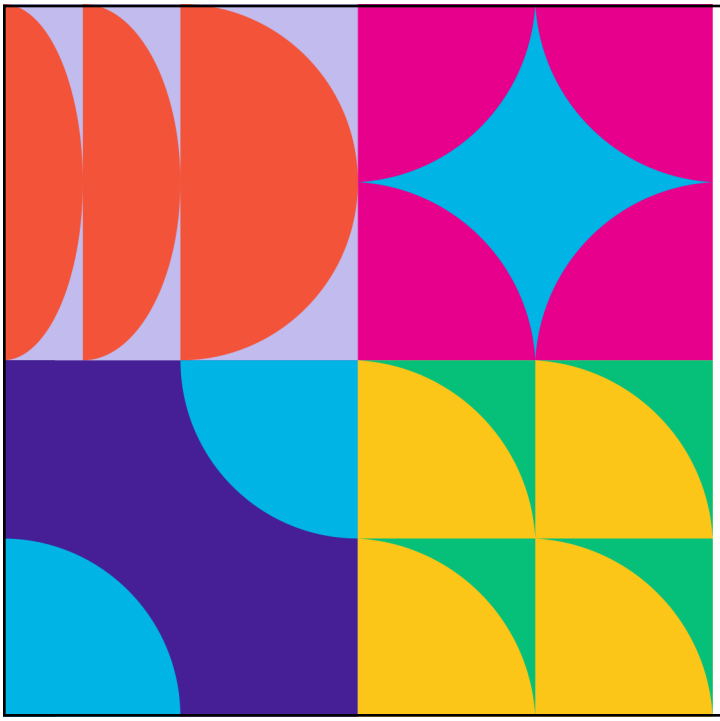

Making 340B Work for Your Pharmacy

Jonathan Grooms,
MBA, CPhT, 340B ACE, CSPO

Description

The 340B Drug Pricing Program continues to shape access, reimbursement, and partnership models for many community pharmacies. Strengthen your understanding of how 340B works today and what it takes to participate successfully. Identify practical steps to start, optimize, or evaluate a 340B arrangement while maintaining compliance and long-term sustainability.

Meet the Faculty

Jonathan Grooms,
MBA, CPhT, 340B ACE, CSPO

Senior Director 340B Pharmacy Relations
Cencora

Jonathan Grooms

Jonathan Grooms is a healthcare and 340B industry leader with more than 20 years of experience across health systems, technology, consulting, and program operations. He began his career as a U.S. Navy Hospital Corpsman and independent pharmacy technician before transitioning into civilian pharmacy operations, supporting providers and pharmacies in building sustainable, compliant 340B programs. Jonathan has held senior leadership roles, including Vice President of Account Management at a SaaS company specializing in revenue intelligence and 340B solutions, and leadership positions at a 340B third-party administrator, consulting firm, and covered entity. His expertise spans 340B Industry strategy, 340B pharmacy operations, HRSA audits, data analytics, and customer success.

Disclosures

- Jonathan Grooms is an employee of Cencora. All relevant financial relationships have been mitigated.
- Jonathan Grooms discloses that AI tools were not utilized for this presentation.

Funding for this course was provided by Cencora.

Learning Objectives

Upon completion of this activity, learners should be able to:

- Describe regulatory, operational, and market trends affecting 340B participation and contract pharmacy models.
- Identify operational and documentation requirements that influence compliance, oversight, and financial performance in 340B arrangements.
- Examine partnership considerations that affect whether a 340B model is viable and sustainable while supporting patient access.
- Assess the risk and revenue implications of a current or potential 340B arrangement.
- Determine next steps to start, strengthen, or optimize 340B participation while supporting sustainability, compliance, and patient access.

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340B & Contract Pharmacy Review

What is 340B?

Drug Discount Program

- In 1992, Section 340B of the U.S. Public Health Service Act created "340B" for safety-net providers to stretch scarce resources, reach more eligible patients, and provide more comprehensive services.
- Program eligibility was expanded in 2010 with the Affordable Care Act.

