



# Latest Developments in 340B

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# Agenda

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4. Contract Pharmacy Restrictions
5. Recent Case Study
6. Auditing and Monitoring Importance
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# Introductions

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**Sarah Bowman**

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Sarah serves the Firm's Compliance Advisory Services team as a consulting senior manager. She is a proven healthcare leader with operational process redesign and leadership expertise.

Sarah works as a subject-matter expert, providing analytic and advisory services related to the integration of coding and reimbursement into physician/hospital financial and strategic modeling, business valuations, physician compensation modeling, productivity assessments, and regulatory compliance initiatives. She has experience assisting clients with 340B program assessments and related compliance readiness activities.



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# Introductions

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**Katie Garmon**  
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Katie serves as a manager on PYA's Compensation Valuation and Physician Services Team. Prior to joining PYA, Katie worked as a nationally certified pharmacy technician for more than six years and served as an associate for the Department of Managed Care Contracting at UAB Hospital's Health Services Foundation.

As a manager at PYA, Katie has experience in physician practice operations, revenue cycle and financial controls, physician practice establishment, physician reimbursement, regulatory compliance, and due diligence activities. Katie holds a Bachelor of Science in Management with an emphasis on Healthcare Management and a Minor in Political Science from the University of Alabama. She also holds a Master of Science in Healthcare Administration with an emphasis in Healthcare Finance from the University of Alabama at Birmingham.



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# Pre-COVID

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# 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.

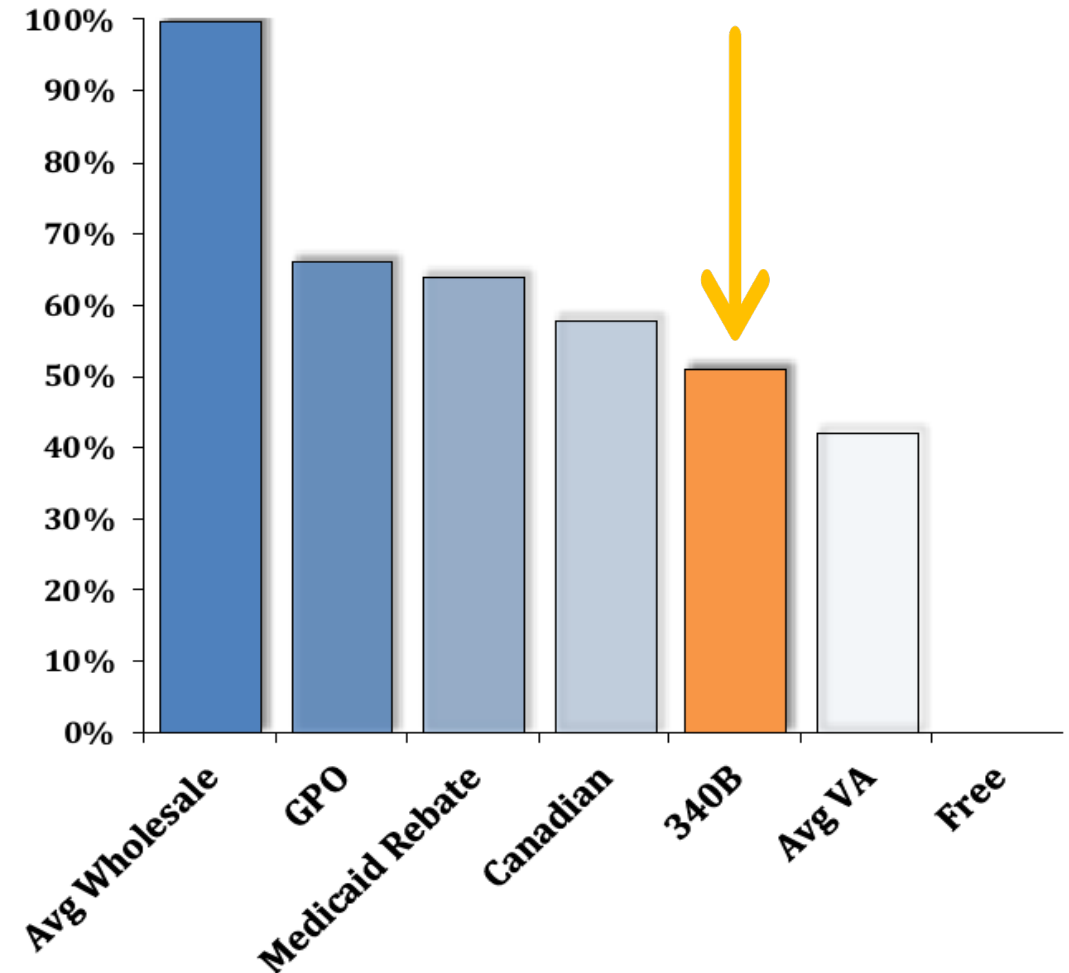
**CEs are responsible for ongoing compliance and must attest annually to 340B Program requirements for annual recertification. Non-compliance can result in repayment to manufacturers and termination from the Program.**

*“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?

