

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

Purpose: This tool provides an example data request list (DRL) for a HRSA 340B audit. 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 and 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/grant-associated sites, and contract pharmacies (including regular review and timely update of 340B OPAIS records)
- C. Process for determining which 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 covered entity's most recently filed Medicare cost report (MCR)
- D. Description of purchasing process (including all pharmacies, 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. Covered entity's process for conducting oversight of its contract pharmacy(ies):
 - Internal audits
 - Independent audits
- H. How the covered entity accounts for 340B inventory or accumulation, if applicable (physical inventory vs. virtual inventory replenishment)
- I. Prevention of diversion at **covered entity**—process for confirming the following:
 - Site eligibility location
 - Referral/responsibility of care remained with covered entity
 - 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 **all pharmacies**—process for confirming the following:
 - Site eligibility location
 - Referral/responsibility of care remained with covered entity
 - Medical/patient health record
 - Patient eligibility
 - Provider eligibility (relationship)
 - Service in the scope of grant (if applicable/non-hospital)

1. Provide Policies and Procedures on the Following Topics: (cont.)

- K. Mechanism to prevent duplicate discounts at **covered entity** and off-site facilities/grant-associated sites for:
- Physician administration
 - Outpatient prescriptions
 - Billing multiple state Medicaid agencies, if applicable
- L. Mechanism to prevent duplicate discounts at **all pharmacies** for outpatient prescriptions
- M. When and how covered entity would self-disclose and covered entity's definition of noncompliance material breach
- N. Definition of eligible site when the location is not on the MCR (for hospitals) or grant (for grantees) for special circumstances (e.g., flooding, public health emergencies)

2. Provide Covered Entity Eligibility Documentation

Hospitals (*skip this section if not a hospital covered entity*)

- A. A listing of locations where health care services are provided to persons for whom the hospital deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including physical addresses
- B. The applicable MCR(s), including the encrypted signature stamp on Worksheet S:
- The MCR that was used at the time of the last recertification in OPAIS
 - The MCR filed closest to the start of the sample period
- C. The MCR(s) filed since the start of the sample period through the date of the on-site/remote audit. For each off-site outpatient facility that utilizes 340B drugs (at the facility or through contract pharmacy), provide the unbundled trial balance that was **submitted to CMS** with the MCR(s). For each MCR and corresponding trial balance, include a trial balance crosswalk.
- For each off-site facility, the trial balance crosswalk should include:**
- 340B ID
 - Name of each off-site outpatient facility as identified on 340B OPAIS
 - Address of the off-site outpatient facility
 - MCR line number and cost center description, as listed on MCR worksheets A and C
 - Trial balance name and department code/account
 - The location code or shorthand used to identify the site in the electronic health record (EHR)
 - Whether 340B drugs are utilized during encounters at each site
- D. If a hospital is owned or operated by a state or local government, provide documentation that indicates that the hospital is owned or operated by a state or local government.
- Examples of documentation to demonstrate that the hospital is owned or operated by a state or local government may include a copy of the law that created the hospital, documentation from the state or local government that clearly demonstrates ownership, hospital's charter, bylaws, and/or documentation from the IRS describing the hospital.

2. Provide Covered Entity Eligibility Documentation (cont.)

Hospitals (cont.)

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 a 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.
- 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.
 - The following are examples to demonstrate the hospital's private nonprofit status: hospital's charter, articles of incorporation, bylaws, other documentation 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 that is formally granted governmental powers by a unit of state or local government, provide documentation that demonstrates the hospital's status.
- Examples of documentation to demonstrate a public corporation may include a copy of the law that created the hospital, documentation from the state or local government that clearly demonstrates ownership, hospital's charter, bylaws, and/or documentation from the IRS describing the hospital.
 - 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.
- G. In addition, provide documentation that confers governmental powers, which should contain ALL of the following elements:
- Identity of the government entity granting the governmental powers
 - 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
 - Official documentation issued by the government to the hospital granting formal governmental powers

Note: 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.

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2. Provide Covered Entity Eligibility Documentation (cont.)

Grantees (skip this section if not a grantee covered entity)

A. A listing of locations where health care services are provided to persons for whom the grantee deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including:

- Name
- Physical address
- Location code or shorthand used to identify the site in the covered entity's electronic health record (EHR).

B. Notice of grant award or designation of look-alike status (for all grantees except FQHC638)

Note: The document should list the grantor, grant number, period of funding, and the primary grantee by name and address. In addition, if the grant is listed in HRSA's electronic handbooks (EHB), include Form 5A (scope of services) and Form 5B (service locations)

-OR -

Tribal Contract/Compact with Indian Health Service (for FQHC638 entity only)

C. Sub-grantee documentation may include:

- Notice of Funding Award between the primary grantee and sub-grantee
- Notice of Grant Award project narrative that clearly indicates the sub-grantee's receipt of funding
- In-kind support (e.g., contracts, agreements, or memoranda of understanding)

Note: Documents should list the grant number, period of funding, the primary grantee by name and address, and the subgrantee service location(s) by name and address

3. Provide a 340B Universe for the Sample Period

Note: The covered entity must ensure that uploads to the NIH secure workspace do not include protected health information (PHI) and personally identifiable information (PII) (e.g., patient name, date of birth, address).

