>
<tr>
<td>ADR Panel decision submitted to parties and to HRSA, as necessary, for enforcement. Proposed 42 C.F.R. § 10.23(b).</td>
<td>No deadline.</td>
<td>30 calendar days from receipt of the parties’ comments on the ADR Panel’s draft decision.</td>
</tr>
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</table>
II. Proposed Rule Section 10.3 – Definitions

HRSA proposed definitions of four terms: ADR Process, ADR Panel, Claim and Consolidated Claim. We do not have any comments on HRSA’s proposed definitions.

III. Proposed Rule Section 10.20 – ADR Panel

Section 10.20 establishes the ADR Panel and addresses conflicts of interest. We suggest that HRSA revise this regulation to create greater stability on the ADR Panel and to strengthen the conflict of interest provisions. HRSA should also set a deadline of one year for the ADR Panel to issue a decision and provide the claimant with a means of seeking further review if the ADR Panel fails to issue a decision by the deadline.

A. Composition of the ADR Panel

HRSA proposes to establish a three-member ADR Panel to be chosen from a roster of potential members. We believe that ADR Panel members should be appointed to fixed terms and that the roster of potential members should be limited to five individuals. Office of Pharmacy Affairs (OPA) staff should not serve on the ADR Panel in order to preserve its objectivity. Likewise, OPA contractors should not be permitted to serve on the ADR Panel or to advise the ADR Panel unless it invites the contractor to comment.

1. The ADR Panel Should Have a Fixed Membership and Adequate Support Staff

We recommend that HRSA revise the Proposed Rule to establish a fixed pool of seven potential ADR Panel members who would serve on the pool for a defined term. HRSA has requested comments on whether the ADR Panel should be comprised of a set number of voting members to maintain consistency and transparency across each claim that is reviewed. We agree with HRSA that the ADR Panel must be consistent and transparent in its decision making. We are concerned, however, that the proposal to rotate members from a roster of eligible individuals will lead to conflicting decisions if the roster is unduly large. Similar claims may be decided by different ADR Panel members, who would be free to decide the disputes inconsistently with past decisions. In addition, ADR Panel members cannot develop expertise in the details of 340B policies if they serve on the ADR Panel only occasionally. Therefore, the ADR Panel should consist of three members, drawn from a roster of seven individuals, and each individual should serve on the roster for a defined term.

The Medicare Provider Reimbursement Review Board (PRRB) provides a useful model.3 That board is created by statute to decide Medicare reimbursement disputes. The PRRB is

3 42 U.S.C. § 1395oo.
composed of five members, each of which serves a term of five years. The terms are staggered, which ensures that all appointments do not expire simultaneously. Although the statutory provision creating the ADR Process lacks these specific requirements, HRSA should consider emulating aspects of the PRRB.

The PRRB has existed for 40 years and has an established record of issuing consistent decisions and deciding complex Medicare disputes. Its members develop considerable expertise in the fine points of Medicare Part A reimbursement. Like Medicare reimbursement, the 340B program is highly technical and requires adjudicators with experience interpreting and applying the law and agency policies.

Similar to the PRRB, the roster of potential ADR panel members should be limited, and their terms on the roster should be fixed, perhaps for one or two years. We agree with HRSA’s proposal for a three-member ADR Panel, but the panel should not vary in size from case to case. It should always consist of three members. If the panel consists of three members drawn from a limited roster of only seven individuals, the individuals on the roster will develop expertise in 340B matters because they will be called on to decide multiple claims during their terms in office. Limiting the roster to only seven individuals will also increase the likelihood that the ADR Panel will issue decisions that are consistent with one another.

In addition, HRSA should ensure that the ADR Panel has adequate support staff to prevent lengthy adjudication delays. Other adjudicatory bodies within HHS, such as the PRRB, ALJs, and the DAB, all have dedicated staff to perform the many tasks necessary to decide cases, which can include everything from researching legal issues to filing and mailing. Without support staff, the ADR Panel may become backlogged, which would severely diminish the usefulness of the ADR process. HRSA should monitor the ADR Panel’s caseload and add staff as needed to ensure that the Panel can decide disputes expeditiously.

2. OPA Staff and 340B Contractors Should Not Serve on the ADR Panel in Any Capacity

We oppose HRSA’s proposal to include an OPA staff member on the ADR Panel. We also oppose any participation on the ADR Panel by 340B contractors, including the Prime Vendor,

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4 Id. § 1395oo(h).
5 Id.
6 PRRB members are paid a salary for their service on the Board, while HRSA proposes that ADR Panel members will be on loan from subcomponents of HHS or from other federal agencies and will not be paid for service on the ADR Panel. We believe that the PRRB nonetheless is a good model for the ADR Panel, notwithstanding the differing compensation schemes. PRRB members serve full time and have a heavy docket, thus necessitating establishing PRRB membership as a salaried position. The ADR Panel, on the other hand, will likely have a light caseload, and membership on the ADR Panel is unlikely to require members to take significant time away from their usual duties.
and therefore request that HRSA clarify that its contractors will not serve on the 340B ADR Panel.

HRSA proposes to include a non-voting OPA staff member and has requested comments on whether the OPA member should be permitted to vote. We strongly oppose the appointment of OPA staff to the ADR Panel in any capacity, whether voting or non-voting. Many disputes will concern the interpretation of 340B statutory requirements, and the parties may argue that OPA policies are inconsistent with statutory requirements. An OPA staff member would not be an impartial adjudicator in these disputes. Even a non-voting member would exercise too much influence over the voting members, particularly if the voting members serve only part-time on the ADR Panel. In addition, the necessarily close working relationship between OPA and 340B stakeholders makes it difficult to guarantee that any member of that office would not be, or be perceived to be, biased in one direction or another. ADR Panel members must be completely objective and lack bias for or against any party to the dispute.

OPA should instead serve in a strictly “technical assistance” role to be called upon at the ADR Panel’s discretion to clarify OPA policies. The role of OPA in administrative dispute resolution should be limited to serving as a resource for basic information to parties or potential parties as to the applicable rules and procedures and conducting basic training on 340B program for individuals unfamiliar with the program who have volunteered or been appointed to serve as ADR Panel members.

Likewise, OPA contractors should not be permitted to serve on the ADR Panel. Contractors should only be permitted to assist in the ADR adjudication process to answer occasional questions of fact upon request by the ADR Panel. Contractors should not be permitted to advise the ADR Panel on interpretations of the 340B statute or 340B policies, which is HRSA’s responsibility.

B. Conflicts of Interest

We support HRSA’s proposal to screen ADR Panel members for conflicts of interest. HRSA should inform the parties of the identities of the ADR Panel members concurrently with notifying the filing party that it has met the filing requirements. HRSA should clarify that a member who has a conflict will be excluded from that ADR Panel. HRSA should also state who will screen the ADR Panel members. Members should be excluded if their employing agency has a conflict of interest or if the member has a personal objection to the mission or work of particular party. Parties should be permitted to object to the participation of an ADR Panel member.
1. HRSA Should Inform the Parties of the Identities of the ADR Panel Members When HRSA Notifies the Parties That the Claim Is Valid

HRSA should inform the parties as soon as possible of the identities of the ADR Panel members. As explained below, we contend that the parties must be permitted to object to particular ADR Panel members. The parties cannot assess whether ADR Panel members have conflicts of interests until the parties know the identities of the ADR Panel members. We therefore recommend that HRSA revise the Proposed Rule to require that HRSA notify the parties of the ADR Panel members’ identities at the same time that HRSA notifies the parties pursuant to proposed 42 C.F.C. § 10.21(d)(3)(A) that the claim may move forward.

