# Delta Region Community Health Systems Development Program

## Best Practice for 340B Program Application, Implementation, and Management

April 26, 2023

National Rural Health Resource Center

525 South Lake Avenue, Suite 320

Duluth, Minnesota 55802

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U65RH31261, Delta Region Health Systems Development, $10,000,000 (0% financed with nongovernmental sources). This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

## Prepared By:

910 E. St. Louis Street, Suite 200
Springfield, Missouri 65801
Phone: 417-865-8701
FORVIS | CPA Firm, Accountants & Financial Accounting (www.forvis.com)

And

525 South Lake Avenue, Suite 320
Duluth, Minnesota 55802
Phone: (218) 727-9390
www.ruralcenter.org

# 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 Drug 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; FORVIS; 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.

# Table of Contents

# Introduction

This guide is intended to provide rural hospital leaders and rural health programs with relevant information to assist in managing the 340B Drug Pricing Program (340B Program) and to ensure compliance with Health Resources and Services Administration (HRSA) requirements. While the 340B Program provides hospitals with savings on covered outpatient medications to better serve their communities, the 340B Program also comes with compliance risks and challenges. Participating hospitals must meet 340B Program requirements. Savings from purchasing medications at reduced cost may be used to expand the number of drugs and services offered to patients and increase the number of indigent patients served. The eligible hospitals and health centers or covered entities participating in the 340B Program are responsible for ensuring program integrity and maintaining accurate records documenting compliance with all 340B Program requirements.

# 340B Drug 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 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).

The term "covered outpatient drug" is defined at section 1927(k)(2) of the Social Security Act and includes the following:

- United States Food and Drug Administration (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][2] As reported in the *2020 340B Health Annual Survey*, "All hospitals reported using their savings to benefit patients with low incomes and/or those living in rural communities. The most common ways savings were used were to increase access for patients with low incomes or living in rural areas, support uncompensated care, and expand service offerings." Moreover, three-quarters of critical access hospitals (CAHs) rely on 340B savings to keep their doors open and cuts to the Program would force nearly all respondents to scale back key Programs. [3]

[1] Health Resources and Services Administration, 340B Drug Pricing Program; May 2021;
[2] See H.R. Rep. No. 102-384, pt.2 (1992).
[3] 340B Health; 340B Reports; *340B Health Annual Survey: 340B Hospitals Use Savings to Provide Services and Improve Outcomes for Low-Income and Rural Patients*, 2020

# Apexus 340B Prime Vendor

While the 340B Program is overseen and administered by HRSA, Apexus serves as the Prime Vendor for the 340B Program.[4] Covered entities have the option of enrolling in the Apexus Prime Vendor Program (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, Apexus also communicates policy, provides education, training, and support to all 340B stakeholders. Apexus offers the following education resources for 340B stakeholders:

- 340B University (in-person)
- 340B University (on-demand)
- 340B Frequently Asked Questions
- 340B tools
- 340B oversight templates, including c-suite guide, 340B job descriptions, 340B vendor request for proposal (RFP), calculation of 340B net savings, and Medicaid Exclusion File (MEF)
- 340B registration resources
- Policy and procedure templates
- Auditing/compliance templates
- HRSA audit and self-disclosure resources and templates
- 340B operational/purchasing resources
- Medicaid Profiles per State/Territory
- Live Chat feature

Covered entities should review the information provided by Apexus and consider including 340B University within the 340B training plan for employees that have roles and responsibilities within the covered entity related to the 340B Program. Covered entities can access the Apexus website (membership login may be required).

How can a health care organization (HCO) apply and/or register? Visit Hospital Registration (hrsa.gov).
While the 340B program is overseen and administered by the Health Resources and Services Administration (HRSA), Apexus serves as a liaison to the HCO for the registration process in addition to providing a plethora of education, training, and resources to the HCO. These resources are available at cost and/or no cost depending on the training requested.

[4] Apexus, 340B Prime Vendor Program at https://www.340bpvp.com; August 2021

# Eligibility

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

Ryan White HIV/AIDS Program Grantees

Health Centers:

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

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 in the 340B Program 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, 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 within the HRSA 340B Office of Pharmacy Affairs Information System (OPAIS) database.

# Registration

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. **Table 1** indicates the registration period and the corresponding participating start date.

