Challenges at the Intersection of Medicaid and 340B

Sara Drake, RPh, MPH, MBA
Principal, Mercer

Mickey Morgan
Senior Associate, Mercer

Instructional Slide

- AMCP will add Housekeeping slides related to full faculty information, financial disclosures, ACPE info, audience polling instructions, etc.
- Moderator will be covering these housekeeping slides

Learning Objectives

1. Explain the role and historical context of the 340B program
2. Identify the operational, financial, and political considerations of the 340B program from the perspective of a State Medicaid Agency
3. Describe potential options for a Medicaid 340B strategy that will achieve the state's policy objectives

Pre-Test

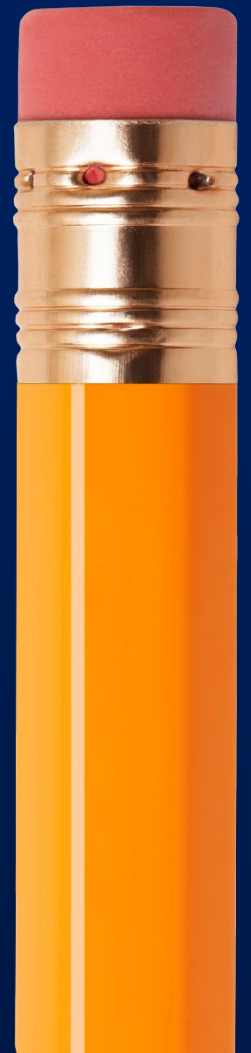
LQ1: Which of these changes to the 340B program was a direct result of the 2009 Affordable Care Act?

a) The 340B discount amount was tied to the federal Medicaid rebate amount

b) Expansion of the definition of covered entities eligible to participate in the 340B program

c) 340B entities were allowed to contract with external contract pharmacies for the first time

d) The average 340B drug discount decreased



LQ2: Which of these is not a consideration for a State Medicaid Program when determining 340B policy?

a) Compliance with duplicate discount prohibition
b) Terms of the contract between the 340B entity and the contract pharmacy
c) Characteristics of 340B providers in the state
d) The state Medicaid program's pharmacy program design (fee-for-service vs. managed care)

LQ3: If a State Medicaid program's primary objective is budget savings, which of these policy options would be the best fit?

a) Identify alternative provider revenue streams

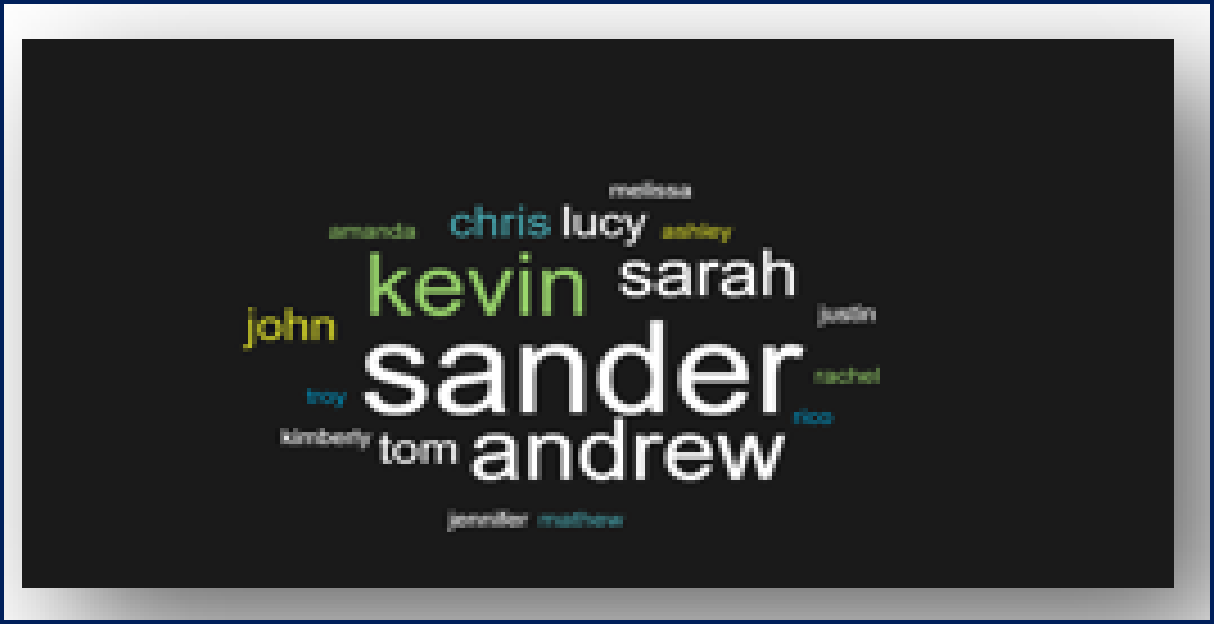
b) Disallow the use of 340B drugs in the Medicaid program

c) Apply AAC reimbursement to all 340B claims, including Physician-Administered Drugs

d) Move away from per-Rx payment to a bundled payment methodology

Word Cloud

What do you think of when you hear the term 340b?