2. HRSA Should Assign Responsibility for Screening ADR Panel Members; Clarify That ADR Panel Members with Conflicts Shall Be Removed; and Disqualify ADR Panel Members if They Personally Object to the Mission or Work of a Party or if Their Employing Agency Has a Conflict of Interest

The Proposed Rule states that all ADR Panel members will be screened for conflicts of interest. The regulation does not state who will screen the members for conflicts. The conflicts screen should be performed by individuals who (1) are familiar with ethics standards, (2) are not political appointees, and (3) operate independently.

The regulation also does not expressly state that members who are determined to have conflicts will be disqualified from the ADR Panel, though this is implied. HRSA should revise the proposed regulation at 42 C.F.R. § 10.20(b) to state that a member who is determined to have a conflict of interest by the office responsible for screening conflicts shall be removed from the ADR Panel.

HRSA should also exclude from the ADR Panel any member who has a personal objection to the mission or work of a particular party or whose employing agency would have a conflict of interest. For example, CMS personnel may have a conflict of interest in duplicate discount cases because the results could benefit the Medicaid program, which CMS administers. In a 340B duplicate discount claim, a manufacturer would allege that a covered entity purchased a drug at a 340B price that was also subject to a Medicaid rebate. If the ADR Panel held in favor of the manufacturer, the covered entity would likely have to repay the 340B discount to the manufacturer, which itself may not impact the Medicaid rebate. Our concern is that CMS personnel would have an interest in construing 340B policies in ways that increase the types of transactions deemed to be ineligible for 340B discounts. This would result in state Medicaid agencies seeking rebates on a greater number of drugs, thus benefiting the Medicaid program at the expense of safety-net 340B covered entities.
The potential conflict of interest is likely to arise in diversion cases involving Medicaid managed care drugs. Many outpatient drugs dispensed or administered to the Medicaid managed care population are purchased through the 340B drug program. States are precluded from seeking rebates on such drugs because a duplicate discount problem would arise if they did. If, consistent with a manufacturer’s claim, the ADR Panel decides that the respondent applied the 340B patient definition too broadly, then fewer of the entity’s drugs would qualify for 340B pricing which, in turn, would mean that fewer of the entity’s drugs would be subject to duplicate discounts. The Panel’s decision would entitle the Medicaid program to collect rebates on a larger share of the drugs furnished to the Medicaid managed care population because fewer of those drugs would be eligible for 340B discounts.

To avoid conflicts of interest like these, the parties must have a way to challenge the inclusion of CMS personnel on the ADR Panel. CMS is charged with administering the Medicaid drug rebate program and maximizing the rebates that states can legally collect. A CMS representative has an inherent conflict of interest if the Panel’s decision could affect the quantity or size of rebates collected by states. We ask HRSA to disqualify ADR Panel members if the member works at an agency, such as CMS, that has a conflict of interest.

3. **Parties Should Be Permitted to Object to Particular ADR Panel Members**

The Proposed Rule does not create a mechanism for parties to the proceeding to request recusal of particular ADR Panel members. Parties must have the opportunity to object to ADR Panel members in order for the proceedings to be fair and objective. The right to object to adjudicators is enshrined in other HHS proceedings, and HRSA should include it in its ADR regulations. For example the PRRB regulation permits a party to file an objection to a Board member, which will be considered by that member, and, in some cases, by the full Board:

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.7

The regulations governing Medicare Administrative Law judge hearing for appeals of claim determinations also permit parties to object: “If a party objects to the ALJ who will

7 42 C.F.R. § 405.1847.
conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party’s objections and decides whether to proceed with the hearing or withdraw.\"\"8

These regulations should serve as a model for the 340B ADR regulations. The PRRB regulation is particularly applicable, because the PRRB consists of an ADR Panel of decision-makers, much like the ADR Panel. We therefore request that HRSA adopt the core components of the PRRB regulation at 42 C.F.R. § 405.1847. Parties to the ADR proceeding should have the right to object to an ADR Panel member. The ADR Panel member should then consider the objection. If the ADR Panel member does not recuse himself or herself, the party should then have the right to bring its objection to the full ADR Panel.

There should be a limited period to lodge objections to ensure that the right to object is not used improperly as a tool to delay the proceeding. The ten-day deadline in the ALJ regulation is too short for the ADR Process. An ALJ must issue a decision within 90 days of receiving an appellant’s request for hearing.9 The ADR Panel will not operate under such a tight timeframe. Currently, there is no deadline for a 340B ADR decision in the Proposed Rule, and we propose below a one-year deadline that is four times as long as the ALJ deadline. If HRSA adopts our proposal for a one-year deadline for an ADR Panel decision, we suggest that parties have 20 calendar days to object to ADR Panel members, which should start from the date that the party is notified of the identities of the ADR Panel members.

C. HRSA Should Set a Deadline for the ADR Panel’s Decision

We recommend that HRSA add a deadline for the ADR Panel to issue a decision. The Proposed Rule contains no such deadline, and we are extremely concerned that difficult cases could languish for unacceptably long periods, perhaps even years. A timely decision is central to due process in administrative proceedings. We therefore suggest a deadline of six months from the conclusion of briefing for the ADR Panel to issue a decision. HRSA could create exceptions that would extend the deadline, for example if a party fails to produce documentation requested by the ADR Panel that is necessary to decide the case.

We believe that a deadline of six months to issue a decision is reasonable. This deadline is twice the 90-day deadline for Medicare ALJs, who not only must issue a decision in 90 days but also must conduct an evidentiary hearing.10 Although there is currently a large backlog of Medicare ALJ appeals, this is due to the quantity of appeals, not with the deadline itself. Prior

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8 Id. § 405.1026(b).
9 Id. § 405.1016(a)
10 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016(a)
to 2010, ALJs were generally able to meet the deadline.\textsuperscript{11} After that, a number of factors led to a dramatic spike in the number of appeals. This dynamic is unlikely to repeat itself in the 340B context. HRSA has acknowledged that covered entities and manufacturers are unlikely to file large numbers of 340B ADR claims.\textsuperscript{12} A deadline of six months to issue a decision should give the ADR Panel ample time to consider the parties’ arguments and to issue a decision.

We are concerned, however, that decisions of the ADR Panel could in some cases be delayed unacceptably, even if HRSA establishes a deadline for the ADR decisions. If the decision is unduly delayed, a claimant should have a way to bypass the ADR Panel and proceed to federal court. Again, the Medicare claim appeal procedures provide a useful model.\textsuperscript{13}

IV. Proposed Rule Section 10.21 – Claims

A. § 10.21(a)(1) – Claims Permitted by Covered Entity

The proposed regulation at § 10.21(a)(1) states that, for covered entities, the ADR Process is limited to “[c]laims by a covered entity that it has been overcharged, as defined in § 10.11(b), by a manufacturer for a covered outpatient drug.” HRSA should clarify that this definition includes claims by a covered entity that the data and calculations used to determine the 340B ceiling price were inaccurate or incorrect.

1. Claims Related to Manufacturer Overcharges

As stated above, HRSA’s proposed regulation states that covered entities may bring claims to the ADR Panel alleging that a manufacturer “overcharged” it for a covered outpatient drug. The discussion in the preamble to the proposed rule makes clear that HRSA considers an overcharge claim to include instances in which a covered entity is charged more than the manufacturer ceiling price that will be made available in the web portal that HHS is developing or, prior to that time, that HRSA has on file.\textsuperscript{14} HRSA should clarify that an overcharge may also result from a miscalculation or misstatement of the data used to determine the 340B ceiling price and that these miscalculations or misstatements may also provide the basis for a covered entity claim against a manufacturer.

