Sample HRSA 340B Audit Data Request for Covered Entities

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

Covered Entity Data Request
1. Provide policies and procedures on the following topics:

A. Description of covered entity's registration/recertification process

B. Process for ensuring that the 340B OPAIS record is up to date and accurate for the parent, applicable off-site outpatient facilities, and contract pharmacies (including regular review and timely update of 340B OPAIS records)

C. Process for determining what sites are eligible; address whether each service area in which 340B drugs are purchased, ordered, or provided is included on the grant or reimbursable on the CE's most recently filed Medicare cost report (MCR)

D. Description of procurement process (including contract pharmacy, if applicable)

E. Prevention of GPO Prohibition violations (applies only to DSH, PED, and CAN)

F. Definition for any exclusions to the definition of covered outpatient drugs (e.g., bundled drugs, orphan drugs, or inpatient drugs)

G. CE's process for conducting oversight of its contract pharmacy(ies):
- Internal audits
- Independent audits

H. How the CE accounts for 340B inventory or accumulation, if applicable (if physical inventory vs. virtual inventory replenishment)

I. Prevention of diversion at **CE**—process for confirming the following:
- Site eligibility location
- Referral/responsibility of care remained with CE
- Medical/patient health record
- Patient eligibility (including status change)
- Provider eligibility (relationship)
- Service in the scope of grant (if applicable/non-hospital)
- Documenting and accounting for wastage of a drug not administered

J. Prevention of diversion at **contract pharmacy**—process for confirming the following:
- Site eligibility location
- Referral/responsibility of care remained with CE
- Medical/patient health record
- Patient eligibility
- Provider eligibility (relationship)
- Service in the scope of grant (if applicable / non-hospital)

K. Mechanism to prevent duplicate discounts at **CE** and off-site facilities for:
- Physician administration
- Outpatient prescriptions
- Billing multiple state Medicaid agencies, if applicable

L. Mechanism to prevent duplicate discounts at **contract pharmacies** for outpatient prescriptions

M. When and how CE would self-disclose and CE's definition of noncompliance material breach

N. Definition of eligible site when the location is not on the MCR yet or for a special circumstance (e.g., COVID-19, flooding)

2. Provide CE Eligibility Documentation

Hospitals

A. A listing of locations where health care services are provided to individuals for which the hospital deems itself responsible for the health care services provided for purposes of meeting 340B eligibility including physical address.

B. The applicable MCR(s) that was most recently filed to the audit period (start of sample period—date of on-site/remote audit).

C. If off-site outpatient facilities utilize 340B drugs (at the facility or through contract pharmacy), provide the trial balance that was **submitted to CMS** with the MCR(s). For each MCR and corresponding trial balance, include a trial balance crosswalk.
The trial balance is to include:
   a. 340B ID
   b. Name of each off-site outpatient facility as identified on 340B OPAIS
   c. Address of the off-site outpatient facility
   d. Worksheets A & C: line number and cost center description
   e. Trial balance name and department code/account
   f. The location code or shorthand used to identify the site in the electronic health record (EHR)
   g. 340B drug utilization during encounters at the site: Yes/No

D. If a hospital is owned or operated by a state or local government, provide documentation that indicates the hospital is owned or operated by a state or local government.
   a. Examples of documentation to demonstrate the hospital is owned or operated by a state or local government may include copy of the law that created the hospital, documentation from the state or local government that clearly demonstrates ownership, hospital's charter, bylaws, documentation from the IRS describing the hospital.

   Note: More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital.

E. If the hospital is private nonprofit with a contract with a unit of state or local government to provide health care services to low-income individuals, provide a copy of the contract and documentation that demonstrates the hospital's private nonprofit status.
   a. Please highlight the following in the document: 1) the provision that the hospital must provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the state plan under this title; 2) names of the hospital and the government agency; 3) signatures of hospital and government agency representatives; and 4) effective dates of the contract.
   b. The following are examples to demonstrate the hospital's private nonprofit status: hospital's charter, articles of incorporation, bylaws, other documents from the state that may certify that the hospital is nonprofit, a copy of the hospital's latest filed IRS Form 990, or other official IRS documentation. More than one document may be necessary to demonstrate eligibility.

F. If a hospital is a public corporation or private nonprofit corporation, which is formally granted governmental powers by a unit of state or local government, provide documentation that demonstrates that the hospital is either a public corporation or a private nonprofit corporation, and documentation that confers governmental powers.
   a. Examples of documentation to demonstrate a public corporation may include copy of the law that created the hospital, documentation from the state or local government that clearly demonstrates ownership, hospital's charter, bylaws, documentation from the IRS describing the hospital. Documents should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility.
   b. Examples of documentation to demonstrate the hospital's private nonprofit status include hospital's charter, articles of incorporation, bylaws, other documents from the state that may certify the hospital is nonprofit, a copy of the 501(c)(3) certification, the latest filed IRS Form 990, or other official IRS documentation. Documents should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility.

2. Provide CE Eligibility Documentation (continued)

Hospitals

c. Documentation that confers governmental powers should contain ALL of the following elements:
   i. Identity of the government entity granting the governmental powers
   ii. Description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental
   iii. A copy of any official documents issued by the government to the hospital that reflect the formal grant of governmental power

Grantees

A. A listing of locations where health care services are provided to individuals for which the grantee deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including physical address and location code or shorthand used to identify the site in the CE's electronic health record (EHR).
B. Notice of Grant Award (NGA) and/or sub-grantee documentation, or FQHC-LA designation or FQHC638 compact agreement.
   a. Include forms 5A (scope of services) and 5B (service locations) if grantee is listed in HRSA's Electronic Handbook (EHB)
   b. Sub-grantee documentation may include the Notice of Funding Award between the primary grantee and sub-grantee, the Notice of Grant Award project narrative that clearly indicates the sub-grantees receipt of funding, or in-kind and/or contracts/agreements/memorandums of understanding.