Our Discussion Today

1. A Brief History of 340B
2. The 340B program today
3. 340B Considerations for State Medicaid Programs
4. Identifying Your State's 340B Objective
5. Matching 340B Strategy to Objective

340B Program:

A Brief History

The year was 1990…

NASA deployed the Hubble Space Telescope.

One of the largest and most well-preserved Tyrannosaurus Rex skeletons (Sue) was found in South Dakota.

The number one Song was “Hold On” by Wilson Phillips.

Congress created the Medicaid drug rebate program (MDRP) to lower the cost of pharmaceuticals paid for by state Medicaid agencies.

Medicaid Drug Rebate Program (MDRP)

Created as a mechanism to lower the cost of drugs for the Medicaid program.

Drug companies must enter into a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) or drugs are not eligible for coverage in Medicaid.

The MDRP requires manufacturers to pay rebates to state Medicaid programs for covered outpatient drugs.

The rebate amount for a brand name covered outpatient drug is based in part on the manufacturer's "best price" for that drug.

Creation of 340B

A 1992 congressional hearing revealed concerns: the Medicaid Drug Rebate Program caused prices to rise "dramatically" for safety net providers.

Congressional response: extend to safety-net providers the same kind of relief from high drug costs that Congress previously provided to the Medicaid program.

Moving ahead to 1992…

NASA launched Space Shuttle Endeavour.

The Mall of America opened in Minnesota, as the largest shopping mall in the United States.

The number one song was “End of the Road” by Boys II Men.

Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992.

Section 340B requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B.

A Transformation

92

Signed into law by George W Bush

Duplicate discounts prohibited

Tied to Medicaid rebates from the beginning

03

Medicare Prescription Drug Act

Allowed more rural and small urban hospitals

05

Deficit Reduction Act: Children's hospitals added

10

New eligible entities plus unlimited contract pharmacies

Affordable Care Act

Duplicate discount issue grows into managed care

Over

2,500

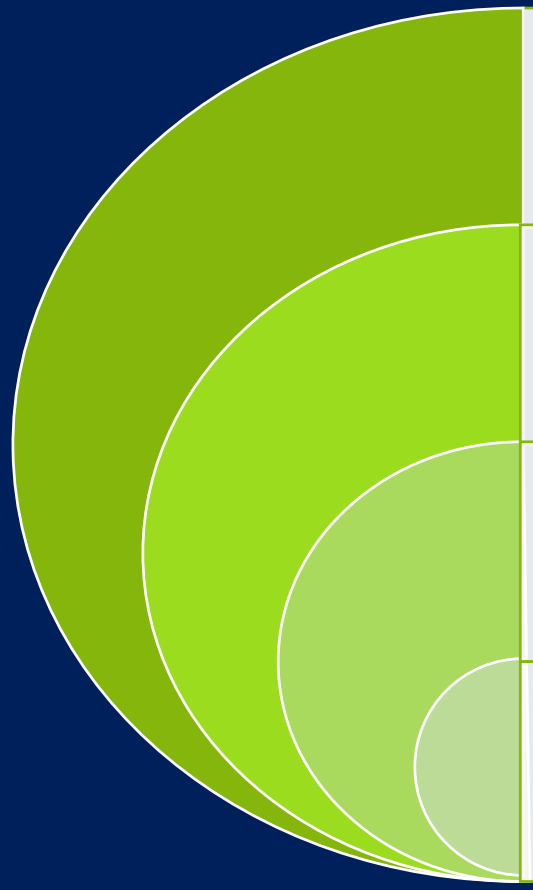
hospitals

25,000

pharmacies

participate in the 340B program which is administered by HRSA

Affordable Care Act



Expanded 340B eligibility to additional categories of hospitals	• Children's hospitals • Clarified eligibility for freestanding cancer hospitals • Sole community hospitals • Rural referral centers • Critical access hospitals (No DSH requirement)
Managed Care	• Medicaid rebates extended to managed care utilization • Drugs purchased under the 340B program are exempt from managed care
Pharmacies	• Expanded contract pharmacies • Created a 340B ceiling price database
Manufacturers and Providers	• Imposed fines on drug manufacturers and providers for 340B program violations

