Revised date: 11/13/25

*2025 Fall National Meeting*
*Hollywood, Florida*

**PRESCRIPTION DRUG COVERAGE (B) WORKING GROUP**
Tuesday, December 9, 2025
11:45 a.m. – 12:45 p.m.
Diplomat Convention Center—Grand Ballroom East—Level 2

**ROLL CALL**

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

NAIC Committee Support: Jolie H. Matthews

**AGENDA**

1. Consider Adoption of its Summer National Meeting Minutes
   *—Joylynn Fix (WV)*

2. Hear a Presentation on Formulary Placement and Specialty Drugs
   *—Matthew Sankey (The INS Companies)*

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

4. Adjournment

# Agenda Item #1

**Consider Adoption of its Summer National Meeting Minutes—*Joylynn Fix (WV)***

Draft: 8/18/25

Prescription Drug Coverage (B) Working Group
Minneapolis, Minnesota
August 11, 2025

The Prescription Drug Coverage (B) Working Group of the Regulatory Framework (B) Task Force met in Minneapolis, MN, Aug. 11, 2025. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Sarah S. Bailey and Molly Nollette (AK); John Buono and Reyn Norman (AL); Crystal Phelps (AR); Erica Bowsher (AZ); Lena Bahar and Michael Shanahan (CT); Howard Liebers (DC); Sheryl Parker (FL); Andria Seip (IA); Shannon Hohl (ID); Matthew Pickett (IL); Julie Holmes (KS); Shaun Orme (KY); Frank Opelka (LA); Brianna Egan (MI); Norman Barrett (MN); Amy Hoyt (MO); Robert Croom (NC); Cheryl Wolff, Martin Swanson, and Margaret Otto (NE); Erin Porter and Ralph Boeckman (NJ); Viara Ianakieva (NM); Krista Porter (NY); Lindsi Swartz and Shannen Logue (PA); Glory Montalvo (PR); Jud Jones (TN); Shelley Wiseman and Ryan Jubber (UT); Jane Beyer (WA); Lori Luder and Darcy Paskey (WI); and Lauren White (WY). Also participating were: Tony Bonofiglio (OH); Mike Rhoads (OK); Chrystal Bartuska (ND); and Patrick Smock (RI).

1. Adopted its May 19 and Spring National Meeting Minutes

The Working Group met May 19 and heard presentations from AHIP, the HIV+Hepatitis Policy Institute, and The AIDS Institute on copay accumulators.

Swanson made a motion, seconded by Scott, to adopt the Working Group's May 19 (Attachment Two-A) and March 24 *(see NAIC Proceedings – Spring 2025, Regulatory Framework (B) Task Force, Attachment Three)* minutes. The motion passed unanimously.

3. Heard Presentations from PhRMA and the CFF on AFPs

Katelin Lucariello (Pharmaceutical Research and Manufacturers of America—PhRMA) said that before she discussed alternative funding programs (AFPs), she wanted to frame the issues that are the source of some of the concerns with AFPs. She said AFPs target specialty drugs, which are types of drugs that typically treat clinically complex conditions and diseases, such as HIV, hepatitis C, multiple sclerosis, rare and genetic conditions, and some cancers. She said these drugs provide significant value, not only from a patient benefit perspective, but from a value to the system perspective, because they often help patients return to daily activities and the workforce.

Lucariello said science has never been more promising in developing drugs to treat these conditions and diseases. She said, however, that insurer tactics challenge patient access to these drugs. She said drug manufacturer cost-sharing assistance is an important source of financial help for commercially insured patients in obtaining access to these drugs because, without such assistance, patients are more likely to abandon new prescriptions.

Lucariello said AFPs steer commercially insured patients to charitable or manufacturer patient assistance funds meant for uninsured and financially disadvantaged patients. She discussed the differences between AFPs and other patient assistance programs (PAPs) (e.g., accumulator adjustment programs and copay maximizer programs). She said AFPs differ because they: 1) are operated by third-party vendors; 2) target specialty medicines; 3) encourage health plans to remove coverage for specialty drugs on the premise that manufacturer PAPs will pay for them; and 4) require patients to enroll in the vendor program or pay 100% of the cost of their medicines if they do not enroll. Lucariello described how AFPs target PAPs, including how, as the first step, AFP

third-party vendors convince employers either directly or through benefits consultants to remove specialty drug coverage, leading to prescription denials for their employees who need a specialty drug. She said that after these denials, the AFP third-party vendor contacts the patient to entice the patient to enroll in the AFP to obtain coverage for the specialty drug, because if they do not, the patient's only option is to pay 100% of the cost of the medicine or not receive the medicine. Lucariello explained that the patient's enrollment through the AFP disguises the insured patient as "uninsured" so the patient can apply for patient assistance to cover the cost of prescriptions.

