Draft date: 7/15/25

2025 Summer National Meeting
Minneapolis, Minnesota

PRESCRIPTION DRUG COVERAGE (B) WORKING GROUP
Monday, August 11, 2025
11:30 a.m. – 12:30 p.m.
Hilton Minneapolis—Grand Ballroom D—Level 3

ROLL CALL

Joylynn Fix, Chair	West Virginia	Amy Hoyt	Missouri
Ashley Scott, Vice Chair	Oklahoma	David Dachs	Montana
Dusty Smith	Alabama	Cheryl Wolff	Nebraska
Kayla Erickson/ Sarah S. Bailey/ Molly Nollette	Alaska	Ralph Boeckman/ Erin Porter	New Jersey
Erica Bowsher	Arizona	Renee Blechner/ Sahar M. Hassanin	New Mexico
Amy Seale	Arkansas	Sylvia Lawson/ Gail A. Ross	New York
Lena Bahar/ Michael Shanahan	Connecticut	Robert Croom/ Charles Whitehead	North Carolina
Howard Liebers	District of Columbia	TK Keen	Oregon
Sheryl Parker/Samantha Heyn	Florida	Lindsi Swartz	Pennsylvania
Shannon Hohl	Idaho	Carlos Vallés	Puerto Rico
Matthew Pickett	Illinois	Scott McAnally/Jud Jones	Tennessee
Andria Seip	Iowa	Tanji J. Northrup	Utah
Vicki Schmidt/Julie Holmes	Kansas	Jennifer Kreitler/Kim Tocco	Washington
Daniel McIlwain	Kentucky	Lori Luder	Wisconsin
Frank Opelka	Louisiana	Lauren White	Wyoming
Joe Stoddard	Michigan		
Norman Barrett/T.J. Patton	Minnesota		

NAIC Support Staff: Jolie H. Matthews

AGENDA

1. Consider Adoption of its May 19 and Spring National Meeting Minutes — Attachment A
   —Joylynn Fix (WV)

2. Hear Presentations on Alternative Funding Programs (AFPs)
   —Katelin Lucariello (Pharmaceutical Research and Manufacturers of America—PhRMA) and Theresa Alban (Cystic Fibrosis Foundation—CFF)

3. Discuss Any Other Matters Brought Before the Working Group
—*Joylynn Fix (WV)*

4. Adjournment

Agenda Item #1

Consider Adoption of its May 19 and Spring National Meeting Minutes—*Joylynn Fix (WV)*

Draft: 6/18/25

Prescription Drug Coverage (B) Working Group
Virtual Meeting
May 19, 2025

The Prescription Drug Coverage (B) Working Group of the Regulatory Framework (B) Task Force met May 19, 2025. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Kayla Erickson, Sarah S. Bailey, and Molly Nollette (AK); Dusty Smith (AL); Amy Seale (AR); Lena Bahar and Paul Lombardo (CT); Howard Liebers (DC); Sheryl Parker (FL); Andria Seip (IA); Shannon Hohl (ID); Adam Flores and Eric Anderson (IL); Craig VanAalst (KS); Daniel McIlwain (KY); Kallie Ruggiero Somme and Nina Turner (LA); Joe Stoddard (MI); Norman Barrett (MN); Amy Hoyt (MO); David Dachs and Matthew Eberhardt (MT); Robert Croom and Charles Whitehead (NC); Cheryl Wolff (NE); Erin Porter and Ralph Boeckman (NJ); Sylvia Lawson and Gail A. Ross (NY); Alejandro Amparan (NM); Colette Hittner (OR); Lindsi Swartz (PA); Scott McAnally (TN); Tanji J. Northrup (UT); Jennifer Kreitler and John Kelcher (WA); Darcy Paskey (WI); and Lauren White (WY).

1. Heard Presentations from AHIP, the HIV+Hepatitis Policy Institute, and The AIDs Institute on Copay Accumulators

Fix said the purpose of the meeting was to hear presentations on the copay accumulator issue. Sean Dickson (AHIP) presented the effects of copay coupons on health insurance markets. He first discussed pharmacy costs and impacts, explaining that for every dollar spent on health care, 24 cents is spent on prescription drugs. He noted that specialty drugs account for 51% of total pharmacy spending, even though less than 2% of patients use specialty drugs. Dickson next discussed copay coupons and the commercial market. He said AHIP believes copay coupons discourage price competition and increase brand utilization. He discussed information supporting this belief. Dickson said banning copay coupons would decrease premiums and total cost-sharing, including lower cost-sharing for consumers who do not use coupons. He noted a study of coupon costs for multiple sclerosis (MS), finding that prohibiting coupons would reduce plan costs by 7.6%. The study also found that cost-sharing for MS patients using drugs without manufacturer coupons would fall by 6% due to lower total spending and greater price competition. Dickson discussed how higher health care costs due to manufacturer coupons impact all Americans. He explained how copay coupons lead to adverse selection and introduce bias by health condition and how health plans leverage coupon accumulators and maximizers to encourage price competition, reduce adverse selection, and treat patients equally. He also discussed coupons and manufacturer revenues.

Carl Schmid (HIV+Hepatitis Policy Institute) discussed how patient out-of-pocket costs have increased over the years, with most of the increase related to non-retail drugs. He noted that as out-of-pocket costs have risen, patients starting new therapy have increasingly abandoned their prescriptions at pharmacy counters. Schmid discussed how manufacturer copay assistance cards have helped consumers to be able to afford their prescription drugs, particularly for those consumers with certain conditions, such as those living with HIV. He also discussed the impact of copay accumulator adjustment and copay maximizers on patient costs in the commercial insurance market.

Schmid discussed the status of the 2021 Notice of Benefit and Payment Parameters federal rule, which permitted insurers to implement copay accumulator adjustment policies (CAAPs), allowing them to not count drug manufacturer copay assistance toward a beneficiary's out-of-pocket costs. He explained that the federal rule was invalidated in 2023, which left a previous 2020 rule in place. Under the 2020 rule, insurers could only use copay accumulators in limited circumstances. Schmid noted that the federal government has declined to enforce the 2020 rule's requirements and has promised updated rulemaking. He said no additional guidance has been provided to date, and insurers are violating the 2020 rule's requirements. Schmid thanked the NAIC for its recent

letter to the Trump Administration asking for clarity on the CAAP issue. He said that in the meantime, some states have moved forward and enacted laws prohibiting insurers from using copay accumulators under certain circumstances.

Stephanie Hengst (The AIDS Institute) provided an overview of how health insurance policies and plan design can help or hinder access to care for individuals with serious, complex, and chronic conditions. She discussed how patient out-of-pocket costs are becoming untenable, citing such costs for the average Silver health insurance marketplace plan in 2025. She noted that prescription drug costs are particularly hard for patients with serious, complex, and chronic conditions to afford because many of the drugs they are prescribed are assigned to the specialty tier, which means they are subject to coinsurance, which, on average, is about 40% after the patient's deductible is met. She said that, as Schmid discussed, this is why individuals with serious, complex, and chronic conditions need financial assistance from drug manufacturers or charitable foundations to afford their prescribed medications.