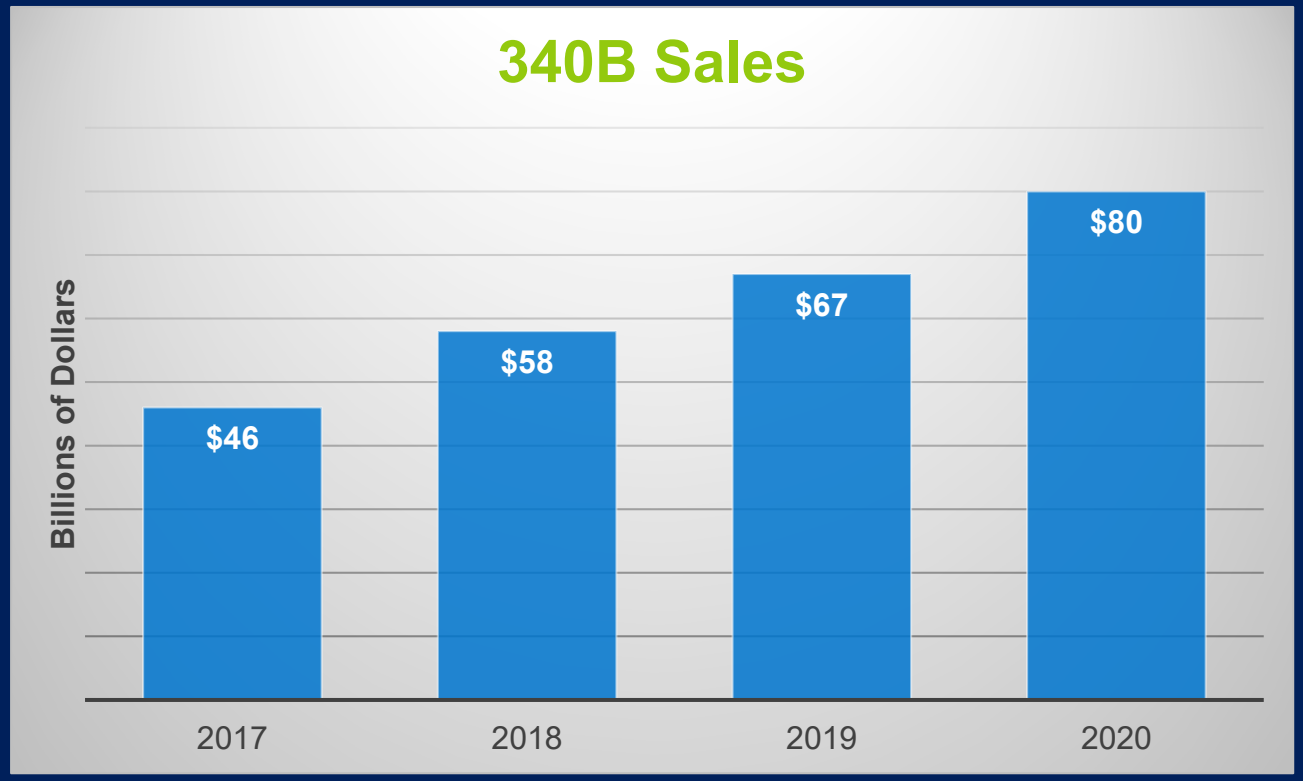
Where are we now?

The 340B program today

Thumbs Up/Down

Have you encountered 340B in your pharmacy practice?

Growing Nationally



Growth = increased scrutiny of benefits, transparency, accountability

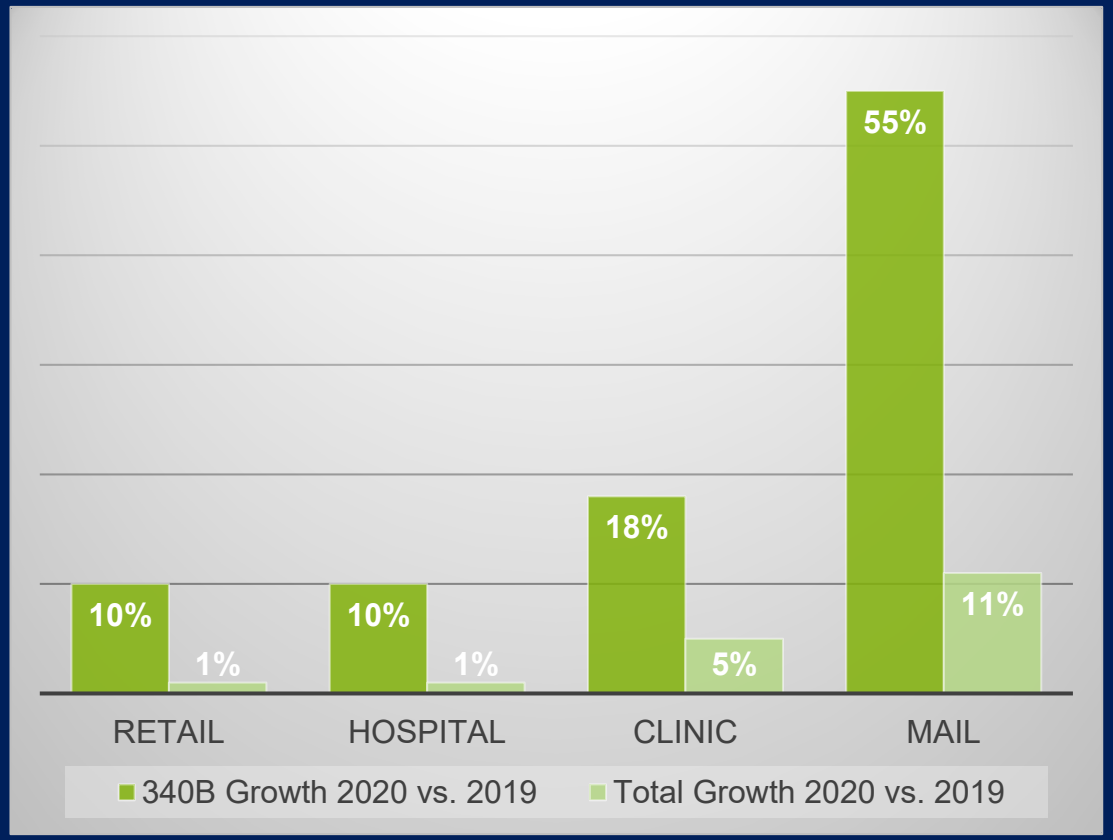
Between 2010 and 2019
340B Covered Entities increased **34%** **from 9,700 to 13,000 CEs**
Contract pharmacies increased **1,669%** **from 1,300 to 23,000**
Between 2017 and 2020
340B Sales have grown **76%**