Lucariello discussed the hidden impacts of AFPs, including: 1) the use of deceptive practices to exploit assistance; 2) the depletion of patient assistance meant for uninsured patients; 3) potentially overpromising savings to employers; and 4) potentially causing delays and disruptions in treatment for patients. She said AFPs are costly, deceptive, potentially discriminatory, and dangerous for patients. Lucariello discussed how the states are beginning to address AFPs. She said Indiana and Maryland recently banned them, and Louisiana recently passed legislation to study them.

Lucariello discussed PhRMA's medicine assistance tool (MAT). She said PhRMA created the MAT to help patients navigate medicine affordability. The 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. She described how the MAT works.

Seip asked about the pricing for the medicines patients obtain through an AFP. Lucariello said AFPs operate outside of the health plan. As such, to help patients pay for the drugs, an AFP accesses manufacturer or charitable dollars. Seip said she is more interested in learning the manufacturer's cost of the drug and whether the manufacturer's cost of the drug is different for certain groups or people because of the differences in the level of drug discounts offered by the drug manufacturer. Lucariello acknowledged the complexity of the drug pricing system in the U.S. She explained that in negotiations between pharmacy benefit managers (PBMs) and drug manufacturers, the PBMs negotiate discounts and rebates with the manufacturer, which impacts the net price the PBM pays for the drug. Lucariello said AFPs are not technically paying a particular price metric for the drug. Charitable foundations and manufacturer PAPs are not offering a discount off the price of a medicine; they are offering a dollar amount toward paying for the medicine. She said that, as such, drug manufacturers are not offering a different price for the medicine; rather, they are offering a dollar value toward the medicine. For commercial insurance, this equates to a dollar amount off the deductible, copay, or coinsurance for the drug.

Hohl asked Lucariello to elaborate on her remarks about AFPs helping people switch to different prescriptions. Lucariello said her statement is based, in part, on anecdotal evidence. She said there are a few lawsuits against AFPs on this issue. She said PhRMA has heard that in some cases, AFPs have reached out to physicians or encouraged patients to reach out to their physicians to obtain an alternative prescription.

Fix asked Lucariello to clarify the impact of patients using an AFP versus a manufacturer PAP regarding the patient's ability to draw down their out-of-pocket (OOP) costs. Lucariello said that, unlike manufacturer PAPs, patients using an AFP to obtain their medicine are not drawing down their OOP costs because they are outside of insurance coverage. As such, the patient could ultimately pay more for the drug.

Bartuska asked Lucariello to elaborate on her discussion about AFPs being potentially discriminatory because she would argue that there is discrimination in the entire medical market, not just the prescription drug market. As such, she believes more should be done to lower costs for all consumers, not just those consumers with high prescription drug costs. Lucariello said she can only speak from a drug manufacturer's perspective, and the

assistance drug manufacturers offer to reduce prescription costs for consumers. She acknowledged Bartuska's concern about health care costs across the entire medical system and the need to address those costs.

Rhoads asked what role consumers play in being enrolled in an AFP. Lucariello said that it is typically an employer plan sponsor contracting with the AFP, particularly in the self-insured market, where plan sponsors have more flexibility over the coverage they choose to offer to their employees. She said the employee technically has a choice of whether to enroll in the AFP, but it is an impossible choice, as they must decide whether to enroll with the AFP and have their medicine covered through these alternative routes or pay 100% of the cost for the medicine.

Fix asked how AFPs are funded. Lucariello said that sometimes smaller PBMs are the AFP's vendor, and they reach out to employers. She said that the AFP typically earns a fee from the employers they contract with, and that fee is based on the percentage of the assistance they can capture, which is typically 20% to 30%. Lucariello gave an example that if the AFP captures $100 in drug assistance, then the AFP would charge the employer $30 because it offset $100 in prescription drug costs for the employer.

