340B Grantees Conference

Working Lunch

STATE LEVEL 340B ISSUES: The Good, the Bad, & the Ugly

340B GRANTEES SPRING CONFERENCE
WORKING LUNCH
PROVIDED BY

pharmalytiq

PRXP | PHYSICIANS Rx PHARMACIES

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Conflict of Interest Disclosures

- None of the speakers have any conflicts of interest.

Four Featured States

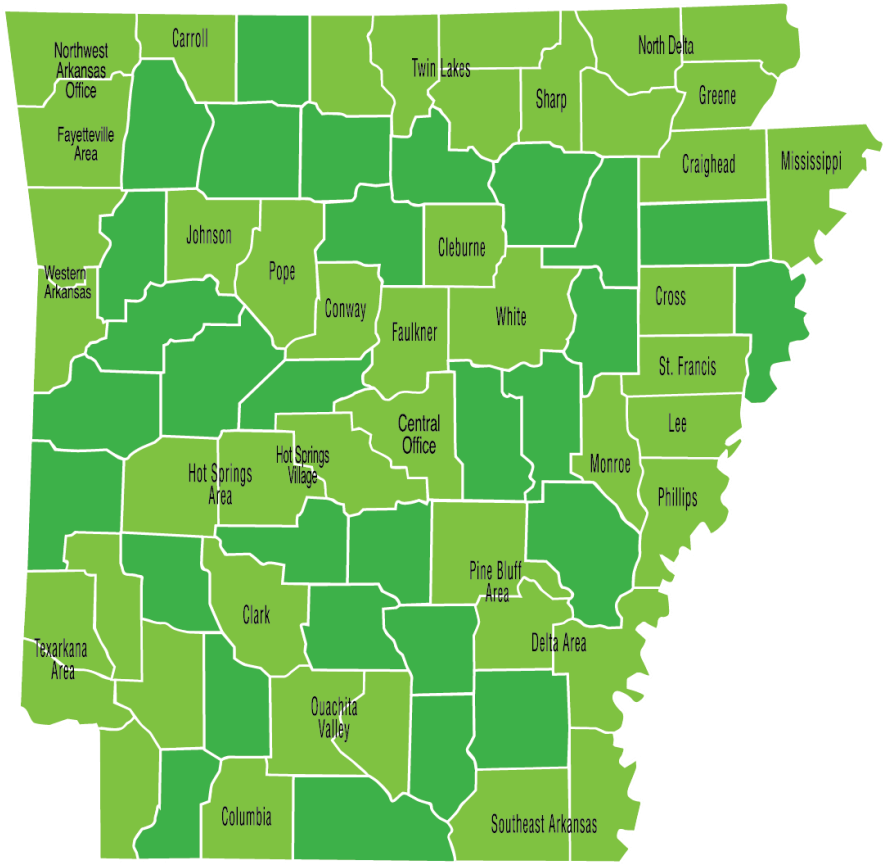
Arkansas – State law prohibiting contract pharmacy restrictions

California – The aftermath of a Medicaid managed care carve-out

New York – Medicaid managed care carve-out

Pennsylvania – Medicaid issues around carve-out, modifiers, etc.

Arkansas



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State Laws to Protect Contract Pharmacy Arrangements

The Arkansas Model

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WHAT IS THE ARKANSAS STORY?

- Arkansas is the FIRST state to enact a law (Ark. Act 1103) prohibiting manufacturers from impeding **distribution** of 340B-priced drugs to contract pharmacies
- Pharmaceutical Research and Manufacturers of America (PhRMA) sued Arkansas Insurance Department on **Sept. 29, 2021**, for two main claims

1) Preemption

Field Preemption: Federal 340B program is comprehensive, leaving no room for state laws

Obstacle Preemption: State law conflicts with new law and Congressional objectives of 340B

2) Dormant Commerce Clause

Extraterritoriality: State law regulates transactions occurring exclusively outside of Arkansas, Commerce Clause of U.S. Constitution

WHAT IS THE ARKANSAS STORY?

- Community Health Centers of Arkansas & Piggott Community Hospital intervened to defend Arkansas' law and safety-net providers (with support f Firm)

- District Court Rules in Favor of State on Preemption/PhRMA Appeals to 8th Circuit
  - **In December 2022, defendants won at district court on motion for summary judgment regarding all issues related to preemption of Act 1103**
  - **PhRMA submitted brief in 8th Circuit, intervenors/defendant submitted response brief, and PhRMA will submit reply brief in May; oral arguments may be scheduled by court; decision could be as early as September**

- Several states introduce bills to protect contract pharmacy arrangements
  - **Connecticut, Louisiana, Missouri, California, etc.**

- **Contact experienced legal counsel to assist with drafting and revising state bills protecting 340B contract pharmacy arrangements against constitutional challenges & manufacturer workarounds**

Implications of Arkansas Litigation?

- **Reduced need for federal legislative compromise by removing manufacturer power over distribution of 340B drugs? Other states are emboldened to pass similar bills?**
- **Increased bargaining leverage to reach a more balanced, covered entity-friendly federal compromise?**
- **Immediate changes in manufacturer contract pharmacy restriction policies to benefit covered entities?**
- **Added protections for specialty contract pharmacy arrangements by prohibiting limited distribution plans that are not approved by FDA or focused on patient safety?**
- **Protects against new manufacturer restrictions, including patchwork of direct manufacturer distribution mechanisms (e.g., Direct Customer Solutions)?**
- **Discourages manufacturers from pushing policies further, such as their newer requests for in-house pharmacy data?**

Implications of Arkansas Litigation?

