

340B Program Overview and Update

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Statement of Disclosure

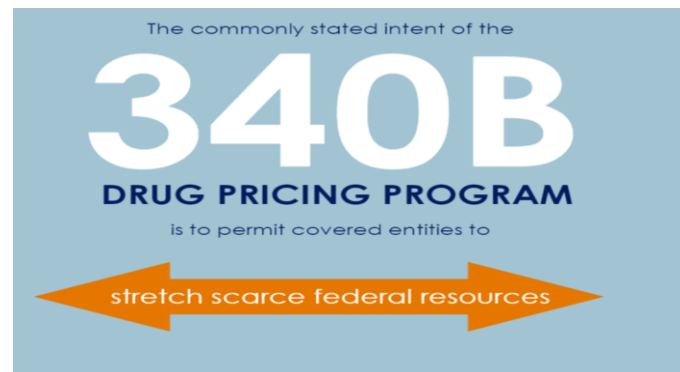
- I am in charge of a Covered Entity 340B program at Penobscot Community Health Care (PCHC)
- I have no real conflicts of interest

Objectives

- ▶ 1. Describe how the 340B program was developed.
- ▶ 2. Be able to distinguish between 'In House' and 'Contract' 340B Pharmacy savings
- ▶ 3. Understand and discuss issues related to 340B savings

340B Beginnings

- ▶ What is 340B?
 - President Bush signed into law the Veterans Health Care Act of 1992
 - As part of negotiating rebates for Medicaid with manufacturers. Drug manufacturers who seek reimbursement from Medicaid are required to provide 340B price (typically 50% of AWP) to eligible entities
 - the 340B Drug Pricing Program was created to assist safety-net providers “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
 - Hospitals (safety-net) and Clinics (FQHC) must meet criteria to be eligible to buy 340B priced medications



Apexus 340B Prime Vendor

- ▶ Health Resources and Services Administration(HRSA) contracts a Prime Vendor
- ▶ Apexus 340B Prime Vendor: Administering the 340B Drug Pricing Program
 - ▶ Voluntary Program: Need to enroll to participate
 - ▶ Resource for all 340B entities
 - ▶ Training and Education of 340B Programs: 340B University
 - ▶ Negotiate 340B Pricing with manufacturers
 - ▶ Technical assistance
 - ▶ Apexus Answers: Access for questions related 340B
 - ▶ Policies and Procedure examples
 - ▶ The Prime Vendor Program (PVP) has partnered approximately 130 manufacturers and over 45,500 covered entities receive best 340B drug pricing