\textsuperscript{12} See 81 Fed. Reg. at 53,386 (discussing Paperwork Reduction Act and stating that the small number of informal ADR cases indicates that the “proposed rule will not have a significant impact on the current reporting and recordkeeping burden for manufacturers or covered entities under the 340B Program.”)
\textsuperscript{13} See 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132.
\textsuperscript{14} See discussion at 81 Fed. Reg. 53,383 regarding covered entity claims.
In the proposed regulation, an overcharge is defined by reference to § 10.11, which is a definition included in HRSA’s proposed regulations addressing the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties. Proposed § 10.11(b) defines an overcharge as “any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug.” There are numerous factors that may result in a covered entity paying more than the 340B ceiling price for a drug, and so HRSA should clarify that an overcharge can occur if the ceiling price in HRSA’s database has been miscalculated.

The 340B ceiling price is the result of several calculations using a significant amount of data. In its proposed regulations defining the 340B ceiling price, HRSA defined the 340B ceiling price at § 10.10(a) as “equal to the Average Manufacturer Price (AMP) for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places . . . . HRSA then multiplies this amount by the drug’s package size and case package size.” HRSA proposed to define AMP as having the same meaning as set forth in the Medicaid rebate statute, 1927(k)(1) of the Social Security Act. Section 1927(k) of the Social Security Act defines AMP as the average price paid to manufacturers by wholesalers and retail pharmacies during the rebate period, with a number of exclusions, including exclusions for prompt pay discounts.

Again, the 340B ceiling price calculation is the result of numerous data points and calculations, and, if the manufacturer uses incorrect data or does not apply the correct formula to the data, a 340B covered entity pays an incorrect 340B ceiling price and may be overcharged. A 2006 HHS Office of Inspector General report on the accuracy of 340B ceiling prices found that 14% of the prices in its sample were incorrect, which resulted in overpayments by covered entities of almost $4 million in only one month. Clearly, the risk of overcharges to covered entities is real. Therefore, we request that HRSA make clear that an overcharge claim can include one involving the data or calculations that are used to determine the 340B ceiling price.

2. Claims Related to a Manufacturer’s Refusal to Offer a Covered Outpatient Drug at or below the Ceiling Price

HRSA should clarify that an overcharge claim includes instances in which a manufacturer fails to offer a drug to the covered entity at or below the 340B price. The 340B statute requires

15 80 Fed. Reg. 34,583, 34,585 (June 17, 2015).
16 Id. Proposed § 10.11(b) includes subsections that refine this definition (e.g., each order for an NDC will constitute a single instance of overcharging). Id.
17 Id.
18 Id. at 34,587.
manufacturers to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” This “must offer” provision is a broad statutory mandate that makes no exceptions. If a drug requires special handling, storage, and preparation to ensure patient safety (e.g., a Risk Evaluation and Mitigation Strategy (REMS) required by the Food and Drug Administration), then it is reasonable for a manufacturer to require that purchasers be able to meet those requirements. If the covered entity can meet those requirements, the manufacturer is clearly required to sell the drug at a 340B price to the entity. Even if the entity itself cannot meet the requirements (e.g., the entity does not have its own specialty pharmacy), then the entity must still be able to purchase the drug through a contract pharmacy arrangement with a specialty pharmacy in the manufacturer's network, assuming the arrangement meets all safety requirements. There is no legitimate reason for a manufacturer to withhold 340B pricing in this situation. A manufacturer’s failure to offer 340B pricing in such instances is a clear violation of the “must offer” provision and is an overcharge that should be subject to the ADR process.

B. § 10.21(a)(2) – Claims Permitted by Manufacturer

The proposed regulation at § 10.21(a)(2) states that the ADR Process is limited to “claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) 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.” 340B Health agrees with HRSA’s decision to include the prerequisite of a manufacturer audit to describe a manufacturer claim. As explained below, we urge HRSA to incorporate provisions that exclude from the description of a manufacturer claim certain disputes related to duplicate discounts.

1. Statutory Requirement for a Manufacturer Audit

We recognize that the 340B statute mandates that manufacturers conduct an audit before entering into the ADR Process. We support HRSA’s proposal to incorporate this statutory requirement in the regulation.

2. Types of Manufacturer Claims

We support HRSA’s proposal to limit manufacturer claims to allegations of diversion and duplicate discounts as required by the statute. The 340B statute restricts manufacturer claims to “violations of subsections (a)(5)(A) or (a)(5)(B).” Subsection (a)(5)(A) concerns duplicate discounts, while subsection (a)(5)(B) concerns diversion. By expressly referencing subsections

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20 42 U.S.C. § 256b(a).
(a)(5)(A) or (a)(5)(B), the statute forecloses other types of manufacturer claims. HRSA’s proposal is thus compelled by the statute.

3. Allegations Involving Duplicate Discounts

HRSA should exclude certain types of allegations involving duplicate discounts from its description of a manufacturer claim. Specifically, we request that HRSA exclude allegations of duplicate discounts on claims submitted to Medicaid managed care organizations (MCOs); 2) a covered entity was at fault by not notifying the state Medicaid agency that it furnished 340B drugs to Medicaid fee-for-service (FFS) beneficiaries in accordance with federal or state requirements (e.g., the covered entity incorrectly elected Medicaid carve out status on the OPA database or failed to include state-mandated modifiers on its claims), but the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity; 3) a covered entity has correctly listed its carve in status on the OPA database and has included state-mandated modifiers on its claims, or otherwise followed state requirements to identify 340B drugs, but the state Medicaid agency claimed rebates on the 340B drugs purchased by the covered entity nonetheless.

In this regard, we urge HRSA to include a provision stating that a manufacturer claim alleging a duplicate discount violation is complete only if the manufacturer can demonstrate that: 1) the covered entity acted in error by, for example, selecting carve out status on the OPA database when the covered entity used 340B drugs for Medicaid FFS patients or failing to include the 340B modifier on a claim submitted to the state Medicaid agency; and 2) that the state Medicaid agency received a rebate on a drug purchased with 340B drugs and furnished to a Medicaid fee-for-service beneficiary. With regard to the second requirement, HRSA should require the manufacturer to submit documentation from the state Medicaid agency to show that the agency received rebates on the drugs at issue.

a) Allegations Involving Medicaid Managed Care Organization Claims

We recognize the interest in ensuring that manufacturers do not pay a 340B discount and a Medicaid rebate on the same drug, and we support having all stakeholders working to ensure that this does not occur. With respect to claims submitted to Medicaid MCOs, however, both the 340B and the Medicaid rebate statutes dictate that the state is responsible for avoiding duplicate discounts. A covered entity should not be held responsible if a state incorrectly claims a rebate.
Since its enactment in 1992, the 340B statute has recognized that drug manufacturers might be subjected to “duplicate discounts” if a state Medicaid agency requested a Medicaid rebate on a drug that was sold to a covered entity at or below the 340B ceiling price.\(^22\) The 340B statute states that a covered entity “shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under [the 340B statute] if the drug is subject to the payment of a rebate under [the Medicaid drug rebate statute].”\(^23\)

From 1990 to 2010, the Medicaid drug rebate statute only allowed state Medicaid agencies to claim a rebate on covered outpatient drugs when the drug was paid on a FFS basis.\(^24\) When the Affordable Care Act was enacted in 2010, it amended the Medicaid drug rebate statute to permit states to seek rebates for drugs covered by MCOs.\(^25\)

Congress also amended the Medicaid rebate statute to state that “[c]overed outpatient drugs are not subject to the requirements of this section [i.e., not subject to a rebate] if such drugs are . . . (A) dispensed by health maintenance organizations including Medicaid managed care organizations . . . and (B) subject to discounts under section 340B of the Public Health Service Act.”\(^26\) Notably, Congress did not amend the duplicate discount provisions of the 340B statute. The language of the duplicate discount provision in the Medicaid rebate statute clearly puts the onus on state Medicaid agencies to avoid duplicate discounts on Medicaid MCO claims. Because it is the state Medicaid agency’s responsibility to avoid duplicate discounts for drugs reimbursed by a Medicaid MCO, manufacturers should not be permitted to bring a claim against a covered entity through the ADR Process in these cases.

