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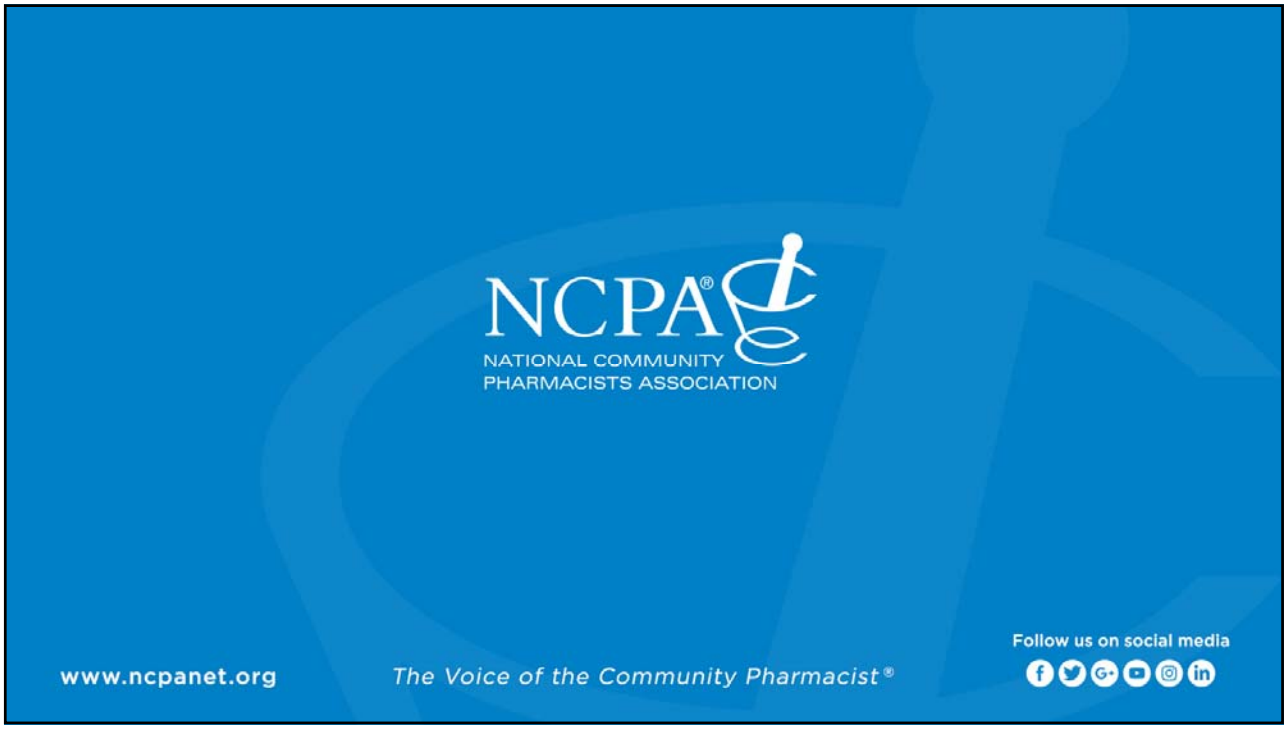
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# The Future of 340B

**NCPA 2018 Annual Convention**

Susan Pilch, JD, Senior Vice President, Legal and Advocacy, 340B Health
Amanda Gaddy, RPh, Co-Founder, Secure340B

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## Disclosure

Susan Pilch declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Amanda Gaddy is receiving an honorarium for this program. Amanda has an ownership interest in Secure340B. This conflict of interest was resolved by peer review of the content.

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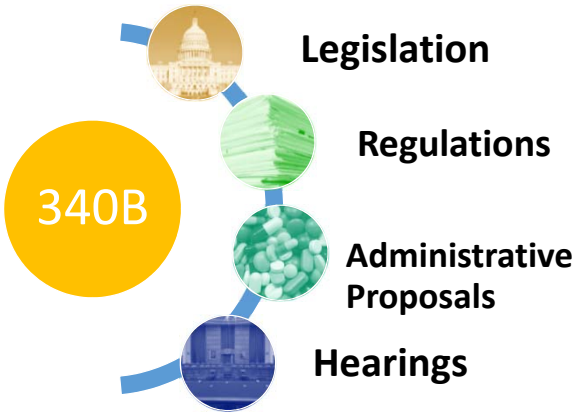
# Learning Objectives

1. Discuss likely 340B Program legislative and regulatory changes and the impact on community pharmacy.
2. Examine the relationship between covered entities and contract pharmacies.
3. Summarize ways for contract pharmacies to maximize positive results in the 340B Program.