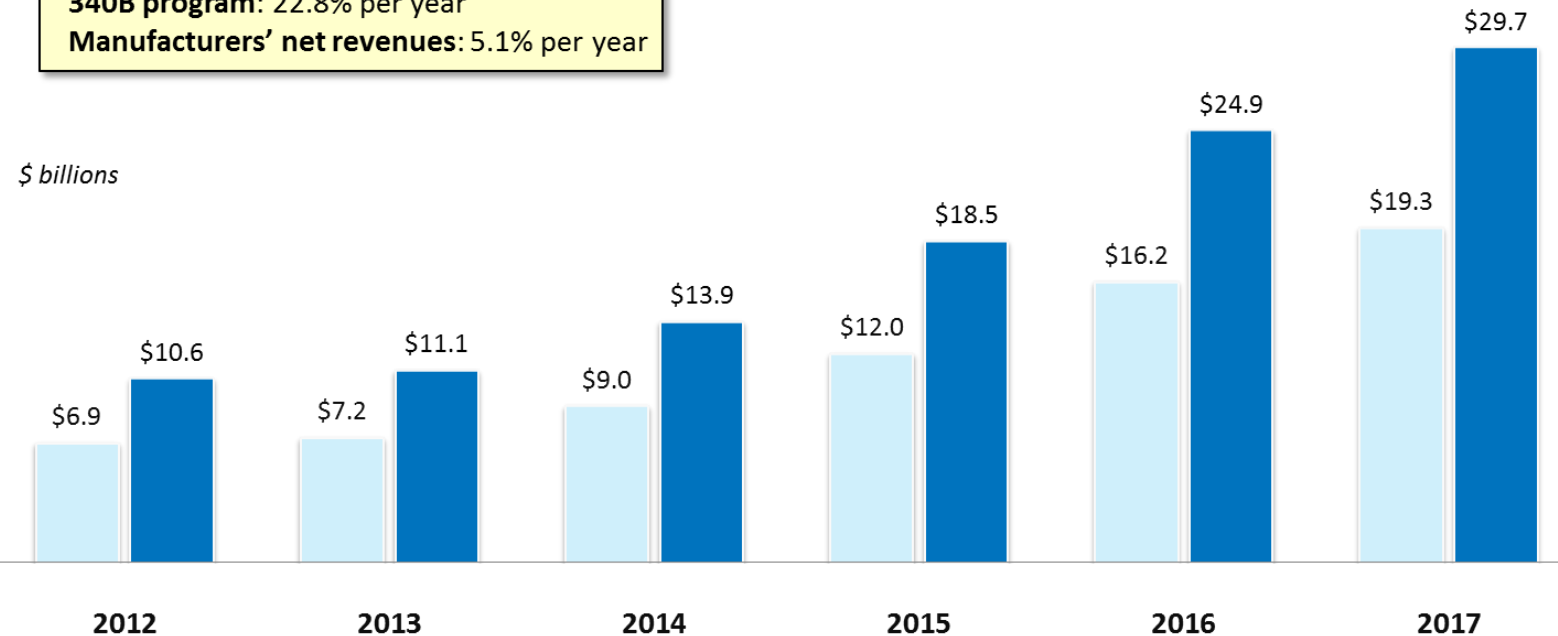
Growth of 340B: 2012 to 2017

340B Program Growing at Double-Digit Rates

TOTAL PURCHASES MADE UNDER THE 340B DRUG PRICING PROGRAM

■ Purchases at discounted 340B prices ■ Estimated purchases at invoice prices

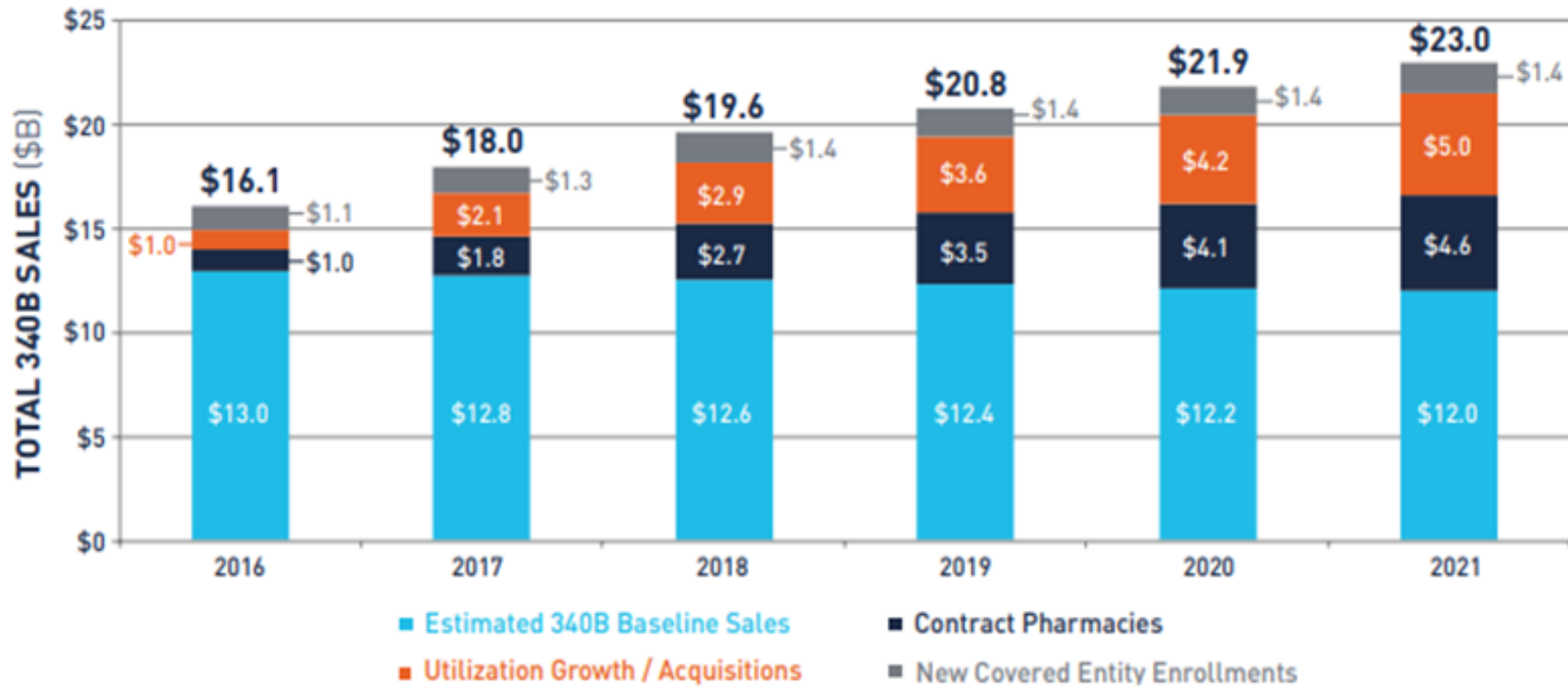
340B program: 22.8% per year
Manufacturers' net revenues: 5.1% per year



Source: Drug Channels Institute analysis of data from Health Resources and Services Administration and IQVIA. Dollar figures in billions. Excludes sales made directly to healthcare institutions by manufacturers. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices. Data at invoice prices reflect DCI estimates. Growth rates show compound average growth rate.