If HHS/DOJ litigation is unfavorable in all three circuits, is the Arkansas model covered entities' last chance to protect 340B contract pharmacy arrangements?

Louisiana

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California

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California Primary Care Association

Medi-Cal Rx Implementation The Before & After

Presenter: Elizabeth Oseguera

Assistant Director of Policy

- Medi-Cal Rx: How We Got Here
  - Past Advocacy Battles pertaining to 340B / pharmacy services
  - 2019 Pharmacy Transition Executive Order Announced
- Advocacy Efforts: Pushing Against Medi-Cal Rx
  - Legal Efforts
  - Partner Efforts / Stakeholder Efforts
  - Creation of $105M pool of funding for Non-Hospital 340B Health Centers.
- Medi-Cal Rx Implementation
  - January 2022 Debacle
  - DHCS / Magellan Monthly Meetings w CPCA
  - Remaining Issues
  - DHCS' Phased Implementation Plan
- Next Steps: Medi-Cal Rx Implementation, 340B Legislation & Advocacy Efforts
  - Supplemental Payment Program
  - Directed Payments
  - SB 786 (PBM State Protection Bill)

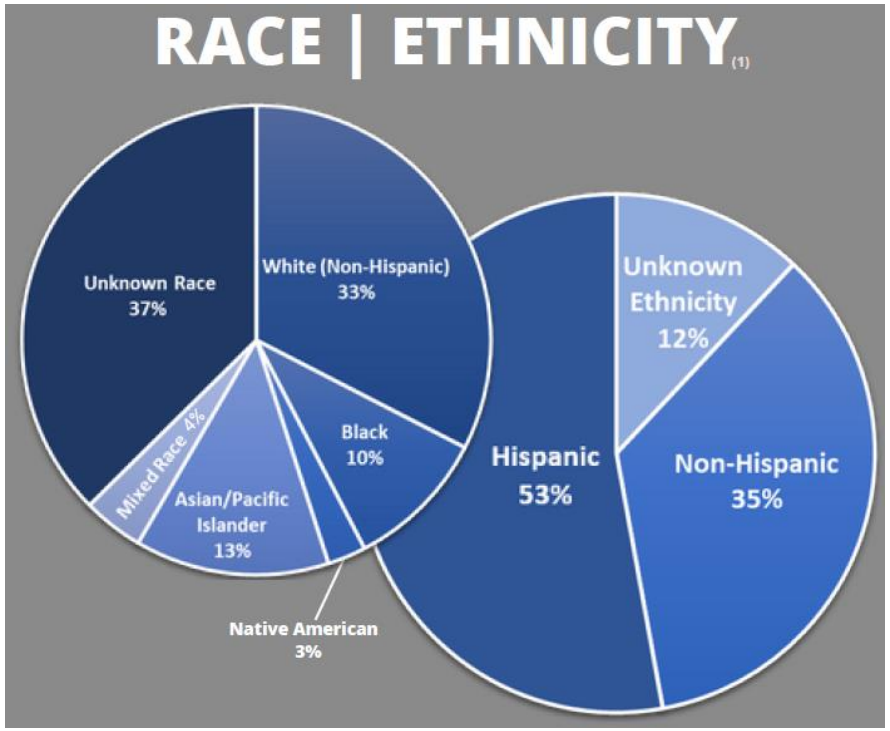
Mission

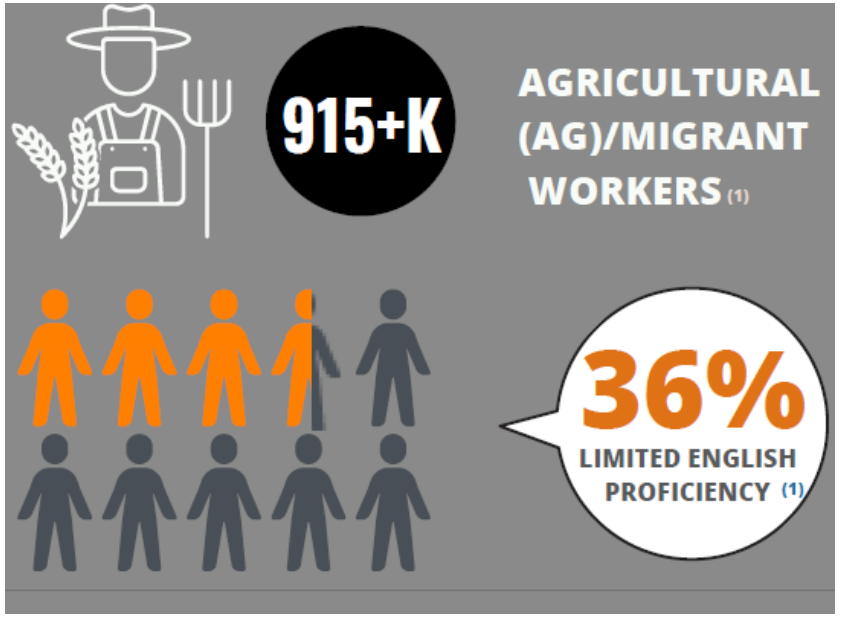
The mission of CPCA is to lead and position community clinics, health centers, and networks through advocacy, education and services as key players in the health care delivery system to improve the health status of their communities.

