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HHS Proposes Administrative Dispute Resolution Process for 340B-Related Claims

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Summary

On August 12, 2016, the US Department of Health and Human Services (HHS) Health Resources and Services Administration issued a notice of proposed rulemaking that establishes an administrative dispute resolution process for claims brought by both covered entities and drug manufacturers related to the purchase and sale of covered outpatient drugs pursuant to the 340B Drug Pricing Program. HHS will accept public comments on the proposed rule until October 11, 2016.

In Depth

On August 12, 2016, the US Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) issued a notice of proposed rulemaking (Proposed Rule) related to the 340B Drug Pricing Program. Specifically, the Proposed Rule establishes an administrative dispute resolution (ADR) process for claims brought by hospitals and other entities participating in the 340B Program (Covered Entities), as well as by drug manufacturers, arising from the purchase and sale of covered outpatient drugs pursuant to the 340B Program. HHS will accept public comments on the Proposed Rule until October 11, 2016.

The 340B Program was established by the Veterans Health Care Act of 1992 and allows Covered Entities to purchase covered outpatient drugs from drug manufacturers at discounted prices. The Office of Pharmacy Affairs (OPA), an office within HRSA, administers the 340B Program. The Affordable Care Act (ACA) expanded the scope of the 340B Program and provided HHS with specific authority to take certain actions with respect to program administration. Pursuant to the ACA, HHS is required to establish and implement a binding ADR process for certain disputes arising in connection with the 340B Program.

In 2010, HHS published an Advanced Notice of Proposed Rulemaking related to the ADR process and incorporated comments received in response to that Advanced Notice into this Proposed Rule. The Proposed Rule sets forth HHS's proposed ADR mechanism and the processes for bringing and adjudicating a claim through such mechanism. HHS emphasizes that the ADR process is not intended to replace good faith efforts by Covered Entities and manufacturers to resolve disputes on their own; rather, the ADR process should be considered a "last resort." HHS also cautions that Covered Entities and manufacturers should query whether "*de minimis*" claims are appropriately brought to the proposed ADR process, given the time and expense of the process.

To resolve specified 340B-Program-related disputes, HHS proposes to have such disputes reviewed and decided by a 340B Administrative Dispute Resolution Panel. A separate Panel would be convened to hear each dispute and would consist of three voting members, selected from a rotating pool of eligible, experienced federal employees and one *ex officio*, non-voting member from OPA staff. HHS proposes screening individuals for potential conflicts of interest before placing them on a Panel.

The Proposed Rule addresses claims by both Covered Entities and drug manufacturers that may be brought before the Panel for ADR in a manner consistent with the 340B statute provisions related to the ADR process. Covered Entities would be permitted to bring a claim alleging overcharges by a manufacturer for covered outpatient drugs, and manufacturers would be permitted to bring a claim alleging that a Covered Entity violated 340B Program prohibitions on diversion (the dispensing of a 340B drug to an ineligible person) and/or duplicate discounts (where the Covered Entity received a 340B Program discount on a drug and dispensed the drug to a Medicaid patient, and the applicable state Medicaid agency received a rebate on the same drug). Manufacturers could only bring such claims against a Covered Entity after conducting an audit of the applicable Covered Entity, in accordance with 340B Program guidance governing manufacturer audits of Covered Entities. Under current 340B Program manufacturer guidance, manufacturer audits may take place only when approved in advance by OPA and when performed by an independent third-party auditor at the manufacturer's expense.

Also consistent with the 340B statute's limitations on the scope of the ADR process, the Proposed Rule does not include disputes regarding classification of drugs as orphan drugs or violations of the group purchasing organization prohibition within the scope of disputes eligible for resolution through ADR. The Proposed Rule is silent as to whether the Panel will address disputes regarding orphan drug classifications or group purchasing organization prohibition violations that may be related to claims made within the scope of the ADR process, or how Covered Entities and manufacturers are expected to resolve disputes involving such issues. Although the Proposed Rule does not address the anticipated volume of claims that may be submitted for ADR, as a result of the statutory limits on the scope of claims eligible for the ADR process and the historic use of the manufacturer audit process, it appears likely that the volume of claims submitted for ADR will be low.

The Proposed Rule recognizes the statutory ability of both Covered Entities and manufacturers to bring "consolidated claims" for ADR. Consolidated claims involve a group of Covered Entities or group of manufacturers bringing claims against an individual manufacturer or Covered Entity, respectively. Pursuant to the Proposed Rule, an association or organization may bring consolidated claims on behalf of Covered Entities; associations and/or organizations may not, however, bring consolidated claims on behalf of manufacturers.

The Proposed Rule describes the proposed process for ADR in detail. First, the claimant entity must produce an initial submission to HHS, including relevant background data and information

substantiating the claim. The Proposed Rule sets forth categories of information that would be required as part of a claim submission. As an initial matter, HHS will make a determination as to whether the claim will be sent to a Panel for review. HHS indicates in the Proposed Rule that a claim submitted more than three years after the date of the applicable sale or purchase of covered outpatient drugs will be rejected as "stale." This three-year period is notable in that it is consistent with current 340B Program guidance regarding record retention periods (as HHS explicitly notes in the Proposed Rule), but it is inconsistent with the proposed Omnibus Guidance record retention period of five years.

If a claim is submitted to a Panel, the Panel will consider the initial submission as well as submissions from the opposing party (if any). A Panel may also solicit insight from subject matter experts to assist the Panel in its decision-making process. Following review of all available information, the Panel will make an initial decision (which, according to the Proposed Rule, need not be unanimous).

The Panel will produce a draft agency decision letter no later than 20 business days after receipt of all information, setting forth its initial decision, and will send this letter to the parties. Following issuance of the draft agency decision letter, the parties will be able to provide additional information and/or rebuttal. Following consideration of any additional information, the Panel will issue a final agency determination letter. Of note, the Proposed Rule states that the Panel's final agency determination will be binding on the parties to the decision "unless invalidated by an order of a court of competent jurisdiction." In accordance with the final agency determination, HRSA would be permitted to take enforcement action or apply sanctions against a Covered Entity or manufacturer as appropriate. Although not explicitly stated in the Proposed Rule, it appears that the ADR process will be conducted exclusively through submission of written documentation to OPA and the Panel, without an opportunity for the parties to the dispute to make oral arguments before the Panel.

The Proposed Rule also provides that HHS may, at its sole discretion, publish a list of claims that have been resolved through the ADR process on the HRSA website, and such list may include the names of the involved parties and a description of the nature of findings. The Proposed Rule explains that HHS may issue further sub-regulatory guidance regarding public dissemination of claims resolved through the ADR process. The Proposed Rule is unclear as to whether HHS will consider the decisions of the Panel to be precedential.

HHS explicitly is soliciting comments from stakeholders on several topics addressed in the Proposed Rule, including without limitation (i) the size and composition of Panels, including whether the OPA member should be a voting or non-voting member, (ii) the look-back period for submitting a timely claim, and (iii) the amount and type of documentation required to be submitted to OPA to substantiate a claim. In light of the foregoing, affected stakeholders should seek to provide commentary on these issues and any other aspects of the proposed ADR process that may be infeasible or overly burdensome.

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