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

340B Growth is not Uniform

Growth by Disease Category

Growth by Distribution Channel



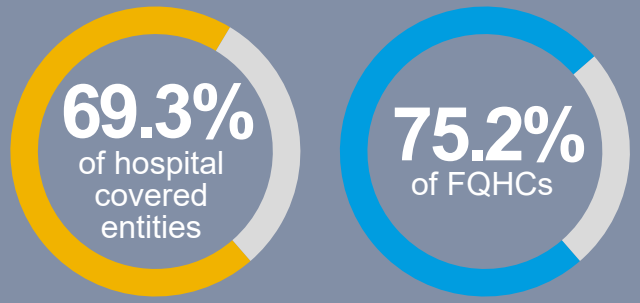
Source: IQVIA: Growth of the 340B Program Accelerates in 2020

340B Contract Pharmacies

Approximately

1/3

of covered entities contract with outside pharmacies



Pharmacies are paid by the covered entity for the dispensing service

- Flat fee per prescription
- Percentage of revenue generated by each prescription

Most Covered Entities also pay Third Party Administrators (TPAs)

Per Prescription

Flat Monthly Fee

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 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

Interactive Question: What Trump-era policy(s) was recently rescinded by the Biden Administration? *(Check all that apply)*

a) Discounted Medicare payment for urban hospitals using 340B product

b) Requirement for FQHCs to pass on 340B discounts on insulin and epinephrine autoinjectors to patients

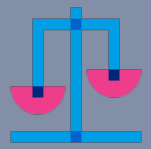
c) Requirement for pharmaceutical manufacturers to deliver 340B drugs to contract pharmacies working on behalf of 340B covered entities

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.

February 2022, Federal courts ruling in manufacturers' favor

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.

Supreme court is expected to release its opinion by **July 2022.**

Navigating the Medicaid and 340B Intersection

Assess

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

Objective

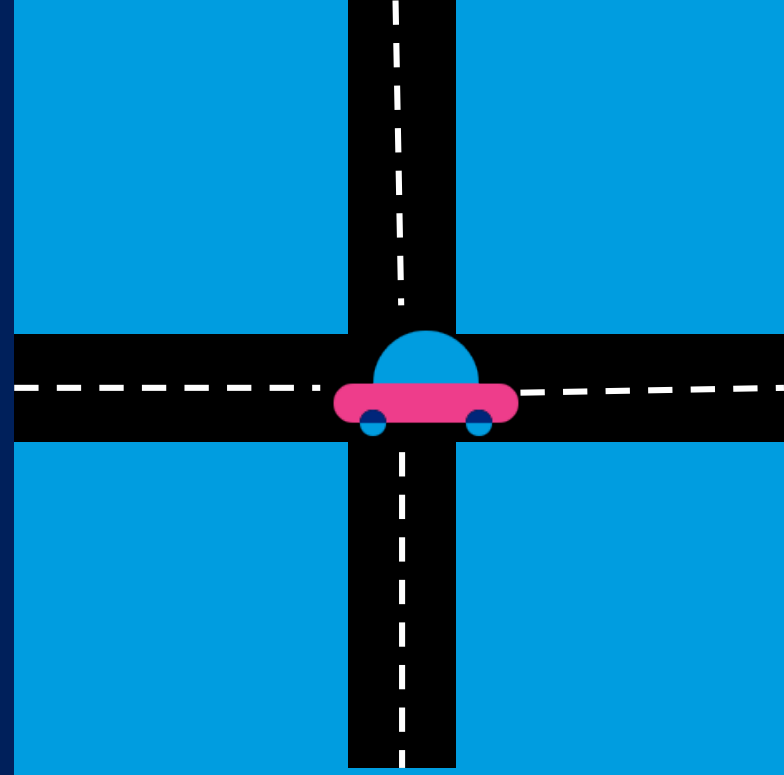
The state must determine the primary policy objective related to 340B.

Implement

The state must take steps to implement the policy.

Select

The state must select a policy consistent with the primary objective.



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.

State Medicaid 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.

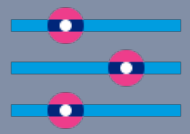
Managed care plans must identify and/or remove 340B claims from data going to the state for rebate purposes.

Agreement Likert Scale

“Achieving 340B duplicate discount compliance is an easy task…”

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

340B State Medicaid Considerations Program Design Considerations

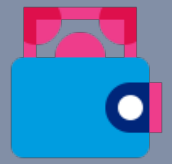


Managed care program

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.

340B State Medicaid Considerations 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

340B State Medicaid Considerations
Understanding the 340B Entity Population

AMCP

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?

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

Likeliness Likert Scale

How likely is it that policy makers are hearing the same concerns from all 340B stakeholders?

