

**Auditing the 340B Program**

**For Disproportionate Share Hospitals**

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# Abstract

The 340B Drug Discount Program offers safety net hospitals and qualified hospitals/entities~~,~~ with a cost saving mechanism to stretch scarce resources, by requiring drug manufacturers participating in the program to sell outpatient drugs at discounted prices. Based on an article released on July 2017, by the United States Government Accountability Office, covered entities can realize substantial savings of an estimated 20 to 50 percent of drug cost. As such, it is imperative that covered entities who participate in the program comply with the guidelines set by the Health Resources and Services Administration (“HRSA”).

This paper will provide a guide as to possible inherent risks that could occur with the deployment of the program, as well as suggested audit steps that should be considered when reviewing compliance with the program.

# What is the 340B Program

In 1992, Congress enacted Section 340B of the Public Health Service Act to provide relief to covered entities for high drug cost. The intent of the program is to enable these entities to stretch limited resources while providing comprehensive care/services. Under the 340B program, covered entities have the opportunity to obtain significantly reduced outpatient drug prices from participating manufacturers.

# Who Administers the Program & How Does it Work

The Office of Pharmacy Affairs (“OPA”), which is located within HRSA, oversees the program. Both OPA and HRSA are responsible for interpreting and implementing the 340B law. Therefore, to participate in the program, institutions must meet the program requirements listed below:

1. The institution should be considered a “covered entity”[[1]](#footnote-1) and must apply to participate in the program through the 340B online registration portal, which takes place during the first two weeks of a calendar quarter ( i.e., January 1 - 15, April 1 -15, July 1- 15, October 1- 15). When applying online, the information captured within the OPA database should be accurate, complete and include the exact addresses of child site clinics and contracted pharmacies.

1. The covered entities should recertify their eligibility every year and provide notification to OPA when there is a change in their eligibility status. Once approved and admitted into the program, the covered entities are eligible to receive covered outpatient drug discounts starting the first day after the next calendar quarter. Subsequently, the covered entity should notify drug manufacturers or wholesalers that the entity would be purchasing outpatient drugs at 340B prices. Additionally, HRSA also uses the hospital Medicare Cost Report (“MCR”)[[2]](#footnote-2) when validating eligibility information for hospitals, both during registration and during audits. As such, HRSA reviews the following areas of the MCR to determine eligibility:
* Line 33 shows the DSH adjustment percentage, which is needed to be eligible (if applicable).
* Lines 50 to 118 contain cost centers (e.g. operating room, recovery room) that must be reimbursable, and have expenses and outpatient revenue to be considered 340B eligible.
1. The covered entity should establish controls/processes to prevent diversion of 340B drugs to ineligible patients. That is, the covered entity should not resell or transfer discounted outpatient drugs to anyone who is not a covered entity patient as defined by HRSA. A patient is defined as:
* An established relationship with the individual~~,~~ in which the covered entity maintains the individual’s health record;
* The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements, such that responsibility for the care remains with the covered entity;
* The individual receives health care services or range of services from the covered entity, which is consistent with the service, or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.[[3]](#footnote-3)
1. The covered entity should establish processes/controls that prohibit duplicate discounts. That is, manufacturers should not provide the same drug with a discounted 340B pricing and a Medicaid drug rebate. As such, covered entities should determine whether they would be using 340B drugs for their Medicaid patients (carve-in) or whether other mechanisms will be used to purchase drugs for their Medicaid patients (carve-out). If carve-in drugs will be used, the covered entity is required to inform OPA as well as Medicaid of its plan to bill and the billing number [i.e. provider’s national provider identifier (“NPI”) and/or the state assigned Medicaid number] that will be listed on the claim to the State. The Medicaid billing information lists on the 340B OPA will be reflected on the HRSA Medicaid Exclusion File (“MEF”). In the case of carve-out drugs,the above would not apply, as the drugs dispensed to patients were purchased outside of the 340B program. In addition, disproportionate share hospitals, freestanding cancer hospitals, and children’s hospitals must refrain from participating in group purchasing organization (“GPO”) for covered outpatient drugs.
2. Covered entities participating in the 340B program should prepare for audits, which includes maintaining auditable records.

# The “Carve-In” and “Carve-Out” Drug Dispensation Model

There are two models used by covered entities when dispensing drugs to Medicaid patients. The carve-in model used by covered entities includes dispensing drugs purchased under the 340B program to their Medicaid patients. However, the carve-out model excludes Medicaid patients, and drugs dispensed to these patients are purchased outside of the 340B program[[4]](#footnote-4), resulting in no savings being achieved under the program.

