Testimony on H. 266

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Key Points about Federally Qualified Health Centers (FQHCs)

- Provide primary, behavioral, dental, lab, and preventive care.
- FQHCs are known as “the backbone of the health care safety net”, as they:
  - Are intentionally located in areas where there are large numbers of medically-underserved patients.
  - Serve largely low-income patients (roughly 70% below the poverty level.)
  - Provide care to everyone, regardless of ability to pay.
  - Charge patients using a sliding fee scale, based on their income.
  - Are community-based non-profits -- never owned or controlled by an outside organization.
  - Are managed by their own patients.
- **FQHCs serve 1 in 3 Vermonters, at 93 sites located in every county in the state.**

TOPICS

- An Overview of 340B
  - Program Basics
  - How 340B Generates Savings, & How FQHCs Use Them
- The Need for H. 266

An Overview of 340B

Name & Overview

- **Name**: "340B" refers to the section of the Public Health Service Act that created the program in 1992.

- **Structure:** The program requires drug manufacturers to sell drugs at discounted rates to certain "safety net" providers for outpatient use.
  - Drug makers must agree to this as a condition of getting their drugs covered by Medicare and Medicaid

Key Points:

1. 340B discounts are funded entirely by drug makers – NOT by taxpayers.

2. 340B accounts for 7-8% of total US drug sales.

Which providers qualify for 340B?

"Covered Entities" – This term refers to all safety net providers that are eligible to participate in 340B.

- **Many hospitals, including those that:**
  - Have a DSH percentage of at least 11.75%.
  - Critical Access & Sole Community Hospitals
  - "Public" hospitals
  - Children's, cancer, and rural referral hospitals

85% of 340B purchases

- **Grantees** – providers who get HHS grants
  - FQHCs
  - Ryan White Clinics
  - ADAPs
  - STD, hemophilia, family planning, and other clinics

15% of 340B purchases

How big is the discount?

- **Required Discount** *(calculated off the best-guess of "sticker" price):*
  - 13.1% for generic drugs.
  - 23.1% for brand-name drugs.
- **Penalty discounts:**
  - If a drugmaker raises a drug's price faster than inflation, then an additional discount is applied.
  - The faster the drugmaker raises the price, the higher the discount.

Whenever a drug's 340B discount exceeds 23.1%, it's because the drugmaker raised the sticker price faster than inflation.

Key Point:

Drugmakers can reduce the size of 340B discounts by slowing down how fast they raise drug prices.

Why was 340B created?

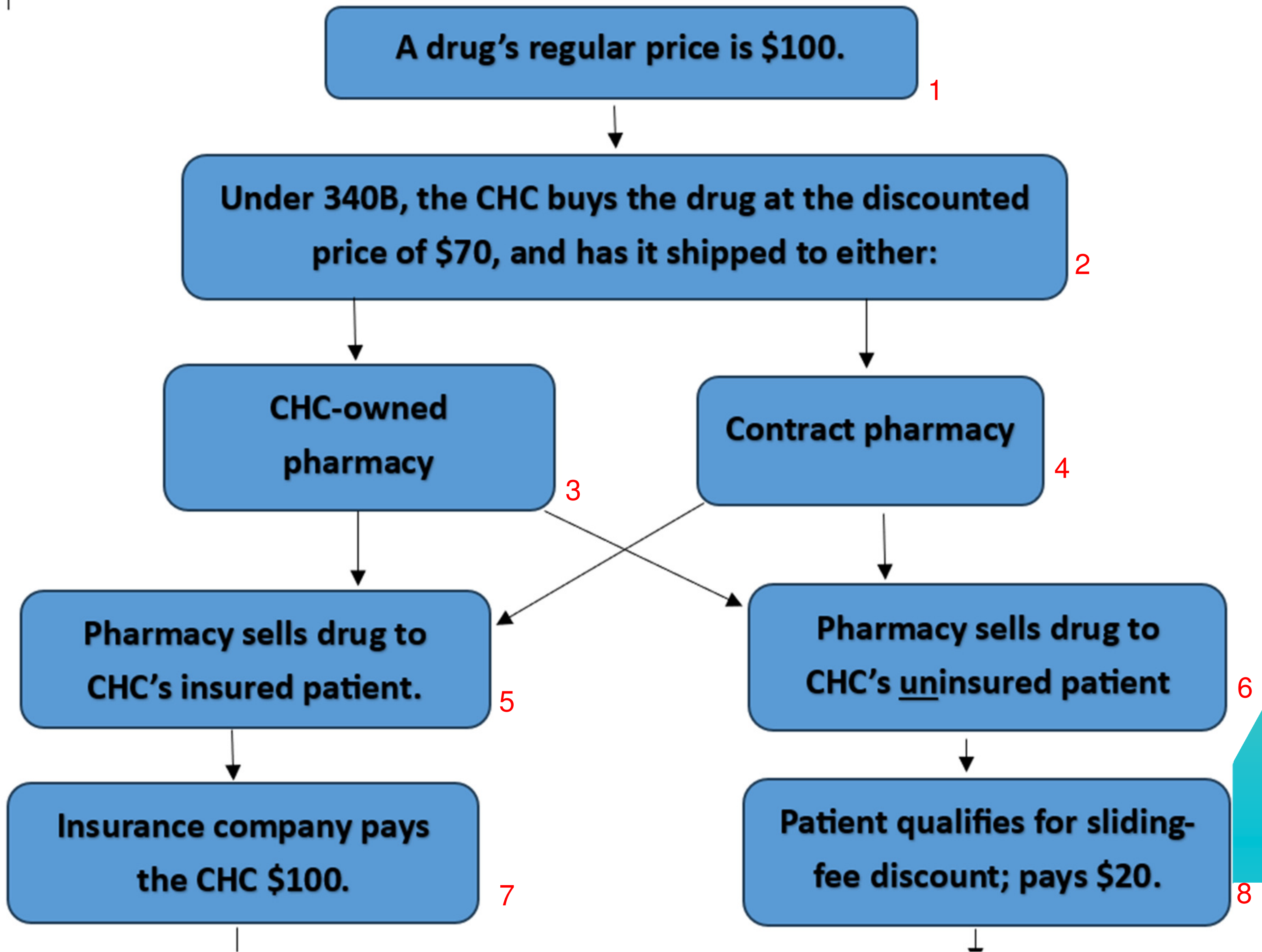
When creating 340B in 1992, Congress said its purpose is to:

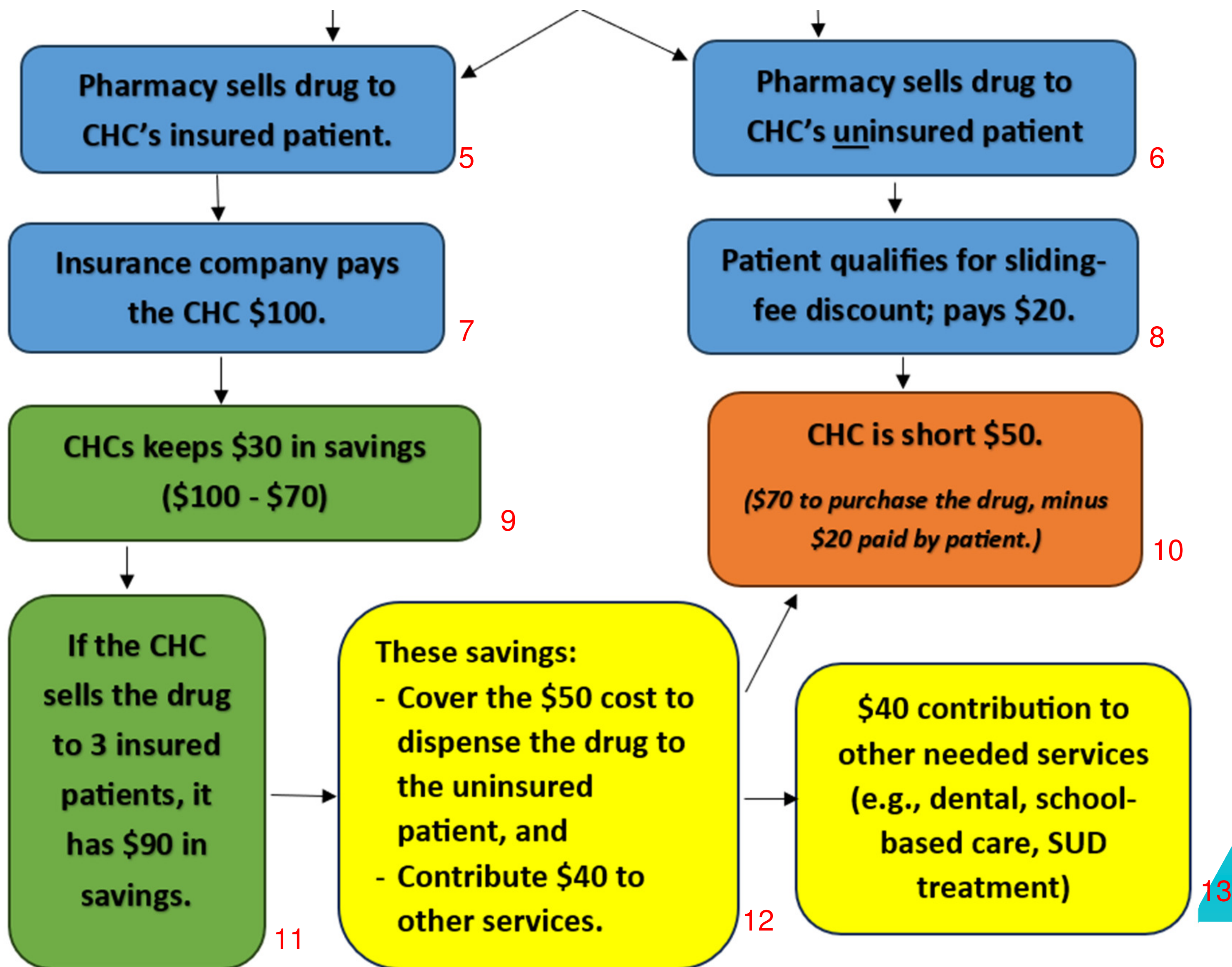
"permit covered entities ***to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.***"

