2023 SUMMER CPE SYMPOSIUM: HOT TOPICS IN HEALTHCARE

Understanding Your 340B Program – Key Updates for 2023

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Introductions

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Agenda

1. 340B Eligibility Requirements and Program Overview
2. Pre-COVID-19 Compliance Requirements
3. Public Health Emergency (PHE) Flexibilities and Post-PHE Considerations
4. Recent Industry Events and Activity

340B Overview

1. The 340B Program was created in 1992 by President Bush and requires drug manufacturers to provide covered outpatient drugs to eligible Covered Entities (CEs) at significantly reduced prices.
2. The CEs benefit from the difference between the drug's reduced cost and the unadjusted reimbursement received from payers.
3. Many CEs use these savings to provide additional community benefit programs to patients who are uninsured or underinsured.

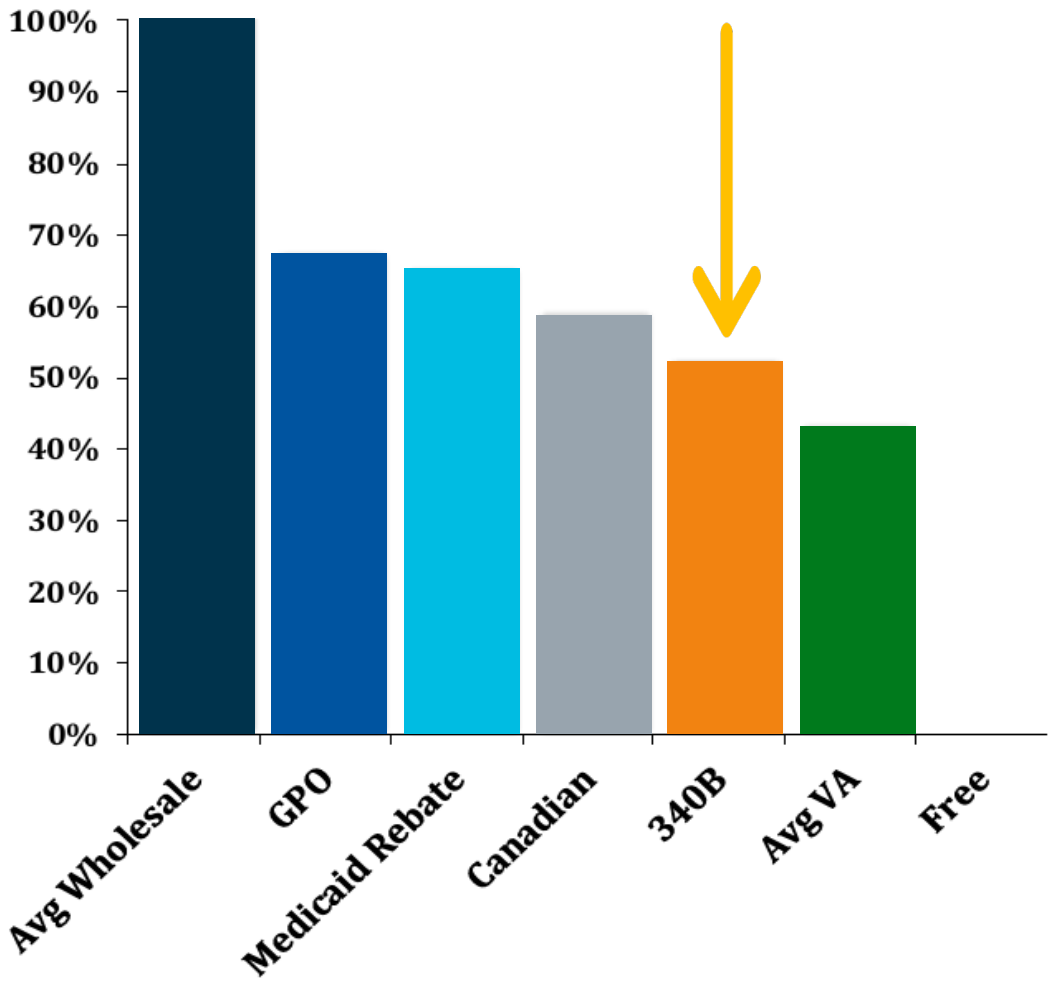
CEs are responsible for ongoing compliance and must attest annually to 340B Program requirements for annual recertification. Non-compliance can result in repayment to manufacturers and termination from the Program.

