

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.

Covered Entity Data Request

1. Provide policies and procedures on the following topics:

- A. Description of CE'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 violations (applies only to DSH, PED & CAN)
- F. Definition for any exclusions to the definition of covered outpatient drugs (i.e. 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 non-compliance material breach

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.
- C. If offsite 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 crosswalk should include the 340B ID, name of each offsite outpatient facility (as identified on 340B OPAIS), the routine service line number on the MCR Worksheets A and C, the department code, and the location code or shorthand used to identify the site in the electronic health record (EHR).
- 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.
 - b. 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 non-profit status: hospital's charter, articles of incorporation, bylaws, other documents from the State that may certify the hospital is non-profit, a copy of the hospital's latest filed IRS-990 form, 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 non-profit corporation, which is formally granted governmental powers by a unit of state or local government, provide documentation that demonstrates the hospital is either a public corporation or a private non-profit 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 non-profit status include: hospital's charter, articles of incorporation, bylaws, other documents from the State that may certify the hospital is non-profit, a copy of the 501(c)(3) certification, the latest filed IRS-990 Form, 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.
 - 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; and
 - iii. A copy of any official documents issued by the government to the hospital that reflect the formal grant of governmental power.

2. Provide CE Eligibility Documentation (continued)

Non-Hospitals:

- A. A listing of locations where health care services are provided to individuals for which the non-hospital deems itself responsible for the health care services provided for purposes of meeting 340B eligibility including physical address.
- B. Notice of Grant Award (NGA) and/or sub grantee documentation, or FQHC-LA designation or FQHC638 compact agreement. Sub-grantee documentation may include the Notice of Funding Award, the Notice of Grant Award project narrative and/or contracts/agreements/memorandums of understanding.

3. Provide a 340B Universe for the Sample Period

- A. Include a narrative describing the methodology, by which the data was gathered, and any limitations or exclusions (e.g. whether reversed transactions, or any other elements, were excluded or other 340B orders or dispenses, were direct purchases 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 drug orders and administrations provided to patients from the parent site, offsite facilities/child sites, and pharmacies (in-house/entity-owned and contracted) during the sample period (preferable in Excel format or another electronic format).
Include the following data elements in the listing:
 - a. The drug/product name/NDC
 - b. The acquisition price
 - c. The type of account the drug was purchased through, purchase account and the associated 340B ID number
 - d. The quantity issued
 - e. 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 CE's system to retrieve all information associated with the order)
 - f. The payer (all payers including Medicaid)
 - g. The date of the order (mixed-use pharmacy) or date(s) written and filled (in-house/entity-owned or contract pharmacy)
 - h. The ordering provider
 - i. The location/site 340B drug was administered/ordered (mixed-use pharmacy) or prescribed (in-house or contract pharmacy)
 - j. The date the drug was administered, or dispensed

A sample of prescriptions will be selected for testing while the audit team is on site. For the selected items, individual records will need to be available in either electronic or paper format. If electronic health records (EHRs) are utilized, please provide an individual with system knowledge to navigate the EHR. Scans of hardcopies of selected documents may be requested to be uploaded to the NIH Secure Site.

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 (preferable in Excel format). Be prepared to show the auditor proof of employment, contract, or credentialing for providers during the audit.

5. Provide Purchasing Documentation

- A. Listing of CE's wholesalers and 340B drug purchase orders made between dates of selected time frame, including price paid.
- B. Listing of all accounts used to purchase drugs for the parent, off-site facilities, and contract pharmacies, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B - with 340B ID identified on account listing, GPO, WAC, CSOS, other).

6. Provide Contract Pharmacy Documentation

- A. List of all covered entity's contract pharmacies during the audit period.
- B. For each of the contract pharmacies, provide the original agreement and any amendments/addendums. Highlight the following areas in each contract pharmacy agreement/amendment/addendum:
 - a. Name and address for each contract pharmacy location participating in the contract pharmacy agreement
 - b. 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

For each CE 340B ID that carves-in (provides 340B drugs to patients with fee-for-service Medicaid), list the Medicaid billing number(s) (e.g. national provider identifier or state-assigned billing number) that are listed on the paper or electronic claim to Medicaid to identify the "pay-to" provider. Include out-of-state Medicaid billing numbers and the state associated with that number, if applicable. The CE should be prepared to present copies of claims while the auditor is onsite.

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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