Hengst discussed The AIDS Institute's "Our Loss, Their Gain: Copay Accumulator Adjustment Policies in 2025" report and its findings on state report cards with respect to CAAPs. She discussed how the information in the report is compiled by reviewing plan documents available during open enrollment and looking for any indication in the language for copay accumulators, copay maximizers, or any sort of copay diversion policy in place. Hengst said that as part of that review, The AIDS Institute issues report cards for each state. The report cards provide a quick snapshot of what is happening in a particular state regarding CAAPs. She said a grade is assigned from A to F based on the percentage of health plans in the state with CAAPs. She said that prior to 2025, The AIDS Institute carved out states from its review that had passed laws prohibiting copay accumulators. However, for this year's report, The AIDS Institute reviewed all 50 states and the District of Columbia because it had been hearing from fellow advocates and patients that despite a state's prohibition on the use of copay accumulators, health plans still included CAAPs in their plan documents. Hengst discussed The AIDS Institute's efforts to confirm which plans have CAAPs in their plan documents, but that are not actually applying them because they have not updated their plan documents to reflect state law prohibiting CAAPs.

Hengst discussed one of the analyses that The AIDS Institute included in its 2025 report, which compared health insurance marketplace Silver plan premiums in each state for insurers with plans that have copay accumulators and those without copay accumulators. While acknowledging the many factors that impact rate-setting and premium costs, she said the analysis showed that there was not much of a significant difference in premium cost between those plans with or without copay accumulators. Hengst highlighted advocacy efforts to advance policy solutions on both the state and federal levels to address the copay accumulator and copay maximizer issue, including recent state laws enacted prohibiting CAAPs.

Fix asked for questions. Stoddard asked whether Dickson believes that AHIP considers rebates to have the same effect on price competition as copay accumulators. Dickson said rebates complicate an already confusing prescription drug distribution system, which does not allow consumers to compare prescription drug prices easily and directly.

Fix said that because the presenters differed on the impact of copay accumulators and CAAPs on premium costs, she believes the Working Group would appreciate more clarity on the reasoning for the different viewpoints.

Dickson discussed how the regulation of Affordable Care Act (ACA) marketplace plans, such as the medical loss ratio (MLR) requirements, results in more drug cost transparency, particularly regarding the dollars paid to the plan and not the pharmacy. He explained that when the manufacturer makes a payment directly to the pharmacy on behalf of the patient, it uses the same format insurers use to pay the pharmacy. This payment offsets the amount of money the plan and the patient pay to the pharmacy for the drug. He said that for an ACA marketplace

plan, if this results in the total net cost of the plan being lower than projected, the difference is paid to the patient in the form of a rebate due to MLR requirements.

Schmid said this discussion raises an issue that has been a point of contention for a while. He suggested that the NAIC seek clarity on the issue by talking to pharmacists and other stakeholders with the requisite knowledge. Schmid questioned why plans oppose copay accumulator bans if they have no financial impact. He said someone is collecting the money, and someone is spending it. He said someone is benefiting, and the NAIC should try to determine what is happening.

Hengst expressed support for Schmid's comments. She discussed The AIDS Institute's understanding of how CAAPs impact costs. Hengst also noted that the American Pharmacists Association (APhA) has volunteered to speak on this issue during a future Working Group meeting.

Fix thanked the speakers for participating in the meeting. She said the Working Group will continue its discussions of copayment accumulators and patient assistance programs during future meetings. She also said the Working Group will follow up with the APhA to schedule a future Working Group meeting to discuss the financial implications of copay accumulators and CAAPs.

Having no further business, the Prescription Drug Coverage (B) Working Group adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/PBM Regulatory Issues Subgrp/PDCWG MtgMin 5-19-25.docx

Draft: 4/1/25

Prescription Drug Coverage (B) Working Group
Indianapolis, Indiana
March 24, 2025

The Prescription Drug Coverage (B) Working Group of the Regulatory Framework (B) Task Force met in Indianapolis, IN, March 24, 2025. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Jacob Lauten and Molly Nollette (AK); Jimmy Gunn (AL); Crystal Phelps (AR); Paul Lombardo (CT); Howard Liebers (DC); Sheryl Parker (FL); Andria Seip (IA); Dean L. Cameron, Shannon Hohl, and Weston Trexler (ID); Matthew Pickett (IL); Vicki Schmidt and Julie Holmes (KS); Shaun Orme (KY); Frank Opelka (LA); Joe Stoddard and Julie Merriman (MI); Norman Barrett (MN); Amy Hoyt and Cynthia Amann (MO); Robert Croom (NC); Cheryl Wolff, Michael Muldoon, and Maggie Reinert (NE); Erin Porter and Tim Stroud (NJ); Krista Porter (NY); Viara Ianakieva (NM); Cassie Soucy (OR); Dave Yanick (PA); Jud Jones (TN); Tanji J. Northrup (UT); Jane Beyer (WA); and Jill Reinking and Lauren White (WY). Also participating were: Kevin Beagan (MA); Chrystal Bartuska (ND); Christine Moller (OH); Jill Kruger and Travis Jordan (SD); and Patrick Smock (RI).

1. Heard Opening Remarks

Fix discussed the changes to the Working Group's focus since it last met. She said that based on its revised charges and new name, the Working Group will focus on prescription drug coverage, pharmacy benefit managers (PBMs), and other stakeholders in the prescription drug ecosystem. She said the new Pharmacy Benefit Management (D) Working Group, under the Market Regulation and Consumer Affairs (D) Committee, will focus on PBM enforcement, including taking over the work of the Working Group to develop a PBM examination chapter for inclusion in the *Market Regulation Handbook*. Fix encouraged all those interested in PBM enforcement issues to join the Pharmacy Benefit Management (D) Working Group, which will be meeting for the first time March 25.

Fix said she and Scott are seeking input from Working Group members and interested regulators on topics the Working Group should discuss this year. She said she has already received some suggestions, such as prior authorization (PA), accreditation, formulary placement and design, and specialty drugs. She said anyone with additional suggestions should reach out to her, Scott, or NAIC staff.

2. Adopted its 2024 Fall National Meeting Minutes

Beyer made a motion, seconded by Scott, to adopt the Working Group's Nov. 18, 2024, minutes (Attachment ?-A). The motion passed unanimously.

3. Heard a Presentation from the HIV+Hepatitis Policy Institute on PBMs and How They Function from the Consumer Perspective

Carl Schmid (HIV+Hepatitis Policy Institute) discussed the role of PBMs in patient access and affordability of prescription drugs. He explained how PBMs impact prescription drug coverage and prescription drug benefit design. He cited information showing the rise in the number of products on PBM formulary exclusion lists from the three largest PBMs between 2012 and 2025. Schmid provided an example of one health plan placing all HIV drugs, including generics, on the highest tier and not covering some of the recommended treatments for HIV. He said another plan in the New England area was not covering some of the HIV treatment recommended drugs, but the state stepped in to address the issue by requiring the plan to add the drugs back to the formulary. Schmid also

discussed how the placement of certain prescription drugs on higher tiers impacts consumer out-of-pocket costs, which have increased over the years, causing many consumers to not pick up their prescription drugs at the pharmacy.