- 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 included, or other purchasing mechanisms).
- B. Provide a crosswalk to describe each column header included in each universe of data provided.
- C. Provide a list of all 340B drugs that were administered or dispensed to patients from the parent site, off-site facilities/grant-associated sites, and pharmacies (entity-owned and contracted) during the 6-month sample period (preferably in Excel or another electronic format).

Include the following data elements in the listing:

- Drug/product name
- NDC
- Acquisition price
- Type of account the drug was purchased through, purchase account, and the associated 340B ID
- Quantity issued

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

- 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 covered entity's system to retrieve all information associated with the order)
- Payer (all payers including Medicaid, primary, secondary and tertiary payers)
- Date on which the order (mixed-use pharmacy) or prescription (entity-owned or contract pharmacy) was written
- Ordering provider
- Location
 - a. For medical encounters, the location/site the drug was ordered/administered.
 - b. For prescriptions dispensed at contract pharmacy(ies) and any other pharmacy(ies) that dispensed the covered entity's 340B drugs, include the location/site that prescribed the drug and the pharmacy location that dispensed the drug
- Date on which the drug was administered or dispensed

A sample of administrations/dispenses 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, 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.

4. Provide a Provider List

Note: The CE must ensure that uploads to the NIH secure workspace do not include protected health information (PHI) and personally identifiable information (PII) (e.g., provider name, date of birth, address, telephone number, photo, compensation, etc.).

Provide a list of the covered entity's eligible providers, including:

- First name
- Last name
- National provider identifier (NPI)
- Whether employed/contracted, including start and termination dates of employment/contract (preferably in Excel format)

Note: Be prepared to show the auditor proof of employment, contract, or credentialing for providers during the on-site/remote audit.

5. Provide Purchasing Documentation

Note: The CE must ensure that uploads to the NIH secure workspace do not include protected health information (PHI) and personally identifiable information (PII) (e.g., provider name, date of birth, address, telephone number, photo, compensation, etc.).

A. Provide a list of all accounts (wholesaler, direct, and consignment) used to purchase drugs for the parent, off-site facilities/grant-associated sites, and **all pharmacies** (entity-owned and contracted).

For each account, provide the following (preferably in Excel format):

- Wholesaler name
- Account number

5. Provide Purchasing Documentation (cont.)

- Account name
 - Location that receives the drugs (e.g., unique identifier for covered entity site or pharmacy)
 - Locations that dispense the drugs (e.g., unique identifier for covered entity site or pharmacy)
 - Pricing associated with each account (e.g., 340B, GPO, WAC)
 - For 340B accounts, include the 340B ID associated with account (the 340B ID used to open/establish the account).
- B. Provide a copy of one invoice, during the sample period, for **each** account identified in the listing of accounts requested above. If an invoice is not available within the sample period, provide the most recent invoice available.
- C. Provide a list of covered entity's (parent, off-site facilities/grant-associated sites) and all pharmacies' (entity-owned 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:

- Ordering location (parent, off-site facilities/grant-associated sites, and all pharmacies)
- Wholesaler name
- Account number
- Invoice number
- Invoice date
- Drug description
- Drug NDC
- Quantity ordered
- Price paid

6. Provide Contract Pharmacy Documentation

- A. Provide a list of all covered entity's contract pharmacies from the beginning of the audit period through the date of the on-site/remote audit. **For each contract pharmacy location, indicate whether the pharmacy is used by the covered entity.**
- 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:
- Signatures, including dates, of both parties executing the contract
 - Name and address for each contract pharmacy location participating in the contract pharmacy agreement
 - Each covered entity location by name and address **or** a general statement that inclusively identifies the parent and all covered entity location(s) participating in the contract pharmacy agreement
- C. Provide a cover page or a statement on letterhead from the organization that conducted the last independent audit of the covered entity's contract pharmacies.

The document should include:

- Audit date
- Period audited
- Who performed the audit

6. Provide Contract Pharmacy Documentation (cont.)

- Scope of the audit
- D. Provide supporting documentation of any internal contract pharmacy audits conducted by the covered entity from the start of the sample period through the date of the on-site/remote audit.
- E. Provide a list of all Medicaid fee-for-service BIN and PCN numbers that are carved out (i.e., provide non-340B drugs to patients with Medicaid fee-for-service).

7. Provide Entity-Owned Pharmacy Documentation

- A. Provide documentation for any pharmacy (e.g., mixed-use, retail/community, infusion, specialty, compounding) that is not registered as a contract pharmacy and is dispensing the covered entity's 340B drugs.
- B. Provide a list of pharmacy(ies) (other than contract pharmacy[ies]) used from the start of sample period through the date of the on-site/remote audit.