Theresa Alban (Cystic Fibrosis Foundation—CFF) discussed AFPs, international drug importation, and patient experience. She highlighted how patients, particularly those requiring specialty medications, like those with cystic fibrosis, are particularly at risk of additional administrative burdens and other adverse impacts when an AFP is involved. Alban described how patients navigate AFPs and how AFPs try to source medication internationally. She said some AFPs have advertised to employers that drug importation is an effective way for their employees to receive their drugs and that the federal government has endorsed drug importation. AFPs have also said drug importation lowers drug costs for both the employer and the employee.

Alban said the CFF has concerns about the patient risks associated with drug importation, such as the potential for the lack of proper storage and handling, and the lack of transparency in the drug supply chain to understand who is supplying the medications. Alban also highlighted how patients navigating AFPs are subject to potential gaps in care and a constantly changing process to obtain their drugs because AFPs are increasingly requiring patients to obtain their medications internationally due to the increasing cost of specialty drugs.

Alban discussed potential issues with international drug importation. She described existing laws and regulations related to drug importation, including the U.S. Food and Drug Administration's (FDA's) personal importation policy and the Section 804 importation program under the federal Food, Drug, and Cosmetic Act, which allows states and American Indian tribes to import prescription drugs from Canada under specific conditions, potentially lowering drug costs for consumers. She said that despite these laws and regulations, patients are at risk of unregulated importation. Alban said state insurance regulators and other state policymakers can help prevent this by: 1) ensuring that scrutiny and oversight are incorporated into a Section 804 importation program proposal application; and 2) working with the FDA to enforce existing laws against illegal importation.

Wolff asked for more clarification on who pays for the drug in the AFP scenario. Alban said the employer, who has contracted with the AFP, or third-party administrator (TPA), pays a flat fee to the AFP as outlined in the contract. Then, the AFP tries to source the medication as cheaply as possible, which may be through drug importation or a drug manufacturer PAP.

Hohl said AFPs seem to target employer-based plans, particularly self-insured employer-based plans. She asked whether anyone on the federal level tracks complaints or if the CFF is working with federal agencies, such as the U.S. Department of Labor (DOL), the U.S. Department of Health and Human Services (HHS), or other federal

agencies to address some of the concerns and issues related to AFPs. Alban said the CFF has been working with some of these federal agencies, particularly with the FDA, to address concerns with drug importation.

Wolff asked how the pharmacy is paid. Alban said she can only speak from an international sourcing perspective. She said that from that perspective, the pharmacy has an exclusive contract with the AFP to source the medications. Alban noted the lack of transparency in this area, which hampers everyone's ability to truly understand how it all works.

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

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# Agenda Item #2

**Hear a Presentation on Formulary Placement and Specialty Drugs**
***—Matthew Sankey (The INS Companies)***

# *Prescription Drug Formularies and Specialty Medications*

**Dr. Matthew Sankey, MCM, PharmD**

**Market Regulation Pharmaceutical Manager**

**The INS Companies**

Tuesday, December 9, 2025 – Hollywood, FL

# Presenter

Dr. Matthew Sankey, MCM, PharmD

Market Regulation Pharmaceutical Manager

# Objectives

- Formulary Development
- Formulary Design
- Specialty Medications
- Consumer Impacts
- State Oversight
- Conclusion

# Formulary Development

# Formulary Development

- Pharmacy and Therapeutics Committee
  - Required Representation
- Formulary Committees
  - Clinical vs. Cost
- Rebate Optimization
  - Implications on a health plans inclusion or exclusion



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# Formulary Design

# Formulary Design

- Formulary Tiering
  - Preventative
  - Preferred Generic
  - Preferred Brand
  - Non-Preferred Brand
  - Preferred Specialty
  - Non-Preferred Specialty

# Formulary Design

- Tiering ≠ medication characteristics
- Prior authorizations
- Step therapy requirements
- Approval durations
- Stability (patient outcomes)
- Non-formulary medication reimbursement

# Specialty Medications

# Specialty Medications

- Definition(s)
  - Complex, chronic, or rare condition
  - Limited distribution
  - Specialized administration and handling
  - Patient management
- Can a non-specialty pharmacy or pharmacist dispense and provide these services for the medication?