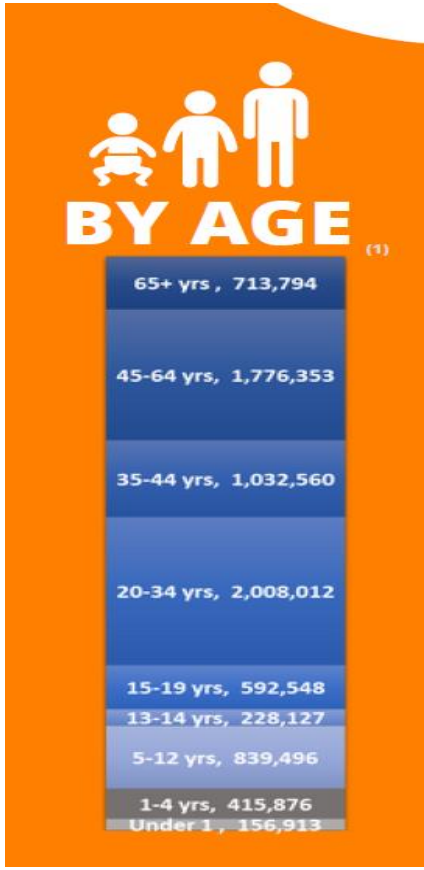
CPCA was founded in 1994 to create a unified, statewide voice for community clinics and health centers.

More than 1,270 Community Health Centers (CHCs) in California

- 1 in 5 CA patients are served by CHCs
- CA CHCs see about 7.8 million patients a year







January 2017: The Department of Health Care Services (DCHS) proposed to require both Medi-Cal FFS and Medi-Cal managed care to bill for 340B drugs at *acquisition cost plus any applicable dispensing fee*.

CPCA legal interpretation: FFS requirements don't apply to Managed Care (Federal Covered Outpatient Drug Rule (COPD Rule) only applies to FFS)

May 2017: DHCS attempted to prohibit the use of contract pharmacies, which would have a huge impact on 340B

January 2018: The Governor's Proposed Budget seeks to eliminate 340B program participation for Medi-Cal fee-for-service and Medi-Cal managed care effective July 1, 2019.

CPCA & local health plans were in conversations w DHCS to address duplicate discount issue, positive progress made. We thought a resolution was reached

Governor Newsom signed an Executive Order (N-01-19) to create a single-purchaser system of drugs in California.

The EO directs DHCS to transition all pharmacy services from Medi-Cal Managed Care to Fee For Service (FFS) by January 2021 (delayed to Jan 2022).

- We explored legislative and legal pushbacks to no avail
- This was done without conversing w stakeholders

Millions of dollars lost in 340B savings by CHCs

- Exploring Legal Avenues
  - CPCA worked with a couple of law firms to review the active legal strategy, review congressional intent argument and look for any other legal mechanisms.
    - Unfortunately, there is not sufficient data / information to support a Congressional intent argument to push against the pharmacy transition. No other legal argument was found.
  - Conduct an analysis of the way in which the State resolved the Magellan conflict of interest issue and determine if there is a basis to challenge the Conflict Avoidance Plan.
    - Worked with local health plans, but attorneys said it was to early to tell. Needed to wait for implementation to occur to find if violations occurred.
- Legislative Engagement
  - CPCA approached CHC champions within the legislature to see if any were willing to push back on the executive order. Given 2019 was the first year of the Governor's term, none were willing.
  - Legislature did assist CPCA in securing $105M to help offset losses of 340B savings incurred through the pharmacy transition.

Loss of 340B savings will impact access to care

- **22** health centers will have to reduce hours of operation and care access
- **1,024** less hours that health centers will be open on a weekly basis across the state
- **3,664** fewer appointments statewide on a weekly basis
- **20** health center organizations will close at least one site of operation
- **36** new health center sites will not open as previously planned

Health center corporations will have to eliminate services

- **45** will be forced to stop subsidizing low cost or free medications to low-income patients.
- **29** will have to eliminate Nutrition and Diabetes education programs/classes
- **25** will have to eliminate population health and chronic care management services for the chronically ill
- **24** will end their education and outreach programs offered to community members
- **24** will be forced to stop subsidizing and paying deductibles related to the cost of care for homeless and low-income patients
- **19** will have to eliminate care coordination for HIV and Hepatitis C patients, as well as STI prevention (PrEP and PEP)
- **13** will have to eliminate transportation vouchers
- **10** will have to eliminate automated systems that electronically dispense prescribed medications & mail-order prescription delivery programs
- **7** will no longer be able to sustain innovative programs that are medication heavy
- **8** will have to close their food pantries, harming the communities access to nutritional food
- **3** will have to close legal clinics
- **2** will have to eliminate transitional housing programs

Stakeholder Engagement

CPCA worked with partnering associations (CHA, Local Health Plans, public hospitals) to try and advocate against the transition. We were successful in creating a stakeholder process, but we couldn't stop the transition.

By end of 2021, partners just wanted it to be implemented and weren't as strongly in opposition as CHCs were.

