



Challenges at the intersection of

Medicaid and 340B

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Mercer Government
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Our 340B discussion today



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1

A brief history

2

340B considerations for state Medicaid programs

3

Identifying your state's 340B objective

4

Matching 340B strategy to objective



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Slido Warm-up: four truths and a lie about my experience with 340B. Identify the lie.

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**What do you think of when you hear
"340B?"**

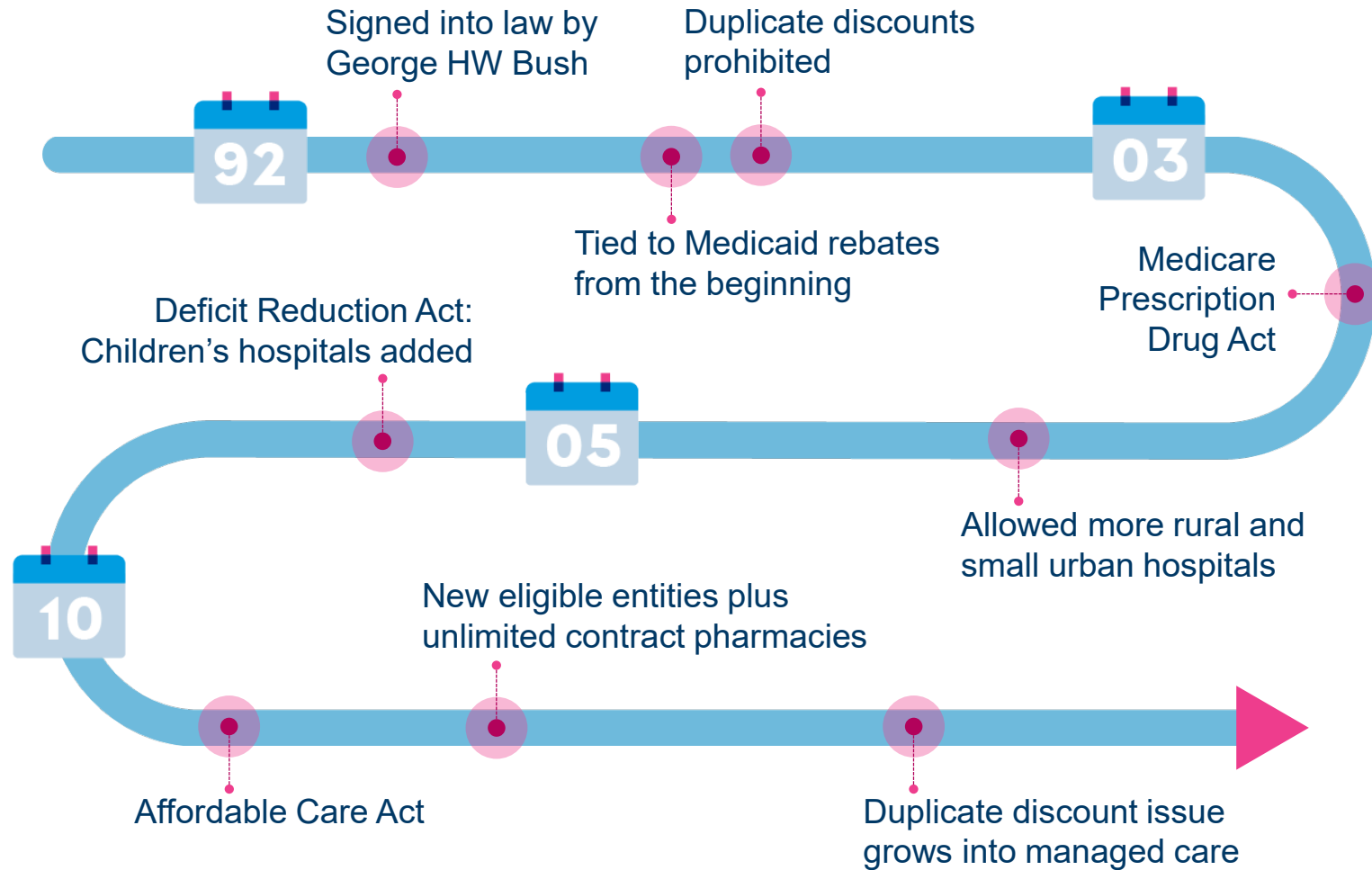
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340B program

