Drug Pricing Program Reporting Requirements

Process for audits:

1. A manufacturer must notify the entity in writing when it believes a violation of Section 340B of the Public Health Service (PHS) Act has occurred.

2. The manufacturer must submit an audit work plan describing the audit to the Office of Pharmacy Affairs for review. The work plan will be reviewed for reasonable purpose, scope, and a determination that only those records of the covered entity that directly pertain to the potential violation will be accessed.

3. The manufacturer must submit the audit report to the Office of Pharmacy Affairs and informational copies to the Office of Inspector General and the PHS Office of Audit Services. The audit report must be prepared in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision.

4. The covered entity must provide a written response to the audit report.

Process for formal dispute resolution:

1. The participating manufacturer or covered entity requesting the dispute resolution must submit a written request to the Office of Pharmacy Affairs. Upon receipt of the request for a review, the chairperson of the review committee will send a letter to the party alleged to have committed a violation. The letter will include: a) the name of the party making the allegation; b) the allegation; c) documentation supporting the party's position, and; 4) a request for a response to or rebuttal of the allegation within 30 days.

2. The party alleged to have committed a section 340 violation is required to provide a written response or rebuttal.

3. The review committee, chaired by a representative from the Office of Pharmacy Affairs, shall review all documentation submitted by the disputing parties and made a determination. The review committee shall prepare a written document containing the findings and detailed response supporting the proposed decision. The written decision will be sent with a transmittal letter to both parties.