Creation of $105M Pool of Funding

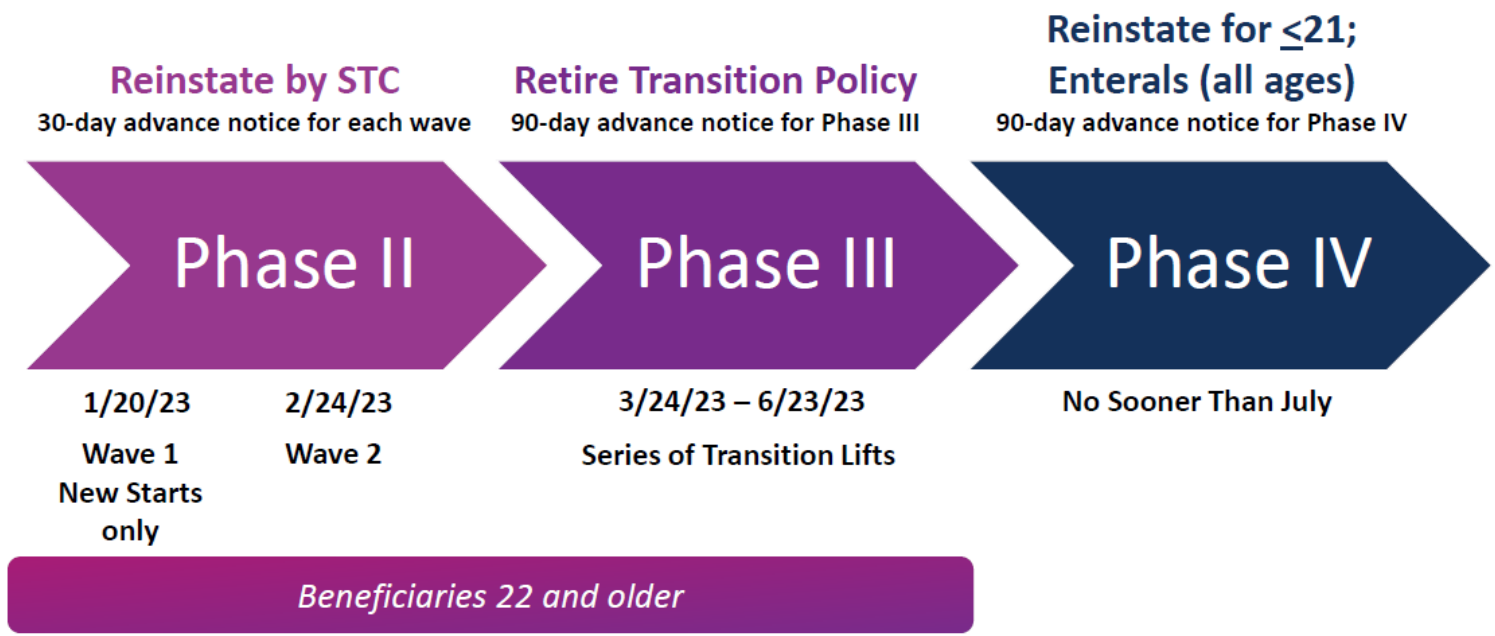
CPCA strongly advocated against the transition and were able to show that CHCs would lose as much as $150M if the transition was implemented.

After further analysis we believe it could be as high as $205M

DHCS wanted to 'validate' the data, so they ran their own survey, which created the $105M

Legislative advocacy was key in ensuring the $105M made it into final state budget.

Reinstatement Phase II – Phase IV



- CPCA worked closely with Magellan to prepare CHCs for Medi-Cal Rx implementation.
  - Magellan staff joined our 340B Peer Network meetings to help answer member questions / concerns
  - CPCA worked closely w Magellan to develop an FAQ document that responded to member questions.
  - CPCA has collaborated with Magellan / DHCS to offer training to CHC staff, particularly CFOs and pharmacy staff to help respond to issues post implementation

- CPCA Resources:
  - CPCA FAQ Document (created in partnership with Magellan & DHCS)
  - CPCA & CCALAC's Pharmacy Transition Checklist
  - Factsheet: How to Conduct a Cost Analysis in Preparation for Medi-Cal Rx

Medi-Cal Rx / Pharmacy Transition officially went into implementation on Jan 1, 2022

In Feb DHCS removed PA requirements given long backlogs, but they are looking to reinstate these through a phased plan (more info in future slides)

MANY issues within the first few months of implementation

- Long wait times, call back message issue / wrong call back number used
- How to share claims data with plans if your CHC carves in pharmacy services into their PPS rate
- Getting kicked out of Medi-Cal Rx portal and unable to access system given password lock out
- Adding more OTC drugs to CDL & Shortages on drugs found on CDL
- Reimbursement Levels – How are they calculated? Some CHCs getting less than AAC while others getting more.
- Clarification on billing, how should Medi-Medi patients be billed.
- Issues finding patients in the system
- Obtaining medical supplies as a pharmacy benefit
- How can patients access medications if they are out of state on vacation or caring for family member?
- Issues with rejection of claims / rejection codes
    - Concerns w PA Reinstatement & Reject Code 80

- CPCA will continue to work w members to capture issues to bring to Magellan / DHCS

- CPCA is also in communication w local health plans, CMA, CHA and public hospitals regarding issues w transition (meet bimonthly)

- CPCA has monthly meetings w DHCS / Magellan
  - CPCA invites CHCs who have issues that will be covered during the discussion with DHCS / Magellan to join the call
  - CPCA partnered with CMA and Magellan / DHCS to host trainings:
    - Medi-Cal Rx Reinstatement - A Phased Approach on August 18 & Related FAQs

- CPCA will continue to work w members to capture issues to bring to Magellan / DHCS
  - CHCs: **Report Issues around Medi-Cal Rx Implementation HERE**

- CPCA is also in communication w local health plans, CMA, CHA and public hospitals regarding issues w transition (meet bimonthly)