"The 340B Program enables Covered Entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

– Health Resources and Services Administration (HRSA)

Why is 340B Important?

- On average, 340B pricing is:
  - **51% lower** than the Average Wholesale Price (AWP)
  - **23% lower** than the Average Manufacturer Price (AMP)
  - **15% lower** than Group Purchasing Organization (GPO) pricing



Source: SUNRx, Safety Net Hospitals for Pharmaceutical Access.

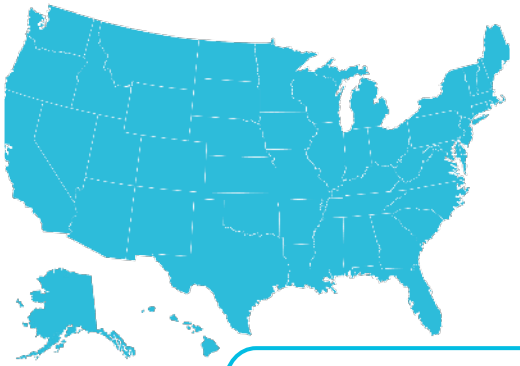
Why is 340B Important?

- HRSA's increased focus on compliance

$43.9 Billion

Total 340B Program drug sales in 2021

53,146



Total registered sites participating in the 340B Program as of January 1, 2022 *(includes CEs and associated sites)*

$7 Million

- Additional budgetary funding for FY 2023
- **Goal:** Expand program integrity efforts with increased audit and oversight

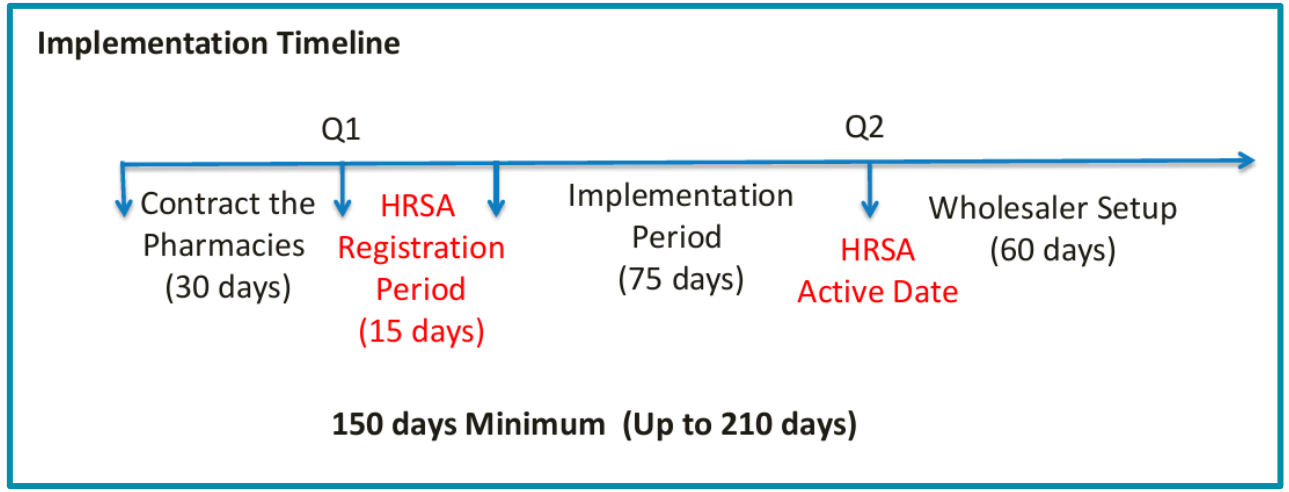
Source: HRSA 2021 340B Covered Entity Purchases and Fiscal Year 2023 Budget Justification Document

Pre-COVID

340B Program Registration

- New covered entities, child sites, and contract pharmacy arrangements must register with the Office of Pharmacy Affairs (OPA) Database.

Registration Date	Start Date
October 1st – 15th	January 1
January 1st – 15th	April 1
April 1st – 15th	July 1
July 1st – 15th	October 1



Source: SUNRx, Safety Net Hospitals for Pharmaceutical Access

Hospital Eligibility

- Eligibility requirements for “parent” sites differ depending on the organization type:

	PED	DSH	CAH	CAN	RRC	SCH
Subject to GPO Prohibition	✖	✖		✖		
Subject to Orphan Drug Exclusion			✖	✖	✖	✖
DSH % Threshold	**> 11.75%**	**> 11.75%**		**> 11.75%**	**≥ 8.0%**	**≥ 8.0%**

- All clinics outside of the four walls of the parent hospital must be registered as “child” sites if they purchase or provide 340B drugs.