# Current 340B Landscape

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# Active Legislative Environment

**Multiple Legislative Proposals**:

- Limit the scope of 340B
- Collect overly broad data
- Significantly curtail the program
- Sustained Committee action in both House and Senate

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# 340B Critics are Out in Force

PhRMA

PRI PACIFIC RESEARCH INSTITUTE

COMMUNITY ONCOLOGY ALLIANCE COA

BLUEGRASS INSTITUTE

AIR 340B

AMERICAN ACTION FORUM

Bio Biotechnology Innovation Organization

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## Multiple Hearings

- Three hearings in Senate Health, Education, Labor, and Pensions (HELP) Committee
- Three hearings in House Energy and Commerce Committee
- More hearings to come? **Mark-up of introduced House legislation unlikely before elections**

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## Legislation that Supports the 340B Program and Hospitals

- Rep. David McKinley (R-W. Va.) bill – Reverses Part B cuts; 199 sponsors!
- Rep. Doris Matsui (D-Calif.) bill – Manufacturer transparency, preserves 340B

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# H.R. 4392 – Reversing Part B Payment Cuts

**Fast Facts**

- Introduced in November 2017 by Reps. David McKinley (R-W. Va) and Mike Thompson (D-Calif.)
- Co-sponsors: 199 (as of August 3, 2018)—Bipartisan support
- Hospital groups and hospital co-plaintiffs also challenging in court

**Overview of Proposed Changes**

- Reverses Part B drug payment cuts to certain 340B hospitals and new modifier requirements for additional 340B hospitals
- Cuts estimated to be $1.6 billion per year

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# H.R. 6071– SERV Communities Act

**Fast Facts**

- Introduced June 12, 2018 with strong support from 340B Health and other hospital groups
- Co-sponsors: 20 (as of August 3, 2018)

**Overview of Proposed Changes**

- Prohibits manufacturers and insurers from discriminating against 340B covered entities
- Requires transparency and accountability for manufacturers, including improvements to HRSA manufacturer audits
- Reverses Medicare Part B Payment Cuts
- Creates a new provider eligibility category for SAMHSA grantees
- Prohibits further delay of Civil Monetary Penalties and establishes deadline for Ceiling Price Website

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# Harmful 340B Legislation/Proposals

- Curtailing the 340B Program
- Limiting the Scope of 340B
- Data Collection Aimed at Altering 340B

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# S. 2312 – "HELP Act"

**Fast Facts**

- Bill in the Senate
- Introduced by Sen. Bill Cassidy (R-La.) in January 2018
- 0 co-sponsors

**Overview of Proposed Changes**

- Freeze on DSH hospitals and child sites and reporting requirements similar to 340B PAUSE Act
- New hospital and child site eligibility requirements for DSH, children's, and cancer hospitals
- Additional reporting requirements, including claim modifiers

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# H.R. 4710 – "340B PAUSE Act"

**Fast Facts**

- Bill in the House of Representatives
- Introduced in December 2017 by Reps. Larry Bucshon (R-Ind.) and Scott Peters (D-Calif.)
- 4 co-sponsors

**Overview of Proposed Changes**

- 2-year freeze on new DSH hospitals and new child sites for existing DSH hospitals
- Burdensome and problematic reporting requirements for DSH, children's, and cancer hospitals



# Proposal to Limit Patient Definition

**Fast Facts**

- Discussion Draft introduced in conjunction with the July 11, 2018 Energy and Commerce Hearing
- Introduced by Rep. Chris Collins (R-N.Y.)

**Overview of Proposed Changes**

- **ONLY** uninsured patients meet new proposed patient definition for DSH, PED, and CAN hospitals
- Applies many of the patient definition changes proposed in the mega-guidance such as discharge prescriptions and infusions

# Proposal to Increase DSH Threshold

**Fast Facts**

- Discussion Draft introduced in conjunction with the July 11, 2018 Energy and Commerce Hearing
- Introduced by Rep. Joe Barton (R-Texas)

**Overview of Proposed Changes**

- Requires DSH hospitals to have an 18% DSH adjustment percentage, a substantial increase from the current 11.75% threshold
- Increase the rebate percentage for all covered entities excluding DSH and CAH
- Would eliminate 51% of DSH hospitals from 340B

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# Regulatory and Administrative Update