a brief history



A transformation



Over

2,500

hospitals

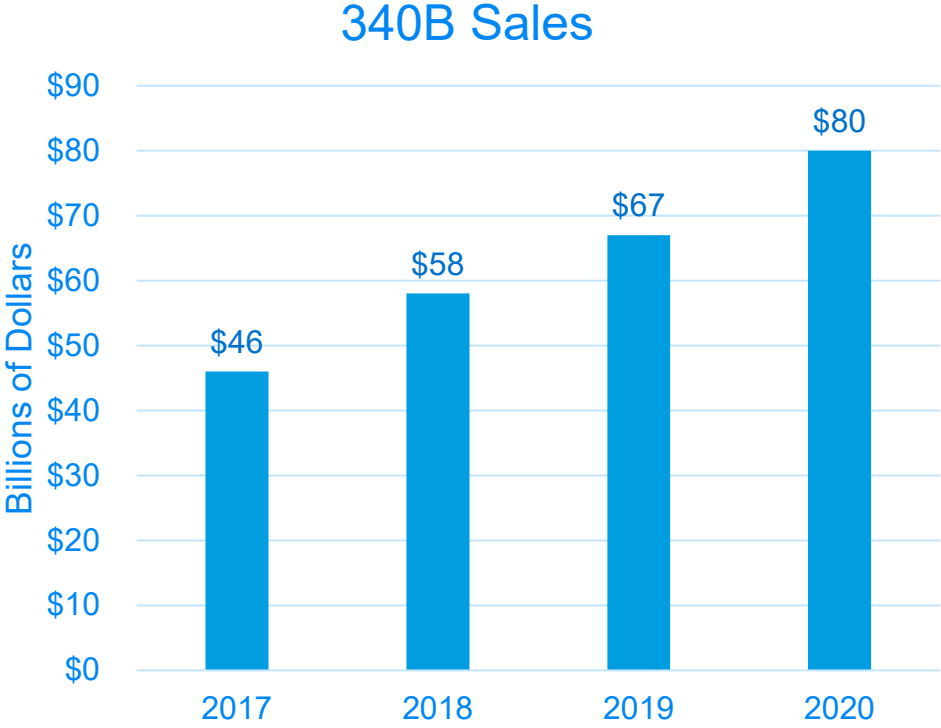
25,000

pharmacies

participate in the 340B program



Growing nationally



Growth = increased scrutiny of benefits, transparency, accountability

Source: IQVIA: Growth of the 340B Program Accelerates in 2020

Between 2010 and 2019

340B CEs increased
34%
from **9,700** to **13,000** CEs

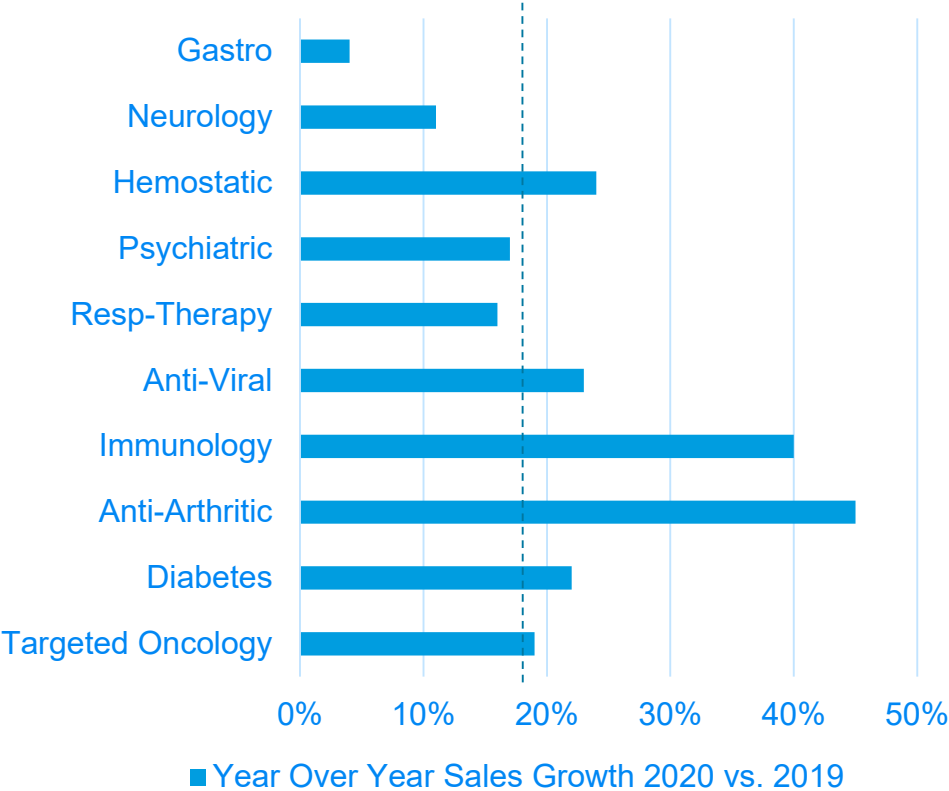
Contract pharmacies increased
1,669%
from **1,300** to **23,000**