Administered by HRSA (government)

- HRSA OPA administers the 340B Program. Apexus won the prime vendor contract to operationalize and manage the program.
- HRSA maintains the 340B registration database, interprets law, and conducts covered entity and manufacturer audits.

Funded by manufacturer discounts

- In order for manufacturers to participate in Medicare and Medicaid, they must agree to sell certain outpatient drugs to 340B-eligible safety-net providers (covered entities) at a discount.
- 340B price discounts can be substantially lower than wholesale acquisition cost (WAC).

Benefits eligible not-for-profit hospitals, centers, clinics, and grantees

- Healthcare providers must qualify for 340B and register with HRSA, adhering to **strict eligibility requirements**.
- 340B benefit is reinvested by covered entity in providing care and additional services to the community.

Not insurance, not taxpayer funded, not prescription coverage

- 340B is not funded by taxpayer dollars.
- 340B is not insurance; it is not a patient benefit plan.
- To be eligible, patients must meet the covered entity's 340B patient definition.
- Many 340B programs do offer patient assistance and uninsured medication programs.

HRSA: Health Resources & Services Administration; OPA: Office of Pharmacy Affairs
www.hrsa.gov/opa

Contract Pharmacy Partnerships

In addition to drug purchase savings for 340B-eligible outpatients, covered entities can choose to partner with pharmacies that dispense medications and provide pharmacy services to their 340B-eligible patients.

340B Covered Entity

- Offers savings benefit with minimal additional expenses.
- Enables funding for otherwise unattainable programs and services for the community.
- Supports payment to pharmacies for clinical services like transitions of care, meds-to-beds programs, and chronic disease management.

340B Contract Pharmacy

- Predictable margin increases per prescription through dispensing fees and inventory replenishment.
- Reduces inventory cost via product replacement dispensed to 340B patients.
- Enhanced profitability allows for the expansion and optimization of clinical and patient services.
- Facilitates partnerships with 340B-eligible hospitals, clinics, and health centers, potentially boosting store foot traffic.

Adding and optimizing clinical programs can improve adherence and decrease readmissions, resulting in decreased penalties, **improved outcomes, and lower healthcare costs**.

www.hrsa.gov/opa
www.gao.gov/products/gao-18-480

340B Contract Pharmacy Appeal

Increased margins

340B dispensing fees earned on qualified dispenses can yield a higher margin than filling a claim at retail.

Reduced inventory cost

Inventory dispensed to 340B-eligible patients is replaced (or reimbursed) to a contract pharmacy by their covered entity partner.

Enhanced patient services

340B participation may allow a contract pharmacy to offer additional patient offerings like cash/uninsured programs, delivery, and more.

Increased patient volume

340B partnerships may result in more patients coming to a contract pharmacy from the covered entity due to the service offerings available to them.

www.hrsa.gov/opa
www.gao.gov/products/gao-18-480

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340B Regulatory, Operational, and Market Trends

The Current State of the 340B Industry

The 3 Pillars of 340B (What's Being Disrupted)

Eligibility

Current debate continues around patient definition, entity eligibility, and child site eligibility, while federal and congressional activity is also examining changes to patient definition and inventory replenishment models.

Discount Access

Manufacturers continue to reshape 340B access through contract pharmacy restrictions, rebate-based models, and claims-level data requirements tied to continued access to 340B pricing.

HRSA OPA registration alone no longer guarantees access to 340B discounts.

Reimbursement

Recent developments have shifted attention to reimbursement transparency, PBM economics, rebate payment delays, and disputes over ownership of 340B-generated value.

www.hrsa.gov/opa
www.gao.gov/products/gao-18-480

340B Market Trends Impacting Contract Pharmacies

HERE-TERM

Maximum Fair Price (MFP) Rebates & 340B

The intersection of MFP rebates & 340B participation is…complicated.

The absence of an intersecting 340B Rebate Program has caused manufacturers' 340B vendors to "guess" if an MFP-eligible Part D claim was deemed 340B eligible and a corresponding 340B discount was issued for the replenishment purchase.

