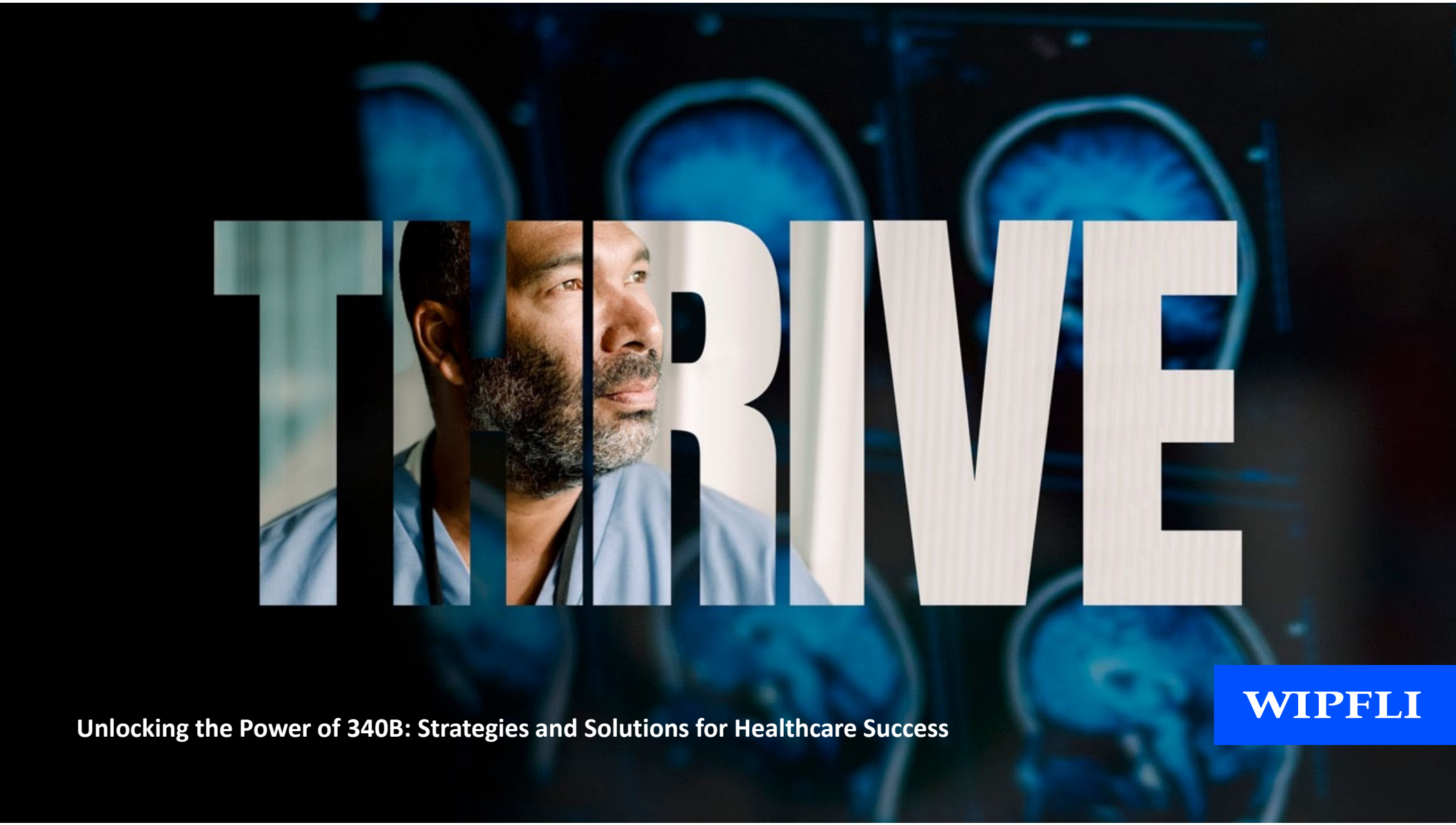


Unlocking the Power of 340B: Strategies and Solutions for Healthcare Success

WIPFLI

Erica Cooperrider, ACE

Senior Consultant

Nathan Smith, ACE

Manager

Overview

https://www.wipfli.com/industries/healthcare/340b-program-compliance

340B Drug Pricing Overview

340B Drug Pricing Program Overview

The 340B Drug Pricing Program ("340B" or the "Program") is a federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide outpatient drugs to enrolled "covered entities" at or below the statutorily defined ceiling price.

The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

Covered Entities

- 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
- **Children's Hospitals**
- **Critical Access Hospitals**
- Disproportionate Share Hospitals
- **Free Standing Cancer Hospitals**
- **Rural Referral Centers**
- **Sole Community Hospitals**
- Black Lung Clinics
- Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

Eligibility Requirements

Eligible locations/sites

- Reimbursable outpatient departments (Hospitals)
- Sites included in 330 grant (FQHCs)

Eligible providers

- Employed by covered entity
- Under contract with covered entity
- Under other arrangements: Referral providers (with caution!)