Not Likely Slightly Likely Likely Fairly Likely Most Likely

Identifying Your State's 340B Objective

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

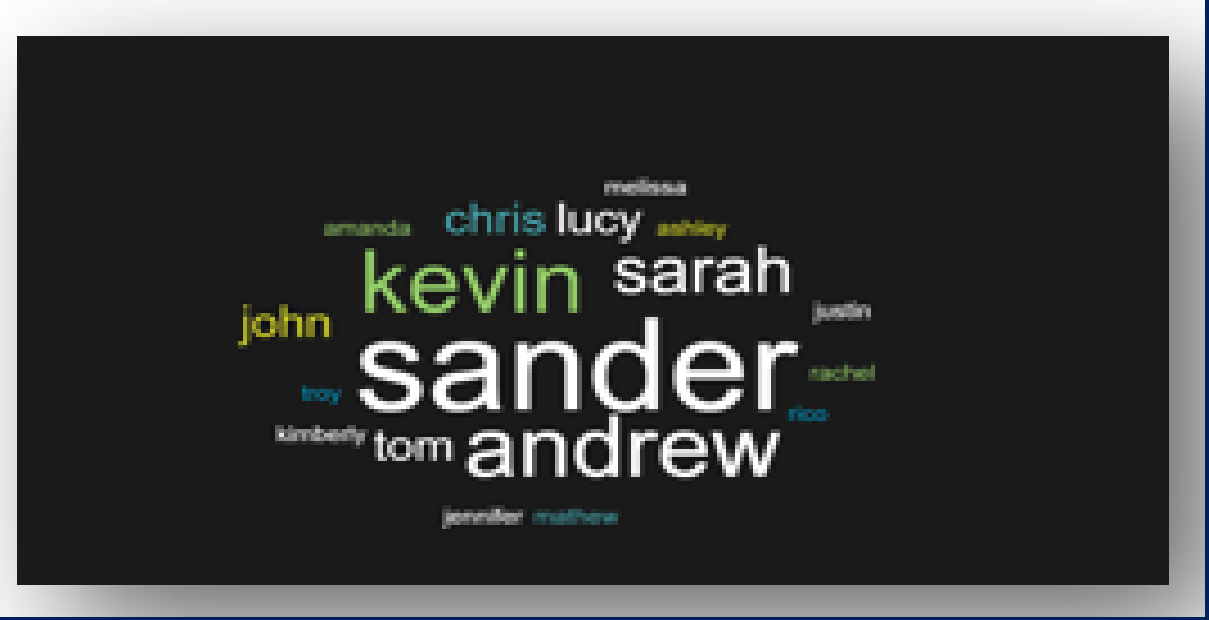
- Ensure members can fill prescriptions easily
- Allow non-Medicaid members access to 340B discounts

Political compromise

- Establish compromise policy that stakeholders can accept

Word Cloud

If you were in charge of a State Medicaid program, what would be your primary objective?



Matching 340B Strategy to Objective

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

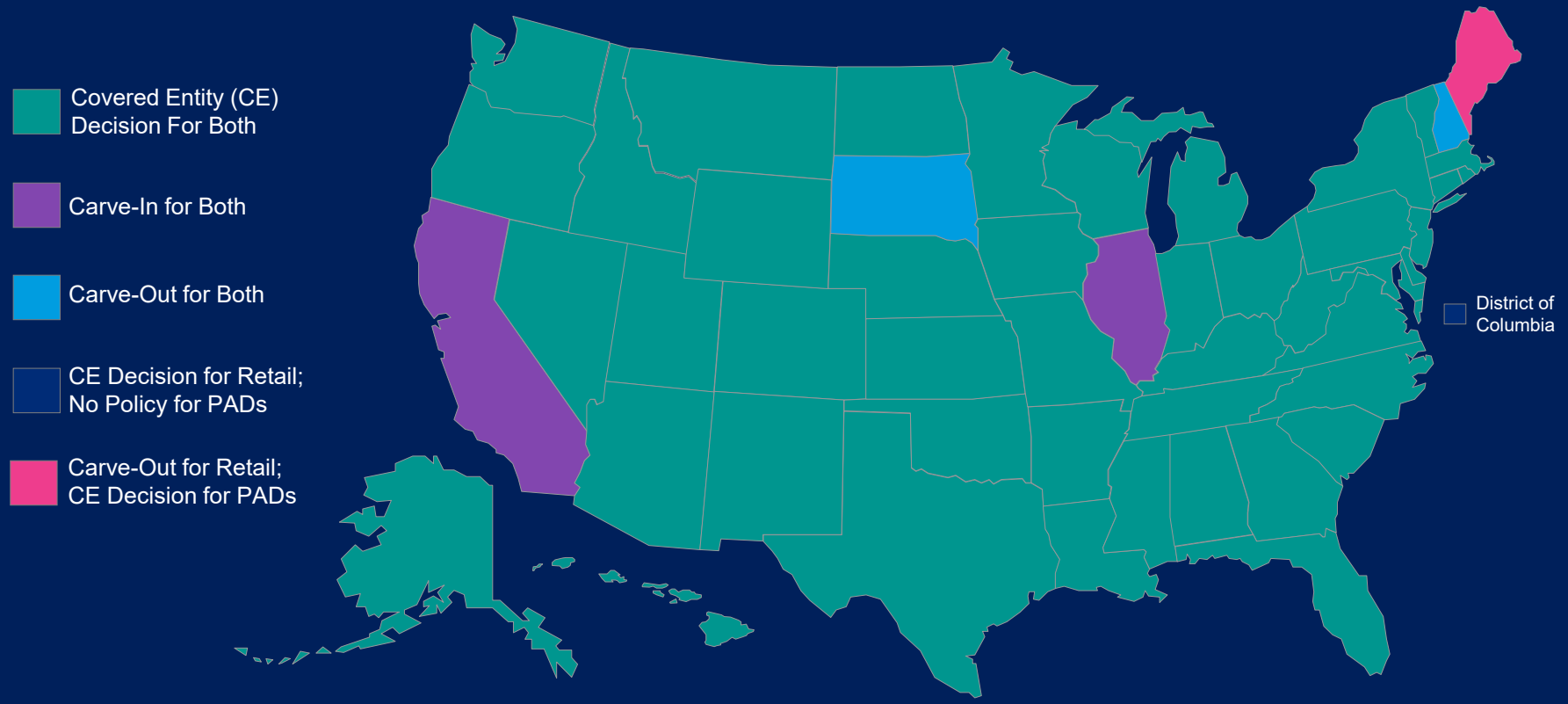
Require pharmacies to identify 340B claims at the point of sale.