Source: Apexus 340B University.

Billing Considerations

- **January 1, 2018**
  - CMS implemented new billing guidelines for 340B drugs, including the use of TB and JG modifiers.
  - At the time, non-excepted off-campus provider-based departments were allowed to report modifier TB for all 340B-acquired drugs (status indicator G and K).
  - Reimbursement reduction from ASP + 6% to **ASP *less* 22.5%**.
- **January 1, 2019**
  - CMS changed this payment policy, requiring the use of modifier JG, and thus reducing the payment, for status indicator G and K drugs for non-excepted off-campus provider-based departments.
  - As a result of this change in payment policy, changes should have been made to billing procedures such that the JG modifier was used (thus reducing the payment).
- **June 15, 2022**
  - U.S. Supreme Court finds HHS violated federal law when it reduced Medicare payment rates in 2018.

Billing Considerations – Case Study

DSH CE did not update billing procedures for their non-excepted, off-campus, provider-based departments. This resulted in a repayment obligation of $10M handled with assistance from counsel.

Billing Considerations – New Guidance

- **January 1, 2023**
  - Medicare will pay 340B hospitals for Part B drugs at the same rate as used for non-340B hospitals (reverting back to ASP + 6% rates)
  - Rural SCHs and children's and cancer hospitals are to continue using the TB modifier, and all other 340B hospitals paid under the OPPS are to continuing using the JG modifier, even though it will no longer impact payment rates.
- Going forward, organizations should ensure billing procedures are in place to append the JG modifier for informational purposes; however, any repayment considerations would stem from prior years' billing (2019 – 2022).

Source: CMS Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System (OPPS), March 2023

PHE Flexibilities and Post-PHE Considerations

During the Pandemic

- ✓ HRSA showed no real leniency with audits and continued to conduct desk audits of CEs.
- ✓ Flexibilities were extended related to entity and child site registration, provider definition and subsequent medical record documentation, and overall program eligibility for some entity types.

Entity and Child Site Registration – PHE Flexibilities

- Prior to the pandemic, registration with the Office of Pharmacy Affairs (OPA) database must have taken place during one of the designated registration windows (typically took 150 to 210 days).
- In light of COVID-19, HRSA allowed some organizations, upon request and review, to enroll in the 340B program without going through the enrollment cycle.
- CEs were also permitted to add and enroll off-site outpatient clinic child sites without having to wait for a registration window, and as soon as the child site was deemed eligible to be listed on the CE's Medicare cost report.

Entity and Child Site Registration – Post-PHE

- Any CE that enrolled during the PHE should ensure they understand and adhere to all requirements for recertification.
- Child sites added during the PHE should be registered with OPA as soon as possible using the pre-pandemic registration process. Confer with 340B legal counsel regarding continued dispensations at locations that are not registered.
- CEs should continually monitor their program eligibility.
- If contemplating new child site additions or contract pharmacy arrangements, identify the appropriate registration window and plan for future start dates.

Provider Definition & Medical Record Documentation – PHE Flexibilities

- Many CEs expanded their provider definitions to meet fluctuations in patient care needs, relying on volunteer health professionals to deliver care.
- HRSA required emergency documentation that clarified the relationship between the provider and the CE.
- HRSA understood that providers may not have had access to full medical histories, patient insurance information, etc. In response, HRSA issued guidance stating an abbreviated health record would be adequate for purposes of documenting the patient/provider relationship, and the CE's responsibility for patient care as required by the 340B program.

Provider Definition & Medical Record Documentation – Post-PHE

- As CEs return to pre-pandemic operations, they should review their provider definition, updating as needed and removing any provider types no longer meeting that definition.
- The eligible prescriber listing should be regularly reviewed with updates communicated to all contract pharmacies and with any applicable split-billing software vendors.
- Policies and procedures should be reviewed to note the effective date of a revised procedure (during COVID-19) and return to pre-pandemic requirements (post-PHE).
- CEs should ensure medical record documentation is sufficient to meet HRSA's pre-pandemic expectations and that all records are maintained in an auditable manner.