Schmid discussed drug manufacturer copay assistance programs. Schmid said insurers have implemented copay accumulator adjustment policies (CAAPs), allowing them to not count drug manufacturer copay assistance toward a beneficiary's out-of-pocket costs, which also leads to higher out-of-pocket costs for consumers, particularly consumers living with chronic and serious illnesses, such as HIV, hepatitis, and other conditions requiring high-cost specialty medications. He explained how PBMs were the middlemen in this process. Schmid cited The AIDS Institute's (TAI's) recently released annual report on insurer CAAPs. According to its findings, more than 40% of individual health plans reviewed for 2025 include CAAPs. He said the analysis also revealed that 39 U.S. states had at least one insurer with a CAAP. Schmid said that in 11 states (Colorado, Delaware, Georgia, Illinois, Louisiana, North Carolina, Oklahoma, Oregon, Tennessee, Texas, and Washington), at least one insurer continues to include CAAPs, in apparent violation of state law.

Schmid thanked the NAIC for its recent letter to the Trump Administration asking for clarity on the CAAP issue and the enforcement of federal rules governing their use since litigation invalidated the U.S. Department of Health and Human Services (HHS) rule from the 2021 Notice of Benefit and Payment Parameters giving insurers wide discretion on how they use copay accumulator programs. The court decision left a previous 2020 rule in place. Under the 2020 rule, insurers could only use copay accumulators in limited circumstances. Since 2023, however, HHS has declined to enforce the 2020 rule and has promised updated rulemaking. State insurance regulators are asking for greater clarification from HHS on the status of federal rules so that they can provide consistent guidance to health insurers on these programs.

Schmid highlighted actions taken on the federal level concerning PBMs. The Federal Trade Commission (FTC) issued two interim staff reports. The first interim staff report looked at the top three PBMs, showing the concentration of the market, how they work with insurers, their ownership, how they function with rebates and extra fees they charge, and how they steer patients to certain pharmacies at the expense of independent pharmacies. He said the PBM industry's response to this report was to sue the FTC. Schmid touched on the role of PBMs and the Section 340B Drug Pricing Program. He also touched on state PBM activities, noting that all 50 states have some type of PBM law, and more and more states are considering PBM laws, particularly laws requiring more transparency and disclosure related to rebates and fees.

4. Heard a Presentation on PBMs and Conflicting Incentives

Edward Kaplan (Segal) presented on PBMs and conflicting incentives. He explained that Segal represents buyers, employers, unions, and governments that purchase PBM services. Segal receives no money from PBMs or drug manufacturers. Its revenue comes from planned sponsors. Kaplan said that from this perspective, he plans to focus his presentation on practical solutions and practical implications concerning PBMs, given how complicated the prescription drug benefit industry is. He provided a high-level overview of the prescription drug benefit industry, including how pharmaceutical therapies as a health plan expense are an increasing share of total health plan spending and some possible reasons for such increases.

Kaplan discussed the current PBM marketplace and explained that the top five PBMs control over 90% of the PBM market. He also provided an overview of the specialty pharmacy industry. He discussed the value that PBMs provide, such as catching physician prescribing errors, providing member support services, and improving

medication adherence rates. He said PBMs are now moving into drug manufacturing by acquiring or owning existing drug manufacturers or taking equity positions with drug manufacturers and distributors.

Kaplan highlighted the need for greater transparency in drug pricing. He discussed how the gap between prescription drug list prices and net prices continues to grow. He also discussed how certain side deals between drug manufacturers and middlemen, such as PBMs, distributors, and retailers, are complex and potentially misaligned with plan sponsor objectives. He noted that PBMs and drug manufacturers do not want to disclose specific drug rebates, which impacts the ability of plan sponsors to see true head-to-head prices and limits competition. To gain greater transparency, Kaplan suggested that plan sponsors: 1) mandate disclosure of all forms of payments to PBMs and their subsidiaries; 2) insist on head-to-head comparisons of competing drugs regarding side effects and efficacy to provide more informed prescribing; and 3) prohibit gag order contracts with pharmacies. He touched on traditional versus transparent pricing models.

Kaplan suggested the following tips for state insurance regulators to reduce waste and abuse: 1) review the competitive landscape of PBMs; 2) apply new contracting terms that move away from inflationary PBM definitions; 3) require drug-specific rebate disclosure; and 4) explore cost risk-sharing strategies in future contracts that tie PBM incentives to containing future price increases. He highlighted specific strategies that plan sponsors are using to more effectively manage the drug trend and reduce costs, such as: 1) smart plan design; 2) comprehensive utilization management; 3) PBM contract alignment with plan objectives; and 4) decisive action. Kaplan discussed best practices that plan sponsors can use with respect to PBM requests for proposals (RFPs)/contracting and rebate contracting. He also highlighted other PBM tools to support policyholders, including 1) developing custom drug formularies; 2) clinical program reviews (CPRs); 3) potential fraud and abuse reviews (PFARs); and 4) PBM audits.

Fix asked if anyone had any questions. Seip said there is transparency between the PBM and the plan sponsor but no transparency regarding the PBM and its payment methodologies with pharmacies. She said Iowa is struggling to make PBMs provide more transparency regarding their payment methodologies with pharmacies. She said this is challenging because Iowa feels its only enforcement tool is administrative, but there does not seem to be a financial penalty large enough to incentivize them to comply. Seip asked if Kaplan had any suggestions to encourage a more transparent relationship between PBMs and state insurance regulators so state insurance regulators can understand how pharmacies are being paid. Kaplan said there is no easy answer other than enacting legislation to require such transparency. Kaplan also said another option is to use an insured-type per member per month (PMPM) model, changing the PBM payment incentive.

Kruger asked Kaplan what makes a specialty drug a “specialty drug.” Kaplan said her question is common because there is no federal or industry definition. He said some of his clients require a PBM to provide a prospective list of its specialty drugs, which means the PBM can only change what it considers to be specialty drugs at policy or contract renewal.

Beyer asked about biosimilar drugs and formulary designs. She asked whether the PBM includes both the brand name drug and the biosimilar drug on the formulary when there is a biosimilar drug equivalent. She said an issue Washington has seen is that when both are on the formulary, the brand drug is preferred, which means that due to rebate considerations, the consumer ends up paying more. Kaplan said he has seen PBMs take various approaches to this issue. There is no consensus.

Commissioner Schmidt asked Kaplan how his clients, particularly those who are self-insured, have addressed transparency and rebates. She asked if they have required PBMs by contract to disclose all forms of payment they

receive from drug manufacturers. Kaplan said some of his clients have tried such an approach, but PBMs still manage to not disclose all fees and rebates because they state that some fees cannot be disclosed for confidential reasons. He reiterated his suggestion that to increase transparency, state insurance regulators should require PBMs to disclose rebates by drug to facilitate a head-to-head comparison.