- CPCA has monthly meetings w DHCS / Magellan
  - CPCA invites CHCs who have issues that will be covered during the discussion with DHCS / Magellan to join the call
  - CPCA partnered with CMA and Magellan / DHCS to host a training:
    - Medi-Cal Rx Reinstatement - A Phased Approach on August 18 & Related FAQs
  - CPCA hosted its last training with Magellan / DHCS on Dec 13


Medical services
Community health
Counselling and support
Primary Health Services
Continuing care
Health promotion

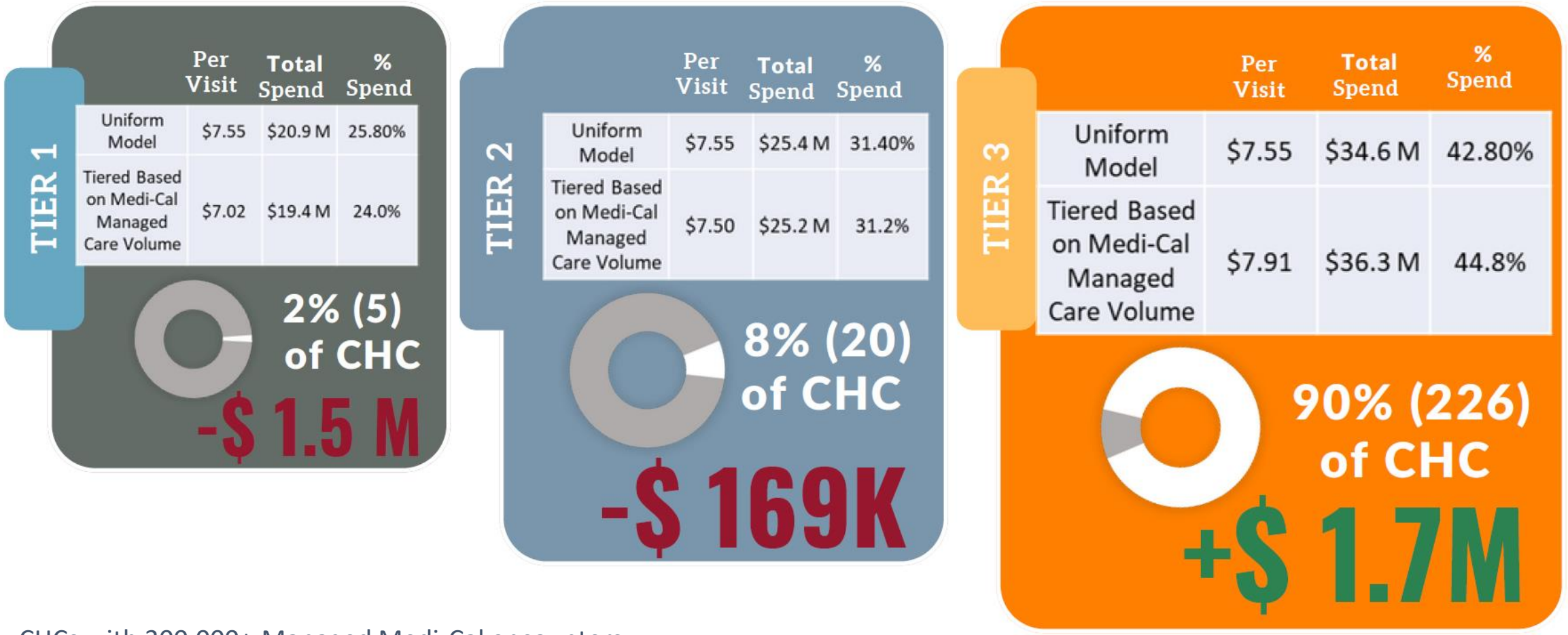
- CPCA & CHCs successfully advocated to create $105M Pool of Funding
  - Governor Newsom has committed to keep these funds available during his tenure
  - Not a perfect approach, but a start

- Currently funds are being distributed under a Supplemental Payment Program (SPP)
  - Based on utilization on PPS billable visits (Code T1015 visits are eligible) – Easiest to set up
  - Took about 2 years to set up the program and get funding distributed to CHCs (SPP rate is about $6)
  - Funds created due to loss of 340B savings via Medi-Cal Rx, but funds not tied to pharmacy
  - Inequitable distribution: Bigger CHCs w larger volume get more funding than smaller CHCs

- Moving to Directed Payment Structure
  - More Flexibilities: Can Use “tiers” / “class of providers” to more equitably distribute funding
  - Ties to quality measures: Helping to prove value of having funds remain at CHCs
  - Avoids reconciliation issues (Goal: CHCs get a fixed rate per claim, offset by quality pool incase utilization increases decreases)