Eligible patients

- Outpatients only
- Covered entity maintains the patient records
- Covered entity maintains responsibility for the care of the patient

340B in Operation

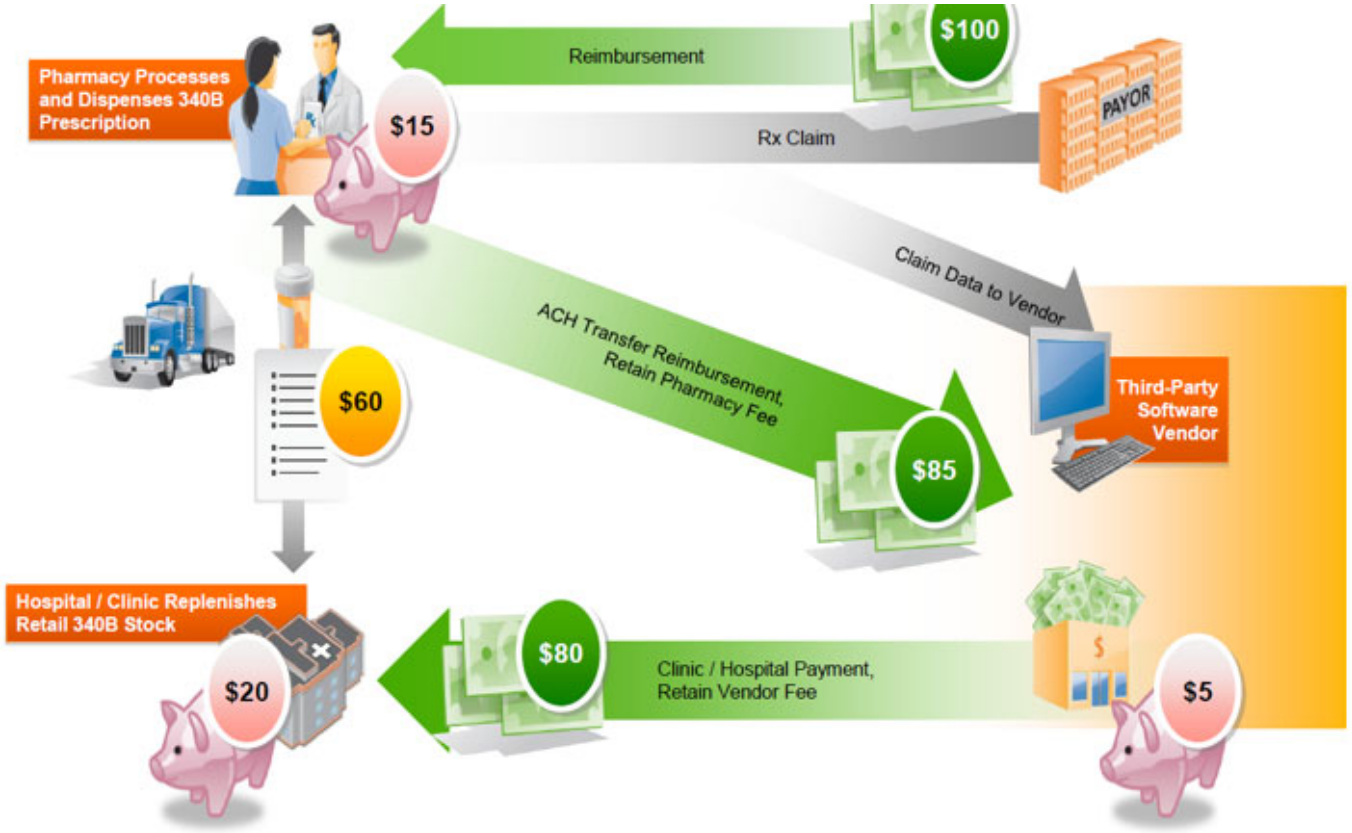
In House Use

- Drugs purchased from a manufacturer or wholesaler can be obtained at 340B prices, savings of 25% - 50%.
- Insurance is billed at the usual rate creating “340B Savings” retained by the covered entity.
- A covered entity saves money on drug or supply purchases even if not billed separately.
- Covered entity must have policies and procedures specific to the 340B program.
- In house pharmacies can be open or closed door. Careful attention must be paid to eligible patients and inventory in open door.