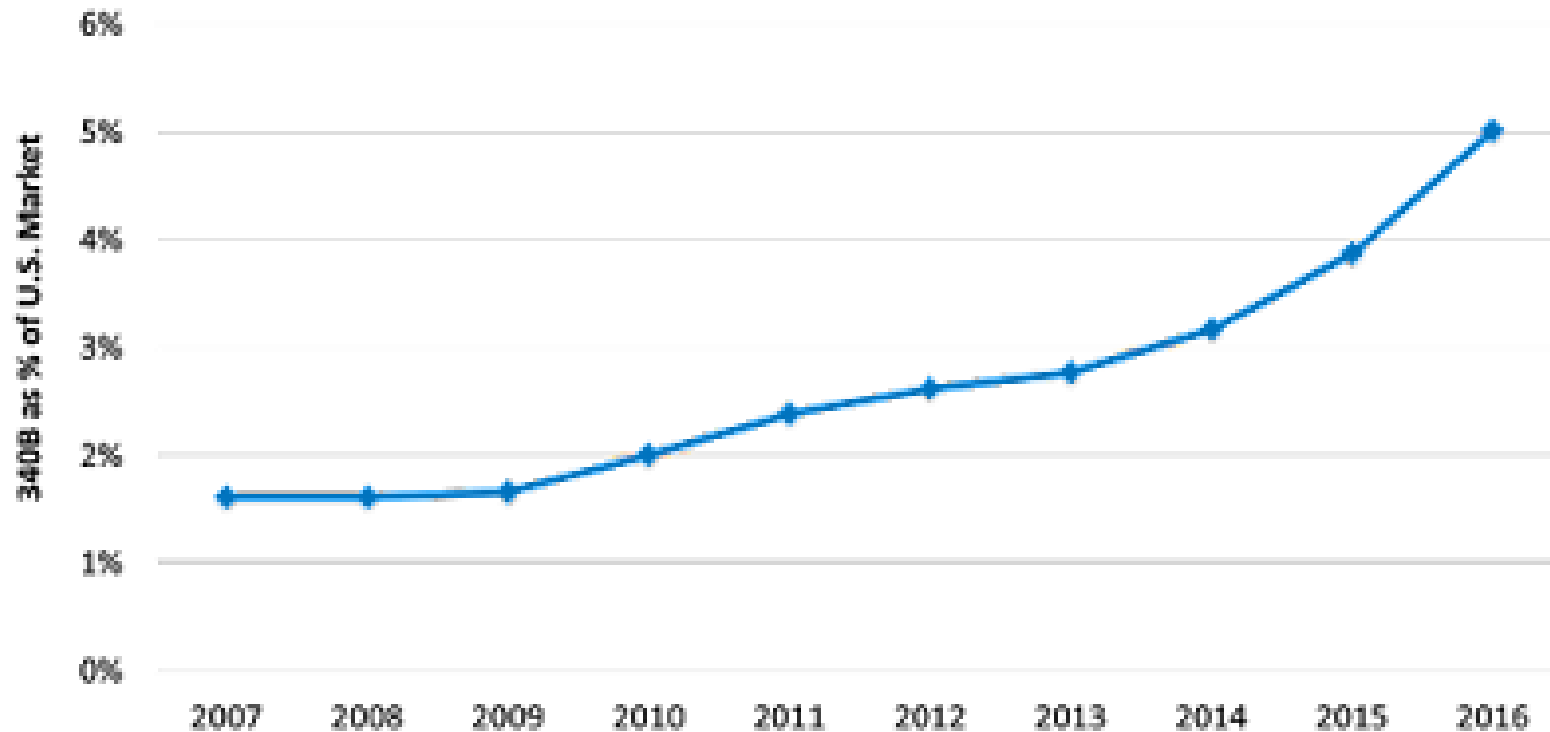
Published on Drug Channels (www.DrugChannels.net) on May 7, 2018.