May limit the number of pharmacies able to participate.

Require entities to submit utilization reports

Require all 340B entities to submit quarterly utilization reports.

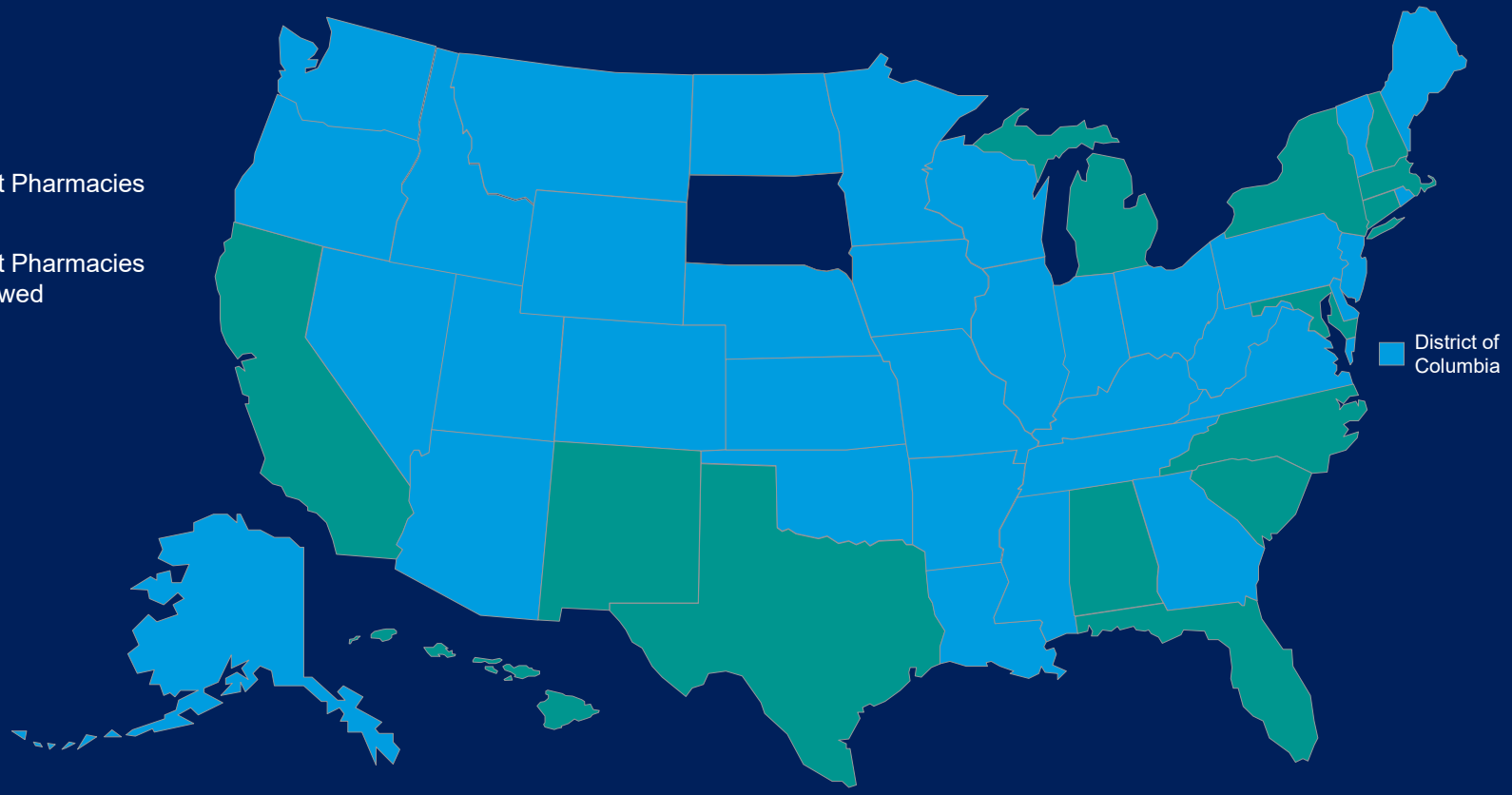
FFS 340B Carve-in or Carve-out by State Retail Pharmacy and PAD Claims



