Delta Region Community Health Systems Development (DRCHSD) Program

340B Pricing Program Hospital Guide

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Preface

This guide is developed to provide rural hospital executive and management teams with information regarding the 340B Drug Pricing Program (340B Program). It is also designed to assist State Offices of Rural Health directors and Flex Program coordinators to better understand the process hospitals must follow to participate in the 340B Program.

The information presented in this guide is intended to provide the reader with guidance regarding the 340B Program. The materials do not constitute, and should not be treated as, professional advice regarding participation in a 340B Program. Every effort has been made to verify the accuracy of these materials. The National Rural Health Resource Center (The Center); the Delta Region Community Health Systems Development (DRCHSD) Program; BKD, LLP; and the authors do not assume responsibility for any individual's reliance upon the written or oral information provided in this guide. Readers and users should independently verify all statements made before applying them to a particular fact situation, and should independently determine the correctness of any particular technique before implementing the technique or recommending the technique to a client.

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340B Pricing Program

In 1992, Congress enacted section 340B of the Public Health Service Act (PHSA). Section 340B of the PHSA requires drug manufacturers to provide up front discounts on covered outpatient drugs to covered entities who participate in the 340B Program. The term "covered outpatient drug" is defined at section 1927(k)(2) of the Social Security Act and includes the following:

- FDA-approved prescription drugs;
- Over-the-counter (OTC) drugs written on a prescription;
- Biological products that can be dispensed only by a prescription (other than vaccines); or
- FDA-approved insulin.

The purpose of the 340B Program is to enable covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] The 340B Program is administered by the Office of Pharmacy Affairs (OPA), which is located within the Healthcare System Bureau, Health Resources and Services Administration (HRSA).

Eligibility

The following grantee types are eligible to participate in the 340B Program based on their grantee status:

Health Centers:

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal/Urban Indian Health Centers

Ryan White HIV/AIDS Program Grantees

[1] See H.R.Rep. No. 102-384, pt.2 (1992).

Specialized Clinics:

- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

The following hospital types are eligible to participate, based on their hospital status. Below are a list of eligible hospital types and specific eligibility criteria:

- **Children's Hospitals (PED)**: must either have a disproportionate share adjustment percentage greater than 11.75% on the most-recently filed cost report; or be eligible under a separate indigent care calculation that meets specific criteria including location in an urban area, 100 or more beds and net inpatient care revenues (excluding Medicare) for indigent care of more than 30% of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.
- **Critical Access Hospitals (CAH)**: all designated CAHs are eligible to participate.
- **Disproportionate Share Hospitals (DSH)**: must have a disproportionate share adjustment percentage greater than 11.75% on the most-recently filed cost report.
- **Free Standing Cancer Hospitals (CAN)**: must either have a disproportionate share adjustment percentage greater than 11.75% on the most-recently filed cost report; or be eligible under a separate indigent care calculation that meets specific criteria including location in an urban area, 100 or more beds and net inpatient care revenues (excluding Medicare) for indigent care of more than 30% of net during the cost reporting period in which the discharges occur. This indigent care revenue must come from state and local government sources and Medicaid.

- **Rural Referral Centers (RRC)**: must have a disproportionate share adjustment percentage greater than or equal to 8% on the most-recently filed cost report.
- **Sole Community Hospitals (SCH)**: must have a disproportionate share adjustment percentage greater than or equal to 8% on the most-recently filed cost report.

In addition to the above criteria, in order for a hospital to participate in the 340B Program, it must meet one of the following:

- A private nonprofit hospital under contract with state or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid; or
- Owned or operated by a unit of state or local government; or
- A public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government.

Covered entities are responsible for ensuring that 340B Program requirements are met. If a covered entity no longer meets the requirements to participate as noted within the "ELIGIBILITY" section and, for example, its DSH percentage falls below the threshold on the most recently filed Medicare cost report, the covered entity is no longer eligible to participate and should terminate via the 340B Office of Pharmacy Affairs Information System (340B OPAIS).

Registration

In order to begin participation in the 340B Program, covered entities must register through the 340B OPAIS. There are four open enrollment periods throughout the year, which occur during the first 15 days of every quarter. Once registered, a covered entity may begin purchasing covered outpatient drugs at a 340B discount the first day following the quarter the registration occurred. **Figure 1** indicates the registration period and the corresponding participating start date.[2]

Figure 1: Registration Period and Start Dates

[2] Figure 1 obtained from the 340B Prime Vendor Program, which is managed by Apexus.