- 2019 Proposed OPPS Rule: Would extend Part B payment cuts for 340B drugs already in effect (Jan. 1, 2018) to 340B drugs provided at non-excepted off campus provider-based departments
- President's Drug Pricing "Blueprint" suggests that the 340B program leads to higher manufacturer list prices
- 340B Ceiling Price & Manufacturer CMPs Final Rule has now been delayed **5 times** (recently delayed until July 2019)

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# GAO Report on 340B Contract Pharmacy

- Released a report on June 28th analyzing covered entities' (CEs) use of contract pharmacies
- "According to GAO, there were 1300 unique contract pharmacies in the 340B program in 2010 and about 18,700 unique pharmacies in 2017—representing a more than 1300% increase between 2010 and 2017.
- "The growth and oversight of contract pharmacies in the 340B program since 2010 has been identified as an issue of concern by HHS OIG and GAO.'
- Of the approximately 20,000 contract pharmacies—75% are chain, 20% are independent and 5 % are "other" (specialty, mail-order, institutional)



# Report on Contract Pharmacy Continued

GAO sent questionnaires to 55 340B providers--28 hospitals and 27 federal grantees

- 1/3 utilize contract pharmacies
- 29 of 30 contracts GAO reviewed included flat-fee payment arrangements. Flat fees were generally higher for hospitals than federal grantees ($15-$20 per prescription for hospitals and $6-$9 per prescription for grantees)
- Larger number of federal grantees than hospitals (15 vs. 8) indicated patients would pay 340B price or less for their drugs at contract pharmacies where discounts were available.
- According to the report, the number of contractual arrangements between contract pharmacies and different sites of a covered entity is unknown—because HRSA does not require a covered entity to register pharmacies with each of its child sites.

# GAO Contract Pharmacy Report Recommendations

- GAO Recommendations: (HRSA did **not** agree with items in yellow)
- HRSA should issue guidance on prevention of duplicate discounts in Medicaid managed care
- HRSA audits should assess for duplicate discounts in Medicaid managed care
- Need HRSA to provide specific guidance to CE on contract pharmacy oversight
- Need HRSA guidance on length of CE lookback period to identify full scope of non-compliance identified in an audit
- Require CE to specify methodology for identifying scope of non-compliance
- Require 340B providers to provide evidence of successful implementation of corrective action plan
- Require CE to register contract pharmacies for each site of the entity for which a contract exists



# Congressional Committee Letters to Contract Pharmacies

- August 1, 2018--House Energy and Commerce Committee sent letters to Accredo, Albertsons, Avella, Cains Drug Store (independent), CVS, Diplomat, Kroger, Walgreens and Walmart.
- Letter(s) request information on contracts, distance from covered entity, fees charged (flat and/or percentage), tracking of 340B prescriptions, arrangements w/covered entity to provide low-income patients w/reduced cost medications, diversion prevention efforts and duplicate discount prevention efforts.
- Responses due August 15th.

# What Next???

- August 27, 2018 - E&C Bipartisan Letter to HRSA: Use Existing Regulatory Authority!
- What could this mean for 340B contract pharmacies??
- 2019??



# Opportunity for Pharmacies to Partner w/Covered Entities to "Tell the 340B Story"—Positive Impact on Patient Care!!!

- To protect the program—A concerted effort by 340B hospitals to share ways in which the 340B program allows them to serve their low-income and rural patients and emphasize the positive impact of the program
- Still a need for a health care "safety-net"
- Opportunity for 340B contract pharmacies to also share how their participation in the program allows them to offer additional services, boost patient outcomes—and lower overall costs to the healthcare system!

# Questions?


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# What is 340B?

- Established in 1992 by Congress:
  - Requires manufacturers participating in the Medicaid program to provide discounts on outpatient drugs purchased by qualifying health systems known as Covered Entities (CEs)
- Allows CEs to reach more eligible patients and provide more comprehensive services and improve access to medication
- CEs may **partner** with pharmacies (Contract Pharmacies-CPs)
- BOTTOM LINE: Safety net for the most vulnerable patient populations

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## Community Pharmacy Life

- Why did you want to be a Pharmacist/Technician/Pharmacy Owner?
- You care about the welfare of your community

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## What If????

- **DREAM**
- Paid at least more than you pay your wholesaler (Don't lose money)
- Preferred/In-network Pharmacy
- No DIR Fees
- Have time to spend with patients – Clinical Services

- **REALITY**
- Losing $$ on prescriptions
- Non-preferred networks
- Pushed for time/Understaffed
- DIR fees/Performance Measurements
- Required to do more with less

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## How is this related to 340B?