Director Cameron asked Kaplan if he saw any changes in the marketplace that would change the dynamics, such as new emerging players like Amazon Pharmacy. Kaplan said the federal action to negotiate drug prices for Medicare Part D is a good start in changing some marketplace dynamics.

Having no further business, the Pharmaceutical Benefit Management Regulatory Issues (B) Working Group adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/PBM Regulatory Issues Subgrp/PDCWG MtgMin 3-24-25.docx

Agenda Item #2

Hear Presentations on Alternative Funding Programs (AFPs)—*Katelin Lucariello (Pharmaceutical Research and Manufacturers of America—PhRMA) and Theresa Alban (Cystic Fibrosis Foundation—CFF)*

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Alternative Funding Programs (AFPs)

NAIC Prescription Drug Coverage (B) Working Group Meeting

Katelin Lucariello, MPH

Deputy Vice President, State Policy

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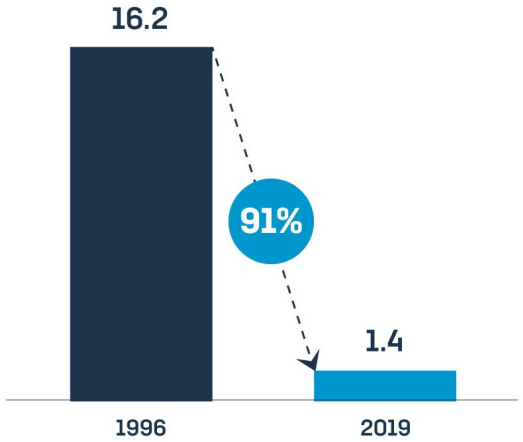
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

"Hepatitis C treatment can cure more than 90% of hepatitis C cases."

AJMC®

Estimated to reach $43 billion in savings by 2026

Decline in age-adjusted HIV/AIDS death rates per 100,000



HIV/AIDS is now a chronic and manageable disease.

CNN

US cancer death rate falls 33% since 1991, partly due to advances in treatment

STAT

HPV vaccine study finds zero cases of cervical cancer among women vaccinated before age 14

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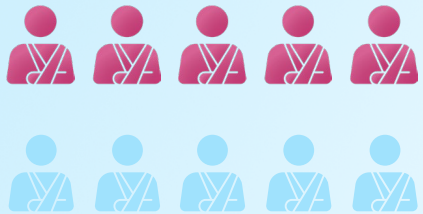
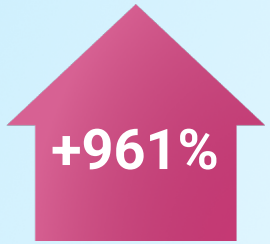
Insurer Tactics Challenge Patient Access

Insurer tactics that limit patient access are widespread



Almost half of insured adults say their health insurance plan has required prior authorization in the past year



The 3 largest PBMs increased the number of medicines excluded from formulary between 2014 to 2022

Source: AmerisourceBergen. (2023). Assessing the impact of formulary exclusion on healthcare costs and outcomes for patients on therapy for certain chronic conditions. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/formulary_excl_issue_brief.pdf ; American Medical Association. (2023). 2023 AMA prior authorization physician survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

As a result, patients may never initiate treatment or experience substantial delays

94%

Almost all physicians report delays in patient access with prior authorization

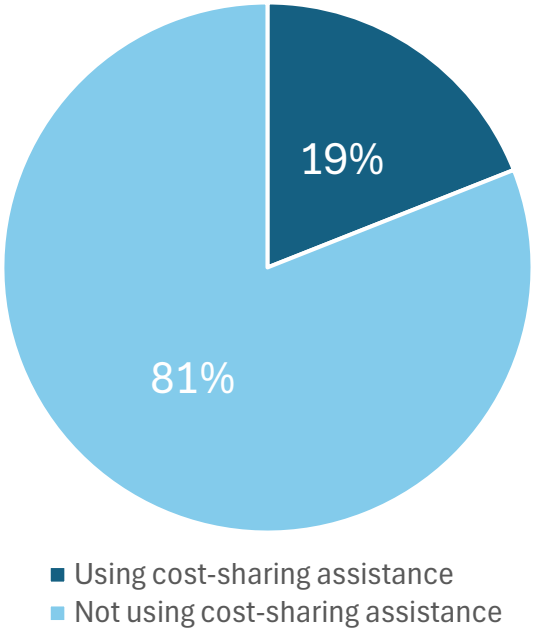
One in three cancer patients who faced a rejection at the pharmacy experienced a treatment delay of 2+ weeks

Source: IQVIA. (2024). Access Challenges in the Cancer Patient Journey: How barriers to oral oncology affect patient initiation and persistency. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-access-challenges-in-oncology-report-white-paper-2024.pdf ; Joszt, L. (2019). How Prior Authorization, Step Therapy Result in Medication Discontinuation and Worse Outcomes. https://www.ajmc.com/view/how-prior-authorization-step-therapy-result-in-medication-discontinuation-and-worse-outcomes-

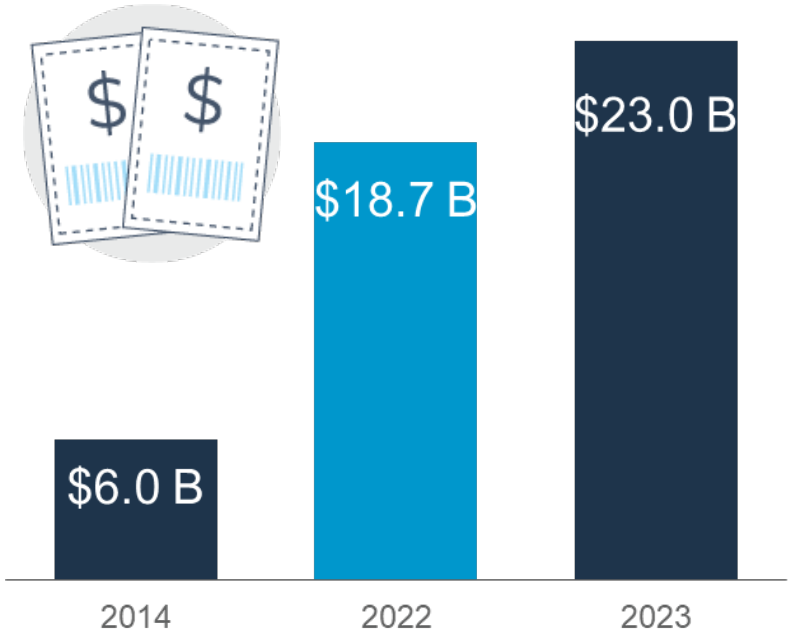
Manufacturer Cost-Sharing Assistance Is an Important Source of Financial Help for Commercially Insured Patients

Manufacturer cost-sharing assistance helps commercially insured patients who otherwise might struggle to afford their out-of-pocket costs.