Growth of 340B: 2016 to 2021



Growth of 340B as a % of Total Drug Market

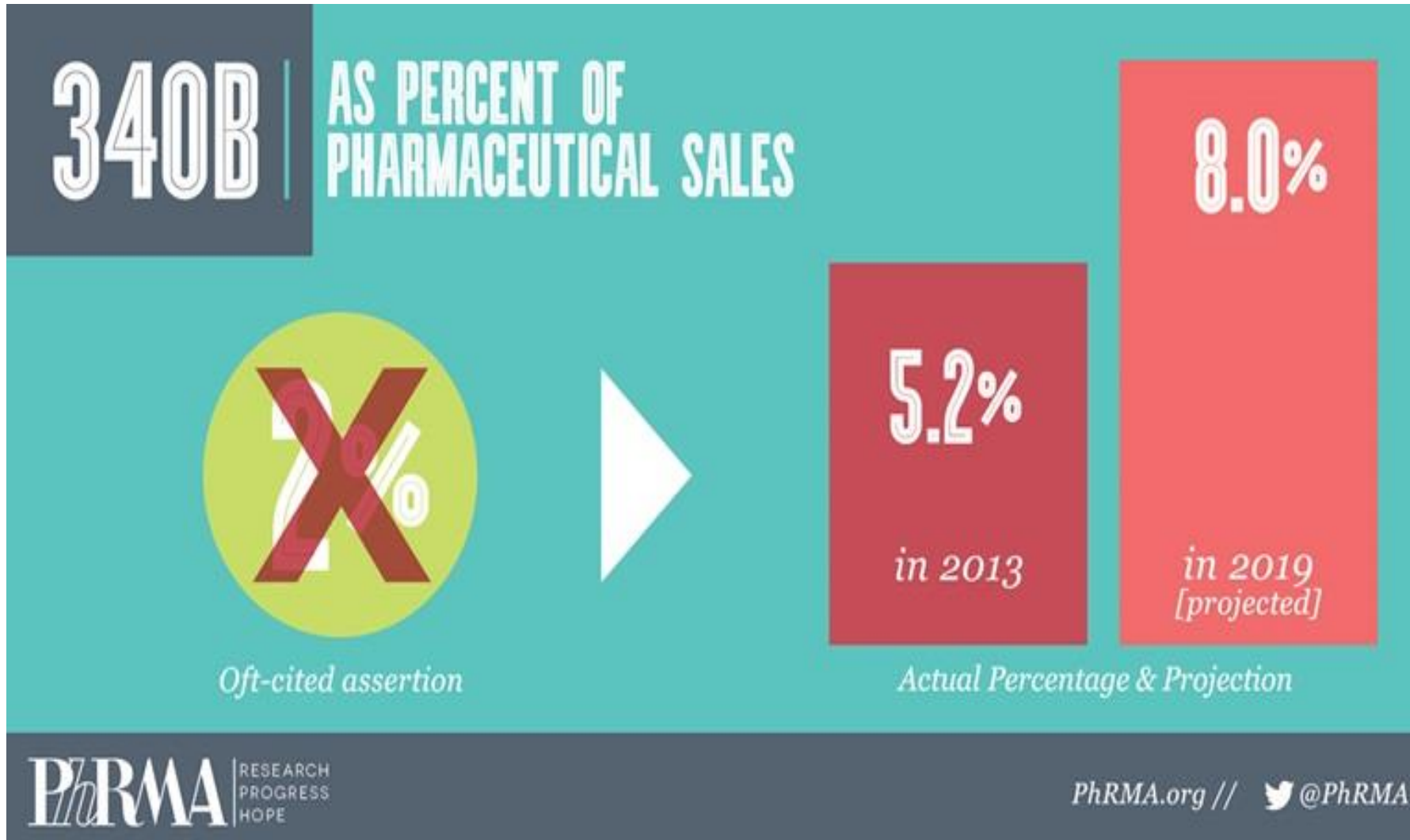
340B Drug Purchases as Percentage of Total U.S. Drug Market, 2007-2016



Source: Pembroke Consulting estimates based on data from Apexus and QuintilesIMS. 340B data show value of purchases at or below the discounted 340B ceiling prices. Total U.S. market measured as net spending adjusted for off-invoice discounts and rebates. See text for details.

Published on Drug Channels (www.DrugChannels.net) on May 17, 2017.

Big Pharma 340B %



Qualifications for Entities to receive 340B Pricing

- ▶ Safety net hospitals
- ▶ Outpatient Clinics
- ▶ Federal Grantees by HRSA
 - ▶ Federally Qualified Health Centers (FQHC)
- ▶ Children's Hospitals
- ▶ Outpatient Cancer Center Hospitals
- ▶ Critical Access Hospitals
- ▶ Rural Referral Centers
- ▶ Sole Community Hospitals

Utilization of 340B Savings

340B Improves Access for Health Center Patients



June 2022

Since 2020, drug manufacturers' 340B contract pharmacy restrictions have greatly impacted health centers' ability to provide affordable medications to the patients that need them the most. NACHC conducted a survey to better understand the negative impact on patient outcomes due to the loss of 340B savings

92% of respondents utilize 340B savings to increase access for low-income and/or rural patients by maintaining or expanding services in underserved communities.



