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Human Resources and Services Administration Proposes Administrative Process to Resolve Disputes Between 340B Program Covered Entities and Drug Manufacturers

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Taking a step toward completing a requirement imposed by the ***Affordable Care Act***, the federal government has proposed regulations that would create an ***administrative dispute resolution ("ADR")*** process to resolve disputes between ***340B Program*** covered entities and drug manufacturers. As proposed, the ADR process would be available for covered entities to submit claims that they have been charged for covered outpatient drugs amounts higher than the 340B Program ceiling price, and for drug manufacturers to claim that covered entities have violated the 340B Program prohibitions on the diversion of 340B drugs to persons who are not eligible patients or the prohibition on duplicate discounts. For manufacturers to bring a claim to the ADR they must have first conducted an audit of the covered entity. Publication of this proposed process has been long delayed, and is of great interest to 340B Program stakeholders. Comments on the proposed rule are being solicited, and are due October 11, 2016.

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In the proposed regulation, the ***U.S. Department of Health and Human Services ("HHS")*** describes a process where ADR claims would be reviewed by a designated Panel of three members chosen from a roster of eligible individuals, each of whom will be Federal employees with expertise or familiarity with the 340B Program, as well as one *ex-officio*, non-voting member chosen from the staff at OPA. Members on the Panel will alternate, and will not be compensated.

ADR claims must be filed within three years of the date of the alleged violation, and must be supported by documentation sufficient to demonstrate the claim. If sufficient documentation is provided, the claim will move forward to review. If the claim is submitted by a covered entity, the covered entity may submit a written request to the ADR Panel for additional information from manufacturers or other third parties, and the ADR Panel will help facilitate those requests if they are reasonable and within the scope of the claim.

The Panel will consider the documentation and the claim in a closed session without the involved parties or the parties' counsel, and without any trade associations or other interest groups present. The Panel would prepare a draft agency decision letter and provide it to all parties, who then have 20 business days to respond. Upon receipt and review of their responses, the Panel will prepare its final agency decision, which would be submitted to HRSA to determine if sanctions or enforcement are appropriate. The final agency decision would be binding on all parties unless invalidated by a court.

In its discussion, the government emphasizes that the ADR process is intended to be a "last resort" available to the parties in the event good faith efforts to resolve disputes without the government's involvement have been unsuccessful. In particular, HHS is requesting comments on a number of areas of the proposed rule, including the makeup of the Panel (such as whether members of the Office of Pharmacy Affairs that oversee the 340B Program should be voting members, or whether the size of the panel should be increased for more complex claims), and with regard to how manufacturers could potentially consolidate claims.