- Intent of 340B program: The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, **reaching more eligible patients, providing more comprehensive services and improving access to medications**
- **Local collaboration** with other healthcare providers to improve welfare of community
- 340B can be the missing link
  - Provide prescriptions to uninsured/underinsured population
  - Improved margins will offset expenses associated with adding clinical services (if structured correctly)



## Partnership: Covered Entity and Contract Pharmacy


Covered Entity (CE)

PARTNERSHIP


Contract Pharmacy (CP)

# How is the revenue used?


**REVENUE FROM INSURED/THIRD PARTY**

- Expansion of primary care or specialty services
- Education and self-management programs
- Medication Management Services
- Transitions of Care
- Medication Reconciliation
- Ensure viability of health center


**UNINSURED/UNDERINSURED**

Provide medications at little or no cost for uninsured/underinsured

Increases access, adherence and ultimately improves outcomes and decreases possible re-admissions at the hospital

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# 340B in Action


Covered Entity (CE)

CE provides patient with prescription


Contract Pharmacy (CP)

Pharmacist fills RX as usual and uses their inventory

Claims sent to 340B Administrator for eligibility testing

340B Administrator

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# 340B in Action

340B Administrator tracks accumulations at the 11 digit NDC level.

Product ordered from wholesaler


Pharmacy Wholesaler

Product shipped to Pharmacy


Pharmacy receives inventory to replace what was dispensed to 340B patient

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# 340B In Action


Contract Pharmacy (CP)

$$ REVENUE RECEIVED FOR 340B RXs


Covered Entity (CE)

Contract Pharmacy passes all revenue received to the Covered Entity minus a negotiated dispensing fee for each 340B claim.

The Dispensing Fee must be, on average, more than the pharmacy's profit would have been without 340B!

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## Why is the dispensing fee important?

- The dispensing fee becomes the **margin** for the prescription
- KNOW YOUR MARGIN WITHOUT 340B:
  Brand and Generic to determine an optimal fee
  - Include estimated rebates when calculating margin without 340B
- Increase in margin (fee) may be used to offset expenses associated with being a contract pharmacy and providing additional services beyond dispensing which will have positive impacts in the community

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## Maximize Positive Results

- Initial and ongoing review of qualifying claims
- Compare the dispensing fee to the margin without 340B to determine viability of program
  - The difference between 340B dispensing fee and retail profit is the pharmacy's **increase** in profit
    - Include estimated DIR fees
    - Include estimated rebates
- **Negotiate or renegotiate a fee which is more than the estimated margin without 340B**

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# 340B Partnership Benefits

Benefits for Covered Entity:

- Revenue stream received with minimal additional expenses
- Revenue used to provide programs and services to uninsured and underinsured
- Revenue may be used to pay for clinical services- Transitions of Care, Medication Reconciliation
- Partner with other providers who can impact outcomes and welfare of community

Benefits for Contract Pharmacy:

- Partner with the Hospital/Clinic
- Increase foot traffic
- Increase average margin per prescription which can be used to add services beyond dispensing: Transitions of Care, Bedside Delivery, Chronic Care Management, Medication Synchronization, Compliance Packaging which ultimately will improve the welfare of the community



# Services Beyond Dispensing

- Clinical medication synchronization program
- Adherence/compliance packaging
- Meds to beds
- Transitions of care
- Medication reconciliation
- Chronic care management

## Services Beyond Dispensing

- Immunizations
- CLIA-waived testing
- Diabetes Prevention Program (DPP)
- Diabetes Self-Management Education (DSME)
- Weight management
- Tobacco cessation

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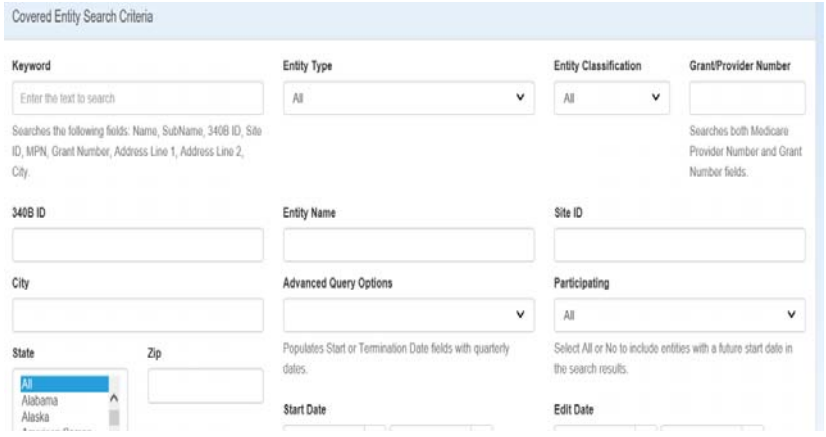
## Identifying Opportunities