This algorithmic approach, using available data, has caused incorrect classification of MFP claims and delays/denials of MFP rebate payments to pharmacies. Additional Claims Level Data (CLD) requirements from manufacturers have been introduced.

HERE-TERM

Manufacturer 340B Claims-Level Data Requirements

Increased audits, conditional access, and reporting burden.

What began with one manufacturer has expanded to 12 total manufacturers, signaling an emerging industry standard with immediate financial implications. More manufacturers and broader data requirements are expected, elevating pharmacy leadership's role in enterprise 340B risk management.

Non-compliance with manufacturer 340B policies could result in suspension of 340B pricing access; without 340B pricing, contract pharmacy claims may not qualify for 340B.

LONG-TERM

State 340B Laws

Split court decisions on state laws governing contract pharmacy access may lead to Supreme Court review.

Manufacturer 340B policies limit the number of 340B contract pharmacy partnerships a covered entity can effectively operationalize, regardless of HRSA registration, through 340B contract access controls.

State laws protecting 340B contract pharmacy access have been moderately effective. Those laws are being increasingly challenged by manufacturers and the federal government.

www.hrsa.gov/opa; www.gao.gov/products/gao-18-480;
www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/regulations-guidance-policy-documents

340B Claims-Level Data

What Pharmacy Leaders Need to Know

- Drug manufacturers are quickly expanding claims-level data requirements and linking them to continued 340B pricing
- In addition to contract pharmacies, these policies now often cover in-house pharmacies and medical claims, increasing operational and financial risk for health systems – including some contract pharmacy partnership viability
- Twelve drug manufacturers now require claims-level data for all 340B dispenses to keep 340B pricing
  - Missing or late data can lead to loss of 340B pricing
- Expect additional manufacturers to continue adopting similar policies, signaling an emerging industry standard, not a one-off policy

340B Claims-Level Data

What Pharmacy Leaders Need to Know

Why This Matters

- In-house pharmacies are fully in scope
- Non-compliance could result in loss of all 340B pricing access for the covered entity (vs. just a single location)
- Loss of 340B could be immediate with significant financial risk and have negative downstream impacts to contract pharmacy partnerships

Being registered as a contract pharmacy with HRSA no longer guarantees 340B contract access.

Failure to meet manufacturer data expectations can directly impact drug acquisition cost and patient access.

340B Claims-Level Data

What Pharmacy Leaders Need to Know

What to Expect Next

- Additional manufacturers are likely to follow
- Data requirements will continue to expand
- Pharmacy leadership will play a growing role in enterprise 340B risk management

Claims-level enforcement is one example of a broader shift toward tighter oversight – creating additional operational burden for covered entities and increased risk to contract pharmacy partnerships.

Contract Pharmacy “Modernization” Continues

- Conventional contract pharmacy models have frequently fallen short in resolving the operational difficulties faced by participating pharmacies
- There is a rising trend moving away from traditional replenishment models toward credit-based approaches to alleviate the operational and financial challenges encountered by covered entities and contract pharmacy partners
- Additionally, manufacturers are playing a larger role in determining 340B eligibility & access

Contract Pharmacy “Modernization” Continues

Invoice on *dispense*

The initial Third-Party Administrator (TPA) model, Invoice on Dispense, accumulated qualified claims on the following 340B invoice regardless of whether the inventory had been restocked.

Because of difficulties with replenishment, pharmacies frequently had to both process claim reimbursements and bear the expense of inventory provided to 340B patients prior to receiving replenishment.

Invoice on *replenishment*

Invoice on Replenishment (also known as Pay on Replenishment) safeguards the pharmacy and prevents TPA Slow Mover Rewinds, True-Up, and minimizes Reconciliation issues.

The contract pharmacy invoice, which transfers savings to the covered entity, is issued only when the product is replenished to the contract pharmacy to replace the dispensed inventory.

Invoice on *reimbursement*

Pharmacies are increasingly focused on managing their finances and 340B-related inventory, while manufacturers keep a close eye on stacked discounts.