Between 2017 and 2020

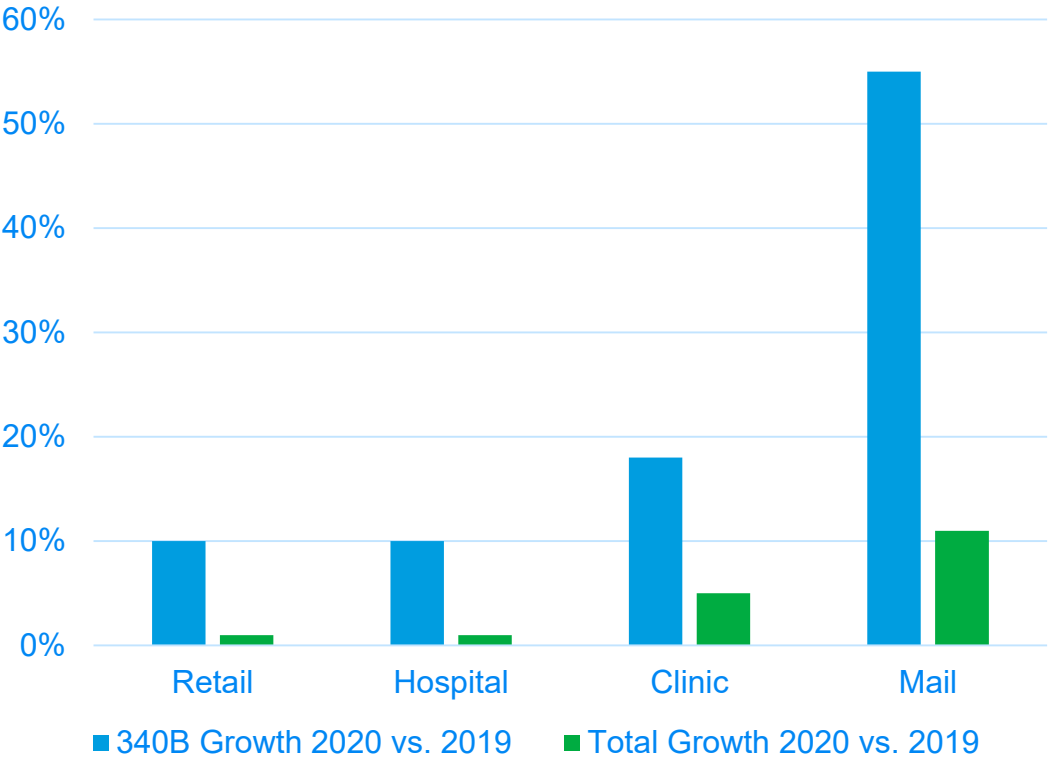
340B Sales have grown
76%

340B growth is not uniform

Growth by Disease Category

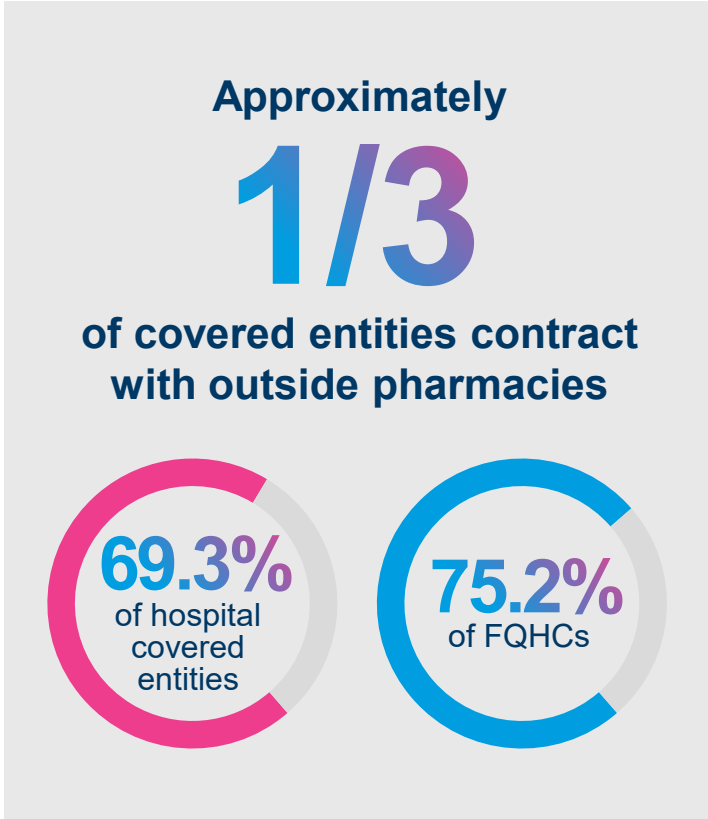


Growth by Distribution Channel



Source: IQVIA: Growth of the 340B Program Accelerates in 2020

340B contract pharmacies



Source: GAO-18-480 Drug Discount Program. Published June 2018



On a collision course?

Four major stakeholders, four different perspectives

340B covered entities

- Provide care
- Expand access
- 340B margins to fund overall operations

Pharmaceutical manufacturers

- Need to participate in 340B to enter Medicaid market
- 340B expansion concerns
- Duplicate discounts

Contract pharmacies

- Revenue and patient volume expansion opportunity
- Increased volume

State Medicaid programs

- Limited state budgets
- Duplicate discounts
- Audits
- Reimbursement benchmark challenges
- Outcomes contracting barriers





What Trump-era policy(s) was recently rescinded by the Biden Administration?

Approaching 30 years

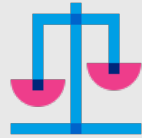
Legal and regulatory challenges



Recession of Trump-Era pass-through requirement

July 24, 2020, executive order requires that community health centers pass all of their 340B drug discount savings on insulin and injectable epinephrine to low-income patients

June 16, 2021, proposed rule from HRSA seeks to rescind those requirements



Sales to contract pharmacies

December 2020, 2020 HHS Office of General Counsel Advisory Opinion: drug manufacturers obligated to provide discounts

June 18, 2021, HHS withdrew advisory opinion

September 22, 2021, HRSA referred six manufacturers to OIG



American Hospital Association vs. et al v. Xavier Becerra

HHS's 2018 OPPS rule included a reduction in Medicare reimbursement rates paid to hospitals for drugs purchased under 340B

To date, courts have ruled in favor of HHS. **On July 2**, the US Supreme Court agreed to hear the case during its next session

Navigating the Medicaid and 340B intersection

Assess

The first step is to assess the state's 340B landscape



Objective

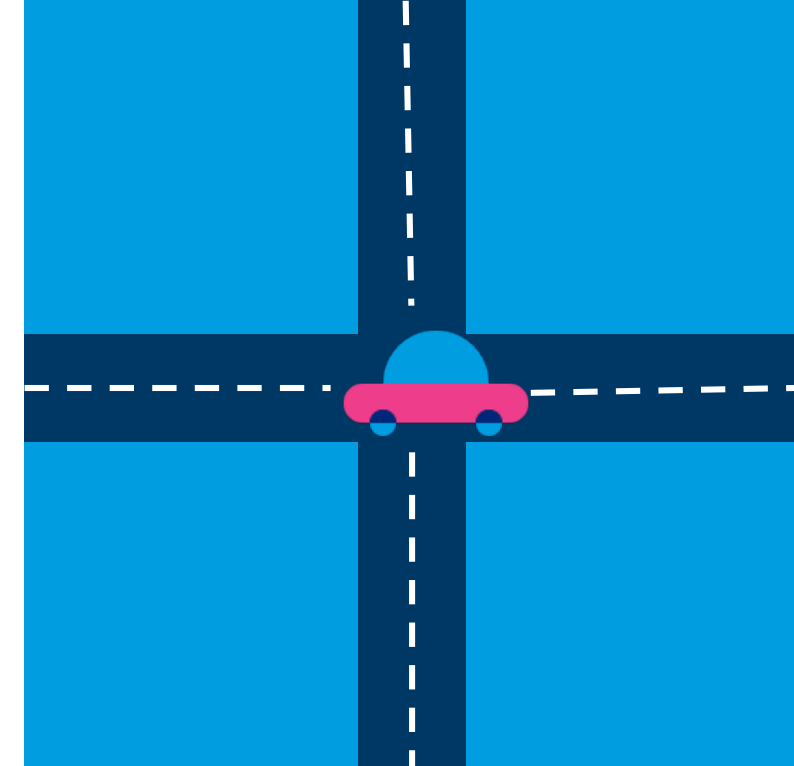
The state must determine the primary policy objective related to 340B