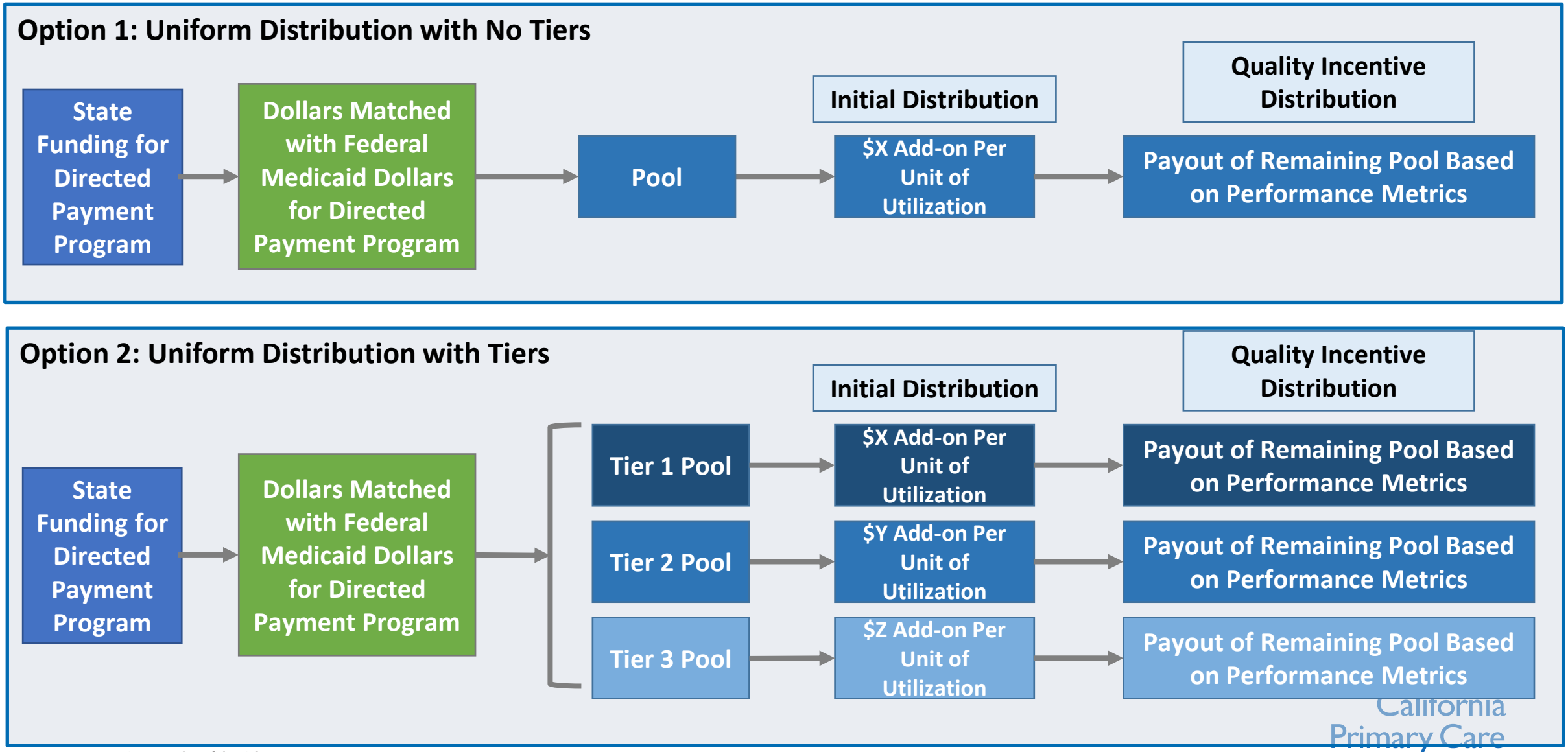
- Directed Payments Pros & Cons:
  - Offers autonomy in how to create the payment model (more flexible)
  - Payments would depend on MCO encounter data
  - 12-24 month delay in accessing the 10% of the quality measures pool for the first year.
  - Can use the tiers to create more equitable distribution of funds
  - Ability to capture data measuring impacts to overall health & support our advocacy
  - Works for APM and non APM CHCs
  - Applies only to Managed Care patient visits
    - However you can reach your quality measures benchmarks using data for all your patients

- SPP Pros & Cons:
  - Requires yearly SPA approvals from CMS (30-day comment period applies)
    - If DHCS delays submitting the SPA then CHCs would see delay in fund rollout.
  - No ability to control where funding goes (creates imbalance in fund distribution)
  - CHCs can access SPP for all PPS visits, no other action needed
  - Unable to gather data showing value of funds at CHCs
  - May not work for CHCs in the APM
  - We've created a model for this, which should streamline payments in the future
  - Could be harder to obtain CMS approval in future years since data collection can't be built into the model.



Tier 1: CHCs with 300,000+ Managed Medi-Cal encounters
Tier 2: CHCs with 100k to 299,999 Managed Medi-Cal encounters
Tier 3: CHCs with fewer than 100k Managed Medi-Cal encounters

MODELING - EXAMPLE PROGRAM DESIGN



California Primary Care ASSOCIATION

- CPCA ran a state 340B protection bill (SB 939) to help CHCs maintain the remaining 340B savings being captured through privately insured patients
  - Bill included a PBM and Manufacturer section
  - We pulled bill given strong opposition from Big Pharma
  - Pharma claimed they would support bill if they were removed

- SB 786 (Portantino)
  - Being sponsored by AHF
  - Only targets PBMs, who are neutral on the bill
  - Big Pharma has an oppose unless amended position because they want to require claims data sharing on Ces
  - CPCA is working closely w AHF on bill

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New York

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New York

- History
- Proposed Solutions
- Outcome?
- Lessons Learned

History

- April 1, 2020
  - Move Medicaid outpatient prescription benefit from managed care to fee-for-service → loss of 340B
  - Effective April 1, 2021
- April 1, 2021
  - Stakeholders secure a 2-year implementation delay
- April 1, 2023
  - Budget delayed
  - “Carve-out” implemented anyway

Solutions

- Repeal or another delay
- Compromise
  - Keep in managed care
  - NADAC + DF, closed pharmacy network prohibition
  - Single statewide PDL → leverage state purchasing power
  - PBMs data processing only
  - Percentage-based CP professional fees prohibited
  - Future: clearinghouse and discriminatory reimbursement prohibition
- Carve-out + "Reinvestment fund"
- Litigation