Table 1: Registration Period and Start Dates[5]

| 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 chief executive officer (CEO), chief financial officer (CFO), chief operating officer (COO) or any other official who can bind the organization to a contract for the health care organization. The Primary Contact is an employee of the organization and typically represents an individual who more closely oversees or the 340B Program within the covered entity. Both the Authorizing Official and Primary Contact will need to create logins for the HRSA OPAIS database.

- **Documentation**: Certain documentation is required when registering for the 340B program. For Grantees, a federal grant number is required. For Ryan White clinics, a Notice of Funding Opportunity (NOFO) number is required. For Hospitals, the most recently filed Medicare cost report is required. The covered entity is required to provide a Medicaid billing number or National Provider Identifier if the covered entity intends to use 340B drugs for Medicaid patients.

- **Child Sites/Grantee Sites**: For a location to receive 340B discounts for hospitals, the location must be on a reimbursable line of the most recently filed Medicare cost report. For a location to receive 340B discounts for grantees, the location must be included within the scope of the grant. If there are eligible locations that have a different physical address than the main hospital or grantee address, the location must be registered as a child site/grantee site.

- **Contract Pharmacy**: If the covered entity is participating in contract pharmacy arrangements, the contract pharmacy must be registered and there must be a written contract in place with the pharmacy prior to registration.

After completing registration, covered entities should work with their wholesaler to set up a 340B purchasing account and a Wholesale Acquisition Cost (WAC) account, if applicable (see GPO PROHIBITION section for more information on WAC account requirement). Once participating in the 340B Program, covered entities may enroll newly eligible clinic sites or contract pharmacies during the four registration periods noted in **Table 1**.

[5] Table 1 obtained from Health Resources and Services Administration, 340B Drug Pricing Program; 340B Eligibility; May 2018. https://www.hrsa.gov/opa/eligibility-and-registration/index.html

# 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 to ensure that any relevant notifications from HRSA are received.

# Diversion

Covered entities are responsible for maintaining compliance and preventing diversion within the 340B Program. Diversion occurs when a 340B drug is dispensed to an ineligible patient. 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 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 look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

Examples of drug diversion include:

- 340B drug dispensed at ineligible site
- 340B drug dispensed to inpatient
- 340B drug ordered by an ineligible provider

# Duplicate Discount

Duplicate discounts are prohibited within the 340B Program and covered entities are responsible for maintaining compliance and preventing duplicate discounts. A duplicate discount occurs when a covered entity obtains a 340B discount and a state Medicaid agency obtains a Medicaid rebate for the same drug.

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 and National Provider Identifier (NPI).

If carving in Medicaid, covered entities must inform HRSA by listing their Medicaid Provider Number and National Provider Identifier (NPI) at the time of registration. The Medicaid Provider Number and 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 their state Medicaid agency has specific billing requirements, such as billing at 340B acquisition cost or appending a modifier to the claim. It is ultimately the responsibility of the covered entity, not the state Medicaid agency, to prevent duplicate discount.

# Group Purchasing Origination (GPO) Prohibition

The GPO Prohibition applies to DSH, PED and CAN covered entities. 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 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. To establish a neutral inventory for replenishment, inventory models and 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

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 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. Unless the covered entity has approval from the manufacturer to receive 340B discounted pricing, orphan drugs should not be purchased under the 340B Program. Covered entities may reach out to manufacturers to inquire whether 340B discounted pricing is offered.

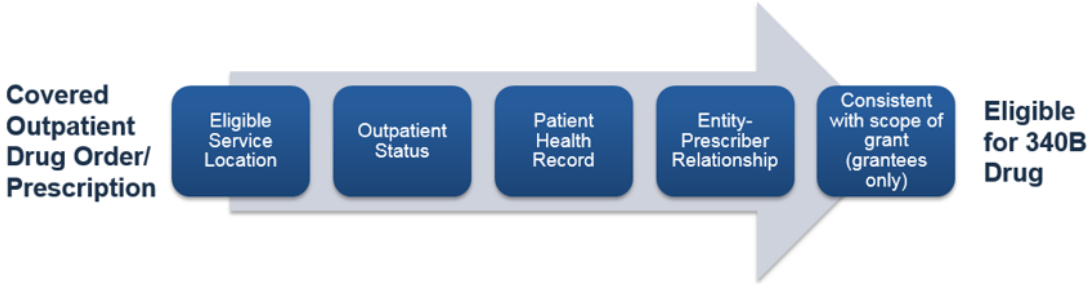
The listing of orphan drugs, which includes each orphan drug's generic name, trade name, orphan drug designation date, designation and manufacturer contact company is available on the HRSA website. The listing of orphan drugs is updated on a quarterly basis.