The disadvantage of the carve-out model is that institutions will be required to maintain separate inventories for 340B eligible patients and their Medicaid patients, resulting in greater administrative burden and cost for the institution. In addition, the institution is also required to implement controls/processes to ensure that no 340B drugs are dispensed/provided to Medicaid patients and lastly, the institution is required to correctly indicate carve-out status on the OPA database to avoid the risk of reflecting an incorrect MEF.

Carve-in drugs on the other hand allow covered entities to obtain cost savings and there is no need to maintain separate inventory systems. However, institutions are required to inform the Medicaid agency that they will be dispensing 340B drugs to Medicaid beneficiaries, in addition to establishing controls that prevent duplicate discounts.

# Dispensing 340B Drugs Through Contracted Pharmacies

Covered entities may elect to dispense 340B drugs to patients through contract pharmacies. As such, covered entities enter into written contracts with pharmacies to dispense 340B drugs on their behalf.

Contract pharmacy arrangements generally use one of two distinct inventory models[[5]](#footnote-5): (1) pre-purchased inventory model or (2) replenishment inventory model. The pre-purchase inventory model requires the covered entity to purchase the 340B drugs, which are stored and dispensed by the contract pharmacy, on behalf of the covered entity. In the case of the replenishment model, the contracted pharmacy uses its own non-340B purchased drugs to fill prescriptions on behalf of the covered entity. When sufficient quantities of the drugs have been dispensed, the covered entity purchases that quantity of each drug at the discounted 340B price and has it delivered to the contract pharmacy, thus replenishing drugs dispensed on behalf of the covered entity.

Regardless of the type of inventory model used, the covered entity is required to have oversight for the contract pharmacy arrangement to comply with the 340B statute and HRSA guidelines. This oversight should include preventing diversion of 340B drugs to ineligible patients and duplicate discounts. HRSA recommends that covered entities oversight activities include periodic reconciliations of covered entity records and contract pharmacy records, in addition to independent audits.

# The Importance of Compliance with the Program

HRSA conducts risk-based and targeted audits to ensure covered entities and manufacturers comply with program requirements. In addition, HRSA has also created a branch devoted to compliance and oversight of the 340B program, with the goal of increasing the number of audits performed[[6]](#footnote-6). As such, compliance with the program should be of paramount importance for those institutions enrolled in the program, due to the potential for lost eligibility impacting cost saving benefits as well as possible repayment to manufacturers.

To prevent deviation or noncompliance with the program, hospital facilities should conduct annual internal audits, to identify and expand controls to prevent noncompliance. Furthermore, adequate policies and procedures should be established to govern the program. Some of the common findings noted during the FY17 through FY19 HRSA program integrity audits were ineligibility, diversion and duplicate discounts.

To prevent ineligibility, health care organizations should gain an understanding of the statute *Section 340B (a) (4) of the Public Health Service Act,* which specifies which covered entities are eligible to participate. Specifically, an institution is at risk when eligibility status changes have taken place and OPA has not been informed. For Example, DSH[[7]](#footnote-7) hospitals are required to have a DSH adjustment percentage greater than 11.75 % to qualify. If this percentage was to fall below the 11.75%, the entity is required to inform OPA and discontinue purchasing drugs under the 340B program.

In the case of diversion, the most significant area of risk would be the mixed used area[[8]](#footnote-8) where both patients who qualify and do not qualify for 340B are served. As such, having an optimal split billing[[9]](#footnote-9) software is critical to separate those drug charges that are 340B eligible. However, the performance of the software is dependent on the quality and accuracy of information exported from the electronic health record.

Lastly, health care organizations should have controls in place to prevent duplicate discounts. One of the possible risks is the lack of listing the Medicaid provider number (i.e. national provider number) on the HRSA MEF at the time of billing for Medicaid 340B drug charges. The MEF informs both State and manufacturers that 340B drugs have administered charges that are not subject to Medicaid rebates therefore preventing duplicate discounts. Hence, it is the institution’s responsibility to ensure that the Medicaid provider numbers are accurate~~,~~ and Medicaid patients using carve-in drugs are appropriately tracked for 340B drugs used.