Share of Commercially Insured Patients Using Manufacturer Cost-Sharing Assistance for Brand Medicines, 2023



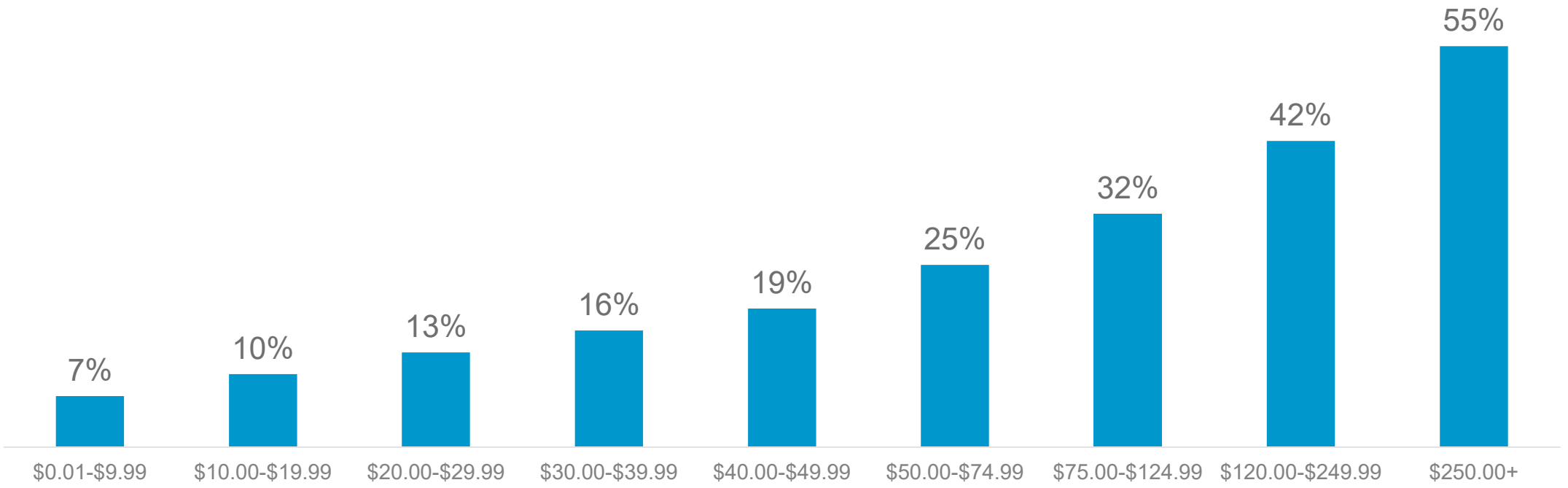
Total Manufacturer Cost-Sharing Assistance Has Grown in Recent Years



Source: IQVIA. The use of medicine in the US. 2024. Usage and spending trends and outlook to 2028. April 2024. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

Without Assistance, Patients Are More Likely To Abandon New Prescriptions

Rate of Abandonment of Newly Prescribed Medicines by Final Out-of-Pocket Cost, 2023



Notes: New to product prescriptions are those where patients have not had a prescription for the specific brand or generic drug within the prior year. Pharmacies in the sample provide information on prescriptions which were prepared for dispensing and whether they were dispensed, with abandonment defined as the prescription in question not being dispensed to the patient within 14 days of the initial fill. Analyses on a sample of claims projected to national totals.

Source: IQVIA. The use of medicine in the US. 2024. Usage and spending trends and outlook to 2028. April 2024. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

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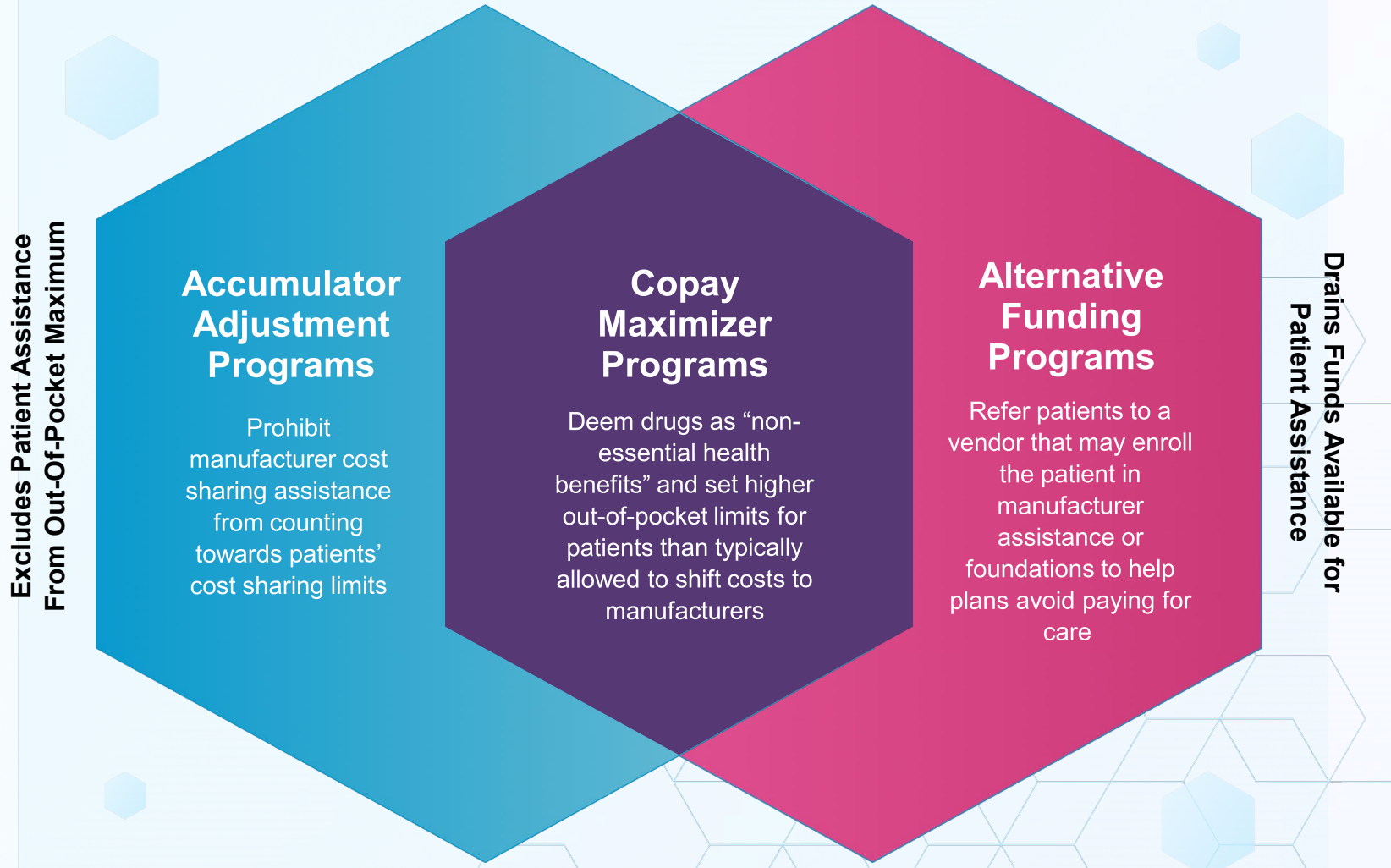
Middlemen divert patient assistance to avoid paying for patient care

Manufacturers provide patient assistance to help people access and afford their medicines. Payers and PBMs exploit this assistance, absorbing **$5 billion** of the funds intended for patients through complicated schemes that help them avoid paying for medicines.