- https://340bopais.hrsa.gov/coveredentitysearch?AspxAutoDetectCookieSupport=1HRSA OPA 340B Database



## Take-Aways

- 340B can be the link bringing local healthcare providers and stakeholders together to improve the welfare of the community
- Must know your business and ensure the model is right for you. Don't lose money!
- Contract Pharmacy should be a true partner with Entity. Improved margins will offset expenses associated with adding and/or optimizing clinical services
- Together you are stronger! Promote your services!



## Active Learning Exercise

- What clinical service do you think impacts patient care the most?
  - Barriers?
  - Cost? Time?
- How do you think partnering with a Covered Entity and participating in 340B could enhance or optimize clinical services offered at your pharmacy?
- Share success stories of current 340B partnerships

## Sources:

https://www.340bhealth.org/340b-resources/340b-program/overview/

https://www.hrsa.gov/opa/index.html

https://340bopais.hrsa.gov/coveredentitysearch?AspxAutoDetectCookieSupport=1HRSA%20OPA%20340B%20Database

Information obtained from experience working with pharmacies impacted by audits



# Questions?

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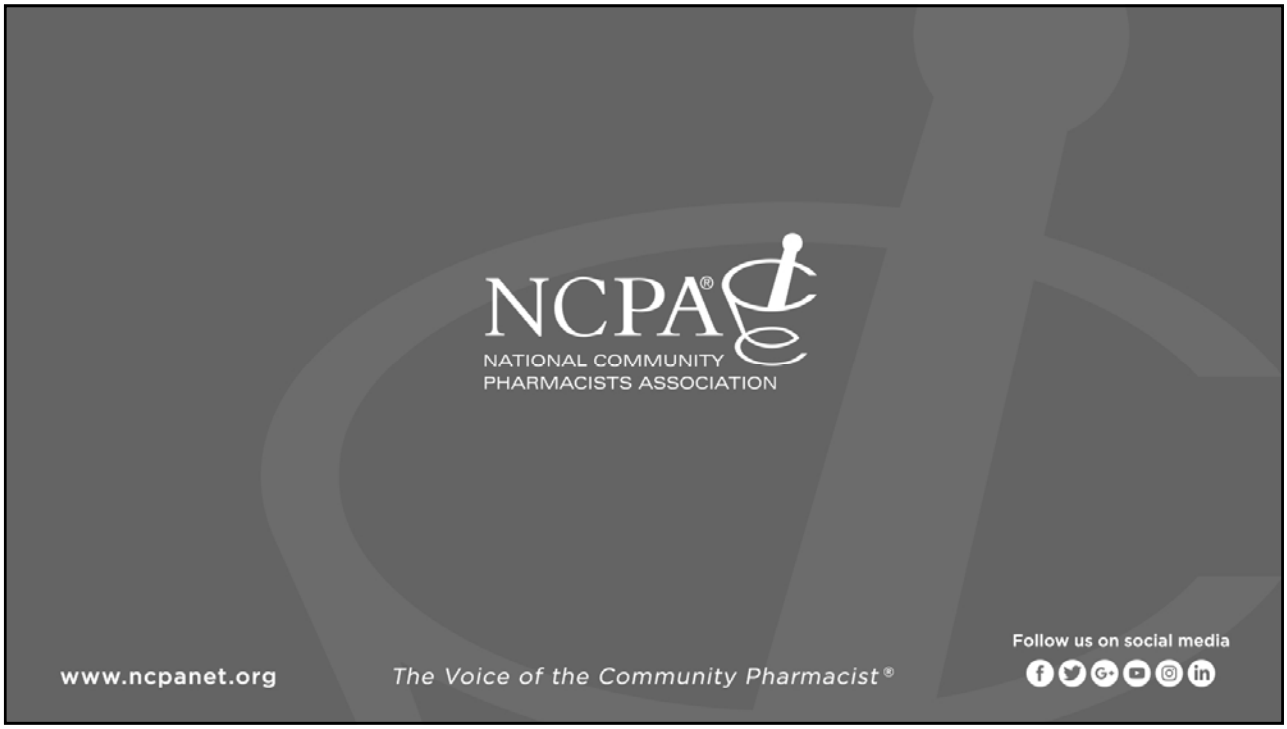
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