Moreover, the 340B statute allows manufacturers to bring claims only with respect to sections 340B(a)(5)(A) and (B) of the statute. Section 340B(a)(5)(A) addresses duplicate

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\(^23\) 42 U.S.C. § 256(a)(5)(A) (emphasis added).
\(^24\) See Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, § 4401 104 Stat. 1388, 1388-143 to -159. This is the subject to the mechanism described above, whereby a state may not collect a rebate covered outpatient drugs purchased at the 340B price.
\(^26\) 42 U.S.C. § 1396r-8(j)(1) (emphasis added). To ensure that states have the data needed to avoid rebates on 340B Medicaid MCO claims, Congress amended statutory contracting rules for MCOs to require MCOs to exclude National Drug Codes (NDCs) for 340B drugs from the reports they provide to states. 42 U.S.C. § 1396b(m)(2)(A)(xiii). The Centers for Medicare and Medicaid Services (CMS) issued a final regulation in May 2016 to implement this statutory requirement. 81 Fed. Reg. 27,498 (May 6, 2016). The regulation mandates that states contractually require Medicaid MCOs to identify and exclude 340B claims from the utilization reports they provide for purposes of requesting Medicaid rebates, or require covered entities to submit 340B claims data directly to the state instead of MCOs. Id. at 27,546–49; codified at 42 C.F.R. § 438.3(s)(3).
discounts for Medicaid FFS claims only. (Section 340B(a)(5)(B) addresses diversion.)

As stated above, the provision protecting manufacturers from duplicate discounts is at 42 U.S.C. § 1396r-8(j)(1). Accordingly, the 340B statute does not permit manufacturers to audit or submit a claim to the ADR Panel related to duplicate discounts for drugs reimbursed by a Medicaid MCO.

b) Allegations Which Do Not Involve Payment of a Duplicate Discount

We request that HRSA define an “alleged violation” to exclude circumstances in which a covered entity has incorrectly elected Medicaid carve out status on the OPA database and purchased 340B drugs to dispense or administer to Medicaid FFS beneficiaries, but the manufacturer did not pay a rebate to the state Medicaid agency for the drug. This situation often arises when the covered entity has included state-mandated modifiers on its claims, or otherwise followed state requirements to identify 340B drugs, such that the state Medicaid agency did not claim rebates on the 340B drugs purchased by the covered entity. In other cases, the state may not have had systems in place to obtain rebates on certain types of drugs. In these instances, the manufacturer did not pay a duplicate discount and, therefore, there is no practical reason for the ADR Panel to review the claim.

The manufacturer should bear the burden to show evidence from the state Medicaid agency that the agency received a rebate, and the manufacturer should be required to submit that documentation with its claim as a condition for HRSA to approve the sufficiency of the alleged duplicate discount claim. Covered entities should not be required to repay 340B discounts to manufacturers if the manufacturer has not, in fact, paid a duplicate discount. The only entity that can definitively verify whether a state Medicaid agency received a rebate for a drug is the state Medicaid agency. The manufacturer should bear the burden to show evidence from the state Medicaid agency confirming that it received rebates on the drugs at issue.

c) Allegations for Which the Covered Entity Is Not at Fault

We request that HRSA define an “alleged violation” to exclude circumstances in which the covered entity has correctly stated its carve in status on the OPA database and has included state-mandated modifiers on its claims, or otherwise followed state requirements to identify 340B drugs, but the state Medicaid agency claimed rebates on the 340B drugs purchased by the covered entity nonetheless. In this scenario, the covered entity followed both HRSA and state requirements to alert the state that it uses 340B drugs for Medicaid beneficiaries, but the state Medicaid agency improperly sought a rebate. In these instances, the covered entity is not at

27 In the conflicts of interest discussion above, we provided an example that concerns *diversion* claims related to Medicare managed care drug purchases. That example is not in conflict with our position here that manufacturers should not be permitted to bring *duplicate discount* claims related to Medicare managed care drug purchases.
fault, and the manufacturer should be seeking redress against the state Medicaid agency, not against the covered entity through the ADR Process.

C. § 10.21(b) – Requirements for Filing a Claim

This provision states that a covered entity or manufacturer must file a claim in writing to HRSA within three years of the date of the alleged violation. The parties must maintain files, documents or records associated with the claim until the final agency letter is issued. The preamble to the regulations states that the three-year limitation period begins on the “date of the sale (or payment) at issue.”

We agree with the three-year time limit but urge HRSA to adopt a different start date to determine the limit when a manufacturer restates the 340B ceiling price or a covered entity discovers that the manufacturer should have restated the 340B ceiling price. We urge HRSA to make available pricing data for the previous twelve quarters when it launches its secure portal to allow covered entities to check 340B ceiling prices so that the three-year look-back period is meaningful for covered entities. We ask that HRSA clarify that covered entities can provide documentation to support a claim that the 340B price was miscalculated to support a claim. Was request that HRSA clarify that any information submitted by either party must comply with federal and state patient privacy laws.

1. We Generally Support a Three-Year Time Limit on Claims but Request Clarification for Certain Claims

We agree with HRSA’s proposal to require that claims be submitted within three years after an alleged violation occurs. Historically, under the Manufacturer Audit Guidelines, HRSA has expected covered entities to retain records for three years. HRSA’s proposed three-year limitation for bringing a claim comports with this period for covered entities to retain documents for purposes of a manufacturer audit.

We also agree that the three-year limitation period should begin on the date of the sale or payment at issue (as stated in the preamble), except in two cases: 1) the manufacturer issues a restatement of the average manufacturer price (AMP), best price, customary prompt pay discounts, nominal prices, or other data that affects the 340B ceiling prices for an NDC; or 2) the manufacturer should have issued a restatement of any of this data. In the first instance, the three-year limit should begin on the date that the manufacturer restates the data, and, in the second instance, the three-year period should begin on the date that the covered entity discovers that the manufacturer should have restated the data. Using a different starting point

to begin the three-year limitation period in these circumstances should not cause any hardship to manufacturers because each manufacturer is required to retain for ten years any records supporting its calculations of AMP, best price, customary prompt payment discounts, and nominal prices.\(^{30}\)

2. **HRSA Should Make Twelve Quarters of Historic Pricing Data Available to Covered Entities When It Launches Its 340B Price Web Portal**

Because HRSA is establishing a three-year limitation on the time that a covered entity may file a claim of an alleged overcharge, it is important that covered entities have access to 340B ceiling prices that coincide with this period. Therefore, we request that, when HRSA implements its web portal to provide covered entities with access to 340B pricing data, it include data for the last twelve quarters. If HRSA does not include this information, a covered entity may have no way of exercising its right to bring an overcharge claim on drugs purchased in the three years prior to the implementation of the HHS web portal.