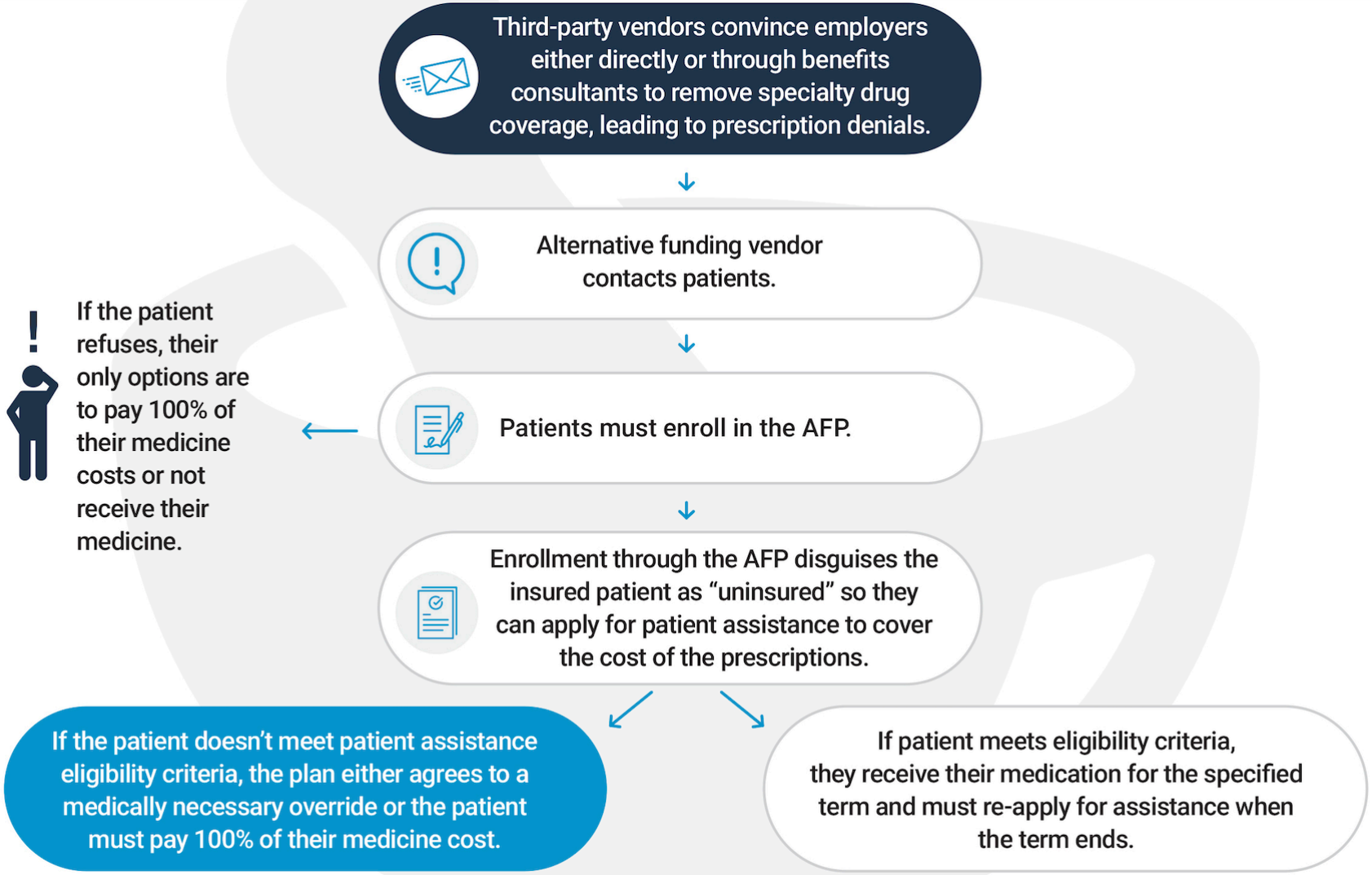
Source: Fein, A. J. (2024). Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html ; IQVIA. (2024). 2023 Update: Six Years of Deductible Accumulators and Copay Maximizers. https://www.iqvia.com/locations/united-states/blogs/2024/03/2023-update-six-years-of-deductible-accumulators-and-copay-maximizers ; Health Capital Group. (2024). The 340B Drug Purchasing Program and Per-Enrollee Medicaid Costs. https://www.healthcapitalgroup.com/340b-and-total-medicaid ; GAO. (2015). Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. https://www.gao.gov/products/gao-15-442

Alternative Funding Programs

AFPs drive patients to charitable or manufacturer patient assistance funds meant for uninsured and financially disadvantaged patients

- Target specialty medicines
- Encourage health plans to remove coverage for specialty drugs on premise that manufacturer PAPs will pay for them
- Patient must enroll in the vendor's program or pay 100% of the cost of their medicines
- Once enrolled, vendor assists patient in applying for PAP
- If patient not eligible for PAP, they can appeal to have their medicine covered under the health plan

