

Sample HRSA 340B Audit Data Request for Manufacturers



Purpose: To provide an example data request list for a HRSA 340B audit. Note this is only a sample and may differ from an actual HRSA data request.

Manufacturer Data Request

Policies and Procedures

1. Provide policies and procedures on the following topics:
 - A. Pricing calculation data
 - a. Penny pricing policy
 - b. New drug pricing estimates
 - c. Calculation and rounding procedures
 - B. 340B OPAIS pricing component upload process
 - C. Notifications to wholesalers (direct sales notices to covered entities)
 - D. Allocations and shortage
 - a. Notification of allocation to HRSA
 - b. Notification of allocation to covered entities/wholesaler (please include a copy of notification)
 - E. Review and self-monitoring
 - F. Refunds and restatement
 - G. Distribution channels (restricted or what wholesalers are used)
 - a. Contract pharmacy policies
 - b. Limited distribution plans
 - H. Wholesaler audit and self-monitoring
 - I. Chargeback approvals and denials

Data Elements

2. Provide a list of all labeler codes for which manufacturer is responsible.
3. Provide a list of new products that were launched or relaunched during the audit review period, include the drug name, NDC and effective date.
4. Provide the details of any mergers or acquisitions of labeler codes and/or NDCs that occurred in the last three years, if applicable.
5. Provide the details of any limited distribution channels established during the audit review period or currently in place, if applicable please provide a copy of the plan(s).
6. Provide original Pharmaceutical Pricing Agreement and all addendums for all labeler codes active during the audit review period.
7. Provide the pricing notifications sent to wholesalers (include the list of wholesalers notified) and covered entities during the sample period.
8. WAC pricing for all active NDCs during the sample period including effective start dates and end dates, if applicable.
9. AMP and URA used to calculate the ceiling price during the sample period for all active NDCs, to include: unit 340B ceiling price, package size, and case package size.
10. Indirect and direct sales data/EDI documents (GPO, WAC, 340B) during the sample period in excel format, for all covered entities, please include covered entity 340B IDs.

Example Data Elements (not an all-inclusive list)

Indirect Sales

- A. Wholesaler Name
- B. Wholesaler Address
- C. Customer 340B ID
- D. Customer Name
- E. Customer Address
- F. Invoice Number
- G. Invoice Date
- H. Chargeback Process Date
- I. Account/Contract Type (GPO,WAC, 340B)
- J. NDC
- K. Product Name
- L. Quantity
- M. Contract/Sales Price
- N. WAC Price
- O. Chargeback Amount

Direct Sales

- A. Customer 340B ID
- B. Customer Name
- C. Customer Address
- D. Invoice Number
- E. Invoice Date
- F. Account/Contract Type (GPO, WAC, 340B)
- G. NDC
- H. Product Name
- I. Quantity
- J. Sales Price

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

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