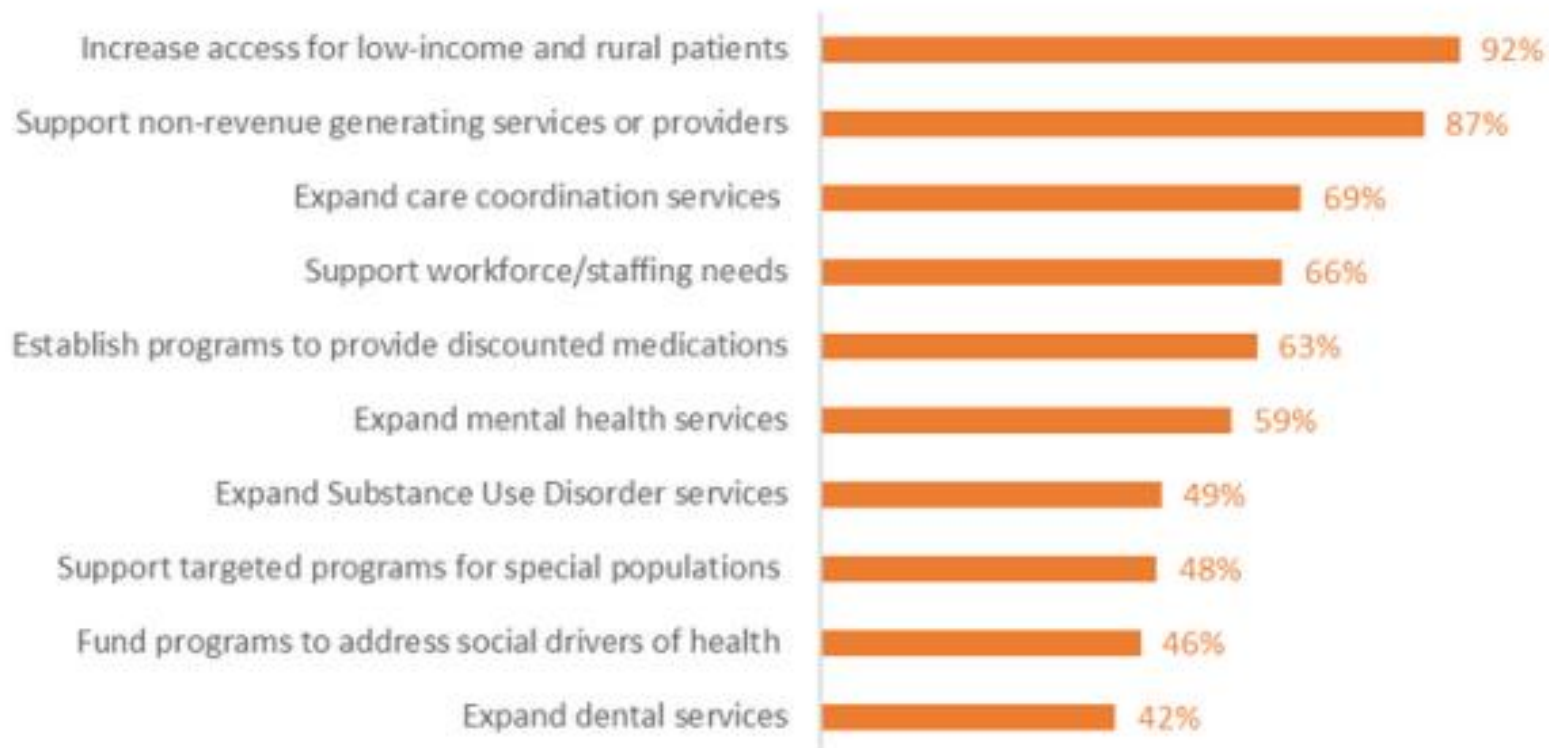
90% of respondents report that their 340B program has led to improved medication adherence, improved clinical outcomes, and improved access to care.

Health center patients with diabetes, heart disease, and behavioral health needs rely on drugs purchased through the 340B program more than other patient population. Without 340B, these patients would face much more severe health outcomes.

Utilization of 340B Savings

Health Centers' 340B Savings' Utilization and Implications for Access

How Does your Health Center Use 340B Savings?



Additionally, **32%** of respondents believe that over **HALF** of their patients would lose access to needed medication without 340B program discounts.

Data comes from 302 individual health center respondents to NACHC's 340B survey, fielded from April 11 to May 13. For more information see accompanying report or contact Gracy Trinoskey-Rice at gtrinoskeyrice@nachc.org.

340B Organizational Uses

- ▶ 340B savings help our patients by:
 - Assists with funding a Sliding Scale Program in the pharmacies and clinics
 - Assists in funding multiple services that may not be sustainable without 340B savings such as:
 - SUD treatment / Primary Care Pharmacy / Care Management / Transitions of Care / many others
 - Ability to have a Discount Medication List - Many chronic medications are priced at \$4 for 30 day-supply or \$10 for 90 day-supply

340B entities realize significant savings by purchasing outpatient drugs through this program. Entities use these savings to provide additional services that will benefit patients.



In-house 340B Pharmacy

- ▶ **Entity owned pharmacies are known as In-house Pharmacies.** Examples are outpatient pharmacies at PCHC, Maine Med, CMMC, Katahdin Valley Health
- ▶ These pharmacies are able to buy 340B medications to fill for patients that qualify otherwise GPO medication will be used and billed.
- ▶ They are not required to partner with a TPA

Contract Pharmacy

- ▶ This is when a **Covered Entity (CE)** sets up a contract with an **individual pharmacy** or a **chain of pharmacies** or **Contracted Pharmacy(s) (CP)** that fill prescriptions for their respective patients
- ▶ A contract is also set up with a **Third Party Administrator (TPA)** that functions as the ‘prescription qualifier’ (340B Eligible) for the CE and the CP’s
- ▶ Accounts are set up with a **Wholesaler** that will **ship** 340B medications to the CP and **bill** the respective CE for these replenished medications
- ▶ Lastly the TPA will inform the CP what 340B savings will be sent to the CE per the contract
- ▶ The Wholesaler will work with the manufacturers to pay the difference of 340B pricing and their procurement costs
- ▶ Each step above has a cost associated with it for CE, TPA, CP, and Wholesaler

Contract Pharmacies

Contract Pharmacies Expand Health Centers' Reach



June 2022

Health centers provide millions of patients each year with life-saving medical prescriptions through the 340B program and contract pharmacies. Recent contract pharmacy restrictions by drug manufacturers are taking a financial toll on health centers' ability to provide affordable care. This detrimentally impacts patients as contract pharmacies serve as an extension of health centers, increasing access for patients and ensuring they can receive discounted medications without creating additional barriers.