How AFPs Target Patient Assistance Programs



The Hidden Impacts of Alternative Funding Programs

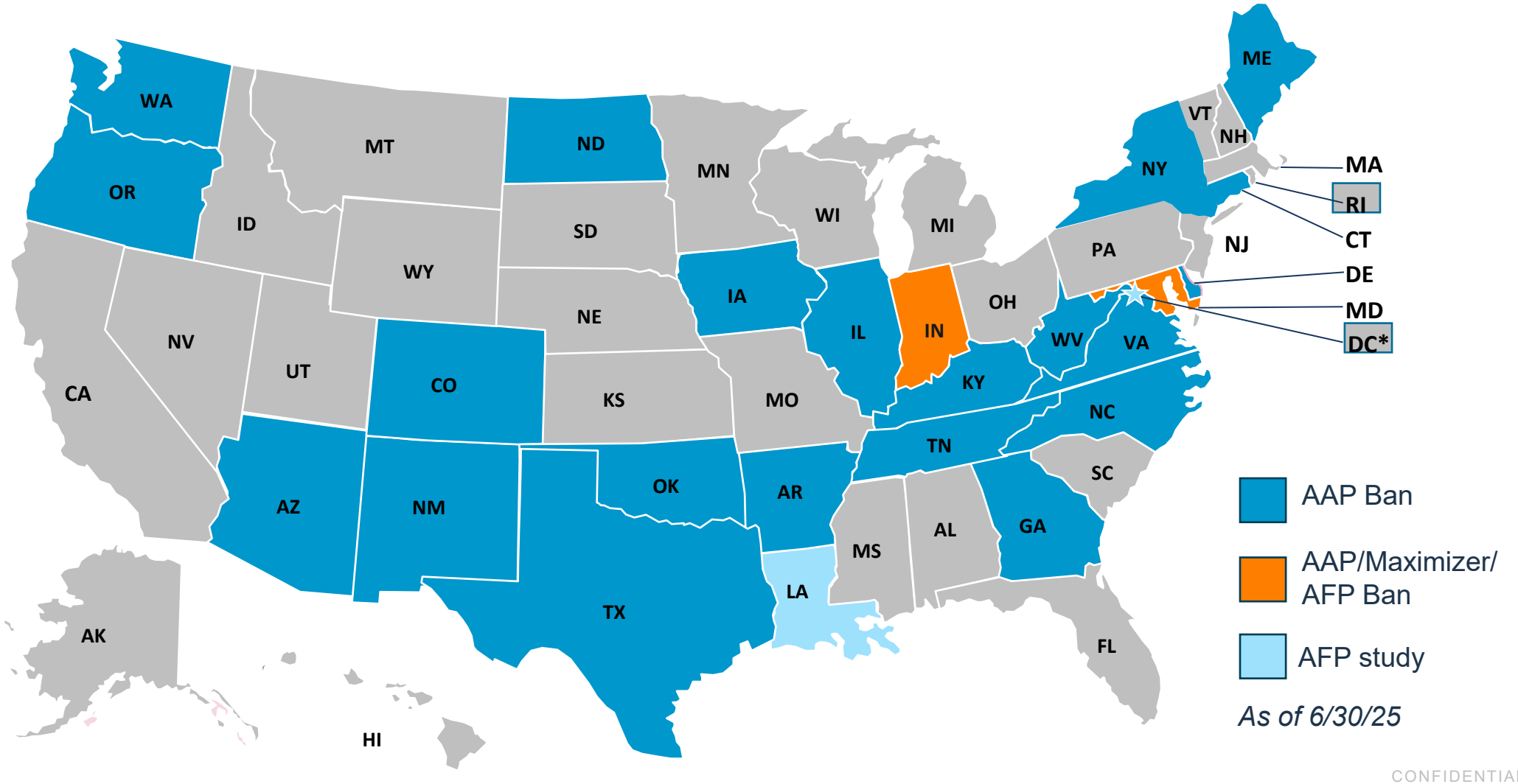
AFPs are costly, deceptive, potentially discriminatory, and dangerous for patients

AFPs…

- Use **deceptive practices** to exploit assistance
- **Deplete patient assistance** meant for uninsured patients
- **Profit** at the expense of patients
- May **over promise savings** to employers
- Are a type of **discriminatory practice**, disproportionately harming patients with chronic illness and rare conditions
- Can cause **delays and disruptions in treatment** for patients

State Laws to Protect Patient Assistance

25 States with AAP Bans, 2 States also Ban Maximizers and AFPs



PhRMA Created the Medicine Assistance Tool, or MAT, To Help Patients Navigate Medicine Affordability

MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

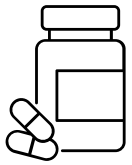
The Medicine Assistance Tool Includes:

A search engine to connect patients with

900+

assistance programs offered by biopharmaceutical companies, including some free or nearly free options

Resources to help patients navigate their insurance coverage



Links to biopharmaceutical company websites where information about the cost of a prescription medicine is available

PhRMA
RESEARCH • PROGRESS • HOPE

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Alternative Funding Programs, International Importation, & the Patient Experience

Theresa Alban

Director of Federal Policy & Legal Advocacy

CYSTIC FIBROSIS FOUNDATION®

About the Cystic Fibrosis Foundation

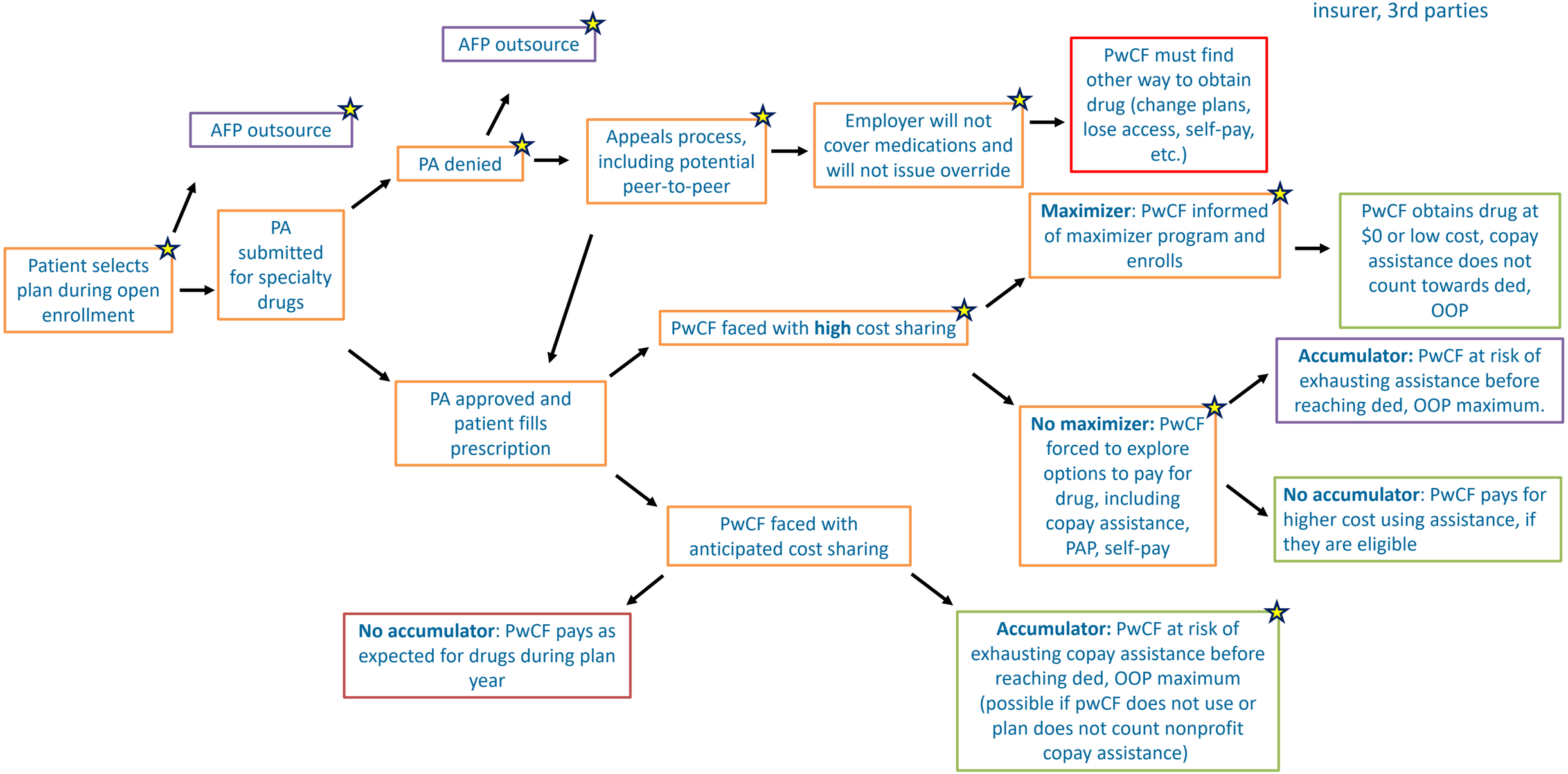
- Non-profit organization dedicated to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care