Overall Program Eligibility – PHE Flexibilities

- **March 15, 2022** – President Biden signed the 2022 Consolidated Appropriations Act which protected some hospitals from losing 340B Drug Pricing Program eligibility due to COVID-19.
- This included hospitals that already lost eligibility during the pandemic by reporting a lower DSH percentage than what is required for 340B Program participation (11.75%, or 8% for rural referral centers (RRCs)). This protection ended December 31, 2022.

Overall Program Eligibility – PHE Flexibilities

- The provisions protected:
  - Disproportionate share hospitals (DSH)
  - Freestanding children's and cancer hospitals (PED & CAN)
  - Rural referral centers (RRC)
  - Sole community hospitals (SCH)
- Hospital was required to have participated in 340B Program prior to the start of COVID-19.

Overall Program Eligibility – PHE Flexibilities

- Attestation must have been provided to HHS related to how COVID-19 impacted the hospital's ability to meet the DSH requirements.
  - Hospitals that had already lost eligibility must have submitted an attestation within 30 days of enactment.
  - If the hospital would lose eligibility upon submitting a new Medicare cost report, an attestation must have been provided within 30 days of filing the new report with the insufficient DSH percentage.

Overall Program Eligibility – Post-PHE

- Presently, there is no indication that this flexibility will be extended.
- CEs (other than CAHs with no DSH percentage requirement) will need to closely monitor their eligibility and plan accordingly.
- If a CE anticipates they may lose eligibility due to an inability to meet the required DSH percentage, they may consider reaching out to the 340B Prime Vendor and/or local legislators.

Additional Post-PHE Considerations

Medicare Advantage (MA) Plan impact

- Patients moving from traditional Medicare to MA are impacting the DSH dollars moving through the Medicare cost report.

Provider-based status is becoming attractive again.

HRSA moving back to in-person audits, rather than desk audits.

Recent Industry Events and Activity

2023 OPPS Final Rule

- Final Rule stemmed from Supreme Court decision to strike originally proposed payment cuts for 340B participants.
- “JG” modifier is now informational and does not include payment impact.
- Continued focus on compliant billing related to 340B program.

Contract Pharmacy Restrictions

- **Brand drug companies unilaterally restricting access in several ways:**
  - Outright denial of 340B pricing for items shipped to contract pharmacy
  - Restrictions tied to contract pharmacy dispense data (requirement to report de-identified dispensation data to 340B ESP)
  - Restrictions but with certain exceptions (e.g., single contract pharmacy only if without an in-house pharmacy)
- **Impact to CEs:**
  - Face declining contract pharmacy reimbursement
  - Making difficult decisions around data sharing
  - Expending funds pursuing advocacy, 340B ADR, etc.

Current Events

- **Restriction on use of 340B drugs at unregistered hospital locations**
  - Interpreted discrepancies in issued HRSA guidance as to continued dispensation from child sites registered during the PHE
- **Manufacturer restrictions on 340B drug sales**
  - More than 22 manufacturers restricting sales despite statue requiring manufacturers to offer drugs to 340B hospitals at the 340B ceiling price
  - Both federal district courts and federal appeals court have determined these restrictions are allowed under the 340B statute

Auditing and Monitoring Importance

- ✓ Policies and procedures should include any child site changes
- ✓ OPA database information should be kept current
- ✓ Any changes that may have occurred due to COVID-19 should be monitored (i.e., new providers, etc.)
- ✓ Billing requirements should be reviewed routinely to ensure billing processes and procedures are current and up-to-date

Source: https://www.hrsa.gov/opa/

Annual Recertification Attestation

- ✓ All information on OPA database is accurate.
- ✓ CE meets all 340B Program eligibility requirements.
- ✓ CE will comply with all 340B Program requirements.
- ✓ CE maintains auditable records.
- ✓ CE has systems in place to ensure ongoing compliance.
- ✓ All contract pharmacy arrangements are in compliance.
- ✓ CE will notify OPA with any significant changes.
- ✓ CE understands they may be liable for any breaches.

Source: https://www.hrsa.gov/opa/

340B Program Infrastructure

- All policies and procedures should be written and address compliance with the areas that are noted in the annual recertification attestation.
- A strong 340B Program infrastructure includes the following internal controls:

Detailed policies and procedures

Retention of applicable records

Appropriate oversight, including formal auditing and monitoring processes

Well-documented and defined patient definition

How Can We HELP?

A national healthcare advisory services firm providing consulting, audit, and tax services