



# 5 Keys For A 340B Program Check-up

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# Agenda

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Patient Eligibility And Accurate Records

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Prevention of Diversion And Duplicate Discounts

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Program Audits And Compliance

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ESP Management

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Other Key Considerations

# Patient Eligibility And Accurate Records

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Verify Patient Status

Accurate OPAIS Records

Auditable Records

Contract Pharmacy Oversight



**Table 2: 340B ID Site-Specific Drug Universe**

|  |  |            |            |            |
|--|--|------------|------------|------------|
| From Table 1, list the 340B ID of the entity and any child sites or associated sites registered in 340B OPAIS in the column heading to the right and document the following:                   | 340B ID #1   | 340B ID #2 | 340B ID #3 | 340B ID #4 |
| 1. Document the location name.   | Name   |            |            |            |
| 2. Document the physical address, including suite number of the site   | Address  |            |            |            |
| 3. Do providers write prescriptions for patient self-administration that are filled with 340B drugs?   | Yes or No  |            |            |            |
| 4. Does this location administer drugs <b>as part of outpatient encounters</b> ?   | Yes or No  |            |            |            |
| 5. Document type(s) of drug inventory in this site.  | 340B<br>WAC<br>GPO   |            |            |            |
| 6. Document all purchasing accounts used (wholesaler/ manufacturer). Include name and account number for each inventory type used.   | 340B Account# with____<br>WAC Account# with____<br>GPO Account# with____ |            |            |            |
| 7. Document inventory management method used.  | Physical<br>Virtual<br>Both Physical & Virtual                           |            |            |            |
| 8. Document automated dispensing devices used.   | Device Name  |            |            |            |
| 9. Document the inventory tracking system used. Specify software name, if applicable.  | Vendor software<br>Paper tracking log<br>Electronic tracking log         |            |            |            |
| 10. Does this site carve-in Medicaid and bill 340B drugs to Medicaid?  | Yes or No  |            |            |            |
| 11. Document all Medicaid and/or NPI numbers used to bill 340B drugs to Medicaid.<br><br><i>Note: Billing numbers used to carve-in Medicaid must be listed in the Medicaid Exclusion File.</i> | Billing numbers used   |            |            |            |
| 12. Document all Medicaid and/or NPI numbers used to bill non-340B drugs to Medicaid.  | Billing numbers used   |            |            |            |
| 340B ID Site-Specific Drug Universe completed by:  | Name, title, and date  |            |            |            |

# Prevention of Diversion And Duplicate Discounts

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## No Diversion

Prevent the resale or transfer of 340B Drugs to ineligible patients



## No Duplicate Discounts

Ensure Manufacturers don't provide a discounted 340B price and a Medicaid drug rebate for the same drug



## Medicaid Reporting

Report how Medicaid fee-for-service drugs are billed on the Medicaid Exclusion File

### 340B Covered Entity Attestation & Provider Enrollment Form

1. Complete and sign this form for each of your 340B ID numbers assigned by HRSA,
2. Locate your 340B "Covered Entity Information" sheet at HRSA's website located at <https://340bopais.hrsa.gov/coveredentitysearch> and print so that DOM may validate your 340B election and update your Mississippi Medicaid eligibility file, and
3. Submit both documents to Gainwell's Provider Enrollment:
  - a. E-mail to [ms\\_drugrebate@gainwelltechnologies.com](mailto:ms_drugrebate@gainwelltechnologies.com)
  - b. Fax to 1-866-644-6148
  - c. Mail to Gainwell Technologies, P. O. Box 6014, Ridgeland, MS 39158-6014

#### SECTION I: 340B Covered Entity Information as listed on the [HRSA website](#):

Attesting Covered Entity Name: \_\_\_\_\_

Covered Entity Address: \_\_\_\_\_

Medicaid Provider #: \_\_\_\_\_ Billing NPI #: \_\_\_\_\_

(Printed Name of Authorized Official as indicated on HRSA enrollment)

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

#### SECTION II: Election to Opt-In

The above named provider is a covered entity, enrolled with HRSA, has elected to opt-in under the 340B program, and will bill the Division of Medicaid in accordance with applicable policies.

☐ Opt-In Election

340B ID: \_\_\_\_\_

Participating Start Date: \_\_\_\_\_ Date of most recent HRSA Recertification: \_\_\_\_\_

#### SECTION III: Election to Opt-Out

The above named provider is a covered entity and has elected to opt-out of the 340B program and will never bill DOM for any drugs purchased under the 340B program. This entity's provider number/NPI should not be listed on the HRSA Medicaid Exclusion File.

☐ Opt-out of the 340B, beginning \_\_\_\_\_

☐ 340B ID: \_\_\_\_\_

☐ If applicable, dis-enrolled with HRSA on \_\_\_\_\_ and will never bill DOM for any drugs purchased under the 340B program beginning \_\_\_\_\_

By signing this document, I certify that the information provided herein is true, accurate and complete to the best of my knowledge. I understand that any falsification, omission or concealment of any material fact may subject me to civil monetary penalties, fines, criminal prosecution, or disqualification from the Medicaid program. Under Miss. Admin. Code, Title 23, Part 200, Rule 1.3, a provider who knowingly or willfully makes, or causes to be made, false statement or representation of any material fact in any application for Medicaid benefits or Medicaid payments may be prosecuted under federal and state criminal laws. A false attestation can result in civil and monetary penalties as well as fines, and may automatically disqualify the provider as a provider of Medicaid services.

Authorized Official Name (please print): \_\_\_\_\_

Signature of Authorized Official: \_\_\_\_\_ Position: \_\_\_\_\_

Date: \_\_\_\_\_



# **Program Audits and Compliance**

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Prepare for Audits

Compliance Documentation

Self-Disclosure



## 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                                       |   |
|---|---|
| <b>1. Provide Policies and Procedures on the Following Topics</b> |   |
| 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): <ul style="list-style-type: none"> <li>Internal audits</li> <li>Independent audits</li> </ul>  |
| H.  | How the covered entity accounts for 340B inventory or accumulation, if applicable (physical inventory vs. virtual inventory replenishment)  |
| I.  | Prevention of diversion at <b>covered entity</b> —process for confirming the following: <ul style="list-style-type: none"> <li>Site eligibility location</li> <li>Referral/responsibility of care remained with covered entity</li> <li>Medical/patient health record</li> <li>Patient eligibility (including status change)</li> <li>Provider eligibility (relationship)</li> <li>Service in the scope of grant (if applicable/non-hospital)</li> <li>Documenting and accounting for wastage of a drug not administered</li> </ul> |
| J.  | Prevention of diversion at <b>all pharmacies</b> —process for confirming the following: <ul style="list-style-type: none"> <li>Site eligibility location</li> <li>Referral/responsibility of care remained with covered entity</li> <li>Medical/patient health record</li> <li>Patient eligibility</li> <li>Provider eligibility (relationship)</li> <li>Service in the scope of grant (if applicable/non-hospital)</li> </ul>  |

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



### 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 is a sample of the first and last page, of a HRSA Audit DRL for Covered Entities.



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# ESP Management

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- Pharmacy Designations
- Uploads and Accumulations
- Resolving Issues
- HIN Numbers
- TPA's, Wholesalers, and ESP Verifications



# Other Key Considerations

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Hospital Type



Split-Billing  
Software



Contract Pharmacy  
Agreements



Program  
Oversight



Training and  
Education



Policy and  
Procedure

# Sample of Policy And Procedure Contents

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**Q&A**

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# 340B TOGETHER

HELPING YOU HELP OTHERS

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