Select

The state must select a policy consistent with the primary objective

Implement

The state must take steps to implement the policy



Not one size fits all

There is no one right answer for a 340B strategy

Each state must determine a primary objective and then match a strategy to the objective

considerations

assessing the landscape



340B State Medicaid considerations

Double discounts and compliance



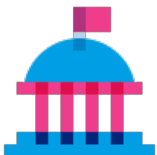
Medicaid cannot claim rebate on a drug that was purchased through the 340B program



340B entities must register with HRSA through the 340B database



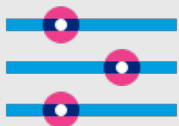
Pharmacies are not always able to consistently use claim level identifiers at the time of dispensing



Managed care plans must identify and/or remove 340B claims from data going to the state for rebate purposes

340B State Medicaid considerations

Program design considerations

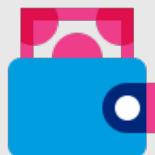


Managed care program

State can establish payment rates for 340B in the MCO contracts

States can allow MCOs to pay regular network rates for 340B products

Additional duplicate discount complexity



Fee-for-Service program

Medicaid can pay no more than the 340B ceiling price plus a professional dispensing fee

State can establish payment rate for 340B physician-administered drug products



Single PBM structured as Prepaid Ambulatory Health Plan

State can establish payment rate for 340B products

State can allow PBM to set rates for 340B products

Physician Administered Drugs

340B entities can purchase PADs through 340B

**Hospital market consolidation has increased 340B
PAD activity**

State Medicaid considerations

Duplicate discount prevention

Flexibility in payment methodology



Understanding your 340B entity population

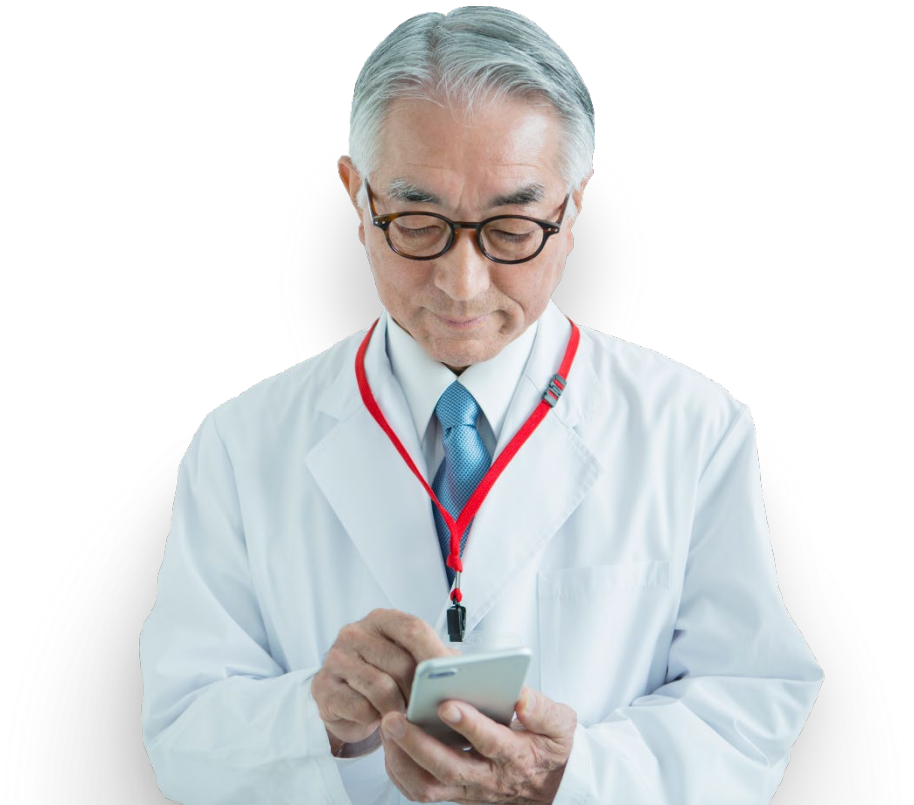


What 340B entities are present in your state?

- Federally Qualified Health Centers (FQHCs)
- Disproportionate Share Hospitals (DSHs)
- Critical Access Hospitals (CAHs)
- Family Planning Providers
- Hemophilia Treatment Centers



What do you know about how the providers are using the discounts?



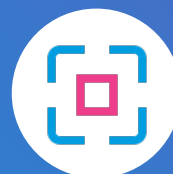
What other entities might have interest in 340B?



Ryan White/AIDS
Drug Assistance
Program



State Employee
Insurance Program



Corrections
Department



University Hospital
Systems

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State reps only: Who is reaching out to you about 340B?

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The reference of 340B to a “political football”

Who is politically powerful in your state?