3. **HRSA Should Clarify That the Documentation to Support a Covered Entity’s Claim May Include Documents to Show That the 340B Ceiling Price Was Not Calculated Correctly**

The proposed regulation at § 10.21(b)(2) states that a covered entity filing an overcharge claim must provide documents sufficient to demonstrate the claim. The preamble to the Proposed Rule states that HHS is developing a system for covered entities to verify ceiling prices and, “[u]ntil 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.”\(^{31}\) We ask HRSA to clarify that a covered entity would not be required to provide the 340B ceiling price in its claim for the relevant calendar quarter or quarters until the system to verify these prices is available to covered entities.

HRSA also provides examples in the preamble of the type of documentation that a covered entity would have to submit to support a claim. This documentation could include a 340B purchasing invoice, the 340B ceiling price for the applicable quarter or quarters, and records of attempts to buy the drug at 340B ceiling prices.\(^{32}\) HRSA states that it believes that this documentation should be readily available to a covered entity but requests comments on the feasibility of producing the documentation.

\(^{30}\) 42 C.F.R. § 447.510(f).
\(^{32}\) Id.
We appreciate the detail that HRSA provided regarding the type of documentation that a covered entity might provide to support a claim. HRSA’s examples of the documentation that might support a claim appear to be related to a situation in which the 340B covered entity could not purchase a drug at the 340B ceiling price reported by HRSA or on the web portal that HRSA is developing. We agree that this type of documentation should be readily available to a covered entity, particularly after HRSA implements the secure website to document 340B ceiling prices.

As discussed above, however, we propose that a covered entity may also bring a claim under the ADR Process when a manufacturer’s data, or the calculations on which the ceiling price is based, is incorrect. For these types of violations, a covered entity might include with its claim documentation showing (for example) that a better price for a drug was available in the open market than was offered to the covered entity; that a drug price has increased faster than the CPI-U rate of inflation; that the initial price charged for a new drug in the first three quarters was higher than the calculated 340B ceiling price and the manufacturer did not offer refunds for prior quarters; settlements between drug manufacturers and federal and/or state government agencies alleging underpayment of Medicaid rebates; or that manufacturers have not been following CMS policy in calculating AMP, best price, or other factors that are used to calculate the 340B ceiling price. 33 We request that HRSA confirm that this type of documentation would also support a claim of an overcharge against a manufacturer.

4. All Parties to the Dispute Must Comply with Patient Privacy Laws

Any information provided by either party to the dispute must comply with federal and state patient privacy laws. Therefore, it is essential that any data submitted to HRSA or the ADR Panel throughout the dispute resolution process be de-identified to protect the confidentiality of legally protected patient information.

D. § 10.21(c)(1) – Consolidation of Covered Entity Claims

HRSA’s proposed regulation at § 10.21(c)(1) states that covered entities may consolidate claims against a manufacturer for the same drug or drugs if each of the covered entities could have brought a claim against the manufacturer individually. The regulations also allow an association or organization representing covered entities to bring a claim against a manufacturer if each of the covered entities could have brought a claim against the manufacturer individually. We support HRSA’s proposed regulation related to consolidation of

33 We note, for example, that CMS recently uncovered a situation in which a manufacturer’s “best price” was higher than its AMP for the same drug. See CMS Medicaid Drug Rebate Program Notice, Release No. 100, (07/21/16); available at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-100.pdf.
covered entity and manufacturer claims, but requests that HRSA include clarifying language on some issues.

1. **We Support HRSA’s Proposed Regulation to Allow Covered Entities to Consolidate Claims against Manufacturers Alleging Overcharges for the Same Drug or Drugs**

   We support HRSA’s proposal to allow covered entities to consolidate claims against manufacturers alleging overcharges by the same manufacturer for the same drug or drugs and to allow an association or organization to file claims on behalf of multiple covered entities in these circumstances. HRSA’s proposed regulation is consistent with the language of the 340B statute, which permits “multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding”. 34

2. **HRSA Should Clarify That Covered Entities May Consolidate Claims without Complete Commonality of All Drugs at Issue**

   HRSA should make clear that multiple covered entities may consolidate claims as long as they have in common an overcharge allegation relating to at least one of the same NDCs. For example, if one covered entity alleges overcharges against a manufacturer for three NDCs and another covered entity alleges overcharges against the same manufacturer for two out of three of those NDCs (potentially because the second covered entity only purchased two of the three drugs), the covered entities should be permitted to consolidate their claims.

E. **§ 10.21(c)(2) Consolidation of Manufacturer Claims**

   The proposed regulation at § 10.21(c)(2) allows manufacturers to consolidate claims against covered entities if each manufacturer could individually file a claim against the covered entity, and the ADR Panel determines that consolidation is appropriate and consistent with the goals of fairness and economy of resources. In addition, the proposed regulation states that associations or organizations may not bring claims on behalf of manufacturers.

   HRSA requests comments on the grounds under which consolidation of manufacturer claims would be consistent with the statutory goals of fairness and economy of resources. HRSA also requests comments how manufacturers requesting to consolidate claims can satisfy the audit requirement.

   First, the statute clearly requires that each manufacturer in a consolidated claim must conduct an audit prior to bringing the claim. Second, we believe that consolidation of

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manufacturer claims would not be consistent with the statutory goals of fairness and economy of resources if the facts underlying the claim are different. Lastly, we support HRSA’s decision, which is required by the statute, not to permit associations or organizations to bring claims on behalf of manufactures.

1. The 340B Statute Requires That Each Manufacturer Complete an Audit before Bringing a Claim

We support HRSA’s proposal to allow manufacturers to consolidate claims if, among other requirements, the manufacturer could individually file a claim against a covered entity. As noted by HRSA, one of the requirements for a manufacturer to file an individual claim is that the manufacturer must have conducted an audit of the covered entity. In fact, the 340B statute states two times that a manufacturer must audit a covered entity before bringing a claim. This statutory requirement precludes the ADR Panel from allowing manufacturers to consolidate claims unless each of the manufacturers has audited the covered entity. This requirement is statutory, and manufacturers must follow the requirement despite any “operational challenges” it may create. Therefore, we ask HRSA to clarify that if manufacturers bring a consolidated claim against a covered entity, each of the manufacturers must have individually audited the covered entity.

2. Comments on Consolidation “Consistent with the Goals of Fairness and Economy of Resources”

We also support HRSA’s proposal to incorporate the statutory language that allows manufacturers to consolidate claims only if the ADR Panel “determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources.” As stated above, HRSA requested comments on the circumstances in which consolidation would be consistent with the statutory goals of fairness and economy of resources.

Consolidation of manufacturers’ claims would be “consistent with the goals of fairness and economy of resources” only if the facts related to the covered entity are the same for both manufacturers. For example, the ADR Panel should not consolidate claims alleging that a hospital provided 340B drugs to an inpatient because it did not follow its policies and procedures for determining when a patient is admitted as an inpatient if one manufacturer’s allegations involve a patient initially treated in the emergency department and another

38 Id. at 53,384.
39 Id. at 53,384.
manufacturer’s allegations involve a patient initially under observation. Each of these claims would require the covered entity to respond to the specific facts supporting the claim and consolidating such claims would not be consistent with the goals of fairness and economy of resources.