Registration Period	Effective Start Date
January 1 – January 15	April 1
April 1 – April 15	July 1
July 1 – July 15	October 1
October 1 – October 15	January 1

When registering for the 340B Program, covered entities should consider the following:

- **Identification of Authorizing Official and Primary Contact**: the Authorizing Official is typically the CEO, CFO, COO, or any other official who can bind the organization to a contract. The Primary Contact is an employee of the organization and typically represents an individual who more closely oversees the 340B Program within the covered entity. Both the Authorizing Official and Primary Contact will need to create logins for the 340B OPAIS.
- **Documentation**: certain documentation is required when registering for the 340B program. For grantees, a federal grant number is required. For hospitals, the most recently filed Medicare cost report is required.
- **Clinics/Departments/Services**: in order to access 340B drugs for certain offsite outpatient clinics/departments/services, the facility must be both reimbursable and included in the hospital's most recently filed Medicare cost report. HRSA's guidelines for outpatient facilities be found at 59 Fed. Reg. 47884 (Sept. 19, 1994). In addition, clinics/departments/services at an offsite location from the registered parent must separately register on 340B OPAIS, even if they are located within the four walls of that child site. This applies to hospitals that are registered as child sites – every eligible clinic which will purchase or use 340B drugs within such a hospital must register separately as a child site.
- **Contract Pharmacy**: if the covered entity is participating in contract pharmacy arrangements, the contract pharmacy must be registered in

the 340B OPAIS and there must be a written contract in place with the pharmacy prior to registration.[3]

Once participating in the 340B Program, covered entities may enroll newly eligible clinic sites or contract pharmacies during the four registration periods noted in **Figure 1** above.

Recertification

Participating covered entities are required to recertify for the 340B Program on an annual basis in accordance with section 340B(a)(7)(E) of the PHSA. The Authorizing Official and Primary Contact will receive email notification prior to recertification. The Authorizing Official will need to complete recertification within the 340B OPAIS and will need to attest that the covered entity still meets the requirements to participate in the 340B Program.

Covered entities should ensure that the Primary Contact and Authorizing Official contact information is up to date within the 340B OPAIS in order to ensure that any relevant notifications from HRSA are received.

Diversion

Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling, transferring, or diverting 340B drugs to an individual who is not a patient of the entity. HRSA developed programmatic guidance issued in the Federal Register (61 FR 55156, October 24, 1996) in 1996 to further define an eligible patient. Specifically, the guidance states that in order for a covered outpatient drug to be considered 340B eligible, it must meet the requirements of the 340B patient definition:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- 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 (e.g. referral for

[3] See HRSA 2010 Contract Pharmacy Guidelines at https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

consultation) such that responsibility for the care provided remains with the covered entity; and
- The individual receives a health care service 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 (FQHC) look-alike status has been provided to the entity. In general, hospital entities are exempt from this section of the guidance.

Duplicate Discount

Section 340B(a)(5)(A)(i) of the PHSA prohibits duplicate discounts whereby a state obtains a rebate on a drug provided to a Medicaid patient when that same drug was discounted under the 340B Program.

In order to prevent duplicate discounts, covered entities indicate whether they will obtain 340B discounts for Medicaid patients when registering for the 340B Program. Covered entities may choose to carve-in Medicaid, in which they will use 340B drugs for Medicaid patients or carve-out Medicaid, in which they will not use 340B drugs for Medicaid patients. If carving out Medicaid, covered entities must have the appropriate mechanisms in place to prevent 340B drugs from being dispensed to all Medicaid patients billed under the covered entities' Medicaid Provider Number/National Provider Identifier (NPI).

If carving in Medicaid, covered entities must inform HRSA by listing their Medicaid Provider Number/NPI at the time of registration. The Medicaid Provider Number/NPI is then listed in the Medicaid Exclusion File (MEF), which indicates to state Medicaid agencies and manufacturers that the covered entity has elected to carve-in Medicaid and covered outpatient drugs dispensed to Medicaid patients are not eligible for a Medicaid rebate.

A covered entity may elect to change its Medicaid carve-in/carve-out status in the 340B OPAIS at any time; however, the change is effective the following quarter after the change request is received.

If a covered entity has decided to carve-in Medicaid, the covered entity should determine whether its state Medicaid agency has specific billing requirements such as billing at 340B acquisition cost or appending a modifier to the claim.