DSH
hospitals

FQHCs

Patient
advocacy
groups

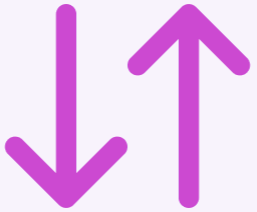
Pharmaceutical
manufacturers

Managed
care plans

Other



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Rank these entities from the most to least politically powerful in your state

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340B objective

your preferred route



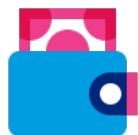
Identifying your Medicaid 340B objective

To find the policy that is the best fit for your state, first identify your priority objective



Compliance

- Reduce/eliminate audit findings
- Minimize potential for duplicate discounts



Budget

- Reduce the gross Medicaid pharmacy budget
- Reduce net cost of prescriptions purchased by Medicaid
- Offer savings opportunities to budget officials



Safety net provider revenue

- Maintain status quo safety net provider revenue
- Fund innovative patient care models and programs



Patient access

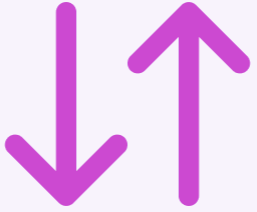
- Ensure members can fill prescriptions easily
- Allow non-Medicaid members access to 340B discounts



Political compromise

- Establish compromise policy that stakeholders can accept

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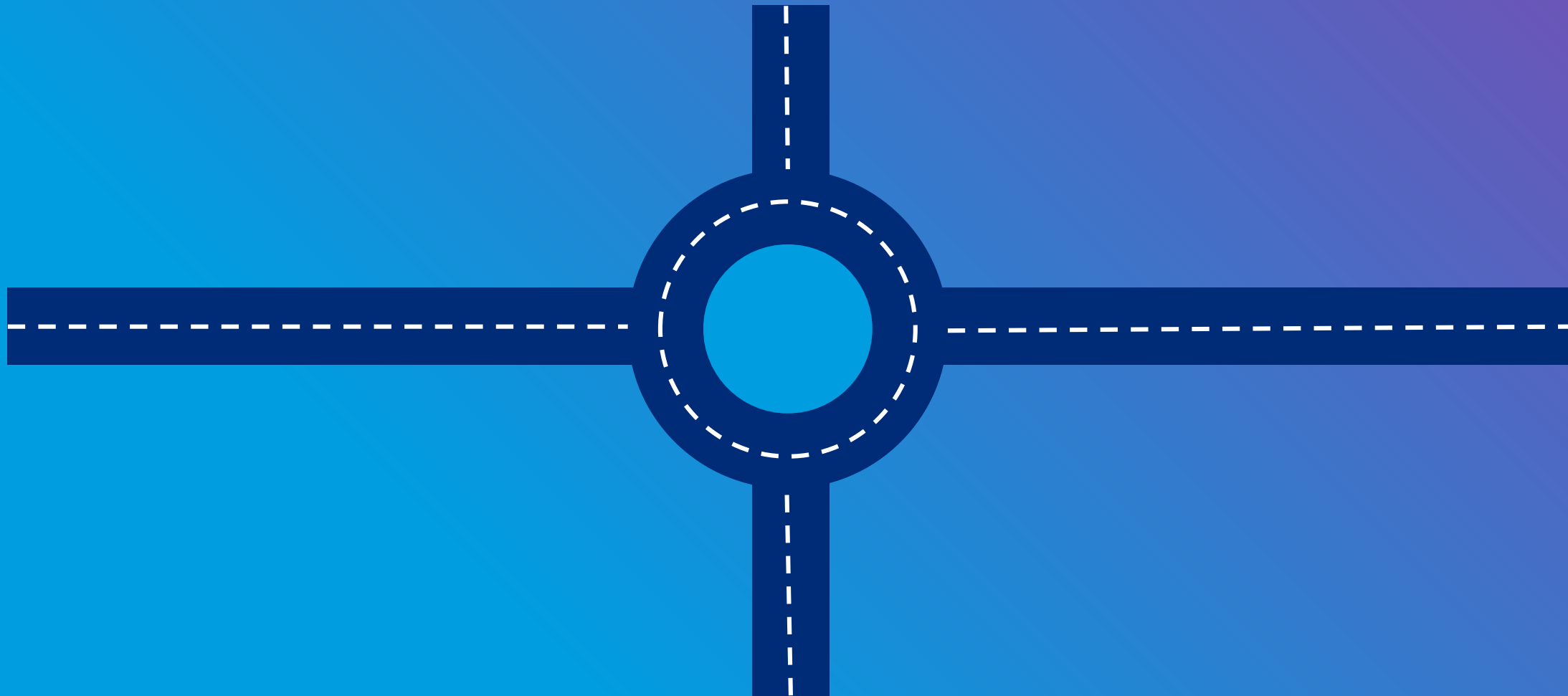


What are your top 340B objectives?