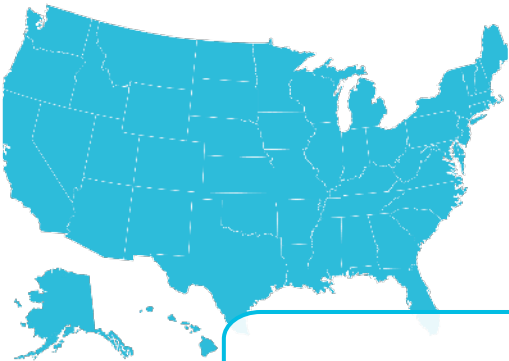
- HRSA's increased focus on compliance

**\$29 Billion**



Total 340B Program drug sales in 2019

**51,952**



Total registered sites participating in the 340B Program as of April 1, 2021 (includes CEs and associated sites)

**\$7 Million**



- Additional budgetary funding for FY 2022
- **Goal:** Build upon program integrity efforts with increased audit and oversight

Source: HRSA Fiscal Year 2022 Budget Justification Document

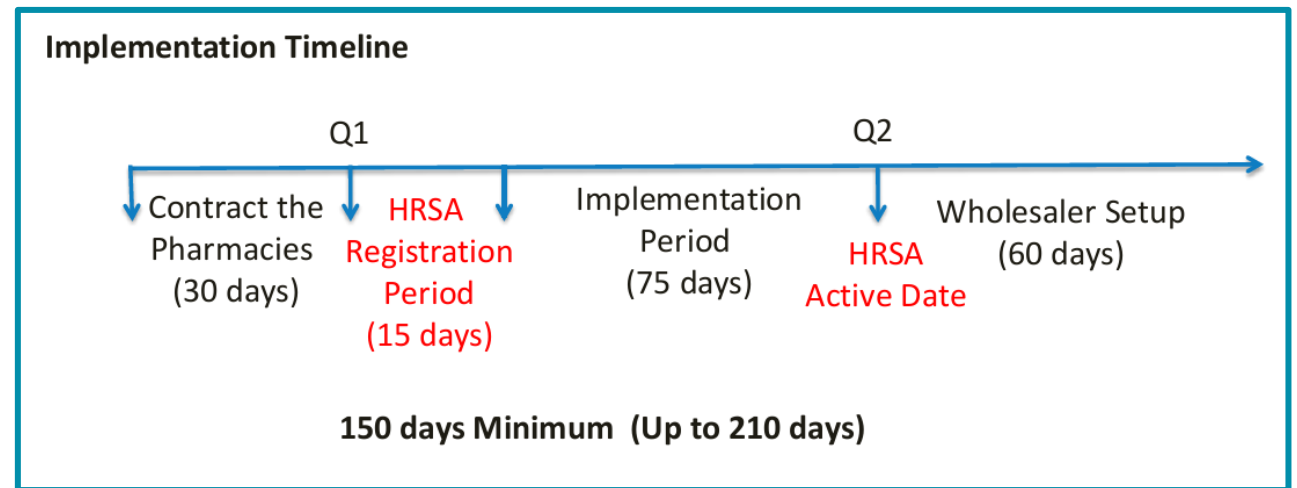


# 340B Program Registration



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

Registration Date	Start Date
October 1 <sup>st</sup> – 15 <sup>th</sup>	January 1
January 1 <sup>st</sup> – 15 <sup>th</sup>	April 1
April 1 <sup>st</sup> – 15 <sup>th</sup>	July 1
July 1 <sup>st</sup> – 15 <sup>th</sup>	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.

# During COVID

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# During the Pandemic



Jun	1-Jul	1-Aug	1-Sep	1-Oct	1-Nov
307,85	1.240,64	1.235,42	939,09	1.300,67	843,29
0,00	698,18	0,00	0,00	40,07	0,00
15,80	78,42	38,16	15,62	256,67	25,46
2,03	1.485,22	6.062,23	447,24	16.048,05	349,55
5	677,87	503,91	1.094,97	5.620,31	2.560,60
	0,00	310,01	3.142,38	9.779,24	14.693,60
	0,00	670,64	1.259,50	4.294,85	7.473,20
	83,58	39.386,87	17.848,02	34.414,47	0,00
	0,00	0,00	0,00	0,00	0,00
	19.577,90	11.799,74	14.874,16	14.874,16	33.010,20
	1.335,55	21,76	865,15	348,70	348,70
	0,00	0,00	12.032,74	24.740,00	24.740,00
	0,00	0,00	4.387,73	18.444,00	18.444,00
	0,00	701,60	4.796,53	502,00	502,00
	0,00	2.144,68	2.000,27	1.727,00	1.727,00
	0,00	10.857,02	0,00	0,00	82,00
	0,00	0,00	0,00	0,00	0,00
	0,00	0,00	0,00	0,00	4.829,00
	0,00	0,00	0,00	0,00	0,00
	0,00	0,00	48.000,19	160,07	160,07
	0,00	131,43	160,07	160,07	160,07
	0,00	101.087,81	143.638,64	143.638,64	143.638,64
	0,00	8.466,82	16.979,67	16.979,67	16.979,67
	0,00	0,00	0,00	0,00	0,00
	63.475,90	17.167,82	50.288,56	50.288,56	35.500,00
	492,26	391,49	586,00	586,00	586,00

- ✓ HRSA showed no real leniency with audits and continued to conduct desk audits of CEs.
- ✓ Flexibility was extended regarding provider definition and the addition of child sites.

# Omnibus Protection



- **March 15, 2022** – President Biden signed the 2022 Consolidated Appropriations Act which will protect some hospitals from losing 340B Drug Pricing Program eligibility due to COVID-19.
- This includes 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 is through December 31, 2022.**



# Omnibus Protection



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



# Omnibus Protection



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

# Additional COVID Impacts

- Medicare Advantage (MA) Plan impact
  - Patients moving from traditional Medicare to MA are impacting the DSH dollars moving through the Medicare cost report because MA DRGs are not included in the DSH calculation.
- DHS percentages may also fall as a result of less Medicaid patients receiving in-hospital services during COVID-19.
- Provider-based status is becoming attractive again.



# Contract Pharmacy Restrictions

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# Recent Case Study



- **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).

- **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 the client's billing procedures such that the JG modifier was used; however, this was not completed for eight non-excepted off-campus provider-based departments.

# Recent Case Study



This resulted in an estimated overpayment of over \$10M, which must now be repaid.



# 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



# Thank you!



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