FQHC
340B Compliance

ADMINISTRATIVE DISPUTE RESOLUTION (ADR) PROCESS

The 340B Administrative Dispute Resolution (ADR) process serves as a mechanism created to settle conflicts between covered entities and drug manufacturers participating in the 340B Program. By tackling concerns like overcharges, duplicate discounts, and drug diversion, this procedure guarantees adherence to regulations and equitable pricing. It entails a specialized ADR Panel comprised of OPA employees who are 340B specialists, offering impartial and prompt resolutions. This process provides covered entities and manufacturers a structured platform to address disputes if a resolution cannot be reached without HRSA's involvement.

For more information on the 340B ADR Process and an in-depth overview:

- HRSA.gov/opa/340b-adr
- Federalregister.gov

"Good Faith" Resolution Attempt

Before filing a claim, a covered entity must attempt to resolve the dispute directly with the manufacturer and document these efforts. This documentation is essential to demonstrate that a genuine attempt was made to settle the issue without involving the ADR process.

Claim Initiation

To start a claim, send an email to 340BADR@hrsa.gov with the petitioner's contact information, opposing party details, and a brief description of the claim. This step formally initiates the ADR process. **Claims must be filed within 3 years** of the alleged violation.

340B ADR Panel Decision

If the claim meets process requirements, it is forwarded to the 340B ADR Panel for review. The panel may request further information from either party and will issue a decision within one year of receiving a complete claim.

Reconsideration

If an error is believed to have occurred in the final ruling, a reconsideration request can be submitted to the HRSA Administrator within 30 business days of the ADR Panel's decision.

OPA Follow-Up

Upon receiving a claim, OPA will provide instructions via email for accessing the ADR workload in OPAIS and may request more information. Submit all necessary documentation through the ADR Petitioner portal for OPA to review and assess if the claim meets submission requirements.

Document Preparation

Gather all necessary documentation to support the claim, including purchase records, communication logs, and other relevant evidence. Ensure all records are maintained until the final agency decision is reached.