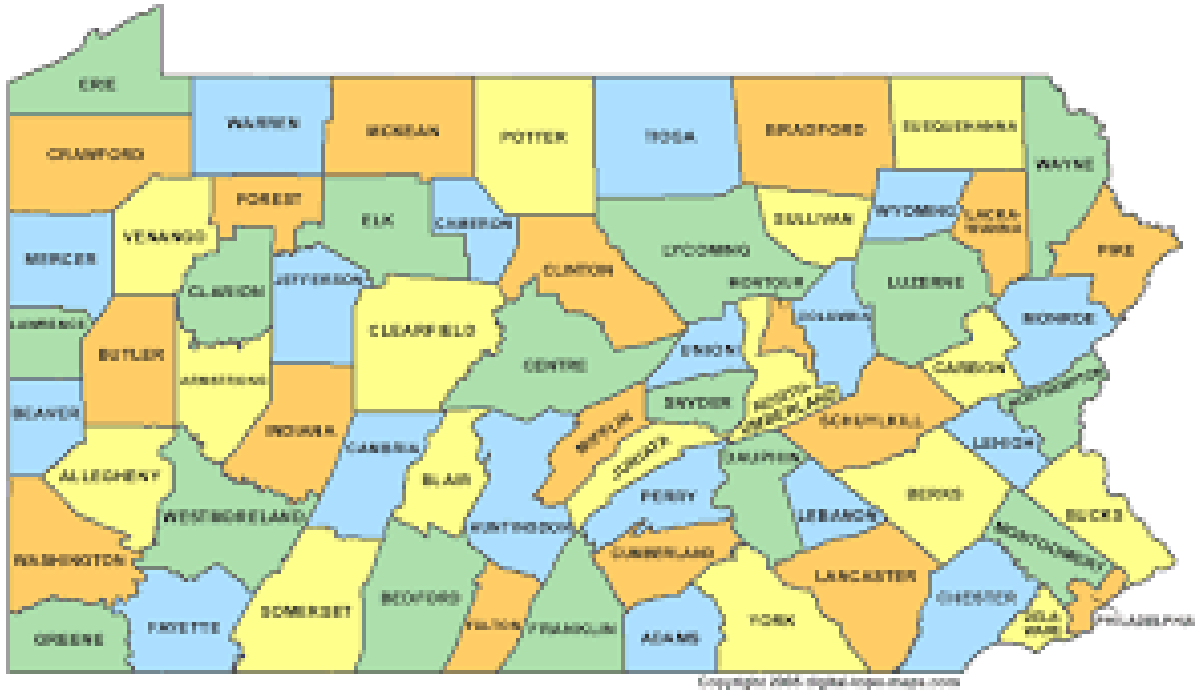
Outcome?

- DOH went forward April 1, 2023
- "Reinvestment fund"
  - ➢ No clarity, no timeline
  - ➢ No mechanism articulated for grantees
  - ➢ Need CMS approval
- Budget's not done- *"it ain't over 'til it's over"*
- Late-breaking?

Lessons Learned

- Grassroots coalition
  - Grantees
  - Hospitals
  - Unions, other community organizations
  - Plans
  - Friends in California
- Pharmacy owners/chains vs. contract pharmacies
- 340B ignorance
  - Pharma talking points
- State failure to capture all statutory rebates
- ACA – managed care – federal match

Pennsylvania



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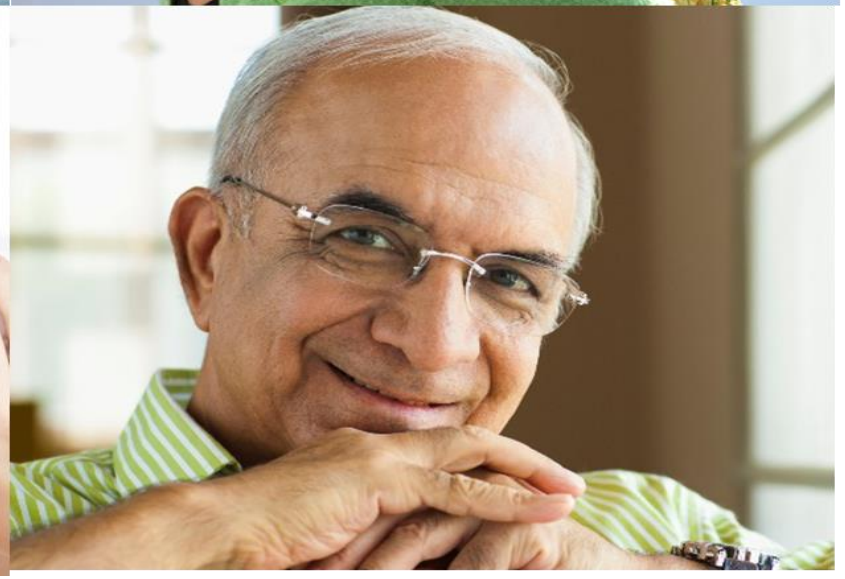

STATE-LEVEL 340B ISSUES:

PRESENTED BY
NICOLE CONEYBEER,
CORNERSTONE CARE

340B Grantees Spring Conference
May 3-5, 2023
New Orleans, LA

340B Grantees Conference

BACKGROUND

MA Bulletin 99-13-08 published on May 16, 2013, effective May 1, 2013,

- No mention of the use of contact pharmacies with MCO patients
- Some FQHCs have been securing 340B savings through contract pharmacies for MCO patients
- In 2018, DHS partnered with several FQHCs to put together a pilot project to ensure there were no duplicate discounts. The project was never completed.

