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

Purpose: This tool provides an example data request list (DRL) for a Health Resources and Services Administration (HRSA) 340B audit. Note: This is only a sample and may differ from an actual HRSA DRL.

Manufacturer Data Request

Policies and Procedures

Provide policies and procedures for the following topics:

1. Ensuring that the 340B Office of Pharmacy Affairs Information System (OPAIS) registration record(s) is/are up to date and accurate for all labeler codes, including regular review and timely update of 340B OPAIS registration record(s)
2. Uploading and reviewing data in the 340B OPAIS pricing component for each national drug code (NDC)
3. Determining entity eligibility for 340B Program pricing
4. Describing distribution channels and the process for offering covered entities 340B ceiling prices, such as:
   a. Direct sales
   b. Indirect sales
   c. AIDS Drug Assistance Program (ADAP) rebate option and direct option sales
   d. Specialty and contract pharmacies
   e. Limited distribution plans
5. Calculating prices and rounding procedures
   a. 340B ceiling price
   b. Penny pricing
   c. New drug pricing estimates
6. Sending pricing notifications to wholesalers and/or covered entities
7. Processing 340B sales transactions for direct, indirect, and ADAP sales, such as:
   a. Eligibility determination
   b. Adding and terminating customers
   c. Tracking, evaluating, approving, and denying
8. Implementing the use of specialty pharmacies, contract pharmacies, and limited distribution plans and notifying:
   a. Wholesalers
   b. Covered entities
   c. HRSA
9. Identifying shortages and allocation methods
   a. Notification of allocations to HRSA
   b. Notification of allocations to wholesalers/covered entities

08272024

10. Identifying and notifying covered entities of overcharges that may result from:
   a. Errors
   b. True-ups
   c. Restatements
   d. Difference between estimated and actual 340B ceiling price for new products
11. Issuing refunds or restatements
12. Conducting oversight of wholesalers and covered entities
13. Performing internal oversight activities, such as:
   a. Pricing
   b. Chargeback reviews
   c. Reconciliations
   d. Restatements
   e. Self-assessments

Data Elements

Provide the following:

1. List of **all associated labeler codes** (in Excel format), including:
   a. Labeler code number (include the labeler code selected for audit)
   b. Manufacturer name
   c. Address
   d. Association to labeler code selected for audit (e.g., parent, subsidiary, sister)
   e. Types of products sold (e.g., brand, generic)
   f. Type of 340B sales (e.g., direct, indirect, ADAP)
   g. System(s) used to process 340B sales transactions (e.g., chargebacks, invoicing systems), by manufacturer or third-party logistic (i.e., 3PL, TPL) provider(s)

2. List of **new products that were launched or relaunched** (in Excel format), including:
   a. NDC
   b. Product name
   c. Launch date
   d. Drug category (e.g., S [single source innovator], I [innovator multiple source], N [non-innovator])
   e. Package size
   f. Case package size
   g. Wholesale acquisition cost (WAC) price
   h. Estimated 340B ceiling price
   i. Date actual 340B ceiling price was established, if applicable
   j. Actual 340B ceiling price, if established

3. **Details of any mergers or acquisitions** of labeler codes and/or NDCs that occurred in the past three years (from audit engagement).

08272024

4. **Details of any limited distribution channel plans established** during the audit review period or currently in place.
   a. Provide the notifications sent to covered entities and HRSA, including a copy of each plan and distribution channel(s) used (e.g., specialty pharmacy, specialty distributor, special distribution network)

5. Original **pharmaceutical pricing agreement and addendum for each labeler code.**

6. **Pricing notifications sent to wholesalers and covered entities, including the list of wholesalers and list of covered entities notified** for the sample period.

7. **WAC pricing** for all active NDCs for the sample period (in Excel format), including:
   a. NDC
   b. Product name
   c. WAC amount
   d. Start date
   e. End date, if applicable

8. **Average manufacturer price (AMP) and unit rebate amount (URA) data** used to calculate the 340B ceiling prices for **all active NDCs** for the sample period (in Excel format), including:
   a. NDC
   b. Product name
   c. Quarter
   d. AMP
   e. URA
   f. Unit 340B ceiling price
   g. Package size
   h. Case package size

9. Documentation of any **refunds or credit/rebills** that were issued for the sample period**.**

08272024

10. **Indirect 340B sales transactions**
    a. Narrative describing the methodology and system(s) used to gather the data, noting any exclusions.
    b. 340B sales data/electronic data interchange (EDI) data for the sample period, in Excel format (e.g., Public Health Service [PHS], Prime Vendor Program [PVP], 340B sub-ceiling prices, 340B negotiated prices). Submit one file for the six-month period for all labeler codes. *The data submitted should represent only sales that occurred during the sample period.*

Example data elements (this is not an all-inclusive list):
    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 (e.g., PHS, PVP)
    j. NDC
    k. Product name
    l. Quantity
    m. Contract/sales price
    n. WAC price
    o. Chargeback amount

11. **Direct 340B sales transactions**
    a. Narrative describing the methodology and system(s) used to gather the data, noting any exclusions.
    b. 340B sales data/EDI data for the sample period, in Excel format. Submit one file for the six-month sample period for all labeler codes. *The data submitted should represent only sales that occurred during the sample period.*

Example data elements (this is not an all-inclusive list):
    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

08272024

12. **ADAP rebate options sales transactions**
    a. Narrative describing the methodology and system(s) used to gather the data, including a description of the different rebate types, noting any exclusions.
    b. 340B sales data/EDI data for the sample period, in Excel format (e.g., rebates, 340B sub-ceiling rebates, subsidized claims). Submit one file for the six-month sample period for all labeler codes. *The data submitted should represent only sales that occurred during the sample period.*

    Example data elements (this is not an all-inclusive list):
    a. Customer 340B ID
    b. Customer name
    c. Customer address
    d. Invoice number
    e. Invoice date
    f. Type of rebate/program
    g. NDC
    h. Product name
    i. Quantity
    j. Expenditure amount
    k. Amount paid

13. Documentation of **written agreements with ADAP rebate option covered entities and/or third parties.**