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

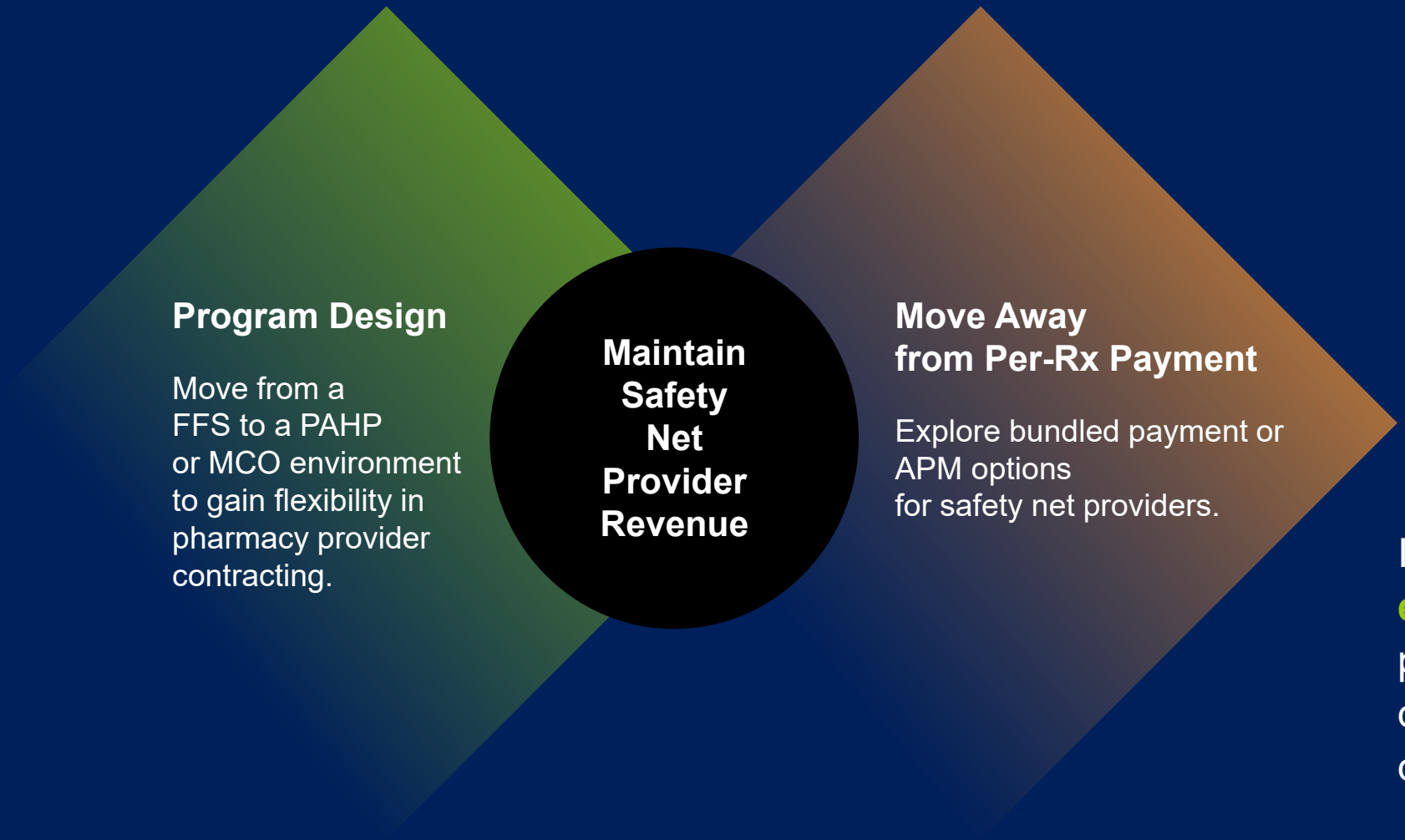
Apply AAC reimbursement to 340B PAD claims

- 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



It may be possible to **maintain** or **enhance** safety net provider payment by implementing a different program or payment design.