Contracting with a Retail Pharmacy

- Can be significant additional revenue for the covered entity
- Prescriptions are filled in the usual manner
  - 340B use is typically invisible to patients
- Cost savings are realized and revenue is received by the covered entity without a significant investment in personnel, equipment, or infrastructure
- Contract pharmacies require compliance attention by the covered entity
  - Onus is always on the CE for compliance
  - Self-auditing and external audits are expected by HRSA
- Louisiana does not allow contract pharmacies to dispense 340B drugs to Medicaid FFS or MCO patients.
  - Covered entity must ensure that TPA has excluded BIN/PCNs for Medicaid

Contract Pharmacy: How Does it Work?



Contract pharmacy arrangements should be beneficial for all

Contract Pharmacy:

How does it Work?

Stand-Alone Pharmacy Arrangement		Contract Pharmacy Arrangement	
Pharmacy prescription reimbursement	$ 100	Pharmacy prescription reimbursement	$ 100
Less drug cost	(90)	Less drug cost	0
		Less revenue passed on to health center	(100)
		Plus dispensing fee received	15
Pharmacy margin	$ 10	Pharmacy margin	$ 15
Health center revenue	$ 0	Health center revenue	$ 100
Less health center drug cost	0	Less dispensing fee to pharmacy	(15)
		Less health center drug cost[1]	(60)
		Third party administrator	(5)
Health center margin	$ 0	Health center margin	$ 20

Manufacturer Restrictions on Contract Pharmacies

- In July of 2020, Eli Lilly set off what would become an explosion of manufacturer restrictions on contract pharmacies by announcing that they would no longer offer 340B pricing of their drug, Cialis, through contract pharmacies.
- The notice allowed for the selection of one contract pharmacy for 340B pricing of Cialis if a covered entity did not have an in-house pharmacy.
- Shortly after Lilly's notification, Sanofi, AstraZeneca, and others followed suit refusing 340B pricing at contract pharmacies except for a single pharmacy if the covered entity had no in-house pharmacy.
- As of July 2023, 24 manufacturers have implemented similar contract pharmacy restrictions.
- Several lawsuits are working their way through the court system.
- The National Association of Community Health Centers (NACHC) has maintained a list of manufacturer restrictions.
- 340B Restrictions Summary Chart

NATIONAL ASSOCIATION OF Community Health Centers

Beginning mid-2020, pharmaceutical manufacturers started overcharging covered entities (CEs) on 340B drugs shipped to CE contract pharmacies. This chart serves as a summary and timeline of these manufacturer restrictions.

Manufacturer Name	Type of Restriction	Who it Applies to	Effective Date
Eli Lilly	Refusing 340B pricing for drugs dispensed at contract pharmacies; recent changes allow 340B pricing if CEs submit contract pharmacy claims data. Any covered entity that doesn't have an in-house pharmacy **can choose a single location contract pharmacy.**	All covered entities (CEs)	September 1, 2020
AstraZeneca	Refusing 340B pricing for drugs dispensed at contract pharmacies. May designate a single contract pharmacy but each parent site can have one pharmacy site for itself. UPDATE: Moves admin of 340B contract pharmacy program to 340B ESP. Covered entities without an on-site dispensing pharmacy will need to select a single contract pharmacy location using the 340B ESP portal.	All CEs	October 1, 2020 **Updated restriction effective:** August 1, 2023
Sanofi	NEW for hospitals: Refusing to ship 340B-priced drugs to contract pharmacies regardless of data submission to 340B ESP. If a CE lacks an in-house, can select 1 contract pharmacy. Doesn't affect CHCs.	5 CE types: Consol, CHC, CAH, DSH, RRC, SCH	**NEW** for hospitals: Effective June 1, 2023 October 1, 2020

Pharmacy Benefit Managers (PBM) and Discriminatory Contracting

Over the past several years several PBMs and health insurance companies have engaged in discriminatory contracting with 340B covered entities and their contract pharmacies.

These contracts either reduce payments on 340B drugs, apply extra fees, or require administrative rules that are prohibitively time-consuming.

Several states have enacted legislation to prevent this type of discriminatory contracting.

This issue is also receiving attention at the federal level and is addressed in legislation moving its way through congress.

Louisiana's New 340B Contract Pharmacy Law

- Act 358 prohibits actions by a drug manufacture or distributor that would "deny, restrict, prohibit, or otherwise interfere" with the acquisition of a 340B discounted drug to a contract pharmacy
- Teva Pharmaceuticals voluntarily halted its 340B contract pharmacy restrictions of limiting covered entities to only one contract pharmacy and submission of 340B claims data
- PhRMA asks federal court to declare Act 358 in violation of the Supremacy Clause of the U.S. Constitution which holds that federal law take precedent over state law
- Louisiana and roughly half of all states have laws protecting covered entities against discriminatory reimbursement from pharmaceutical benefit managers.