As models like rebate or MFP come into play, the process of identifying claims might change to better handle inventory restocking and financial reconciliation after manufacturer reimbursements, detect duplicate discounts, and continue to assess 340B claims qualification based on traditional “patient definition” criteria.

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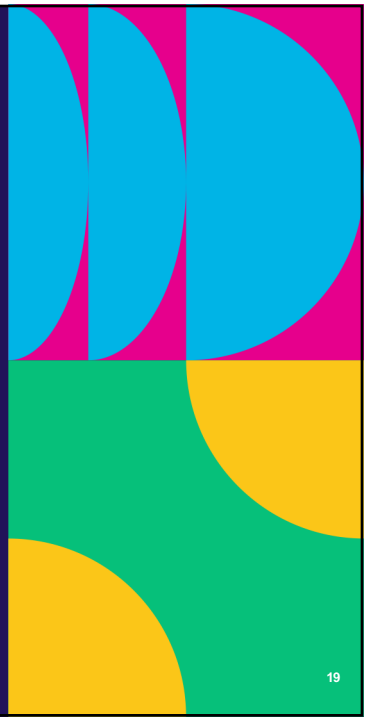
Case Study Evaluations

340B Opportunity or Liability?



Key Evaluation Criteria

- ❑ State law(s) concerning contract pharmacies and manufacturer 340B policies
- ❑ Designation by the covered entity for your contract pharmacy partnership to be eligible for 340B contract access
- ❑ Dispensing fee & inventory replenishment (replacement) structure
- ❑ Clear understanding of operational procedures related to claim eligibility, replenishment orders, 340B billing, and reconciliation

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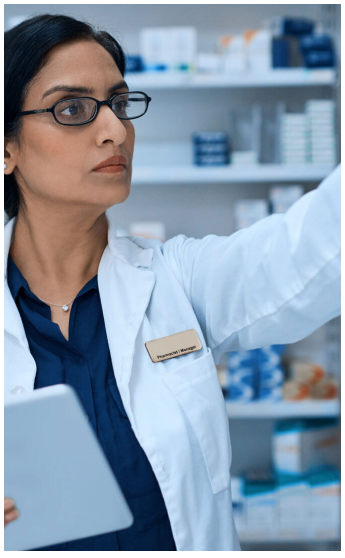
Case Study #1

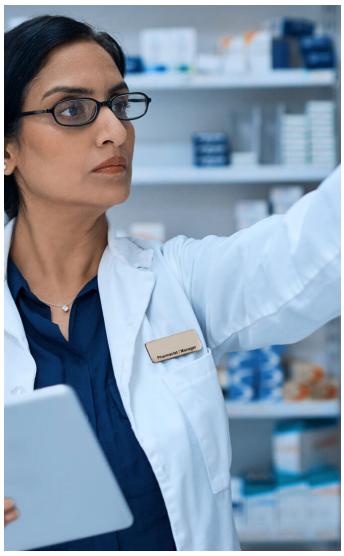
340B Benefit Potential

340B Opportunity or Liability?

- A newly registered covered entity reaches out to your pharmacy about starting a contract pharmacy partnership.
- The covered entity does not have an in-house pharmacy.
- Your state has a 340B Contract Pharmacy Access protection law passed, in-effect, and recognized by manufacturer policies.
- A National Provider Identifier (NPI) analysis shows that a moderate volume of prescriptions are coming from the covered entity's patients.
- There are only a handful of pharmacies in the geographic vicinity of the covered entity's location.
- The 340B Pharmacy Services Agreement (PSA) presented to your pharmacy lists out $15 + 15% of total reimbursement as the 340B dispensing fee for 340B qualified prescriptions.



340B Opportunity or Liability?



- ✓ The Good:
  - ❑ Covered entity is reaching out
  - ❑ State has a contract pharmacy protection law enacted
  - ❑ Covered entity does not have an in-house pharmacy
  - ❑ Your pharmacy is filling a moderate volume of prescriptions for the covered entity's patients
  - ❑ There are a limited number of pharmacies in the area
  - ❑ Covered entity is offering a dispensing fee that produces more margin than existing commercial structure
- ✖ The Potentially Bad:
  - ❑ A brand-new covered entity comes with inexperience

Outcome: Potential Opportunity

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Case Study #2

340B Benefit Potential

340B Opportunity or Liability?