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

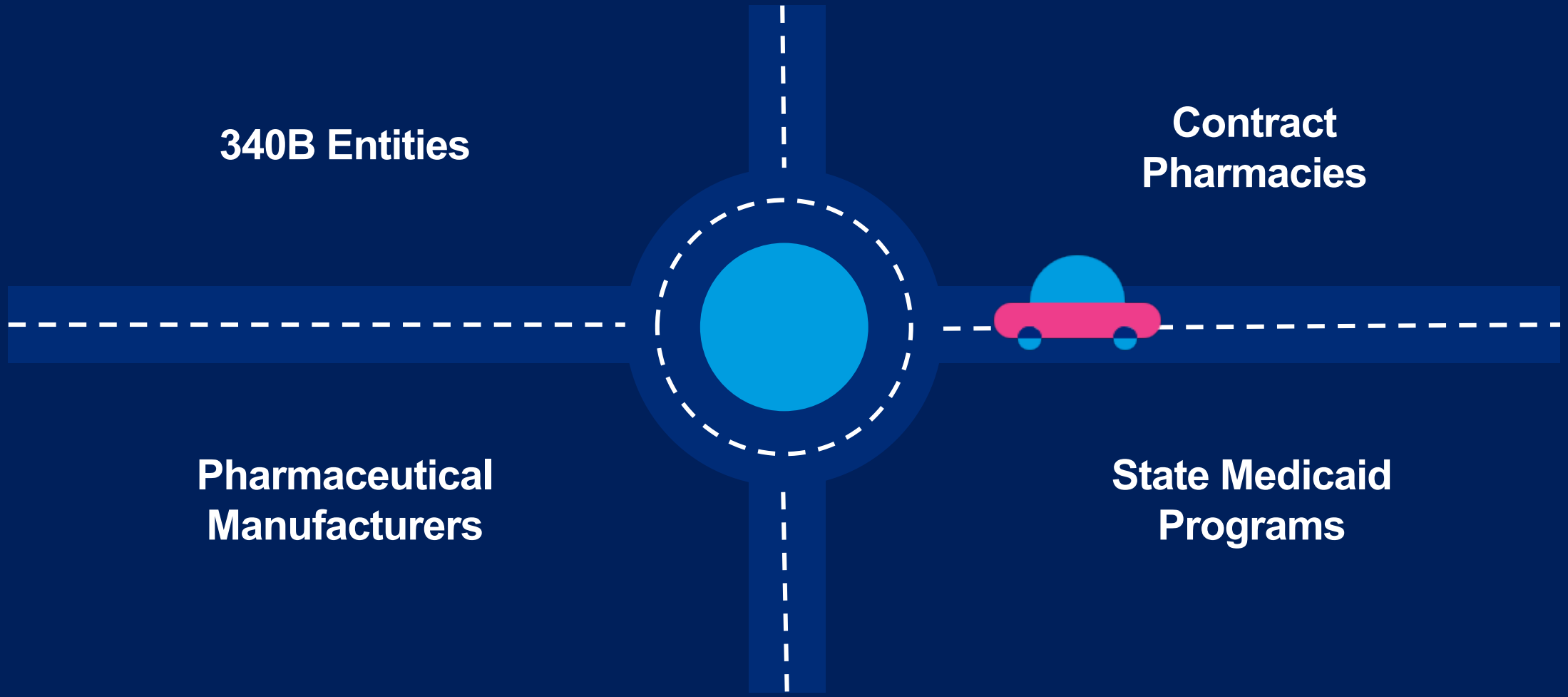
States are not required to pay PADs at AAC.

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

Opportunity for savings on PADs in both FFS and managed care.

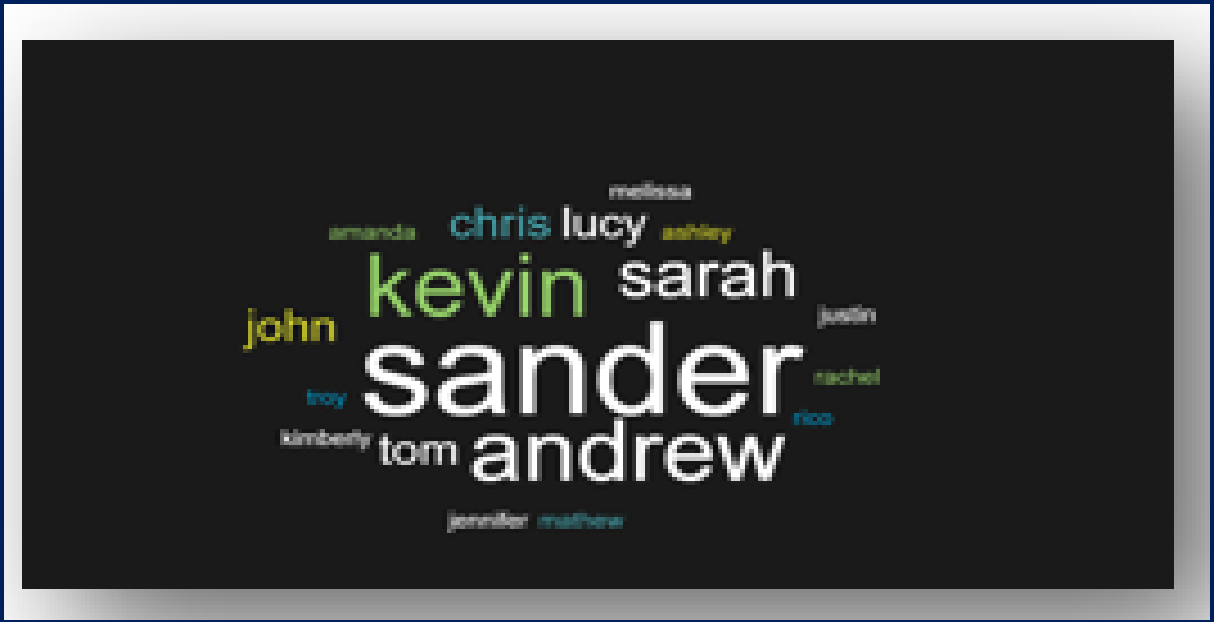
Example: Rate adjustment and requirement for MCOs to pay PADs at shared savings rate.

What is Next in your State's 340B Journey?



Word Cloud

If we are seated next to each other at dinner, what 340B topic would you like to chat about?



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