Other State Legislation

- Minnesota and Maine passed laws this summer that made them the first states to impose 340B reporting requirements on covered entities
- **Minnesota** will require all covered entities to report data from previous year
  - Aggregated acquisition costs for 340B drugs
  - Aggregated payment amounts received from 340B dispenses
  - Aggregated payments to 340B contract pharmacies
- **Maine** requires 340B hospitals report annually
  - How 340B savings are used to "benefit its community through programs and services"
  - Estimate of annual 340B savings by comparing acquisition prices to group purchasing prices
  - Description of "internal review and oversight of 340B program"
- These types of requirements may take hold in other states or at the federal level. Entities should be prepared to show how 340B savings are used and to report data on their 340B savings and expenditures.

Federal Legislation Efforts

Preserving Rules Ordered for The Entities Covered Through 340B Act (PROTECT 340B)

The PROTECT 340B Act would prohibit health insurers and PBMs from discriminating against 340B providers or their contract pharmacies on the basis of their status as providers or pharmacies that dispense 340B drugs.

Alliance to Save America's 340B Program (ASAP 340B)

This advocacy group is an alliance between the Pharmaceutical Research and Manufacturers of America (PhRMA) and the National Association of Community Health Centers (NACHC) along with 14 other health organizations. They are advocating for legislation to "update and strengthen 340B hospital eligibility requirements" which, if enacted, would reduce the number of hospitals eligible for the program.

340C

Advocates for Community Health (ACH) was formed in June of 2021 with the goal of advocating a separate drug discount program they refer to as 340C. This program would be specifically for FQHCs and look-alikes and potentially other grantees and rural hospitals. While their draft bill provisions would likely be positive for the groups included, it contains the implication that hospital-type entities are potentially bad actors in the program. If grantees are split out from 340B it would likely also mean negative actions against hospitals.

03

Compliance Risks, Opportunities and 340B Services

Compliance Risks

Key compliance risks associated with the 340B program

- Lack of proper policies and procedures
- Diversion
- Duplicate Discounts – requirements vary by state, LA requires carve-in/ carve-out designation to apply to both FFS & MCO. Entity must maintain proper listing in the MEF.
- Inaccurate HRSA database information
- Lack of auditable records
- Updating active provider listing and other tables in third-party portal
- Physician Administered Drug (PAD) inventory tracking

Commonly overlooked 340 B opportunities include

340B ESP single contract pharmacy designation and data submission

Contract pharmacy opportunities

Referral Prescriptions – Medication prescribed by referral provider.

Requires strict compliance procedures

Apexus sub-ceiling discounts

340B ESP

- Designate a single contract pharmacy if you don't have an in-house
  - Which pharmacy has the most volume
  - May be different for different manufacturers
- Consider submitting data
- What data do you submit?

Contracted Entity ID	Date of Service	Date Prescribed	NDC	Quantity	Rx Number	Service Provider ID (Pharmacy NPI)
[redacted]	7/16/2023	4/13/2023	00002831501	30.000	[redacted]	1235172081
[redacted]	7/18/2023	1/5/2023	00002771559	15.000	[redacted]	1235172081
[redacted]	7/19/2023	7/18/2023	00024586903	9.000	[redacted]	1235172081
[redacted]	7/21/2023	4/6/2023	00002223680	2.000	[redacted]	1659313468
[redacted]	7/28/2023	5/5/2023	00002143380	2.000	[redacted]	1235172081

- Many TPA's have a specific ESP report and some will even submit for you

Questions and Tips for Your 340B Program

1. Is your 340B Program profitable?
2. Who is charged with oversight of the 340B Program?
3. Are policies and procedures in place and being followed?
4. What procedures are being performed internally to verify the 340B Program is working appropriately and complying with regulations?
5. Do you know when to complete your annual recertification?
6. Have you had an external compliance review of your 340B Program?
7. What software and/or TPA is being used to monitor the 340B Program?
8. If you elect to bill Medicaid, are you following state and federal requirements?

340B Services to Consider

- Financial tracking of 340B revenue, analysis of profitability
- Annual external audits / assessments
- HRSA audit preparedness / assistance during audit
- Assistance in enrolling in program
- Creating appropriate policies and procedures
- Training staff on program compliance / self-auditing
- Assistance in setting up with contract pharmacies
- Identifying and recommending overlooked opportunities

Contact us

Erica Cooperrider, ACE

Senior Consultant
erica.cooperrider@wipfli.com
707 297 3564

Nathan Smith, ACE

Manager
nathan.smith@wipfli.com
509 232 2739

Johnathan Prunty

Senior Business Developer
johnathan.prunty@wipfli.com
312 871 3399

WIPFLI

ONE TEAM, ONE FOCUS. YOU.