# 340B Replenishment System

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 drugs or use a replenishment model, in which there is one physical mixed-use inventory, and a virtual inventory is maintained. 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. Apexus 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 inventory replenishment system, information technology (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.

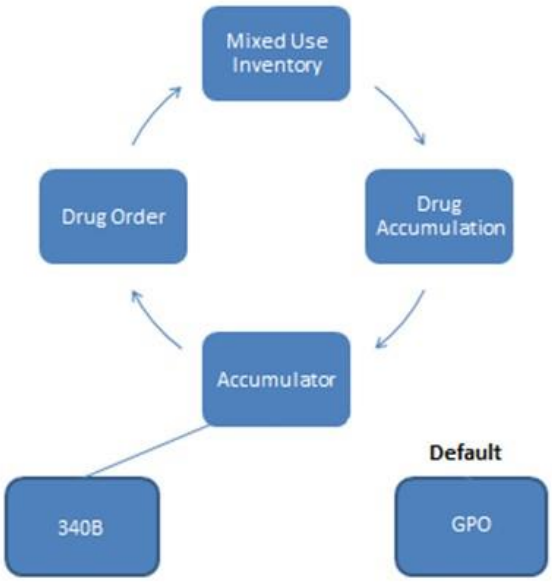
Figure 2: 340B Eligibility Requirements[6]




[6] Figure 2 obtained from Apexus, 340B Prime Vendor Program Tools; Rural Hospitals (CAH, RRC and SCH); *Rural Hospitals Sample Policy and Procedure Manual (CAH/RRC/SCH);* p9. February 13, 2020

After a drug is tested for 340B eligibility, the 340B split-billing software maintains and 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** below outlines the replenishment model process.

Figure 3: Mixed-use Inventory Replenishment System [7]




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 and accurately identifying 340B eligible transactions and excluding ineligible 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.

[7] Figure 3 obtained from Apexus, 340B Prime Vendor Program Tools; Rural Hospitals (CAH, RRC and SCH); *Rural Hospitals Sample Policy and Procedure Manual (CAH/RRC/SCH)*; p20. February 13, 2020

# 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 obtain 340B savings for eligible prescriptions filled through a contract pharmacy arrangement. 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 and be inclusive of all child sites or associated sites. The contract pharmacy must be registered in the HRSA OPAIS database 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 with the "DIVERSION" section of this guide. 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 HRSA OPAIS database
- Patient eligibility
- 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 revenue less a dispensing fee is passed onto the covered entity. The covered entity is responsible for replenishing the drug to the contract pharmacy at the 340B ingredient cost.

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. Only those prescriptions that the provider writes within a 340B eligible location should qualify for 340B.

# 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 compliance with the GPO Prohibition. 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 audit is scheduled.
- **Audit**: A review select 340B program transactions and internal controls are evaluated. 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 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."[8]

- **Post Audit**: The auditor's findings and preliminary report are sent to 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 agrees with the findings, the covered entity has 60 days to submit a CAP. If the covered entity disagrees, the covered entity must submit notification and documentation within 30 days.

HRSA recommends that covered entities establish parameters regarding material breach of non-compliance. Parameters are not defined by HRSA and can be defined by the covered entity. Per Apexus, examples of material breach parameters include, but are not limited to:

- X% of total 340B purchases or impact to any one manufacturer
- X$ (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer
- X% of total 340B inventory (units)

[8] United States Department of Health & Human Services Guidance Portal; 340B Drug Pricing Program; Program Integrity; April 2020; https://www.hhs.gov/guidance/document/340b-drug-pricing-program-program-integrity-0

- X% of audit sample
- X% of prescription volume/prescription sample

# 340B Updates

Starting in 2020, 21 manufacturers have issued notices to covered entities that they would each apply varied approaches of denying 340B pricing, including data submission efforts and reduction in contract pharmacy networks. Some manufacturers have elected to impose further restrictive measures as the contract pharmacy disputes are heard in the U.S. federal appellate courts. The manufacturers involved initiated the price changes effective as of the dates below[9]:

- Eli Lilly – September 1, 2020
- AstaZeneca – October 1, 2020
- Sanofi – October 1, 2020
- Novartis – November 16, 2020
- Novo Nordisk – January 1, 2021
- United Therapeutics – November 20, 2020 (Phase I) & December 1, 2021 (Phase II)
- Boehringer Ingelheim – August 1, 2021 & September 1, 2022 (includes health centers)
- Merck – September 1, 2021 & May 31, 2022 (includes health centers)
- UCB – December 13, 2021
- Amgen – January 3, 2022 & new restrictions effective April 11, 2023
- AbbVie – February 1, 2022
- Pfizer – March 1, 2022
- Bristol Myers Squibb – March 1, 2022
- GlaxoSmithKline – April 1, 2022 & new restrictions effective May 1, 2023
- Gilead – May 2, 2022
- Johnson & Johnson – May 2, 2022 & new restrictions effective March 7, 2023
- Exelixis – July 6, 2022
- Bausch – August 1, 2022
- Biogen – February 1, 2023
- Bayer – March 1, 2023
- EMD Serono – March 1, 2023

On May 17, 2021, HRSA issued individual letters to the six (6) manufacturers involved in withholding 340B pricing to covered entities' contract pharmacy relationships stating that the manufacturers are in direct violation of the 340B statute. In the letters, one consistent statement summarized HRSA's view and stated, "Nothing in the 340B statute

[9] Amerisource Bergen, Provider Solutions; 340B Manufacturer Updates, April 2023
National Association of Community Health Center, 340B: Federal Drug Discount Program; 340B Restrictions Summary, April 2023

grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities".[10]

The letters indicate that these manufacturers must submit plans to reinstate 340B pricing—including crediting and refunding 340B covered entities due to these intentional overcharges—by June 1, 2021. The letters are consistent with the messaging of prior advisory opinion issued on December 30, 2020. To date, HRSA has sent 340B violation letters to 11 of the 21 manufacturers and has referred eight (8) of the 11 manufacturers to the Office of Inspector General (OIG).[11] The OIG has not taken any action against the manufacturers at this time.

The 340B Program is seeing an increase in demands from pharmacy benefit managers (PBMs) and 340B vendors regarding claims submissions. On March 1, 2021, Express Scripts (ESI) issued a new requirement for 340B claims. Contract pharmacies must retrospectively identify drugs filled as 340B by resubmitting the claim as an N1 transaction. A number of states have signed into law protections for 340B covered entities against PBM discriminatory practices (e.g., reimbursing covered entities at lower rates).

Two other organizations, ESP and Kalderos, are simultaneously working with manufacturers and covered entities to request claims submission and modify 340B to a rebate model.

# Administrative Dispute Resolution Process

HRSA issued a final rule on the Administrative Dispute Resolution (ADR) in December of 2020 that established requirements and procedures to file a dispute under the 340B Program.[11] This statutory process allowed for a filed dispute to be brought to a board of appointed members by both covered entities and manufacturers individually or collectively with other covered entities or manufacturers respectively. However, HRSA, "encountered policy and operational challenges" when implementing the final ruling and on November 30, 2022, and issued a proposed rule to revise the 2020 final ruling.[13] HRSA accepted public comments on the proposed rule until January 30, 2023.

[10] Health Resources and Services Administration, 340B Drug Program; *Statement From the HRSA Regarding Recent Court Rulings;* April 2023;
[11] Health Resources and Services Administration, 340B Drug Pricing Program 340B Administrative Dispute Resolution (ADR) [13] Federal Register, Department of Health and Human Services; 340B Drug Pricing Program - Administrative Dispute Resolution

# Medicare Outpatient Prospective Payment System Requirements

In 2018, the U.S. Department of Health & Human Services (HHS) implemented a reduction to reimbursement payments for 340B drugs under the Outpatient Prospective Payment System (OPPS) Rule. This lowered the reimbursement rate from the average sales price (ASP) plus 6% to ASP minus 22.5%. In June 2022, the U.S. Supreme Court vacated the 2018 and 2019 rule and remanded the case back to the federal district court to determine remediation. U.S. District Court Judge Rudolph Contreras ruled to provide hospitals prospective relief by restoring the reimbursement rate for the remainder of the year on September 28, 2022. There has yet to be a ruling on the second motion filed by hospital groups seeking to remedy underpayments to 340B hospitals in OPPS Rules 2018-2022.