# Inherent Risks and Audit Steps to Review Compliance

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| **#** | **Process** | **Risk Event** | **Test Step** |
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| **1.0** | **Governance** | No policies and procedures in place to govern the 340B Drug Discount Program | Obtain all policies and procedures used to govern the 340B Program and determine whether these policies address the HRSA/OPA requirements.  |
| **2.0** | **Eligible Entities** | Incomplete/inaccurate record of the parent entity and child site registration captured in the HRSA database. In addition, the covered entity (i.e. facility, outpatient clinic, child site etc.), where 340B drugs are dispensed/administered, is not listed on:1. A line of the most currently filed cost report that is reimbursable under Medicare and;2. The services provided at the facility/clinic/child site do not have associated outpatient Medicare costs and charges. | 1. Obtain a list of all covered entities within the healthcare system
2. Obtain the most recently filed Medicare Cost Report
3. Obtain the site for HRSA/OPA database in which the covered entities are listed
4. Compare the entities listed as 340B eligible on the HRSA/OPA website with the list provided in step 1 to ensure that all information is the same
5. Compare the entities listed in step 1 against the most recently filed Medicare Cost Report, and then perform the following:
6. Validated that covered entities and child site eligible for 340B location are listed on the HRSA/OPA website, including the accuracy of the addresses.
7. Validate that covered entities including child sites are listed on the reimbursable lines of the Medicare cost report (i.e., anything listed between lines 50 to 118 of the most recently filed Medicare cost report is considered reimbursable).
8. Validate that services provided at the 340B locations have associated outpatient Medicare costs and charges on the Cost Report.
9. Validate that the recertification dates listed are current and within the deadline for hospitals annual 340B recertification
10. Validate that covered entities perform a quarterly review of the facilities and child sites listed on the HRSA/OPA database
11. Validate that the most recently filed Medicare cost report document a DSH level of 11.75% or greater
12. Validate that the OPAIS database website is only available to authorized personnel
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| **#** | **Process** | **Risk Event** | **Test Step** |
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| **3.0** | **Eligible Patient -Medical Record Maintenance** | No process in place to ensure patient medical records are maintained at covered entity. | 1. Obtain transactions file for a particular period of all medications dispensed from the health systems pharmacy locations
2. Gain an understanding of the information systems used in the 340B program including electronic health records, split billing software, vendor software
3. Obtain the NPI listing of all providers and residents for the period under review
4. Obtain the Prescriptions Image

A. Validate that the service provider is the covered entity provider and is eligibleB. Validate whether the prescription to dispense the 340B drugs were written for services rendered at an eligible setting (Outpatient) C. Verify whether the patient is eligible for 340B Drugs by validating the following: I. Patient is a covered entity patient (i.e. medical record exist within the covered entities EHR system) II. The service that the patient receives is from an eligible provider and/or referring provider who is listed on the covered entities NPI listIII. The service location is listed on the reimbursable lines of the most recently filed Medicare Cost Report and on the HRSA/OPA databaseIV. The patient is an Outpatient Status at the time that the medication is dispensed and/or administeredD. Validate that the prescription/image profile dates reconcile with the encounter/discharge date within the covered entities EHR systemE. Validate that the 340B drug name from the transaction file reconciles with the 340B drug name on the prescription/image profile.F. Validate that the quantity dispensed from the transaction file reconciles with the quantity on the prescription/image profile 1. Validate that the hospital certified that they will not be obtaining covered outpatient drugs through a GPO
2. Validate that the hospital maintains separate purchasing records for 340B, inpatient GPO and WAC[[10]](#footnote-10)
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| **4.0** | **Drug Diversion** | 340B drugs dispensed for prescriptions written at ineligible sites and/or ineligible NPI/providers. In addition, medication purchased/replenished through 340B drug discount program is dispensed/administered to patients that do not meet the 340B eligibility criteria or 340B drug is dispensed/administered at an ineligible setting (i.e. inpatient/outpatient). |

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| **#** | **Process** | **Risk Event** | **Test Step** |
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| **5.0** | **Duplicate Discount** | No process in places to prevent duplicate discounts. | 1. Obtain a listing of all NPI's/ Medicaid ID's Master List
2. Obtain the Medicaid Exclusion File ("MEF")
3. Obtain a listing of the 340B Covered Entities list
4. Identify the 340B Covered Entities and associated Medicaid IDs/NPI numbers from the NPI's/Medicaid ID's Master List
5. Reconcile the 340B Covered Entities Listing with the Medicaid Exclusion File and perform the following:
6. Validate that the Medicaid IDs listed on the Covered Entities Listing are listed on the Medicaid Exclusion File
7. Validate that the NPI numbers listed on the Covered Entities Listing are listed on the Medicaid Exclusion File
8. Validate that the drug exclusion lists periodically reviewed and updated
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| **6.0** | **Contract Pharmacy** | Lack of executed contract/agreement to dispense 340B drugs to covered entity patients and inappropriate dispensation of 340B drugs as stipulated in agreed-upon contract terms. In addition, incorrect patient information transmitted to contract pharmacy | 1. Obtain the 340B Contract Pharmacy Services Agreement and validate that a contract exists and has been fully executed and appropriately approved
2. From our Pharmacy department obtain a listing of all 340B drugs dispensed at the various contracted pharmacy locations (i.e. transaction report) for a particular time period.
3. Obtain the NPI listing of all providers and residents
4. Obtain the pharmacy location file and perform the following:

A. Validate that the contract pharmacy store location list on the transaction report reconciles to the pharmacy location list within the HRSA databaseB. Validate that the ordering physician is on the NPI list and eligibleC. Validate that the ordering physician within the transaction report reconciles with the ordering physician in the covered entities EHR system.D. Validate that the order/prescription dates from the transaction report reconciles with the patient encounter/discharge date within the covered entities EHR system.E. Validate that the financial class/insurance plan of the patient is a Non-Medicaid Fee for ServiceF. Validate that the 340B drugs names from the transaction report reconcile with the 340B drugs names in the medication list in the EHR system for that patient encounterG. Validate that the quantity dispensed from the transaction report reconciles with the quantity ordered within EHR system for that patient encounter. |

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| **#** | **Process** | **Risk Event** | **Test Step** |
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| **7.0** | **Monitoring Compliance With The Program** | Lack of oversight of the 340B program and ongoing self-audits performed by the pharmacy department  | 1. Determine whether a 340B oversight committee exist to monitor compliance with the program
2. Validate that meeting minutes are maintained
3. Obtain copies of self-audits performed by the Pharmacy department, for retail/specialty pharmacy, mixed use areas and contract pharmacy
4. Validate that the self-audits address the criteria’s need for compliance for the 340B program
5. Validate that the self- audit deficiencies identified have been addressed
6. Validate that educational processes are in place to ensure pharmacy leadership and staff are versed in 340B guidelines and regulation
7. Validate that 340B Summary Reports, including savings and Impact are generated and reviewed periodically
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1. As per HRSA website, eligible organizations/covered entities include: Health centers (i.e. federal qualified health centers, federally qualified health center look alike, Native Hawaiian Health centers, Tribal/Urban Indian Health Centers) Ryan White HIV/AIDS Program grantees, Hospitals [i.e. Children’s Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals (at least 11.75% disproportionate requirement)], Free Standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals), Specialized Clinics (i.e. Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, Tuberculosis Clinics) [↑](#footnote-ref-1)
2. Medicare Cost report is a required annual cost report submitted to the Center of Medicare and Medicaid Services (“CMS”) by Medicare certified providers. This report contains provider information (i.e. facility, utilization data, cost and charges by cost center as well as settlement and financial statement data). [↑](#footnote-ref-2)
3. Information obtained from Federal Register/Vol. 61, No. 207/Thursday, October 24, 1996/Notices [↑](#footnote-ref-3)
4. http://www.nachc.org/wp-content/uploads/2018/09/Medicaid-chapter-from-NACHC-340B-Manual. [↑](#footnote-ref-4)
5. https://oig.hhs.gov/oei/reports/oei-05-13-00431. [↑](#footnote-ref-5)
6. https://www.hrsa.gov/opa/updates/july-2014 [↑](#footnote-ref-6)
7. Disproportionate Share Hospitals serve a significant number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients. Disproportionate share hospitals are defined in Section 1886(d) (1) (B) of the Social Security Act. To be eligible to participate in the 340B Drug Pricing Program, disproportionate share hospitals must meet the requirements of 42 USC 256b (a) (4) (L). [↑](#footnote-ref-7)
8. Is an area that treats both inpatient and outpatient. [↑](#footnote-ref-8)
9. Split billing is the process of separating the inpatient and outpatient hospital charges from 340B-eligible areas. Effectively, this method identifies all outpatient charge codes and uses them to identify drug replenishment opportunities at 340B pricing. [↑](#footnote-ref-9)
10. There is a statutory prohibition for obtaining covered outpatient drugs through a group purchasing organization. However, the Pharmacy department has the option to purchase drugs at whole sale acquisition cost, which are wholesale prices charged by pharmaceutical manufacturers to the institution. As such, it is imperative, that institution track drugs purchased under 340B, WAC and GPO for inpatient settings. [↑](#footnote-ref-10)