For each pharmacy, provide the following:

- Name and address of the pharmacy. If the pharmacy is located within a registered off-site facility/grant-associated site (selected accordingly), include the 340B ID
 - Pharmacy type (e.g., mixed-use, retail/community, infusion, specialty, compounding)
 - Whether the covered entity owns the pharmacy
 - Documentation to demonstrate ownership of the pharmacy (e.g., pharmacy license, business license, certificate of liability insurance, or listing of the pharmacy on the covered entity's grant or MCR and corresponding trial balance)
- C. Provide a list of all Medicaid fee-for-service BIN and PCN numbers that are carved out (i.e., provide non-340B drugs to patients with Medicaid fee-for-service) for applicable pharmacies (e.g., retail/community, infusion, specialty, compounding).

Note: More than one document may be necessary to demonstrate ownership.

8. Provide Self-Disclosure Documentation

Provide a copy of any self-disclosures made to the Office of Pharmacy Affairs from the beginning of the audit sample period through the date of the on-site/remote audit.

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9. Provide Medicaid Billing Documentation

Note: The covered entity must ensure that uploads to the NIH secure workspace do not include PHI and PII (e.g., patient name, date of birth, address).

Provide Medicaid fee-for-service billing documentation for each covered entity site (340B ID) and pharmacy that carves in (i.e., provides 340B drugs to patients with Medicaid fee-for-service):

A. For clinic-administered drugs at each site, provide a list of the state(s) billed and the corresponding billing number(s) listed on the claims billed to Medicaid fee-for-service for each state. Billing number(s) are listed on paper or electronic claims to Medicaid fee-for-service and may include the billing provider's NPI and/or state-assigned Medicaid number.

- For each covered entity site (340B ID), provide one Medicaid fee-for-service claim during the sample period (INSERT 6-MONTH PERIOD) for each state billed. If a Medicaid bill for a site is not available during the sample period, provide a recent bill.

Example Table A:

340B ID	State	NPI(s)	State Assigned Medicaid Number(s)	Medicaid Fee-for-Service Claim Form
123456	MA	1234567890	101112	[Embedded document]
123456	CT	1234567890		[Embedded document]
123456A	MA	1234567890	131415	[Embedded document]
123456A	CT	1234567890		[Embedded document]

B. For any pharmacy that is not registered as a contract pharmacy, provide a list of the state(s) billed and the corresponding billing number(s) listed on the claims billed to Medicaid fee-for-service for each state. Billing number(s) are listed on paper or electronic claims to Medicaid fee-for-service and may include the billing provider's NPI and/or state-assigned Medicaid number.

- For each pharmacy, provide one Medicaid fee-for-service claim during the sample period (INSERT 6-MONTH PERIOD) for each state billed. If a Medicaid bill for a site is not available during the sample period, provide a recent bill.

Example Table B:

Pharmacy Name	Pharmacy Address	State Medicaid	State Medicaid BIN	State Medicaid PCN	Billing NPI(s)	Billing State Medicaid Number(s)	Medicaid Fee-for-Service Claim Form
		MA			1234567890	101112	[Embedded document]
		CT			1234567890		[Embedded document]
		MA			1234567890	131415	[Embedded document]

9. Provide Medicaid Billing Documentation (cont.)

C. For any pharmacy that is registered as a contract pharmacy, provide a list of the state(s) billed and the corresponding billing number(s) listed on the claims billed to Medicaid fee-for-service for each state. Billing number(s) are listed on paper or electronic claims to Medicaid fee-for-service and may include the billing provider's NPI and/or state-assigned Medicaid number.

- For each pharmacy, provide one Medicaid fee-for-service claim during the sample period (INSERT 6-MONTH PERIOD) for each state billed. If a Medicaid bill for a site is not available during the sample period, provide a recent bill.

Example Table C:

Contract Pharmacy Name	Contract Pharmacy Address	State Medicaid	State Medicaid BIN	State Medicaid PCN	Billing NPI(s)	Billing State Medicaid Number(s)	Medicaid Fee-for-Service Claim Form
		MA			1234567890	101112	[Embedded document]
		CT			1234567890		[Embedded document]
		MA			1234567890	131415	[Embedded document]

D. Describe each state's requirement for billing 340B drugs when dispensed at pharmacy(ies) and when administered at a facility (e.g., claims modifiers). Be prepared to present additional copies of claims during the on-site/remote audit (all payers including primary, secondary, and tertiary).

10. Provide Combined Purchasing and Distribution Model (CPDM) Documentation

(Skip this section if there is no approved CPDM)

A. Provide a description and supporting documentation of the covered entity's most updated CPDM proposal approved by OPA, including the list of the purchaser and all receivers by 340B ID.

Note: The covered entity should be prepared to provide the auditor with additional documentation related to all sites participating in the CPDM.

11. Re-Audit

A. Provide a description and supporting documentation of how the covered entity 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, letters 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).

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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