CMS has announced the final OPPS Rule for 2023, confirming that reimbursement would be restored to ASP plus 6% for the calendar year. CMS requires the appropriate modifiers "JG" or "TB" to be applied to 340B claims for informational purposes, including compliance with requirements under The Inflation Reduction Act. All hospitals are currently required to use the "JG" and "TB" modifiers to identify 340B drugs on claim lines. This excludes rural sole community hospitals, children's hospitals, and Prospective Payment System-exempt cancer hospitals, which are instead required to use the "TB" modifier on claim lines to identify 340B drugs. See **Table 4** and **Table 5** below.

In addition to the final rule, the agency announced it will address the remedy for 340B drug payments from 2018-2022 in future rulemaking prior to the CY 2024 OPPS/ASC proposed rule.

### Reporting Requirements by Hospital Type[12]

**Tables 4 and 5** below describe the modifier a hospital should report depending upon the type of hospital and the pertinent OPPS drug status indicator (SI) for the 340B-acquired drug being furnished.

[12] Table 4 and 5 obtained from CMS, Medicare-FFS Program Frequently Asked Questions. March, 2023.

Table 4: Hospitals Paid Under the OPPS

| Hospitals Paid Under the OPPS | | | | |
|---|---|---|---|---|
| Hospital Type | Pass-through Drug (SI; "G") | Separately Payable Drug (SI "K") | Vaccine (SI "F", "L", "M") | Packaged Drug (SI "N") |
| Children's Hospital | TB | TB | N/A | TB or JG, Optional |
| PPS-Exempt Cancer Hospital | TB | TB | N/A | TB or JG, Optional |
| Rural Sole Community Hospital | TB | TB | N/A | TB or JG, Optional |
| DSH Hospital | TB | JG | N/A | TB or JG, Optional |
| Medicare Dependent Hospital | TB | JG | N/A | TB or JG, Optional |
| Rural Referral Center | TB | JG | N/A | TB or JG, Optional |
| Non-Rural Sole Community Hospital | TB | JG | N/A | TB or JG, Optional |

Table 5: Hospitals Not Paid Under the OPPS

| Hospitals Not Paid Under the OPPS | |
|---|---|
| Hospital Type | Drugs Acquired Under the 340B Program |
| CAH | TB, Optional |
| Hospitals located in Maryland and paid under the Maryland All-Payer or Total Cost of Care Model | TB, Optional |

# Outpatient Location Eligibility

In June 2020, HRSA updated its COVID-19 Resources page stating that patients of outpatient facilities that meet provider-based requirements but are not yet listed on the most recently filed Medicare cost report may still be eligible for the 340B Drug Pricing Program to the extent they are patients of the covered entity. Historically, covered entities would have to wait for the location to be on the most recently filed Medicare cost report prior to being 340B eligible. This change still requires the maintenance of policies, procedures, and auditable records that reflect the respective covered entity's actions. Noted below is the Frequently Asked Questions (FAQ) from HRSA:

- Are hospital covered entities able to register offsite, outpatient facilities before being listed as reimbursable on their Medicare Cost Report?
- In order to register for the 340B Program and be listed on the 340B OPAIS, HRSA must first verify that the offsite, outpatient facility is listed as reimbursable on the hospital's most recently filed Medicare cost report and has associated outpatient costs and charges as outlined in HRSA's 1994 Outpatient Hospital Facilities Guidelines (PDF - 1.2 MB)

- HRSA notes that hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. Learn more about HRSA's patient definition guidance (PDF - 31 KB)

These situations should be clearly documented in the covered entity's policies and procedures. In addition, a covered entity is responsible for demonstrating compliance with all 340B Program requirements and ensure that auditable records are maintained for each patient dispensed a 340B drug.