86% of health centers utilize contract pharmacies, allowing health centers to reach hundreds of zipcodes.

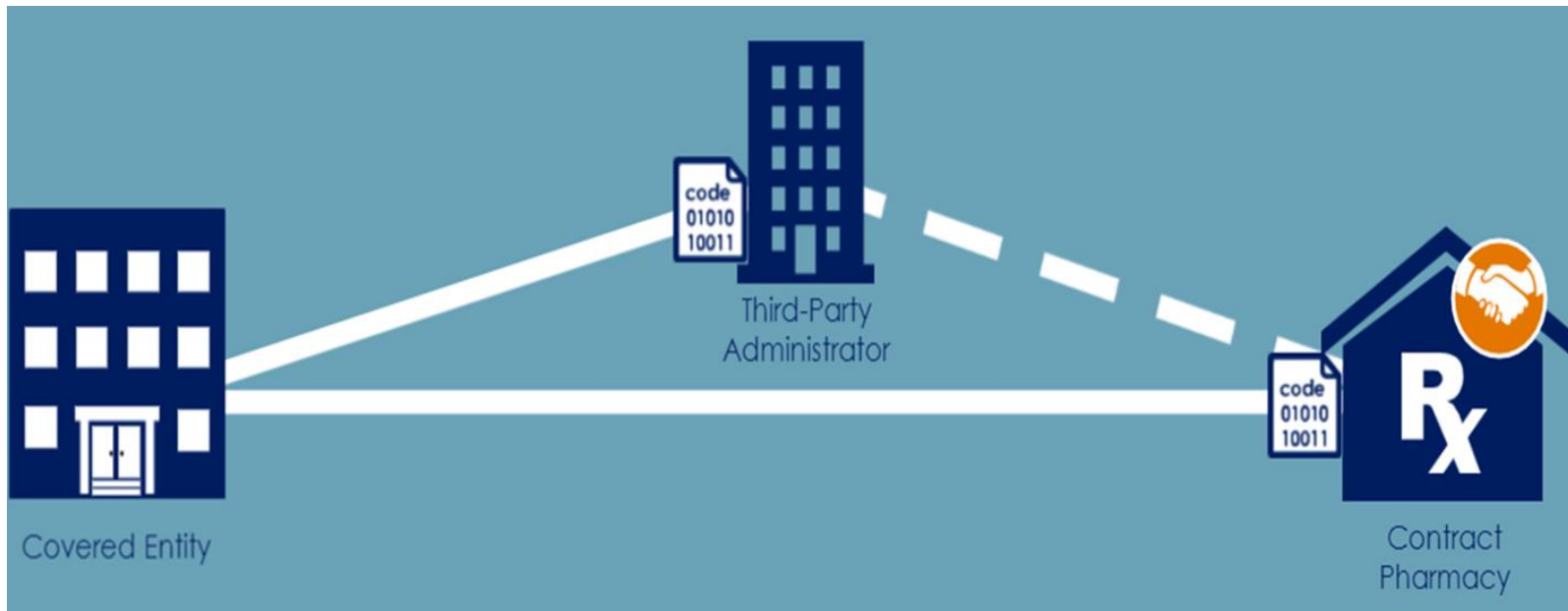


Recent manufacturer restrictions on shipping 340B priced drugs to contract pharmacies could drastically impact health centers' livelihoods and their patients' health outcomes.