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strategy to objective

navigating the intersection



340B Objective | Compliance

Strategy | Reduce opportunity for double discounts

Disallow or Limit 340B

“Nuclear option”
Require all providers to use non-340B drug for Medicaid patients

Require 340B providers to apply for an agreement

Requires State Plan Amendment for FFS and contract provision for managed care

Limit/prohibit contract pharmacies

Require contract pharmacies to carve Medicaid out of 340B operations

Requires SPA for FFS and contract provision for managed care

Require claim level identifiers

Require pharmacies to identify 340B claims at the point of sale

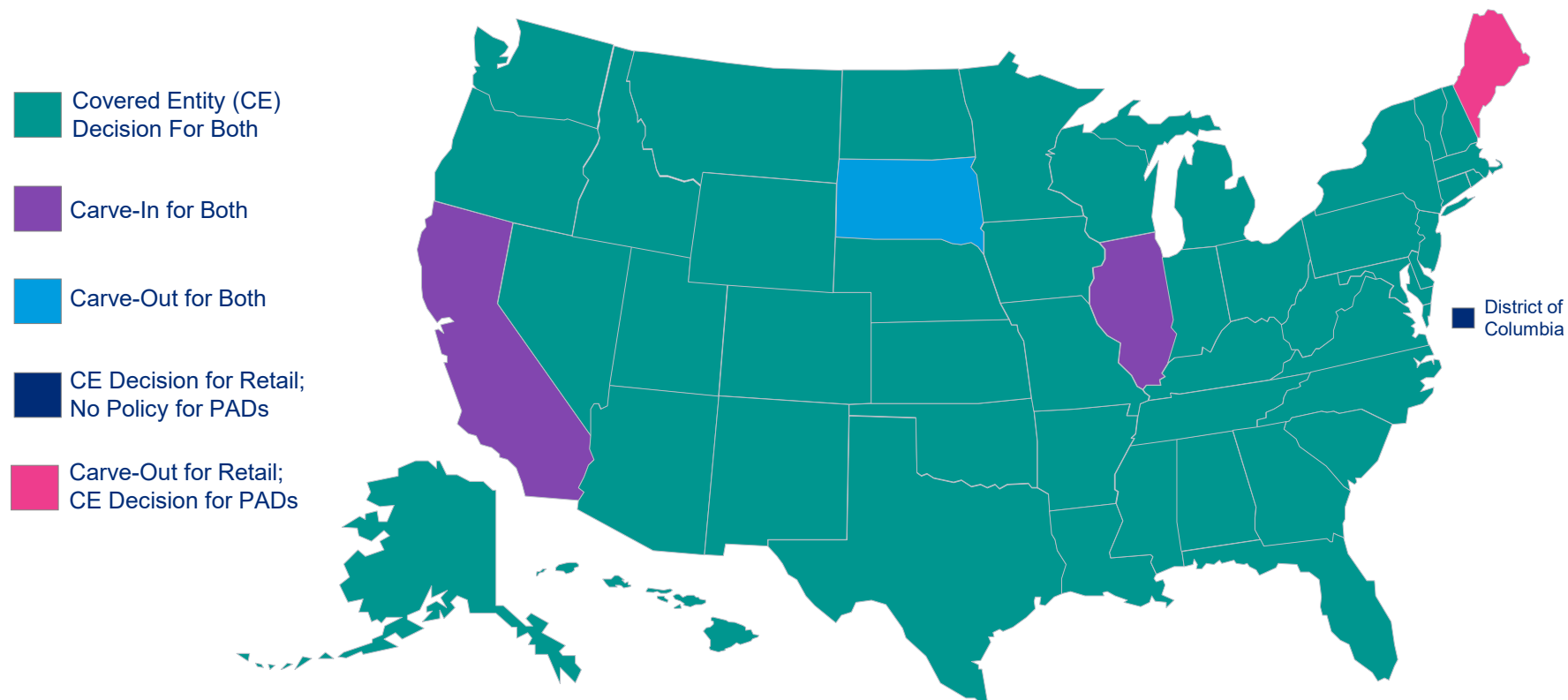
May limit the number of pharmacies able to participate