# Specialty Medications

- Accessibility
  - Tiering
  - Pharmacy network access
- Rebates
- Cost
- Reimbursement

# Specialty Medications

- Humira
  - QTR1 of 2024, adalimumab biosimilars had captured just 1% of the market with the Big 3 PBMs continuing to favor the brand name version of the medicine on formularies.
  - Evidence shows that substituting biosimilars could lower employer costs by 58% and patient costs by 68%.

# Specialty Medications

- PBM Affiliated Drug Procurement
  - CVS Health- Cordavis
    - Hyrimoz
  - Cigna/Evernorth – Quallent Pharmaceuticals
    - Simlandi
  - United Health Group – NUVAILA
    - Amjevita
- Nearly all adalimumab biosimilars are excluded from the formularies except  for their own affiliated products.

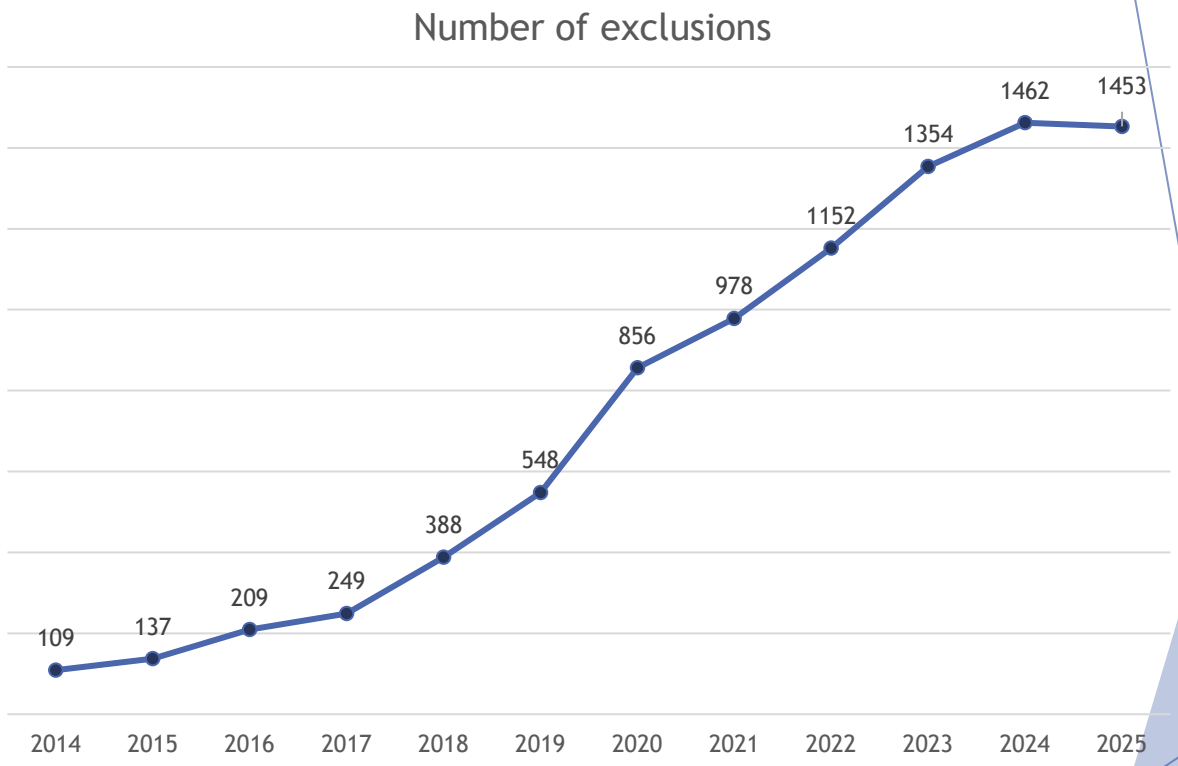
# Consumer Impacts

# Consumer Impacts

- ACA Preventative Medications
  - Oral Contraceptive and HIV PreP
- Mental Health Parity
- Brand Name Medications Preferred
  - Higher Cost Alternative
- Formulary Changes
  - Quarterly, Yearly
- Copay and Coinsurance
- Transparency