Contract Pharmacy

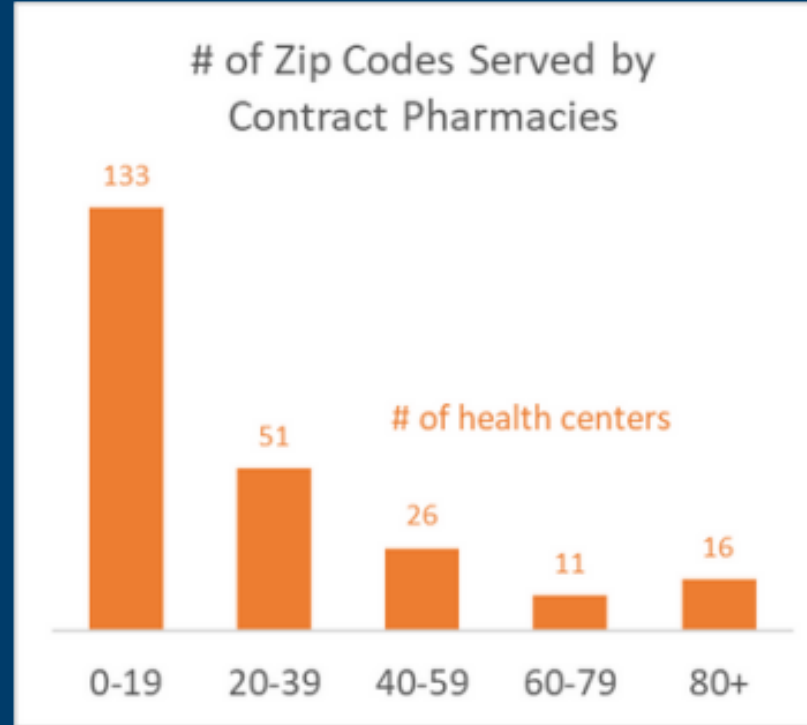
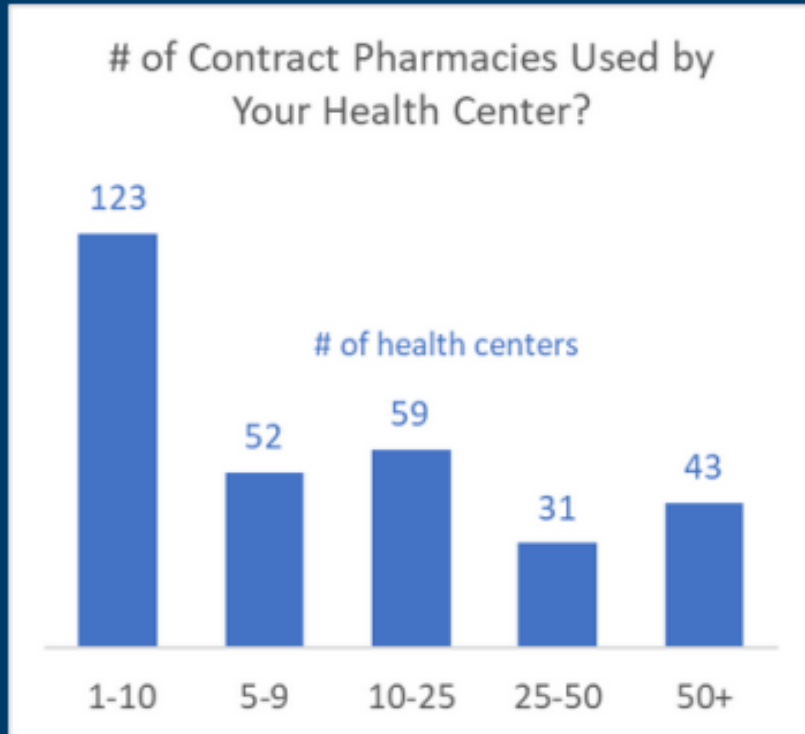
The entity sends eligibility data feeds to the contract pharmacy directly or to the contract pharmacy third-party administrator to ensure the patient's eligibility for 340b.

An eligible patient of the covered entity fills a 340b prescription with the contract pharmacy, either by presenting the prescription to the contract pharmacy or through e-prescribing, whereby the covered entity directly transmits the prescription to the contract pharmacy. The contract pharmacy would dispense the drug from its inventory.



Health Center Contract Pharmacy Totals

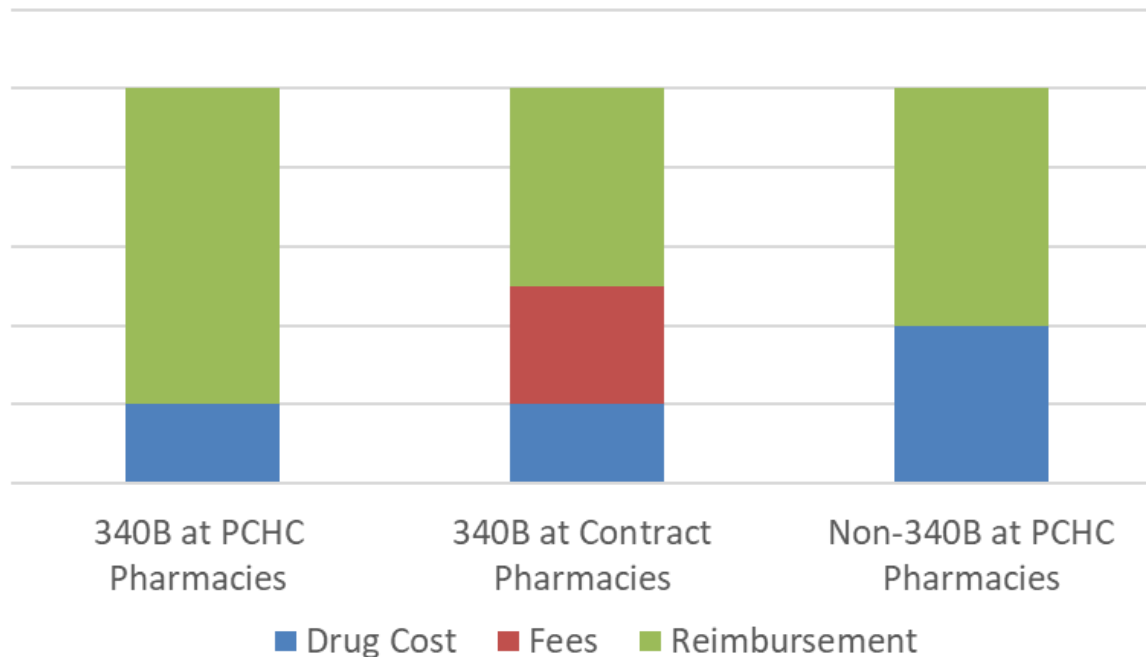
Health centers heavily rely on contract pharmacies to provide their patients with life-saving medications, particularly in rural areas where patients may live far from the health center.