3. Provide a 340B Universe for the Sample Period

A. Include a narrative describing the methodology, system/software by which the data were gathered, and any limitations or exclusions (e.g., whether reversed transactions or any other elements were excluded, other 340B orders or dispenses, direct purchases were included, or other purchasing mechanisms). Define each area(s) of service on the spreadsheet(s) with column headings name and indicate which area the spreadsheet represents.
B. Provide a listing of all 340B drugs that were administered or prescribed to patients from the parent site, off-site facilities/child sites, and pharmacies (in-house/entity-owned and contracted) during the 6-month sample period (preferably in Excel format or another electronic format).
   Include the following data elements in the listing:
   a. The drug/product name
   b. NDC
   c. The acquisition price
   d. The type of account the drug was purchased through, purchase account, and the associated 340B ID number
   e. The quantity issued
   f. The patient ID number (this is typically the medical record number or prescription number, but can be any number you assigned that will allow tracking through the CE's system to retrieve all information associated with the order)
   g. The payer (all payers including Medicaid)
   h. The date the order (mixed-use pharmacy) or prescription (in-house/entity-owned or contract pharmacy) was written
   i. The ordering provider
   j. The location/site at which the 340B drug was administered/ordered (mixed-use pharmacy) or prescribed (in-house or contract pharmacy)
   k. The date the drug was administered or dispensed

3. Provide a 340B Universe for the Sample Period (continued)

A sample of prescriptions will be selected for testing during the on-site/remote audit. For the selected items, individual records will need to be available in either electronic or paper format. If EHRs are used, please provide an individual with system knowledge to navigate the EHR (including billing information) and the split-billing software/third party. Scans of hard copies of selected documents may be requested to be uploaded to the NIH secure site.

The CE must ensure that no protected health information (PHI) and personally identifiable information (PII), such as a patient's name, date of birth, and addresses, is submitted in the data request list uploads.

4. Provide a Provider List

Provide a list of the CE's eligible providers, to include first name, last name, NPI, and whether employed/contracted, including start and termination dates of employment/contract (preferably in Excel format). Be prepared to show the auditor proof of employment, contract, or credentialing for providers during the on-site/remote audit.

5. **Provide Purchasing Documentation**

A. Listing of all accounts (wholesaler, direct, and consignment) used to purchase drugs for the parent, off-site facilities, and pharmacies (in-house/entity owned and contracted), which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B**,** GPO, WAC, CSOS, other).
   a. For 340B accounts, include the 340B ID associated with the account (the 340B ID used to open/establish the account).

B. Provide a copy of one invoice for each account identified in the listing of accounts requested above.

C. Listing of CE (parent, off-site facilities, and contract pharmacies) 340B drug purchase orders made during the 6-month sample period (preferably in Excel format).

Include the following data elements in the listing:
   a. Ordering location (parent, off-site facility, or contract pharmacy)
   b. Wholesaler name
   c. Account number
   d. Invoice number
   e. Invoice date
   f. Drug description
   g. Drug NDC
   h. Quantity ordered
   i. Price paid

6. Provide Contract Pharmacy Documentation

A. List of all covered entity's contract pharmacies since the beginning of the audit period.

B. For each of the contract pharmacies, provide the original agreement and any amendments/addenda. Highlight the following areas in each contract pharmacy agreement/amendment/addendum:
   a. Signatures including dates of both parties executing the contract
   b. Name and address for each contract pharmacy location participating in the contract pharmacy agreement
   c. Each CE location by name and address **or** a general statement that inclusively identifies the parent and all CE location(s) participating in the contract pharmacy agreement

7. Provide Self-Disclosure Documentation

A copy of any self-disclosures made to the Office of Pharmacy Affairs since the beginning of the audit period.

8. Provide Medicaid Billing Documentation

A. Provide Medicaid fee-for-service billing documentation for each CE site (340B ID) that carves in (i.e., provides 340B drugs to patients with Medicaid fee-for-service):
   a. List the state(s) billed and the corresponding billing number(s) listed on the claims to bill Medicaid fee-for-service for the particular state. Billing number(s) are listed on paper or electronic claims to Medicaid fee-for service and may include the billing provider's national provider identifier (NPI) only, the state assigned Medicaid number only, or both the NPI and state assigned Medicaid number.
   b. For each CE site (340B ID) provide a copy of one Medicaid fee-for-service claim for each state billed. Be prepared to present additional copies of claims during the on-site/remote audit.
   c. Describe each state's requirement for billing modifiers.

Below is an example of a table that may be used to provide information requested in this section.

340B ID	State	NPI(s)	State assigned Medicaid number(s)	Medicaid fee-for service claim form
123456	MA	1234567890 1011121314	101112	[Embedded document]
123456	CT	1234567890		[Embedded document]
123456A	MA	1234567890	131415	[Embedded document]
123456A	CT	1234567890		[Embedded document]

The CE should be prepared to present copies of claims that are identified during the testing of samples during the on-site/remote audit.

The CE must ensure that no protected health information (PHI) and personally identifiable information (PII), such as a patient's name, date of birth, and addresses, is submitted in the data request list uploads.

9. Re-Audit

A. Please provide a description and supporting documentation of how the CE determined the full scope of noncompliance (e.g., identified affected manufacturers, amount of repayment, communication with state Medicaid agency).
B. Provide a list of all affected manufacturers, letter sent to manufacturers offering repayment, and list of settlements.
C. Provide description(s) and supporting documentation of continuous monitoring with periodic assessment related to the previous audit finding(s).