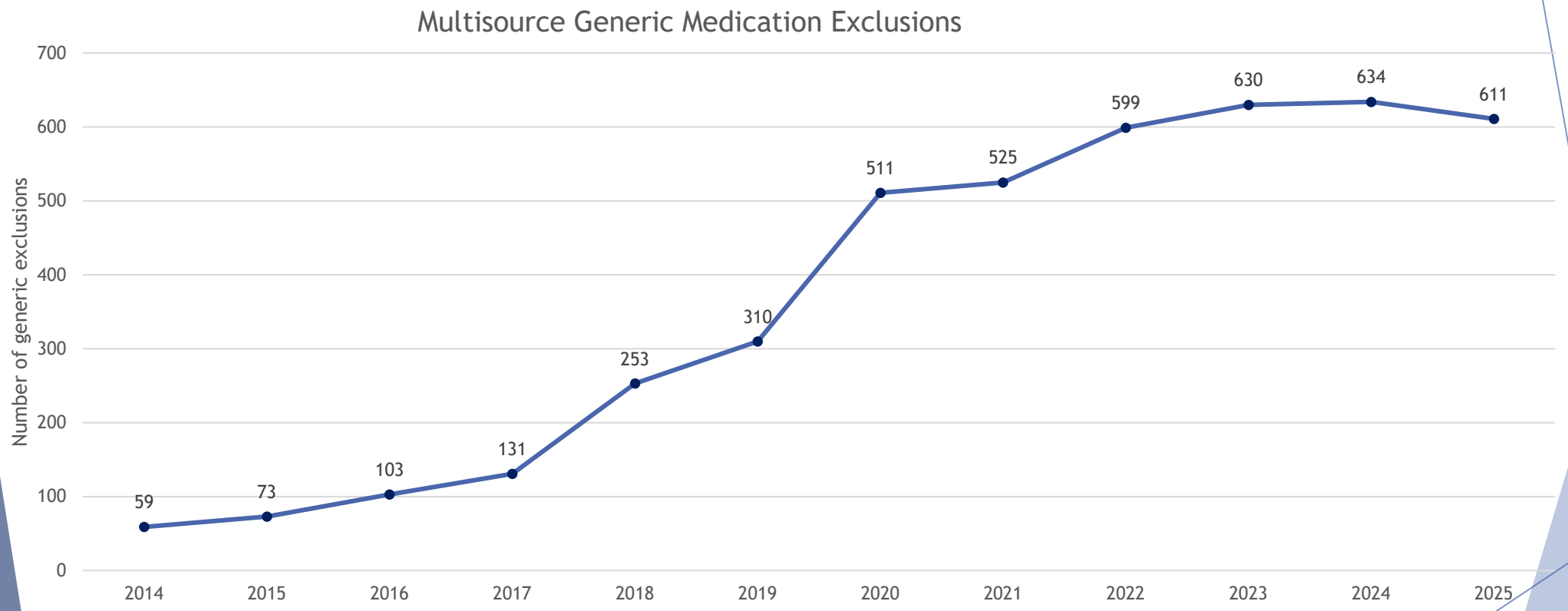
# Formulary Design

- In 2025, the big 3 PBMs excluded a total of 1,453 unique medicines from their formularies, an average increase of 27% per year from 2014 to 2025




Cencora. (2025, July). *Persistent growth in PBM formulary exclusions continues to raise concerns about patient access*. https://phrma.org/resources/persistent-growth-in-pbm-formulary-exclusions-continues-to-raise-concerns-about-patient-access

