ISSUE	Summary of Comments	Actions to Address Comments
Burden estimates are significantly underestimated.	Some manufacturer groups raised concern regarding burden estimate values. Surveys conducted by those group suggest the time to collect data would be double what is currently listed.	HHS agrees the burden estimates may have been too low in the 60 day notice. Estimates are increased by 50% in the 30 day notice.
Request for revision of audit standards.	Manufacturers raised concerns that determining reasonable cause for an audit is difficult to do without the information that would be acquired through the audit. Also, suggestions for allowing manufacturer auditors to conduct audits to decrease costs, in lieu of independent contracted auditors, was proposed.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.
HRSA should enforce audit findings made by manufacturers.	The time and financial burden on manufacturers to conduct audits is significant and the findings should be enforced by HRSA for the audits to be meaningful. Suggestions for timelines for entity responses to manufacturers and repayment deadlines were made. HRSA should allow manufacturers to withhold future discounts until repayment is settled.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.
HRSA should clarify what information it seeks from manufacturers.	Manufacturers request that HRSA define and standardize the information it seeks to collect, through templates or forms, to identify the necessary information to submit. This would assist with estimating the burden for the information collection.	HHS believes that good faith efforts between manufacturers and covered entities are unique to specific situations and by not requiring the use of forms allows both parties to customize the information to suit the current circumstances.
Meaning of "good faith" and "reasonable cause."	Manufacturers and covered entities request HRSA define thresholds for what working in good faith entails. Additionally, criterion for what constitutes reasonable cause is requested.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.
HRSA should clarify this notice does not change the procedures outlined in the 1996 Manufacturer Audit Guidelines or 2011 Policy Releases.	The IRC instructs manufacturers to submit the audit reports to the OPA and to OIG, but is silent on the manufacturers giving the audit report to the covered entity. The 1996 guidelines require the manufacturers to submit the audit report to the covered entity. HRSA should clarify the procedures addressed in the 1996 Guidelines and 2011 Policy Releases remain in effect.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.

Manufacturers should be transparent for information they seek from covered entitles.	Covered entitles should be given the rationale for requested information from manufacturers who are requesting to work in good faith. Further, manufactures should send requests to the primary contact as listed on the 340B database, to assure the appropriate personnel are made aware of these requests. Reasonable cause should not be assumed if an entity fails to comply with data requests without a reason for the manufacturer's inquiries.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.
Burden estimates should include manufacturers' rebuttal to ADR.	Currently burden estimates are given for covered entities to provide a rebuttal. Manufacturers may be required to provide a rebuttal to an ADR initiated by a covered entity.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.
Support for formal dispute resolution process.	Both manufacturers and covered entitles support the development of a formal dispute resolution process.	This comment seeks a statement of policy that is beyond the scope of this notice. This notice addresses information collection prior to audit and dispute resolution, not the audit process.