Require entities to submit utilization reports

Require all 340B entities to submit quarterly utilization reports

FFS 340B carve-in or carve-out by state

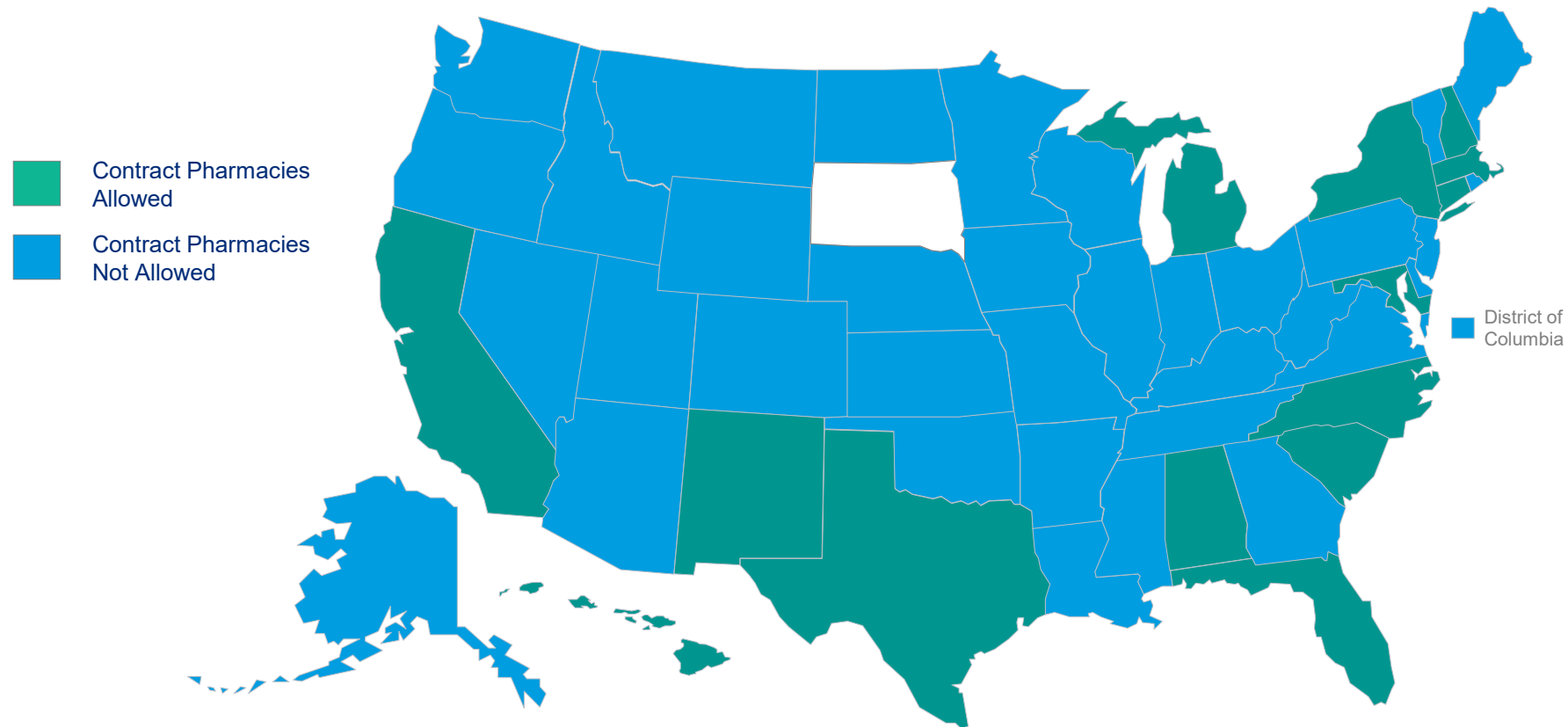
Retail pharmacy and PAD claims



Source: US Government Accountability Office. 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. January 2020.

- **Delaware and North Dakota** — CEs must obtain approval from state
- **New Hampshire** — only state-approved family planning providers are allowed

FFS contract pharmacies policy



- **California** — only hemophilia treatment centers have state-approved contract pharmacy arrangements
- **New Hampshire** — only allowed for family planning medications prescribed at family planning clinics
- **Utah** — would allow contract pharmacies, but currently does not have any state-approved contract pharmacy arrangements

Source: US Government Accountability Office. 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. January 2020.

340B Objective | Improve the state budget

Strategy | Encourage 340B use in target areas

Identify 340B opportunities for other state programs

- State Employee Program
- Corrections
- Non-Medicaid health program such as a Basic Health Plan (BHP)

Avoid the Unit Rebate Offset Amount

- Unit Rebate Offset Amount is returned 100% to federal government
- Some drugs and categories (including line extension drugs) have significant UROAs

Apply AAC reimbursement to 340B PAD claims

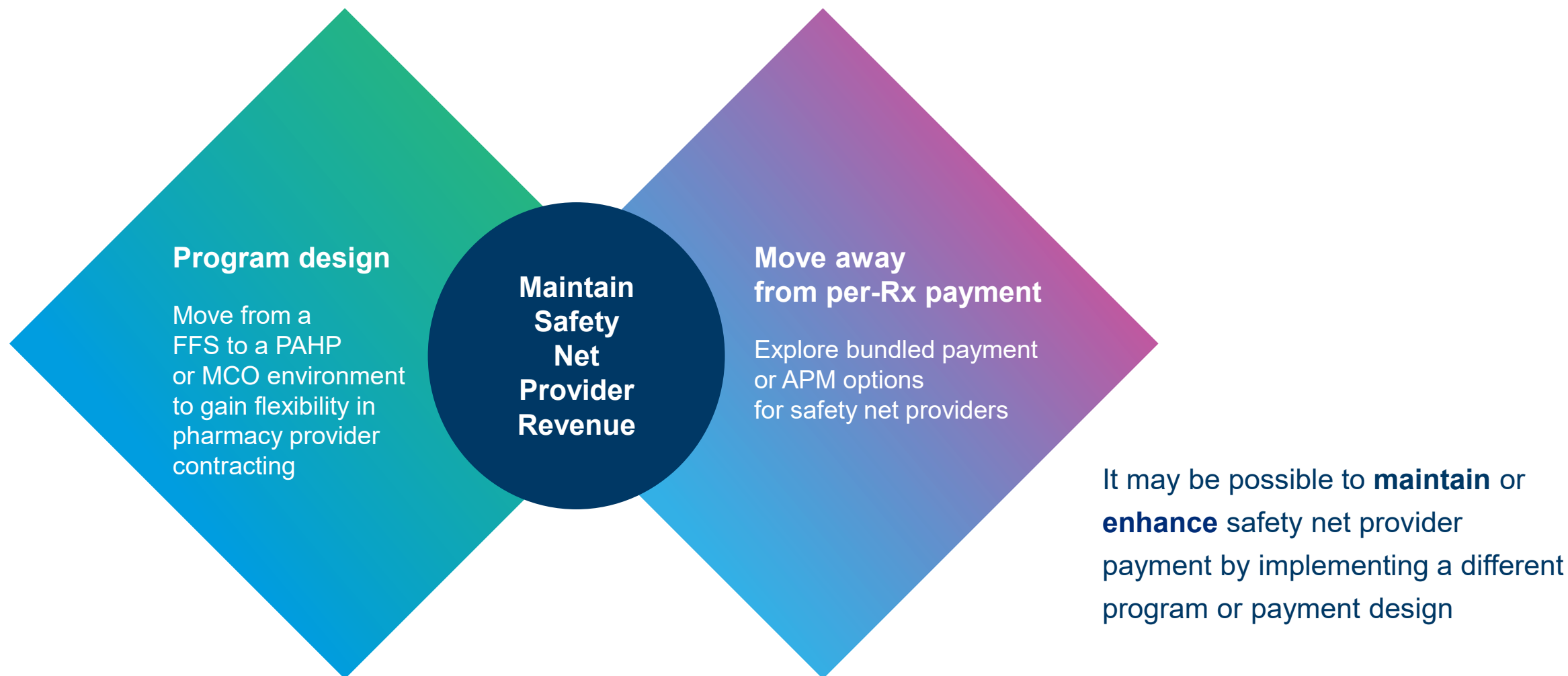
- Pay for 340B procured PADs at the 340B AAC or the HRSA ceiling price
- Encourage buy-and-bill rather than white or brown bagging at DSH owned oncology centers

Require MCOs to accept 340B and pay lower rates

- Build MCO rates assuming 340B savings from covered entities
- Require MCOs to include 340B providers in their networks

340B Objective | Maintain safety net revenue and patient access

Strategy | Seek out new payment models



340B Objective | Achieve political compromise

Strategy | Think outside the 340B box



Identify alternative provider revenue streams

Possible to apply a policy adjustment to select 340B hospitals?

