Sample HRSA 340B Audit Data Request List (DRL) for Manufacturers

Purpose: To provide an example data request list (DRL) 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

Provide policies and procedures on the following topics:

1. Pricing calculation and rounding procedures
    a. Ceiling price
    b. Penny pricing
    c. New drug pricing estimates
2. 340B Office of Pharmacy Affairs Information System (OPAIS)
    a. Accuracy of manufacturer information in 340B OPAIS registration component
    b. Upload and review process in 340B OPAIS pricing component
3. Pricing notifications sent to wholesalers and/or covered entities
4. Shortages and allocations
    a. Notification of allocations to HRSA
    b. Notification of allocations to wholesalers/covered entities
5. Overcharges, refunds, and restatements
6. Distribution channels
    a. Direct sales
    b. Indirect sales
    c. Specialty and contract pharmacies
    d. Limited distribution plans
7. Audits of wholesaler
8. Internal reviews or self-assessments
9. Chargeback process
    a. Eligibility determination
    b. Adding and terminating customers
    c. Chargeback approvals and denials

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Data Elements

Provide the following:

1. List of all associated labeler codes (i.e., common ownership), including manufacturer name.
2. List of new products that were launched or relaunched during review period, preferably in Excel format. Include the NDC, product name, launch date, and CMS drug category (e.g., S (single source innovator), I (innovator multiple source), N (non-innovator), etc.).
3. Details of any mergers or acquisitions of labeler codes and/or NDCs that occurred in the last three years, if applicable.
4. 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).
5. Original Pharmaceutical Pricing Agreement and all addendums for all labeler codes active during the audit review period.
6. Pricing notifications sent to wholesalers (include the list of wholesalers notified) and covered entities during the audit review period.
7. WAC pricing for all active NDCs for the audit review period, including effective start dates and end dates, if applicable.
8. AMP and URA data used to calculate the ceiling prices for all active NDCs in audit review period; please include unit 340B ceiling price, package size, and case package size.
9. Indirect 340B sales data/EDI data for audit review period, in Excel format, for all covered entities (please include covered entity 340B ID's). **The data submitted should represent sales that occurred during audit review period.** Please submit one file for the six-month period for each applicable labeler code.

   Example data elements, this is not an all-inclusive list.

   <u>Indirect Sales</u>

   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
   j. NDC
   k. Product Name
   l. Quantity
   m. Contract/Sales Price
   n. WAC Price
   o. Chargeback Amount

10. Direct 340B sales data/EDI data for audit review period, in Excel format, for all covered entities (please include covered entity 340B ID's). The data submitted should represent sales that occurred during audit review period. Please submit one file for the six-month period for each applicable labeler code.

    Example data elements, this is not an all-inclusive list.

    Direct Sales

    a. Customer 340B ID
    b. Customer Name
    c. Customer Address
    d. Invoice Number
    e. Invoice Date
    f. Account/Contract Type
    g. NDC
    h. Product Name
    i. Quantity
    j. Sales Price