Group Purchasing Origination (GPO) Prohibition

The Group Purchasing Origination (GPO) Prohibition applies to DSH, PED and CAN. Under the GPO Prohibition, covered entities may not use a GPO account for covered outpatient drugs. If a covered outpatient drug administered to a patient is not eligible for 340B, it must be purchased on a Wholesale Acquisition Cost (WAC) account. Therefore, covered entities subject to the GPO prohibition typically have three separate accounts on which to purchase drugs: 340B, GPO, and WAC.

If a covered entity is unable to purchase a covered outpatient drug at the 340B discount, the covered entity should contact the manufacturer to inquire why 340B pricing is not available.

Hospitals subject to the GPO Prohibition should have procedures in place to monitor WAC spend. A certain level of WAC spend is expected as the first package of a drug is purchased at WAC in order to establish a neutral inventory. Covered entities that carve-out Medicaid will have to purchase covered outpatient drugs for Medicaid patients on WAC, however, WAC spend should be minimized as much as possible as it represents the highest cost.

Orphan Drugs

In accordance with section 340B(e) of the PHSA, for certain covered entity types including RRC, SCH, CAH, and CAN, the term covered outpatient drug does not include orphan drugs (a drug designated by the Secretary of HHS under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition). Manufacturers are not required to provide 340B discounts to these covered entity types for orphan drugs; however, they may, at their discretion, provide discounts on orphan drugs.

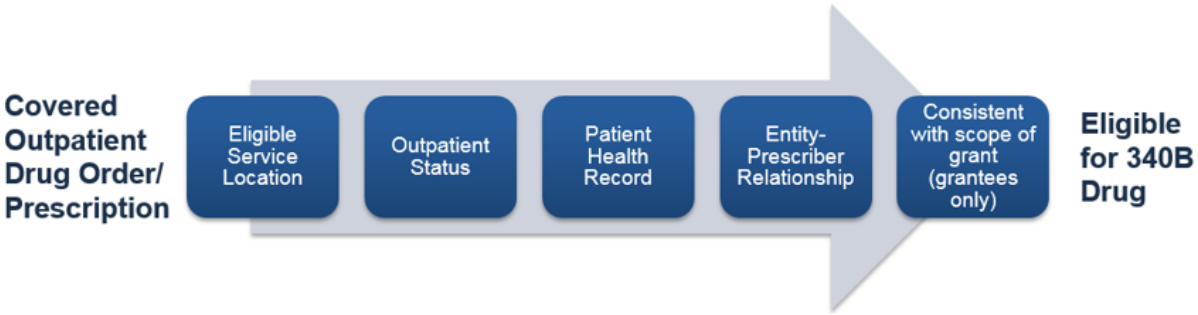
Covered entities may reach out to manufacturers to inquire whether the discounted pricing is offered. The listing of orphan drugs, which includes each orphan drug's generic name, trade name, orphan drug designation date, designation and manufacturer contact company is available on the HRSA website. The listing of orphan drugs is updated on a quarterly basis.

340B Replenishment Model

Covered entities should consider how they will facilitate and operationalize their 340B Program. As 340B drugs may only be used for patients who meet 340B eligibility requirements, covered entities may choose to maintain two separate physical inventories for 340B eligible and non-eligible patients or use a replenishment model, which consists of a single physical inventory with virtual records to substantiate different purchasing accounts comprising that physical inventory. In order to facilitate a replenishment model, many covered entities use a 340B split billing software. Covered entities should consider the lead time needed to complete the vendor selection process as well as implement the 340B split-billing software. The 340B Prime Vendor Program (PVP) provides an evaluation tool for vendor selection. Delays in vendor selection and/or implementation can lead to a delay in realizing 340B savings.

In the replenishment model, IT data feeds, such as a daily drug dispensation file, are sent to the split billing software and each drug dispensation is assessed for 340B eligibility. **Figure 2** represents 340B eligibility requirements, however, there may be additional eligibly filters set up within the split-billing software.