Two Key Points:

- **Congress created 340B to support safety-net providers broadly – not to guarantee drug discounts to specific individuals.** *Safety net providers decide what is the best use the savings to support their patients.*
- **340B is about much more than pharmaceuticals – the funds it frees up support many different types of services.**

How does 340B generate savings for safety net providers?


A drug's regular price is $100.
1
Under 340B, the CHC buys the drug at the discounted price of $70, and has it shipped to either:
2
CHC-owned pharmacy
3
Contract pharmacy
4
Pharmacy sells drug to CHC's insured patient.
5
Pharmacy sells drug to CHC's uninsured patient
6
Insurance company pays the CHC $100.
7
Patient qualifies for sliding-fee discount; pays $20.
8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Patient qualifies for sliding-fee discount; pays $20.
8
CHCs keeps $30 in savings ($100 - $70)
9
CHC is short $50.
($70 to purchase the drug, minus $20 paid by patient.)
10
If the CHC sells the drug to 3 insured patients, it has $90 in savings.
11
These savings:
- Cover the $50 cost to dispense the drug to the uninsured patient, and
- Contribute $40 to other services.
12
$40 contribution to other needed services (e.g., dental, school-based care, SUD treatment)
13

340B Supports Many Safety-Net Services

- 340B grantees like FQHCs are required – by law and regulation – to invest every penny of 340B savings into services that expand access for their medically-underserved patients.
- In Vermont, FQHCs use their 340B to support under- or unreimbursed care and services such as:
  * Dental care for the uninsured
  * Mobile units
  * Mental Health and Substance Use Disorder Treatment
  * Expanded service offerings: transportation, translation, CHWs

This is not an overstatement. For example:

- In 2023, 340B comprised 25% of the net patient revenue to Vermont FQHCs.

The need for H. 266

Congressional Inaction has led States to Step In

Despite multiple efforts, Congress has yet to update the 340B statute to address multiple challenges within the program. So states are stepping in:

PBM 340B law enacted | PBM 340B bill passed at least one legislative chamber

Over 30 states have enacted laws to keep **PBMs** from taking 340B savings away from safety-net providers.

Bill passed | Bill cleared a legislative chamber | Bill introduced

Eight states -- including West Virginia, Arkansas, Kansas, Louisiana, Mississippi, and Missouri – have passed law **banning contract pharmacy restrictions.**

Bans on Contract Pharmacies

- Since 2020, some PhRMA companies have refused to ship 340B-priced drugs to contract pharmacies. Currently:
  - 37 drugmakers ban contract pharmacies for hospitals.
  - 24 drugmakers have extended these bans to FQHCs.
- HHS has tried to stop the drugmakers' actions, but the situation has been languishing in the courts for years.
  - This has enabled PhRMA companies to continue and expand their bans (& avoid offering discounts), which in turn…
  - Deprives FQHCs and other covered entities of the savings from contract pharmacies – which they have relied on for over many years to support many underfunded services.

Key Point:
In another rural state, the losses due to contract pharmacy restrictions forced 75% of FQHCs to lay off staff in 2024

Rebate Model

- Within the past year, multiple PhRMA companies have proposed moving 340B from an "upfront discount" model to a rebate model.
- Under a rebate model, a FQHC (or other 340B provider) would have to:
  - Pay full price for a drug at the time of purchase.
  - Wait until a unit of the drug is dispensed.
  - Submit an extensive set of data to the drugmaker on every individual prescription. (Some have requested over 30 data fields per prescription.)
  - Allow the drugmaker to decide whether the FQHC should receive a rebate.
  - Wait until the drugmaker accumulates enough approved rebates on a specific drug to issue a rebate payment.

Key Points:
A rebate model would;
1. **Impose massive cashflow and administrative burdens on 340B providers.**
2. **Allow drugmakers to decide if and when a 340B provider receives the benefit of 340B pricing.**

Transparency

- Vermont FQHCs support transparency initiatives that :
  1. Allow them to tell their <u>full</u> 340B story – including:
     - how they use 340 savings to expand access for underserved patients.
     - their costs to operate a compliant program.
  2. Minimize burden (e.g., by being coordinated with their many other Federal reporting requirements.)
  3. Are not used by outside groups (e.g., PBMs) to take the 340B savings for themselves.

<u>Key Point:</u>
Any new reporting requirements must be structured in a way that allows 340B providers to tell how they use their 340B savings to expand access.

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