On the other hand, consolidation of multiple claims by manufacturers may be appropriate if the drug at issue is a generic drug, and the facts relating to the alleged violation are identical. A duplicate discount claim, for example, could rest on a set of facts that turn on how a specific generic drug was billed by the covered entity but not on the drug’s manufacturer. If the covered entity purchased the generic drug from multiple manufacturers, and if the identity of the drug’s manufacturer has no bearing on the covered entity’s billing practices that are central to the duplicate discount claim, then it would be appropriate to consolidate the claims brought by the relevant generic drug manufacturers.40

3. We Support HRSA’s Proposal to Prohibit Associations or Organizations from Representing Manufacturers in Claims

We support HRSA’s proposed regulation to prohibit joint claims filed on behalf of manufacturers by associations or organizations representing manufacturer interests.41 A plain reading of the 340B statute dictates that manufacturer associations or organizations may not bring claims on behalf of their members. Congress specifically stated that covered entities may be represented by associations or organizations in consolidated claims, but Congress did not provide for associational representation in the section of the statute addressing consolidation of manufacturer claims. This difference in the two provisions addressing consolidation of claims was clearly intentional: “it is a general principle of statutory construction that when Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” 42 Had Congress intended that associations or organizations could represent manufacturers in the ADR Process, it clearly would have included a provision that authorized such actions. HRSA would be acting contrary to the 340B statute if it permitted manufacturers to be represented by associations or organizations in the ADR Process.

40 In contrast to generic drugs, brand name drugs are generally billed and reimbursed under unique billing codes (for example J codes), and so consolidation would not be appropriate when the alleged duplicate discount involves brand name drugs.

41 Id.

Also, it is reasonable to assume that Congress had sound policy reasons for allowing associations and organizations to represent covered entities in the ADR Process, while not providing that option to manufacturers. Many covered entities, such as small rural hospitals and grantees or FQHC look-alikes, operate on limited budgets. As a practical matter, these covered entities will not have the resources to bring a claim to the ADR Panel if they are not represented by an association or organization. Manufacturers, on the other hand, can be presumed to have sufficient financial resources to bring a claim without the need for an association or organization to represent their interests.

F. Deadlines and Procedures for Filing a Claim – Section 10.21(d)

In subsection 10.21(d) of the Proposed Rule, HRSA establishes the process and timeframe for filing a claim and initiating the ADR Process. HRSA also describes the notice of a filed claim that must be provided to the opposing party. Finally, HRSA establishes the timelines and procedures that it will follow when determining whether a claim will move forward in the ADR Process. In commenting on these proposals, we recognize that Congress charged HRSA with establishing deadlines and procedures that promote the goal of resolving claims “fairly, efficiently, and expeditiously.”

1. HRSA Should Revise the Notice and Delivery Provisions to Improve Transparency and Streamline the ADR Process

Section 10.21(d)(2) provides that the party filing a claim must notify the opposing party:

[N]otify the other 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.

This provision lacks needed specificity regarding the content and delivery of the notice to the other party. First, HRSA should revise section 10.21(d)(2) to specify that the filing party should be required to provide the actual documents submitted to the ADR Panel, including the claim itself, and not just a summary. Second, if a covered entity sends the notice to the address that a manufacturer has listed in the 340B database, the covered entity should be deemed to satisfy the notice requirement.

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a) HRSA Should Specify That the Notice Must Include the Claim Itself and Copies of All Documents Submitted

Section 10.21(d)(2) requires the party filing a claim to submit a notification to the other party, but does not specify that the notice must include the claim itself. The respondent in the ADR Process will be unfairly prejudiced if it cannot see the information that has been filed by the other party. The responding party must be able to evaluate the claim fully so that it can directly address the filing party’s arguments.

Likewise, the filing party should be required to share with the responding party all of the documents it filed with HRSA. The ADR Process benefits from the full and open exchange of information. Though HRSA expects the parties to conduct a good faith effort to resolve a dispute before submitting an ADR claim, it is possible—even likely—that the arguments presented by the filing party will not be fully developed until they are formulated in the more formal claim submitted to HRSA. The parties might be able to resolve the matter without the assistance of the ADR Panel once both sides’ positions are clear.

Full disclosure of the filing documents also might prevent some parties from seeking judicial review of ADR Panel decisions. A party dissatisfied with an ADR Panel decision might be more prone to seek additional review if it has not had the opportunity to review the evidence on which the ADR Panel relied.

Constitutional procedural due process requires that the responding party be given full and adequate notice of the claim being brought against it. The responding party is owed “notice reasonably calculated . . . to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.”

b) The Rule Should Permit Service of Notice to the Address Listed in the 340B Database

Section 10.21(d)(2) addresses not only the content of a notice that a claim has been filed but also the manner and timeframe in which it must be delivered. HRSA has proposed a short timeframe of only three business days in which the filing party must notify the opposing party. To meet that timeframe, covered entities and manufacturers must have a reliable point of contact.

HRSA maintains a 340B database that should be suitable for that purpose. Covered entities are required to maintain accurate database entries and, by law, must recertify annually.

45 See U.S. CONST. amend. V.
that the information in the database is correct.\footnote{47} HRSA expects manufacturers to maintain accurate database entries. Manufacturers already have a significant incentive to maintain accurate contact information in the 340B database because covered entities use that information to refund 340B discounts to manufacturers when necessary. HRSA has also indicated that accurate manufacturer contact information will be necessary to facilitate the 340B price verification system that is currently in development.\footnote{48}

The contact information in the 340B database, therefore, should be reliable. HRSA should clarify in Section 10.21(d)(2) that the party filing a claim is deemed to have notified the opposing party if it sends the notice, claim, and supporting documents to that party’s authorizing official and primary contact listed in the 340B database. HRSA should also clarify that confirmation from a national carrier (like the United States Postal Service, FedEx, UPS, or others) that the documents were delivered suffices as proof of delivery.\footnote{49} Alternatively, HRSA could permit the claimant to identify the tracking number and manner of delivery on the claim itself. That way, HRSA would not have to manage a second submission from the claimant. Finally, HRSA should clarify that the filing party must send the notice to the opposing party within three business days of filing the claim with HRSA, and provide that HRSA will not review the claim until it receives confirmation that the notice was delivered to the opposing party.\footnote{50} Confirmation again can be based on communications by national carriers that delivery was achieved.

c) Alternatively, HRSA Should Permit Service of Claims by Public Posting When Delivery to the 340B Database Address Fails

We understand the importance of accurate entries in the 340B database but recognize that contact information is occasionally outdated or incorrect. Though we believe that a claimant should be able to serve notice of a claim to the address listed in the database, we propose an alternative solution that could be applied when delivery to that address fails. HRSA could post undeliverable claims on the 340B program website, providing the unresponsive party with constructive notice of the claim against it. Either solution helps HRSA meet its

\footnote{47} 42 U.S.C. § 256b(d)(2)(B)(i), (ii).
\footnote{49} FedEx and UPS will not deliver to post office boxes. HRSA should ask all manufacturers to provide HRSA with a street address for deliveries. Covered entities already provide HRSA with a street address.
\footnote{50} Note also that the preamble to the Proposed Rule states that the notice must be sent to the opposing party within three business days and that confirmation that the notice was delivered must be sent to HRSA within three business days. It is not clear whether a single three-day window applies, or if the filing party has three days to send the notice and then another three days to send the proof of delivery. The rule itself states that the opposing party must be notified within three business days, but does not specify a timeframe for submitting proof of delivery to HRSA. This ambiguity would be resolved if HRSA simply deferred review of the claim until it receives proof of delivery from the filing party.
statutory goal of establishing “deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously.”51 At the same time, these methods would fulfill the agency’s constitutional obligation to ensure that the parties receive procedural due process. 52

2. HRSA Should Refine the Claim Review Process to Preserve the Impartiality of the ADR Panel and Clarify Its Role

Section 10.21(d)(3) establishes a clear process that HRSA will follow when evaluating the sufficiency of a claim. We appreciate that HRSA has proposed to decide whether a claim will move forward within 20 business days of receiving the necessary documents. HRSA should include an additional safeguard clarifying that the individual or individuals who review the sufficiency of a claim should not be involved further in the process. The ADR Panel should receive the claim (including any supporting documentation and response) as one complete package. That way, the ADR Panel will be able to review the claim as a matter of first impression. The ADR Panel can remain impartial, and will not be prejudiced by any claims that are initially deemed inadequate or that are further refined through additional exchanges of documentation.