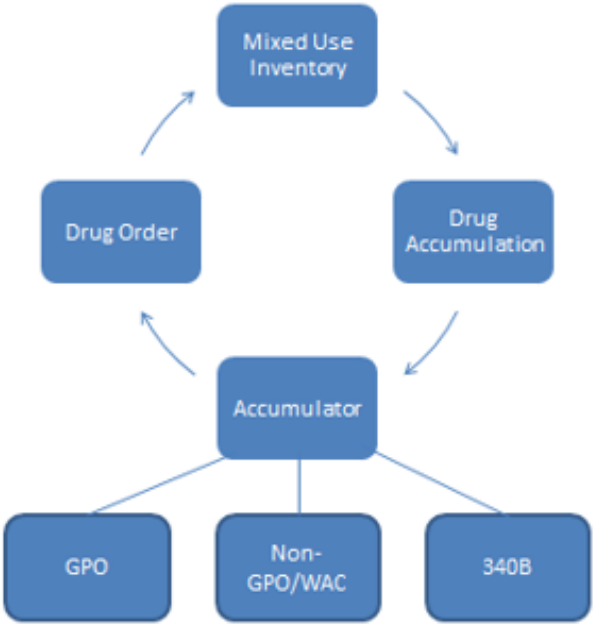
Figure 2: 340B Eligibility Requirements[4]



[4] Figure 2 obtained from https://www.340bpvp.com/controller.html

After a drug is tested for 340B eligibility, the 340B split billing software converts the drug quantity administered in the IT data feed to the National Drug Code (NDC) wholesaler purchase quantity that is eligible to be replenished on the 340B account. The 340B split-billing software maintains accumulations of all drugs eligible to be replenished on the 340B account. **Figure 3** outlines the replenishment model process.

Figure 3: Replenishment Model Process [5]



Covered entities should have resources in place to monitor compliance and self-audits are recommended. Self-audits should include, but not be limited to, assessment of the following:

- Accuracy of information listed in the 340B OPAIS
- Prevention of diversion
- Prevention of duplicate discount
- Virtual inventory accumulation and replenishment reconciliation

In addition to self-audits, ongoing monitoring of the 340B split-billing software is recommended. Settings, eligibility requirements, rules and testing parameters should be monitored to assess whether the software is effectively identifying 340B eligible transactions and excluding ineligible

[5] Figure 3 obtained from https://www.340bpvp.com/controller.html

transactions from 340B eligibility. The mechanism for converting the drug amount dispensed by the hospital to the NDC wholesaler package units, often referred to as a crosswalk, should also be monitored on a routine basis to ensure the covered entity is not over accumulating or under accumulating, which can lead to over or under purchasing on 340B.

Contract Pharmacy

In addition to obtaining 340B discounts for covered outpatient drugs dispensed at the covered entity, covered entities may elect to contract with a pharmacy or multiple pharmacies to dispense eligible prescriptions. In order to participate, a contractual agreement should be in place between the covered entity and the contract pharmacy, and the contract should identify all pharmacy locations for which the covered entity will utilize 340B drugs. The contract pharmacy must be registered in the 340B OPAIS and the same registration timelines noted within the "REGISTRATION" section applies to contract pharmacy registration.

It is the responsibility of the covered entity to maintain compliance with the 340B Program requirements for the contract pharmacy. All prescriptions filled under a contract pharmacy arrangement must meet the 340B patient definition as noted in the "DIVERSION" section. It is HRSA's expectation that covered entities provide oversight of contract pharmacy arrangements and that annual independent audits be conducted. In addition to independent audits, covered entities should have resources in place to monitor compliance and self-audits are recommended. Self-audits should include, but not be limited to, assessment of the following:

- Accuracy of information listed in the 340B OPAIS
- Prevention of diversion
- Prevention of duplicate discount
- Virtual inventory accumulation and replenishment reconciliation

If a prescription is 340B eligible under a contract pharmacy arrangement, the common financial model is for any collected insurance reimbursement (less a dispensing fee for the pharmacy) is passed onto the covered entity. The covered entity is responsible for replenishing the drug to the contract pharmacy if a virtual replenishment model is used.

In addition to self-audits, ongoing monitoring of the 340B split-billing software is recommended. Settings, eligibility requirements, rules and testing parameters should be monitored to assess whether the software is effectively identifying 340B eligible transactions and excluding ineligible transactions from 340B eligibility. The covered entity should consider how a prescription is tested for eligibility as there may need to be different requirements for drugs prescribed by providers that are exclusive to the 340B covered entity, and providers that are non-exclusive to the 340B covered entity and may practice at other non-covered entity locations.