Example: policy adjustor in DRG or EAPG payment system

Is the hospital eligible for an IGT?

Example: increased hospital revenue through IGT



Consider add-on payments for select providers

Is it possible to apply an add-on payment to the provider's other services?

Example: a family planning add-on payment.



Develop a quality incentive program for 340B providers

Can you measure and pay for a higher quality service?

Example: use PQA or other quality measures and pay for performance



Allow for shared savings on PADs

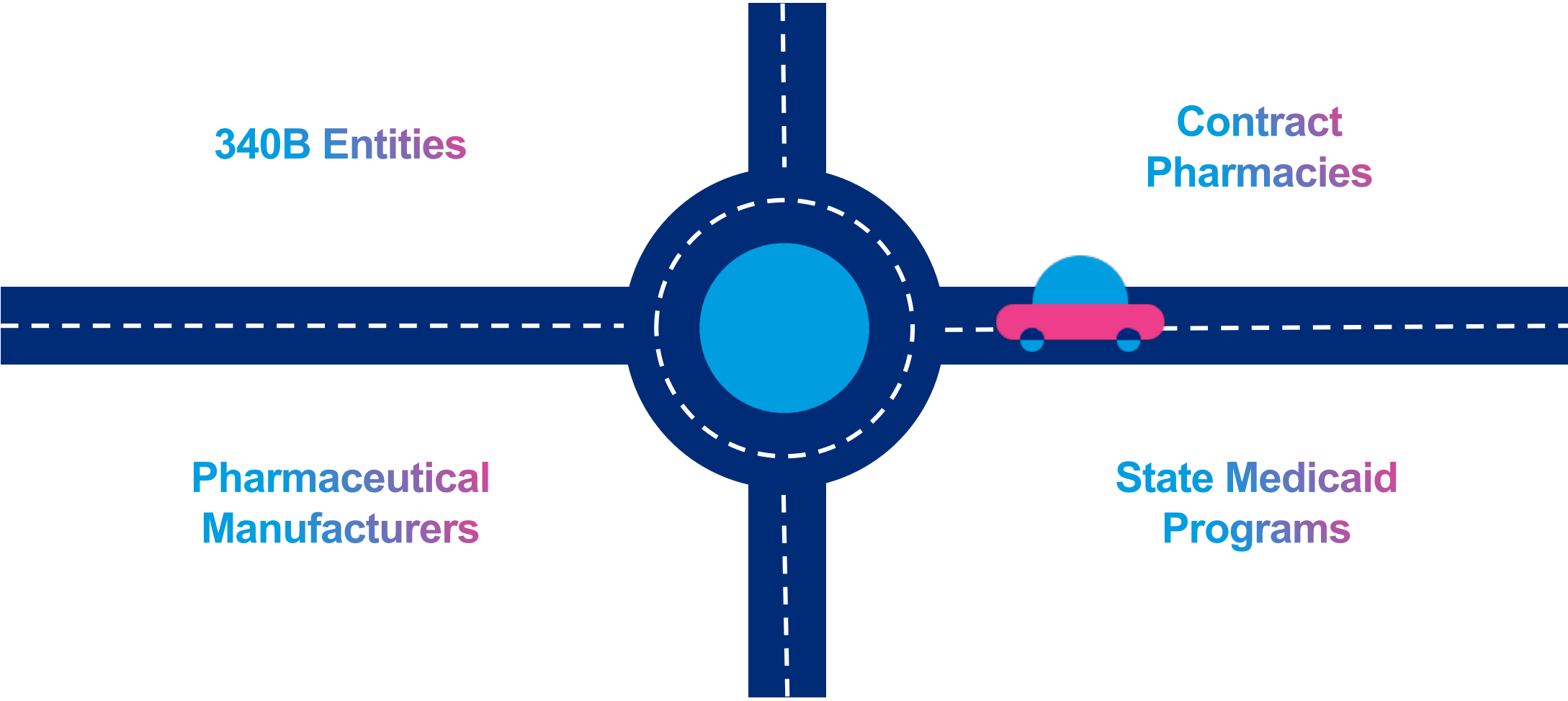
States are not required to pay PADs at AAC

Example: Pay rates between HRSA ceiling and non-340B rates

Opportunity for savings on PADs in both FFS and managed care

Example: Rate adjustment and requirement for MCOs to pay PADs at shared savings rate

What is next in your state's 340B journey?



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It's almost lunch time. If we're sitting next to each other, what 340B topic would you like to chat about?

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Q&A and Resources



Sara Drake, RPh, MPH, MBA

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Submit your questions through the chat section

Stay in the know



Download the deck and find more information on 340B

www.mercer-government.mercer.com/our-insights.html

First in the country



Watch the video

www.mercer-government.mercer.com/medicaid-news-and-more.html

Reach out!



To discuss your specific situation, email Sara

Sara.Drake@mercer.com

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Audience Q&A Session

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