# Telehealth

In March 2020, HRSA updated its COVID-19 Resources page to address flexibilities in telehealth. Noted below is the FAQ from HRSA:

- Given the coronavirus 2019 pandemic, what flexibilities are available to entities to allow a provider to offer telehealth services?
- HRSA understands that telemedicine is a mode by which health care services are delivered. For the 340B Program, HRSA recommends that covered entities outline the use of these modalities in their policies and procedures and continue to ensure auditable records are maintained for each eligible patient dispensed a 340B drug.[13]

Covered entities should clearly define telehealth and the scope of telehealth services within the policy and procedures. Telehealth services that look to qualify prescriptions as 340B eligible will need to meet the patient definition. Covered entities should monitor 340B prescriptions qualifying as a result of telehealth encounters for compliance and ensure that auditable records are maintained for each patient dispensed a 340B Drug.

[13] Health Resources and Services Administration, 340B Drug Program; *COVID-19 Resources*; March 2023.

# Conclusion

Rural hospitals participation in the 340B Program is a best practice for financial performance improvement and meets the intentions of CMS to extend federal resources to better serve patients and communities. The 340B Program has received increased focus from HRSA, Congress, other federal agencies, and there have been many proposed changes since the program was enacted. As the 340B Program continues to evolve, covered entities should monitor and evaluate any proposed changes, such as those highlighted above, to help ensure they are prepared for and understand the effect these changes may have on their program and remain in compliance. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained or removed from the 340B Program. Covered entity leaders should understand current 340B Program requirements and ensure there are adequate policies and procedures in place to comply with all applicable requirements, as well as monitor future developments within the 340B Program.

# Appendix A: Acronyms

340B Program - 340B Drug Pricing Program
ADR - Administrative Dispute Resolution
ASP - Average Sales Price
CAH - Critical Access Hospitals
CAN - Free Standing Cancer Hospitals
CAP - Corrective Action Plan
CMS - Centers for Medicare & Medicaid Services
DSH - Disproportionate Share Hospitals
ESI - Express Scripts
FAQ - Frequently Asked Questions
FDA - United States Food and Drug Administration
FQHC - Federally Qualified Health Center
GPO - Group Purchasing Origination
HRSA - Health Resources and Services Administration
IT – Information Technology
MEF - Medicaid Exclusion File
NDC - National Drug Code
NPI - National Provider Identifier
OPA - Office of Pharmacy Affairs
OPAIS - Office of Pharmacy Affairs Information System
OPPS - Outpatient Prospective Payment System (OPPS)
OTC - Over the counter
PBD - Provider-Based Departments
PBM - Pharmacy Benefit Managers
PED - Children's Hospitals
PHSA - Public Health Service Act
PVP - Apexus Prime Vendor Program
RFP - Request for Proposal
RRC - Rural Referral Centers
SCH - Sole Community Hospitals
SI - Status Indicator
WAC - Wholesale Acquisition Cost

# Appendix B: Best Practice Tools

HRSA's Introduction to the 340B Drug Pricing Program: This resource describes the 340B Drug Pricing Program which resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals. Significant savings on pharmaceuticals may be seen by entities that participate in the Program. This resource includes several different links for additional information including Eligibility, Registration, Program Requirements, Duplicate Discount, Orphan Drugs, Program Integrity, Recertification and Self-Disclosures.

340B Drug Pricing Program Frequently Asked Questions: View HRSA's frequently asked questions regarding the 340B Program.

340B Program Hospital Commitment to Good Stewardship Principles: View principles from the American Hospital Association (AHA) for ensuring good stewardship of the 340B Program. Read recommendations for hospitals to align with the Commitment to Good Stewardship Principles.

340B Program: A Prescription for Success: This webinar presented the 340B Drug Pricing Program Hospital Guide. It discusses eligibility, compliance, billing, and benefits of participation in the 340B Drug Pricing Program.

CAHs: 340B Eligibility, Enrollment and Participation Information

View a document that provides eligible CAHs with basic background information about the 340B Program, instructions on how to enroll in 340B and additional sources for information related to the 340B Program.

340B Program Tools by Apexus: View tools to help covered entities operationalize 340B compliance guidelines. Find tools such as templates for policies and procedures, registration, audit and compliance plans, and additional resources to ensure 340B program integrity. Each of the available tools has been reviewed by HRSA. These tools are meant to be a guide and should be carefully considered and updated based on your particular site's needs.