# Consumer Impacts

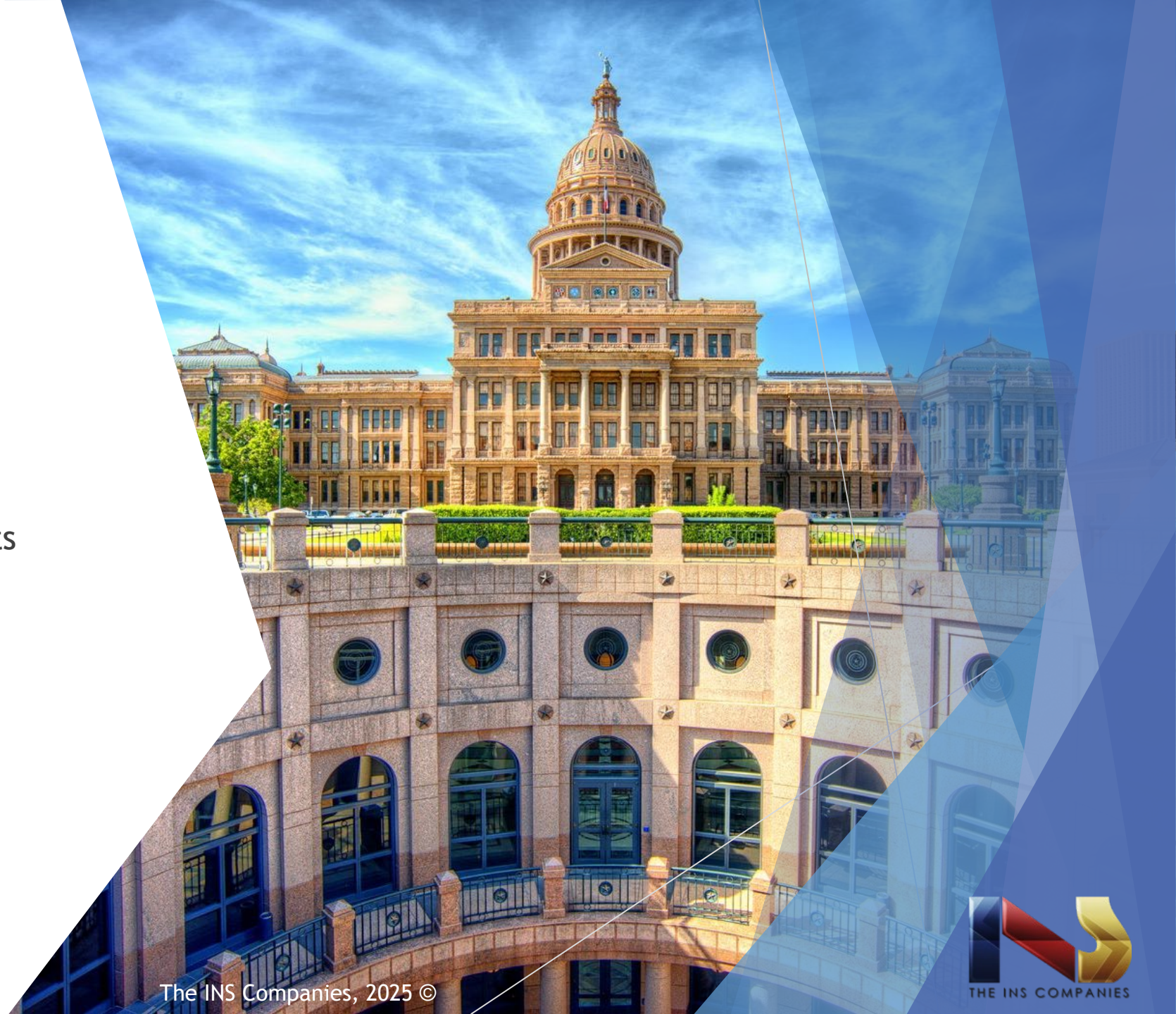



Cencora. (2025, July). *Persistent growth in PBM formulary exclusions continues to raise concerns about patient access.* https://phrma.org/resources/persistent-growth-in-pbm-formulary-exclusions-continues-to-raise-concerns-about-patient-access

# State Oversight

# State Oversight

- PBM Registration / Licensure
- Reporting Requirements
- Statutory Requirements
- Network Requirements
- Formulary Notice Requirements
- Prospective Formulary Review
- Complaints
- Market Conduct Examinations
- MHPAEA Examinations





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# Conclusion

# Conclusion

- Complex formularies with increased number of tiers.
- Higher cost medications incentivized to remain on formularies
- Patients required to try and fail therapy or pay higher costs to remain on treatment
- Specialty medications may not always be “specialty”
- Mental Health Parity and State formulary inclusion requirements

# *Questions?*

**Dr. Matthew Sankey**

**Market Regulation Pharmaceutical Manager**

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# Agenda Item #3

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