- An established covered entity reaches out about a contract pharmacy partnership.
- The covered entity does have an in-house pharmacy.
- Your state does not have a 340B Contract Pharmacy Access protection law passed.
- An NPI analysis shows that a high volume of prescriptions are coming from the covered entity's patients.
- There are several pharmacies in the geographic vicinity of the covered entity's location.
- The 340B PSA presented to your pharmacy lists out $20 + 50% of total reimbursement as the 340B dispensing fee for 340B qualified prescriptions.

340B Opportunity or Liability?

✓ The Good:

- ❑ Covered entity is reaching out
- ❑ Your pharmacy is filling a high volume of prescriptions for the covered entity's patients
- ❑ Covered entity is offering a substantial increase to your dispensing fee structure

✖ The Potentially Bad:

- ❑ The covered entity has an in-house pharmacy
- ❑ Multiple contract pharmacy relationships exist
- ❑ Your state does not have contract pharmacy protection laws

Outcome: Potential Liability

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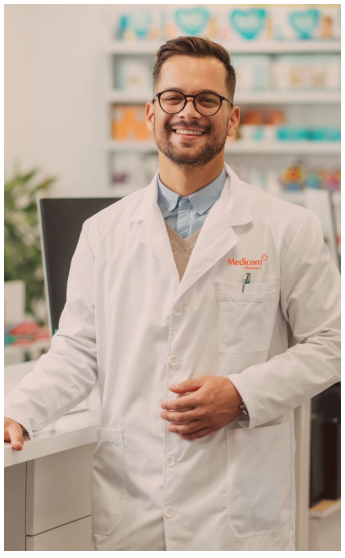
Case Study #3

Contract Pharmacy Designation

340B Opportunity or Liability?

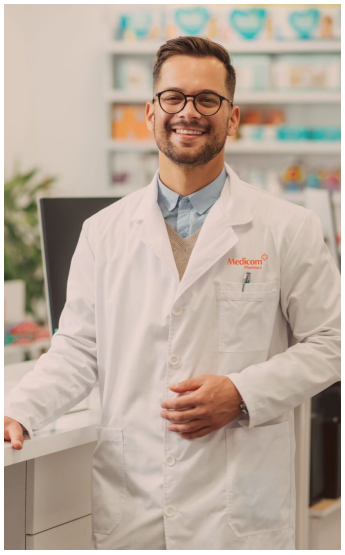
- Your existing covered entity partner reaches out about renegotiating your PSA dispensing fee.
- The covered entity does not have an in-house pharmacy.
- Your state does not have a 340B contract pharmacy access protection law passed.
- Your pharmacy historically has a high volume of 340B qualified claims and subsequent replenishment, but that volume has steadily decreased to almost zero.
- The covered entity has several registered contract pharmacy partnerships on the HRSA OPA website.
- Your pharmacy's existing 340B dispensing fee is $15 + 18% of total reimbursement. The covered entity is proposing $12 + 15%. Despite reduction, 340B would remain advantageous.
- In exchange for the lower dispensing fee, the covered entity has agreed to make you the designated pharmacy to receive 340B pricing for all manufacturers with 340B policies.



340B Opportunity or Liability?

- ✓ The Good:
  - ❑ Covered entity is reaching out
  - ❑ Covered entity does not own an in-house pharmacy
  - ❑ Covered entity is offering to designate your pharmacy for 340B pricing access with applicable manufacturers
- ✖ The Potentially Bad:
  - ❑ Your 340B benefit has been dwindling
  - ❑ Multiple contract pharmacy relationships exist
  - ❑ Your state does not have contract pharmacy protection laws
  - ❑ Per claim dispensing fee and margin may reduce under new PSA terms

Outcome: Potential Opportunity



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Case Study #4

Operations and Reconciliation

340B Opportunity or Liability?

