

42 C.F.R. § 10.3

Definitions.

For the purposes of this part, the following definitions apply:

Administrative Dispute Resolution (ADR) Process means a process used to resolve the following types of claims, including any issues that assist the 340B ADR Panel in resolving claims:

- (1) Claims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers; and
- (2) Claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity (pursuant to section 340B(a)(5)(C) of the Act), that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

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