HRSA Audits and Program Integrity

It is the responsibility of covered entities to maintain compliance with the 340B Program requirements. HRSA has the authority to audit covered entities and began auditing in 2012. All covered entities are subject to HRSA audits and should be prepared should they be selected for a HRSA audit.

Included within the scope of HRSA audits is eligibility status, diversion, duplicate discount and for some hospitals, compliance with the GPO Prohibition.[6] Covered entities can typically expect the following if selected for a HRSA audit:

- **Pre-Audit**: covered entities will receive a notification letter explaining what to expect and documentation/data requests. A telephone conference is scheduled to review the documentation/data requests and the onsite portion of the audit is scheduled.
- **Onsite Audit**: while onsite, auditors will review select 340B program transactions and internal controls. Per HRSA,

  "Audit procedures include, at a minimum:
  - review of relevant policies and procedures and how they are operationalized;
  - verification of eligibility, including GPO and outpatient clinic eligibility;
  - verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid

[6] See section 340B(a)(4)(L)(iii) of the PHSA.

Exclusion File designations, and accuracy of covered entity's 340B OPAIS record;

- review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies; and
- testing of 340B drug transaction records on a sample basis.

Auditors collect the facts throughout the audit but are not authorized to summarize any findings to the entity. Their report to OPA will contain the facts as they understand it and must undergo OPA review. Additionally, any auditor statements made during the audit are not considered final and are subject to change."

- **Post Audit**: the auditor's findings and preliminary report are sent to the OPA for review and the OPA finalizes the report. The OPA may include a request for a corrective action plan (CAP) based on the findings within the report.
- **Audit Results**: Once a final report is issued, the covered entity has 30 days to review the report and CAP, if included. If the covered entity is in agreement with the findings, the covered entity has 60 days to submit a CAP. If the covered entity disagrees, it must submit notification and documentation within 30 days.

For more information on the establishment parameters regarding material breach of non-compliance, covered entities should visit the 340B Prime Vendor's website.

340B Prime Vendor Program

Section 340B(a)(8) of the PHSA directs HRSA to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs." The purpose of the 340B Prime Vendor Program (PVP) is to develop, maintain, and coordinate a program capable of facilitating distribution in support of the 340B Program. Apexus LLC (Apexus) operates as the current PVP and they perform services in accordance with HRSA policy.

Covered entities have the option of enrolling in the PVP, which provides pricing lower than 340B for many drugs as well as cost savings opportunities for other pharmaceutical related items.

In addition to the PVP cost savings opportunities, the PVP also communicates policy, provides education, training, and support to all 340B stakeholders. The PVP offers the following education resources for 340B stakeholders:

- Education
    - 340B University (in-person)
    - 340B University On Demand
    - 340B Frequently Asked Questions
    - 340B tools
        - 340B oversight templates, including c-suite guide, 340B job description, 340B vendor request for proposal, calculation of 340B net savings
        - 340B registration resources
        - Policy and procedure templates
        - Auditing/compliance templates
        - HRSA audit and self-disclosure resources and templates
        - 340B operational/purchasing resources

In addition, The 340B Call Center assists 340B stakeholders with questions regarding 340B Program compliance to promote integrity for 340B Program participants and stakeholders. Contact the PVP call center at 1-800-340-2787 or apexusanswers@340bpvp.com.

Covered entities should review the information provided by the PVP and consider including 340B University within their 340B training plans for employees that have roles and responsibilities within the covered entity related to the 340B Program. Covered entities can access the PVP website.

Acronyms

340B Program ..... 340B Drug Pricing Program

340B OPAIS ..... 340B Office of Pharmacy Affairs Information Systems

CAH ..... Critical Access Hospital

CAN ..... Free Standing Cancer Hospitals

CAP ..... Corrective Action Plan

DRCHSD ..... Delta Region Community Health Systems Development

DSH ..... Disproportionate Share Hospitals

FQHC ..... Federally Qualified Health Center

GPO ..... Group Purchasing Origination

HRSA ..... Health Resources and Services Administration

MEF ..... Medicaid Exclusion File

NDC ..... National Drug Code

NPI ..... National Provider Identifier

OPA ..... Office of Pharmacy Affairs

OTC ..... Over the Counter

PED ..... Children's Hospitals

PHSA ..... Public Health Service Act

PVP ..... 340B Prime Vendor Program

RRC ..... Rural Referral Center

SCH ..... Sole Community Hospitals

The Center ..... National Rural Health Resource Center

WAC ..... Wholesale Acquisition Cost