- Cystic fibrosis is a rare genetic disease close to 40,000 children and adults and can affect every racial and ethnic group in the United States

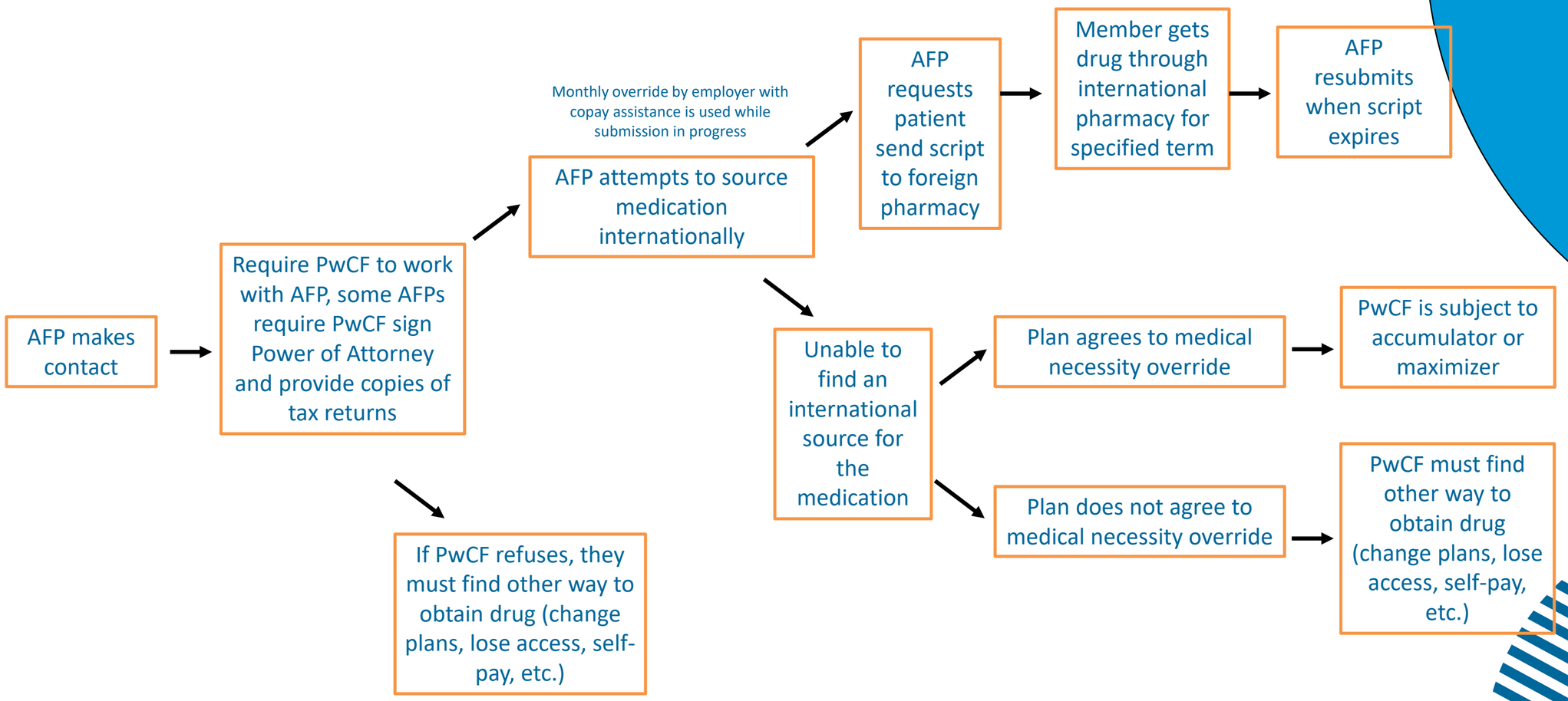
- Through development of transformative therapies and careful, aggressive, and continuously improving disease management, the life expectancy of someone born with CF has doubled in the last 30 years

Patients Accessing Specialty Medications

Risk of admin burden, incl:
- Lack of transparency
- Incorrect information
- Back-and-forth between PBM, insurer, 3rd parties



Patients Navigating AFPs



Patients Navigating AFPs

Administrative Burden

Multiple steps involved with different companies, can take significant amount of time by both PwCF, care team. Process is not transparent throughout and final decision maker is unclear.

Cost Burden

If PAP is denied, accumulator or maximizer component, often no out-of-pocket maximum

Gaps in care

Potential for delays while waiting for decision, especially with manufacturers fighting against AFP

Constantly changing process

Increasingly, AFPs have sought to require people obtain drugs internationally

Quality of Life

Uncertainty of medication access when going through this process and for every year during reapplication process.

Laws and Regulations Related to Drug Importation

- FDA’s Personal Importation Policy
- Section 804 Importation of Prescription Drugs from Canada

FDA’s Personal Importation Policy

The personal use policy provides that an individual may be permitted to import an unapproved prescription drug for personal use if:

- For an individual – not for further sale or distribution in the United States
- Medication not for a serious condition – over the counter
- Medication for a serious condition when:
  - Product is not available in the U.S.;
  - Product was not promoted to the individual;
  - Product does not impose an unreasonable risk
  - Consumer affirms it is for personal use; and
  - No more than three-month supply

Section 804 of FDCA

Pathway for States and Indian Tribes to import drugs originally intended for Foreign Markets

- Executive Order with interest in streamlining this process
- Narrow in scope – Canadian only
- States and Indian Tribes are required to submit proposals for importation
- Cannot import any of the following
  - Controlled substances
  - Biological products
  - Infused drugs
  - Drugs that are inhaled during surgery
  - Intravenous drugs
  - Intrathecally
  - Intraocularly
  - REMS

Patient Risk for Unregulated Importation

Lack of Proper Storage and Handling

The FDA and state pharmacy laws mandate strict temperature and handling regulations to maintain medication efficacy.

Insufficient Transparency

Foreign medications frequently lack essential labeling, patient instructions, and recall mechanisms, leaving patients vulnerable to severe health risks

Risk of Counterfeit Medications

Purchase of medications directly from foreign pharmacies side-steps the Drug Supply Chain Security Act tracking system and operate outside the closed U.S. supply chain.

What can State Policymakers Do?

- **Ensure scrutiny and oversight is incorporated in SIP application and implementation particularly for drugs approved to be imported**

- **Work with FDA to enforce existing laws against illegal importation**

Agenda Item #3

Discuss Any Other Matters Brought Before the Working Group—*Joylynn Fix (WV)*