On the other hand, it is important that HRSA’s review be high level and not involve an evaluation of the merits of the claim. The agency otherwise risks usurping the Panel’s role as adjudicator of ADR claims. We envision HRSA using a simple checklist to ensure that the Panel has a full record upon which to base its decision. Whether the facts and arguments reflected in the record are adequate to support the claim is a matter for the Panel to decide, not HRSA.

3. HRSA Should Confirm That Its Decision Not to Accept a Claim Is Ripe for Judicial Review

HRSA and a party may sometimes disagree about whether the party has presented a claim that qualifies for the mandatory ADR Process. HRSA should confirm that its decision not to present a claim to an ADR Panel is a final action that is ripe for judicial review. In the alternative, HRSA should specify a process through which an initial decision not to move forward with review can be appealed administratively.

52 The Supreme Court described alternative means of service as follows: “The reasonableness and hence the constitutional validity of any chosen method may be defended on the ground that it is in itself reasonably certain to inform those affected, or, where conditions do not reasonably permit such notice, that the form chosen is not substantially less likely to bring home notice than other of the feasible and customary substitutes.” Mullane v. Cent. Hanover Bank & Trust Co., 339 U.S. 306, 314-15 (1950) (internal citations omitted).
G. Responding to a Submitted Claim – Section 10.21(e)

HRSA should revise proposed § 10.21(e) because the proposed 20-business-day response time is insufficient. Also, HRSA should harmonize the response requirements with those applicable to the claim.

1. The Proposed Response Time Is Insufficient

We agree that the ADR Process should advance toward completion in a timely manner, but the proposed 20-business-day window to respond to a claim is insufficient. The responding party might need to retain counsel, prepare a response, and do its own factual investigation. Covered entities, in particular, are safety net providers that often do not have the resources and personnel to devote to a rapid response. Moreover, allowing more time will obviate the need for responding parties to request an extension in many circumstances. The responding party should be given at least 45 calendar days to respond to a claim. This timeframe is more in line with covered entities’ experience in responding to HRSA audit reports which, similar to what we expect with manufacturer ADR claims, require time and resources to address.

2. HRSA Should Also Require the Responding Party to Send Its Response and Supporting Documents to the Filing Party

Above, we proposed that the filing party should be required to send its claim and all supporting documents, and not just a summary, to the opposing party. Similarly, the responding party should be required to send its response and any supporting documents to the filing party. Each party should be given every opportunity to understand the other party’s position and consider or reconsider the strength of its own. The parties might be able to resolve disputes amicably without review by the ADR Panel.

V. Proposed Rule Section 10.22 – Covered Entity Information Requests

Proposed § 10.22 implements the statutory directive to “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 [an overcharge claim] . . .”

We appreciate HRSA’s attention to this important provision, which we believe is necessary for the ADR Process to be a meaningful tool for covered entities. We have a few recommendations to strengthen the proposed process for covered entity information requests.

\[^{53}\text{42 U.S.C. § 256b(d)(3)(B)(iii).}\]
A. The 340B Statute Supports Requiring Manufacturers to Obtain Relevant Information from Wholesalers and Other Third Parties

The 340B statute supports HRSA establishing a discovery process that allows covered entities to obtain information and documents not only from manufacturers, which must participate in the ADR Process, but also from third parties such as wholesalers.\textsuperscript{54} The Proposed Rule puts the burden on a manufacturer responding to an overcharge claim to obtain relevant information from “any wholesaler or other third party that may facilitate the sale or distribution of its drugs.”\textsuperscript{55}

We support HRSA’s proposal to require manufacturers to gather evidence from third parties. A manufacturer that participates in Medicare Part B and/or Medicaid must provide 340B pricing. To comply with this obligation, the manufacturer must necessarily have the ability to access and obtain information from third party sellers, such as wholesalers. Otherwise, the manufacturer would not be taking adequate steps to ensure that it is meeting its 340B pricing obligation for all its distribution channels.

B. HRSA Should Ensure That Manufacturers Provide Requested Information

HRSA should ensure, however, that manufacturers actually obtain all relevant information and submit it to covered entities. A drug manufacturer responding to an alleged violation by a covered entity of overcharging has a natural disincentive to produce evidence that might be used against it. If Section 10.22(c)(1) is finalized as proposed, manufacturers may hesitate to devote resources to pressing third parties, that are their customers and distribution partners, for requested documentation. HRSA should ensure that manufacturers comply with the obligation to produce information requested by covered entities. If a covered entity believes that a manufacturer’s response is incomplete, the ADR Panel should evaluate the response to determine if it indeed deficient. If the ADR Panel determines that a manufacturer’s response is deficient, the panel should remind the manufacturer of its obligation to fully respond to the covered entity’s request for information and give the manufacturer an opportunity to do so. If the manufacturer stills fails to fully respond to the request or if the manufacturer never provided any information, then the ADR Panel should issue a default judgment against the manufacturer and, in appropriate circumstances, impose civil monetary penalties (CMPs) on the manufacturer.\textsuperscript{56}

\textsuperscript{54} Id.
\textsuperscript{55} 81 Fed. Reg. 53,388.
C. Covered Entities Should Be Afforded an Opportunity to Review the Manufacturer’s Response prior to Submitting an Information Request

The Proposed Rule would require a manufacturer to respond to a covered entity overcharge claim within 20 business days of receiving notification that HRSA has approved the claim. The Proposed Rule would also require a covered entity to submit its written request for additional information during the same 20-day window. The covered entity should be afforded an opportunity to review the manufacturer’s response before crafting and submitting its request for additional information. Once the covered entity has seen the manufacturer’s position, it can better tailor its information request to the dispute, and request only those documents it needs to prosecute its overcharge claim. HRSA should allow covered entities 30 calendar days from the date on which it receives the manufacturer’s response to submit an information request.

D. HRSA Should Establish Procedures for the Handling of Confidential Pricing Data

As discussed above, a covered entity’s overcharge claim might be based on a manufacturer’s misstatement of the variables used to calculate the 340B ceiling price—primarily AMP and best price. Because covered entities do not have access to the data used to calculate 340B ceiling prices, we recommend that HRSA establish a discovery process for pricing information that will enable the ADR panel to assess whether manufacturers are properly calculating the data used for 340B ceiling prices. HRSA should establish a system to protect the confidentiality of those metrics while evaluating the merit of the covered entity’s claim. In that circumstance, it may be appropriate for HRSA to remain the custodian of the information requested by the covered entity.