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340B Example of Savings Generated

- ▶ **Non-340B Pharmacy:** \$1000 for medication to insurance which pays the pharmacy \$1100= \$100 to pharmacy
- ▶ **340B Pharmacy:** Bills the same amount to the insurance company and gets paid \$1100 but the 340B pharmacy only paid \$600 for the medication = **\$500 for the pharmacy**
- ▶ Example below:
 - ▶ *The bars are not drawn to scale.*
 - ▶ *The depiction is to show difference in costs for non-340B and costs associated with Contract Pharmacy*



Eligibility to utilize 340B

1. Patient must meet Patient Definition: Patient of that primary care practice. Example. PCHC patient

2. Written by Eligible Provider

- PCHC provider or Non-PCHC provider whom patient referred to by PCHC provider

3. Insurance

- Commercial and Medicare prescription insurances are eligible
- Dual eligible patients (Medicare primary, MaineCare secondary)
- **NOT** MaineCare: Drug manufacturers already give MaineCare a discount (there are exceptions based on 'Carve-in' or 'Carve-out' status)
- Uninsured patients

Patient Definition

What makes a patient eligible?

- The covered entity must have an established relationship with the individual and maintain records of the individual's health care.
- The individual must receive health care services from a health care professional who either is employed by the covered entity or provides health care under contractual or other arrangements (such as referral for consultation) such that the responsibility for the care remains with the covered entity.
- The individual must receive health care services that are 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. Hospitals are exempt from this requirement.
- An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting.

Exception: Individuals registered in a state-operated or funded AIDS drug assistance program (ADAP) that receives federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the state program.

340B Compliance

- Current Policies and Procedures
- Audit of approved claims for in-house and contract pharmacy arrangements
- Work within TPA portal to review all eligible referral claims and process
 - Conduct chart reviews to ensure referral order and consult note are in patients EMR
- Maintains PCHC Provider list to ensure compliance for 340B eligibility
- Quarterly audits and updates of HRSA OPAIS database
- Approve inventory invoices for contract pharmacy medication replenishment
- Entity owned nightly reports to maintain compliance regarding duplicate discount
- Monthly audits of Physician Administered Drugs in all PCHC clinics
- Facilitate a quarterly 340B Advisory Committee Meeting with stakeholders from PCHC
- Conducts a yearly 340B program review with external independent auditor
- Attends all webinars facilitated by Apexus, NACHC meetings, monthly meetings with TPA reps.
- Looks for additional ways to optimize 340B savings through additional Contract Pharmacy arrangements, referrals, etc.

340B Savings Losses and Gains

Losses:

- Manufacturers “bill to and ship to” arrangements blocked
- Contract pharmacy
 - PCHC Third Party Administrator (TPA) admin fees
 - Predatory contracts
 - Contract Pharmacy dispense fees
- Pharmacy Benefit Manager (PBM)
 - Decreasing reimbursements
 - Increasing cost: people and medications
- Direct and Indirect Remuneration fees (DIR)
- Competition for referral claims: Closest to claim vs patient overall care
- Legislation pushes to ‘curb’ program
- HRSA and HHS lack of power to enforce or mandate

340B Savings Losses and Gains

Gains:

- ▶ 340B ESP
- ▶ In-house outpatient pharmacy
- ▶ Referral claims
- ▶ Mail order Contract Pharmacy
- ▶ Specialty Pharmacy
- ▶ Optimizing data sent to TPA's
- ▶ Educating law makers in each state
 - ▶ 340B
 - ▶ DIR
 - ▶ PBM
 - ▶ Pharmacist role

Assessment Question #1

- ▶ 1. 340B savings may be spent on which programs
 - ▶ A. Hot tub for Frank
 - ▶ B. To stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
 - ▶ C. Bonuses for outstanding services provided at an organization
 - ▶ D. To give an organization a chance to reward and develop plans for people to get jobs they have always wanted when they were young and now want to do.

Assessment Question #1 Answer

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Assessment Question #2

- ▶ 2. What can a CE do to increase their Contract 340B savings?
 - ▶ A. Increase the number of TPA recommended 340B contract pharmacies
 - ▶ B. Optimize data from the CE to the TPA's
 - ▶ C. Implement a referral capture process
 - ▶ D. Hire a 'wicked good' compliance oriented person to run your 340B Program
 - ▶ E. All the above

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 - ▶ E. **All the above**