- Your pharmacy has been participating as a contract pharmacy since 2010.
- Your implementation with the 340B TPA went well and you understand all of the TPA's settings and configurations.
- There have been a steady number of 340B claims qualifying, despite current headwinds with manufacturer 340B contract pharmacy policies.
- During monthly inventory, your staff notices that you have not been getting all the inventory replenishment expected from the covered entity.
- After reviewing your recent 340B invoices, you see that all of the revenue for all previous 340B claims has been sent to the covered entity.
- Examining your TPA's configuration settings, you see your pharmacy is set up for invoice/pay on dispense for the billing model.

340B Opportunity or Liability?

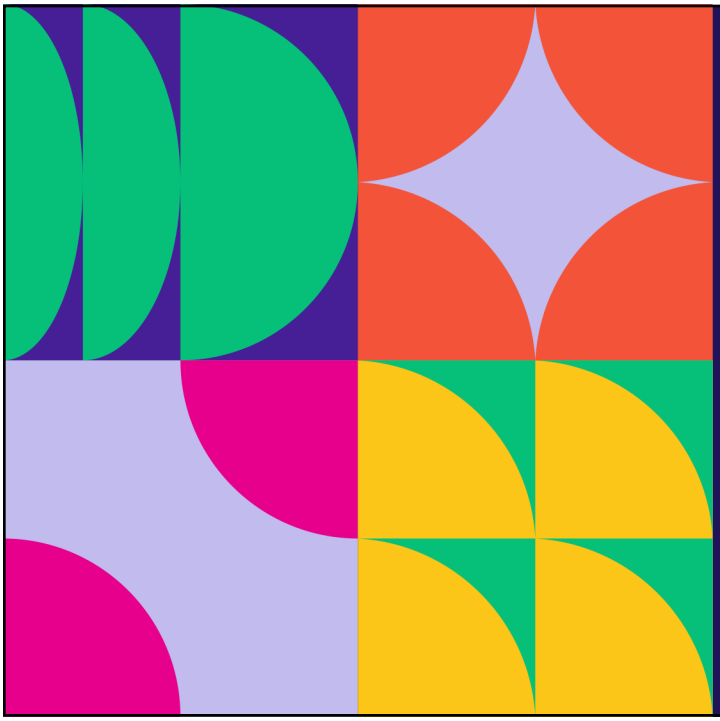
✓ The Good:

- ❑ Long-standing relationship with the covered entity
- ❑ 340B pricing access is available
- ❑ 340B claims are qualifying

✖ The Potentially Bad:

- ❑ TPA/Gateway setting is on pay on dispense
- ❑ Your pharmacy is passing along claim reimbursement without ensuring inventory replenishment first

Outcome: Potential Liability



Key Takeaways

What do I need to remember?

340B Has Changed – Contract Pharmacies Must Too

340B Contract Access

- Stay informed about manufacturer 340B policies and state laws related to 340B contract pharmacies. Continuously evaluate how these may affect your contract pharmacy relationships.
- Maintain ongoing communication with your covered entity partner regarding patient volume trends, 340B policies, and manufacturer designations.
- Treat 340B designation as a key factor during contract negotiations or renegotiations.

Ensure Replenishment

- Make sure your TPA/Gateway configuration does not transfer claim financial value before your pharmacy is fully compensated for the inventory provided to the 340B patient.
- Analyze 340B invoices thoroughly, looking beyond summaries to include claim specifics, replenishment purchase order details, and accumulator balances.
- Consider if credit-based, virtual replenishment solutions are a good fit for your pharmacy's operations, where available.

Audit Claims Data

- Monitor MFP rebate payments and detect any rejections.
- Gain proficiency in handling inquiries related to discrepancies involving various stakeholder vendors (Medicare Transaction Facilitator [MTF], Beacon, TPA, Gateway).
- Regularly review 340B-qualified claims to guarantee complete reconciliation.

What is your next 340B step?

- **If starting:**
  - What partner/access question must you answer first?
- **If participating:**
  - What risk should you audit first?
- **If renegotiating:**
  - What designation, fee, or replenishment issue needs review?

What is one action you will take in the next 30 days?

Questions?