E. HRSA Should Establish Briefing on Manufacturer Information

The Proposed Rule entitles covered entities to request information from the manufacturer necessary to support the covered entity’s claim. The Proposed Rule provides no mechanism, however, for the covered entity to explain to the ADR panel how this information supports the claim. Under the Proposed Rule, the ADR Panel could be left to evaluate the information on its own with no input from the parties. HRSA should establish a briefing schedule for the parties to present their views on how the information affects the case. Covered entities will require time to analyze the information received from the manufacturer, which in some cases may be voluminous. We therefore propose that the covered entity be permitted to submit a brief to the ADR Panel within 60 days of receipt of information from the manufacturer (or a third party). This will provide sufficient time to review the evidence and to

58 Id. at 53,388.
prepare the brief. We propose that the manufacturer be permitted to submit a responsive brief within 30 days of receipt of the covered entity’s brief. The covered entity would then have 14 days from receipt of the manufacturer’s brief to submit a reply brief.

VI. Proposed Rule Section 10.23 – Final Agency Decision

Section 10.23 establishes procedures for the final agency decision. We urge HRSA to provide more specific requirements for the ADR Panel’s decision and to establish deadlines for several stages of the proceedings. HRSA should publish summaries of the decisions and seek further comments on whether to publish the full decisions. HRSA should clarify that the Administrative Procedure Act applies to ADR Panel proceedings and judicial review of the ADR Panel’s decisions. Finally, we support HRSA’s proposal to retain authority to enforce the decisions, rather than ceding this function to the ADR Panel.

A. We Support the Proposed ADR Panel Process, but HRSA Should Provide Greater Details Regarding the Content of the ADR Panel Decision

The Proposed Rule requires the ADR Panel to review the documents submitted by the parties, prepare a draft decision letter with the ADR Panel’s preliminary findings and conclusions, and send it to all parties. The parties would be permitted to respond. We agree that these are reasonable procedures. If the ADR Panel has misunderstood a party’s position or some aspect of the facts or the 340B program, this gives the parties an opportunity to request corrections prior to the final decision.

The Proposed Rule does not, however, address the extent to which the ADR Panel must explain its reasoning or cite the statutory support for its decision. We request that HRSA revise the Proposed Rule to require that both the draft and final decisions must provide the reasoning and the statutory support for the decision. We suggest that the PRRB regulations again provide a model for HRSA to apply to the 340B ADR process. The PRRB regulation at 42 C.F.R. § 405.1871 requires that the decision be in writing, based on evidence and written submissions to the PRRB, include findings of fact and conclusions of law, and cite to the record. These standards should all be incorporated in the 340B ADR regulations.

B. HRSA Should Set Additional Deadlines for the Draft and Final Decisions

As explained above, the ADR Panel should issue a decision within six months after briefing has concluded. Consistent with this one-year timeframe, we propose the following additional deadlines. Section 10.23(a)(2) should be revised to require the ADR Panel to transmit the draft ADR Panel decision to the parties within 120 days of the date that briefing has

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59 42 C.F.R. § 10.23(a)-(b) (proposed rule).
concluded. For claims brought by manufacturers, this would be 120 days after the covered entity’s response to the manufacturer’s claim. For claims brought by covered entities, the deadline would be 120 days after the conclusion of the briefing that we propose above, which would follow the manufacturer’s response to the covered entity’s request for information. The Proposed Rule grants the parties 20 business days to review and comment on the draft decision. We suggest that HRSA change this to 30 calendar days to be consistent with our other proposed deadlines, which are stated in calendar days. Section 10.23(b)(2) should be revised to require the ADR Panel to transmit the final decision to the parties within 30 days after the end of the period for review of the draft decision. Our proposed deadlines would bring the total time for a decision to six months from the end of briefing, as proposed above.

C. HRSA Should Seek Comments on Whether to Publish Summaries of Decisions and/or Full ADR Panel Decisions

The Proposed Rule states that HRSA may publish summaries of the ADR Panel decisions but does not address whether the full decisions will be made public. HRSA should not provide for any form of publication at this time. While publishing ADR Panel summaries or decisions could help educate stakeholders, it would raise important confidentiality concerns that should be addressed through further rulemaking and not through sub-regulatory guidance. HRSA should solicit comments from the public on this topic before publishing summaries or full decisions.

D. HRSA Should Clarify That Settlements Will Be Confidential

Regardless how HRSA treats the ADR Panel decisions, it should ensure that settlements to ADR proceedings are confidential. Confidentiality of the settlement terms will facilitate settlement, which will be in the best interests of the parties and will conserve HRSA’s resources by eliminating the need for further ADR proceedings. We urge HRSA to clarify that settlements will remain confidential.

E. HRSA Should Clarify That Judicial Review of ADR Panel Decisions Is Governed by the Administrative Procedure Act

We contend that the ADR Process will be governed by the Administrative Procedure Act (APA), 5 U.S.C. § 551 et seq. Specifically, a reviewing court will be authorized to hold unlawful and set aside ADR Panel decisions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or unsupported by substantial evidence.\(^\text{60}\) We request that HRSA clarify that the APA will apply to the ADR Process, including judicial review.

\(^{60}\) 5 U.S.C. § 706. Other provisions of § 706 not specifically mentioned here would also apply.
F. We Support HRSA’s Proposal that HRSA, and Not the ADR Panel, Will Enforce the Decision

We support the Proposed Rule at § 10.23(b)(2), which vests HRSA with sole authority to enforce the ADR Panel’s decision. The ADR Panel may not fully appreciate HRSA’s historical enforcement practices, and the Proposed Rule will ensure that HRSA retains responsibility for compliance with 340B statutory requirements. This aspect of the Proposed Rule is fully consistent with the 340B statute.

The statute at 42 U.S.C. § 256b(d)(3)(A) requires the Secretary to develop an ADR Process, “including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).” This provision does not specifically require the formation of an ADR Panel or vest the ADR Panel with enforcement authority. The provision only requires that there be procedures for remedies and enforcement. Section 256b(d)(3)(B)(i), which requires the Secretary to designate an official or body (i.e., the ADR Panel) to resolve certain claims by covered entities and manufacturers, does not mention enforcement or remedies, further supporting the Secretary’s discretion to separate these functions from the ADR Panel.

Moreover, subparagraphs (2)(B)(II) and (2)(B)(v) refer to enforcement actions by “the Secretary,” indicating Congress’s intent that the agency (i.e., HRSA) must make the enforcement decisions. Finally, the ADR provision refers only to sections (1)(B) and (2)(B) and does not incorporate subparagraph (a)(5)(B), which governs repayment of discounts to manufacturers for diversion and duplicate discount violations. The omission of any reference to subparagraph (a)(5)(B) from the ADR statute at § 256b(d)(3)(A) further supports HRSA’s decision to vest enforcement with itself and not the ADR Panel.

G. ADR Panel Decisions Should Not Create Precedents

Finally, we are concerned that HRSA should not use its enforcement authority to transform an ADR Panel decision into a broad 340B policy decision. Enforcement should be limited to the parties to the ADR proceeding. ADR Panel decisions should not have general applicability.
We appreciate the opportunity to submit the above comments. If you have any questions or need additional information, please do not hesitate to reach out to any of individuals in the attached list of organizational contacts.

Sincerely,

National Association of Community Health Centers
The Hemophilia Alliance
Planned Parenthood Federation of America
National Family Planning & Reproductive Health Association
National Alliance of State & Territorial AIDS Directors
National Health Care for the Homeless Council
National Association of Counties
National Rural Health Association
America’s Essential Hospitals
Children’s Hospital Association
340B Health
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