MA Bulletin 01-22-78 published at 4:45 on Dec. 22, 2022, with implementation date of Jan. 1, 2023

- Prohibits use of contract pharmacies for 340B drugs
- PACHC notified members via email on Dec. 22
- DHS Medicaid director outreach to PACHC in response indicating bulletin does not mark a change in policy
- PACHC President and CEO follow-up email to DHS Medicaid director outlining PACHC concerns

CONCERNS RELAYED TO DHS

PACHC and DHS meet on January 4, 2023 to relay concerns with the “new” policy

- First time in writing DHS says contract pharmacies excluded from 340B
- Use of Medicaid Exclusion File as sole resource for DHS to exclude drugs from rebate
- DHS unwillingness to consider processes covered entities have in place with contract pharmacies to identify 340 eligibility/Rx

PACHC surveys FQHCs to determine program impact

PACHC shares the impact statements with DHS

IMPACT AND NEXT STEPS

- DHS rescinds MA Bulletin 01-22-78: 340B Drug Pricing Program
- DHS convened a workgroup of representatives of covered entities and other stakeholders for the purpose of developing potential solutions that will allow for the appropriate identification and recognition of medications dispensed to eligible 340B patients through contract pharmacies.
- At this first meeting, Sally Kozak, OMAP Deputy Secretary, reiterated that the goal of the Dept. is to ensure covered entities can access the 340B savings through contract pharmacies under Medicaid Managed Care.

WORKGROUP OPTIONS

Through the DHS 340B Workgroup meeting, three options for identification of 340B drugs dispensed to MA MCO members were discussed. To date, DHS has not committed to implementing any of the options.

- **Option #1**: When 340B is known at POS, pharmacy includes 340B indicator, i.e., currently 20 code, on claims. If not known at the Point of Sale (POS), no indicator included on claims at POS. After claims are reconciled by the Covered Entity (CE) and reported back to the pharmacy, the pharmacy voids original claim and resubmits with the 340B indicator for confirmed claims.
- **Option #2:** The contract pharmacy would submit no indicators on any claims at POS. All claims submitted as non-340B. The CE then reconciles all contract pharmacy claims to identify 340B eligibility. The CE submits a file identifying all 340B claims to DHS for exclusion from drug rebate. This is the method used during the 2018 pilot. It was cumbersome and manual for both the CEs and the Department. For this to work, a streamlined and automated process is needed for efficiency. The suggestion is to model the file on the current ESP file requirements.
- **Option #3:** The MCOs and/or their subcontracted PBMs would establish a method for identifying 340B eligible drug claims. The MCOs would then transmit the 340B information to DHS for applicable drug claims.

DHS SHARES “BRIEFING DOCUMENT"

- Proposed MA Bulletin on 340B and MEF: On April 19, the PA Department of Human Services (DHS) shared a “**briefing document**” with its Medical Assistance Advisory Committee (MAAC) in preparation for the April 27 MAAC meeting to inform providers of the procedures for dispensing 340B Drug Pricing Program (340B-purchased drugs) to Medical Assistance (MA) Program beneficiaries and the implementation of the MA Program’s 340B Drug Exclusion List.
- The briefing document proposes an implementation date of July 1, 2023.
- The comment deadline on the **briefing document** is May 4, 2023.

DHS SHARES “BRIEFING DOCUMENT" (CONTINUED)

- The document outlines the process DHS proposes to ensure notification when a drug is purchased under the 340B program is dispensed to a Medical Assistance beneficiary in the managed care delivery system. DHS proposes to require inclusion of a claims modifier on all claims billed to MA managed care organizations (MCOs) for 340 drugs dispensed to MA beneficiaries. In addition, the MA program has developed a list—referred to as the 340B Drug Exclusion List—of drugs for which 340B covered entities and contact pharmacies may only dispense non-340B purchased drugs.
- DHS indicates that the MA Program will continue to use the Medicaid Exclusion File to identify 340B purchased drug claims paid by the FFS delivery system to 340B covered entities and will not invoice drug manufacturers for Medicaid rebates on these drugs

CONCERNS WITH “BRIEFING DOCUMENT"

- PACHC has serious concerns about how the state's proposal would impact PA's medically-underserved patients and the safety net providers who care for them, and sincerely hope that the state will reconsider its proposal.
- PACHC is asking DHS to consider the clearinghouse options that were mentioned as part of the 340B workgroup meetings. Under this model – which has been used successfully for years by Oregon and Hawaii Medicaid – covered entities send a Medicaid contractor a “flat file” that lists every Medicaid claim filled with 340B drugs during a recent time period (e.g., the past two weeks, or month).
- Adding the modifier requirement to in-house pharmacy 340B transactions will add a tremendous amount of additional staff time and effort to a system that is already working. This new requirement would be particularly burdensome for a covered entity whose pharmacy is open to the public (aka individuals who aren’t patients of the covered entity). This may result in covered entities closing their pharmacies to the public.

340B Grantees Conference

Questions?

NPS PHARMACY

HUDSON HEADWATERS 340B

Seeking topics for tomorrow peer-to-peer roundtables

To propose a topic, please:

- **Write it on the flipchart near the registration table.**

OR

- **Text Colleen at 301-906-5958**

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NPS PHARMACY

HUDSON HEADWATERS 340B

Session Survey
Session #13
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