#### Update on White Bagging

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# Disclosures

- Pharmacist
- Employed by Essentia Health
- •Led Minnesota white bagging legislation coalition



# Objectives

- Describe the current models for providers obtaining drugs and the different process that payers are using to bypass those models.
- Explain the impact of white bagging on the payer, the provider, and the patient.
- Describe landscape and approaches legislation has taken across the country.
- Outline legislative strategies to respond to white bagging.



# Definitions

• Buy-and-bill: provider purchases medication for stock

✓ patient is billed for medication and administration under medical benefit

• Brown Bagging: unaffiliated specialty pharmacy provides medication

to patient

• White Bagging: unaffiliated specialty pharmacy provides medication

to <u>provider</u>

• Clear Bagging: <u>affiliated</u> specialty pharmacy provides medication

to <u>provider</u>

✓ patient billed for administration under medical benefit

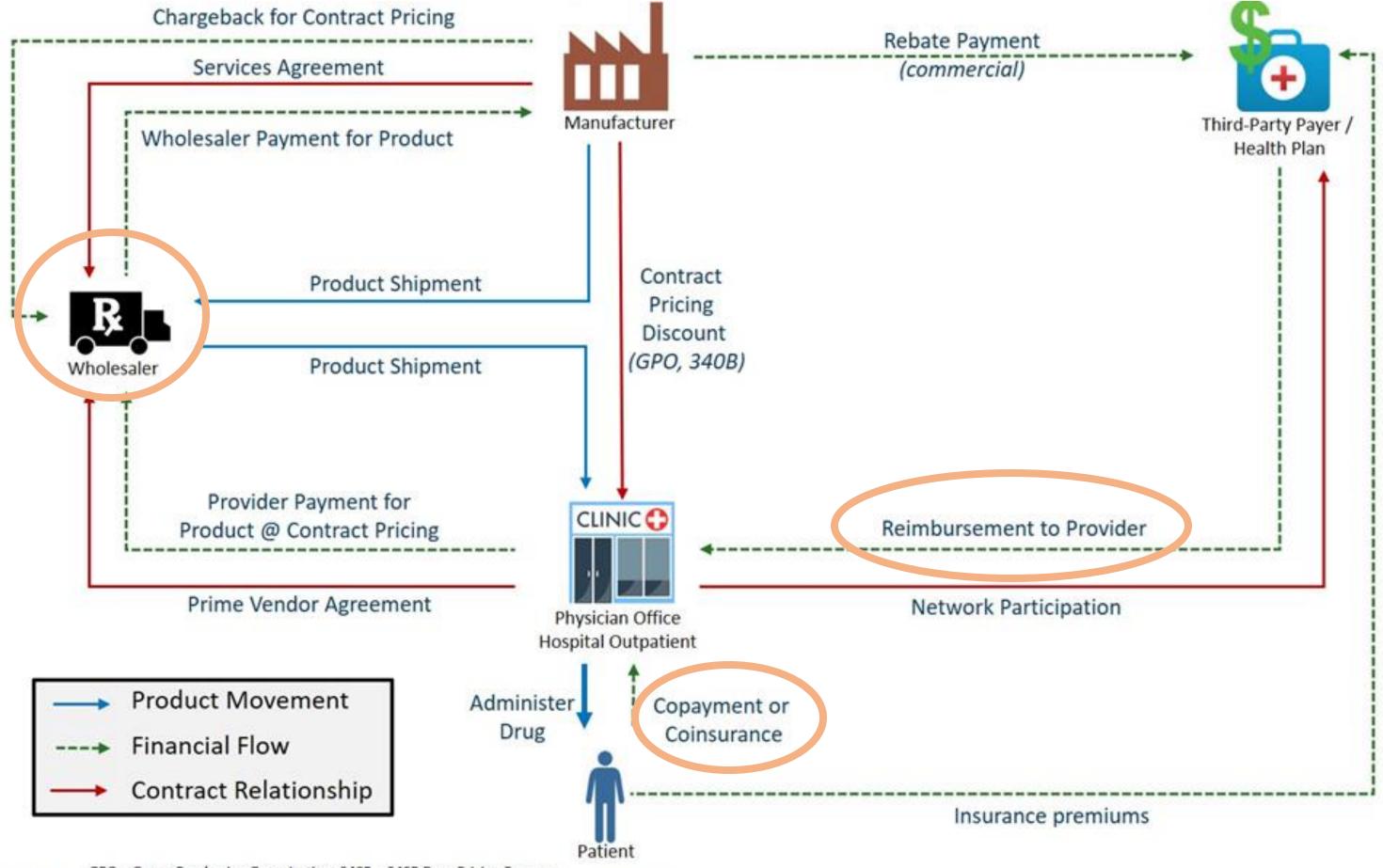
✓ patient billed for medication by specialty pharmacy under pharmacy benefit



#### Distribution and Reimbursement Models



# Buy-and-Bill

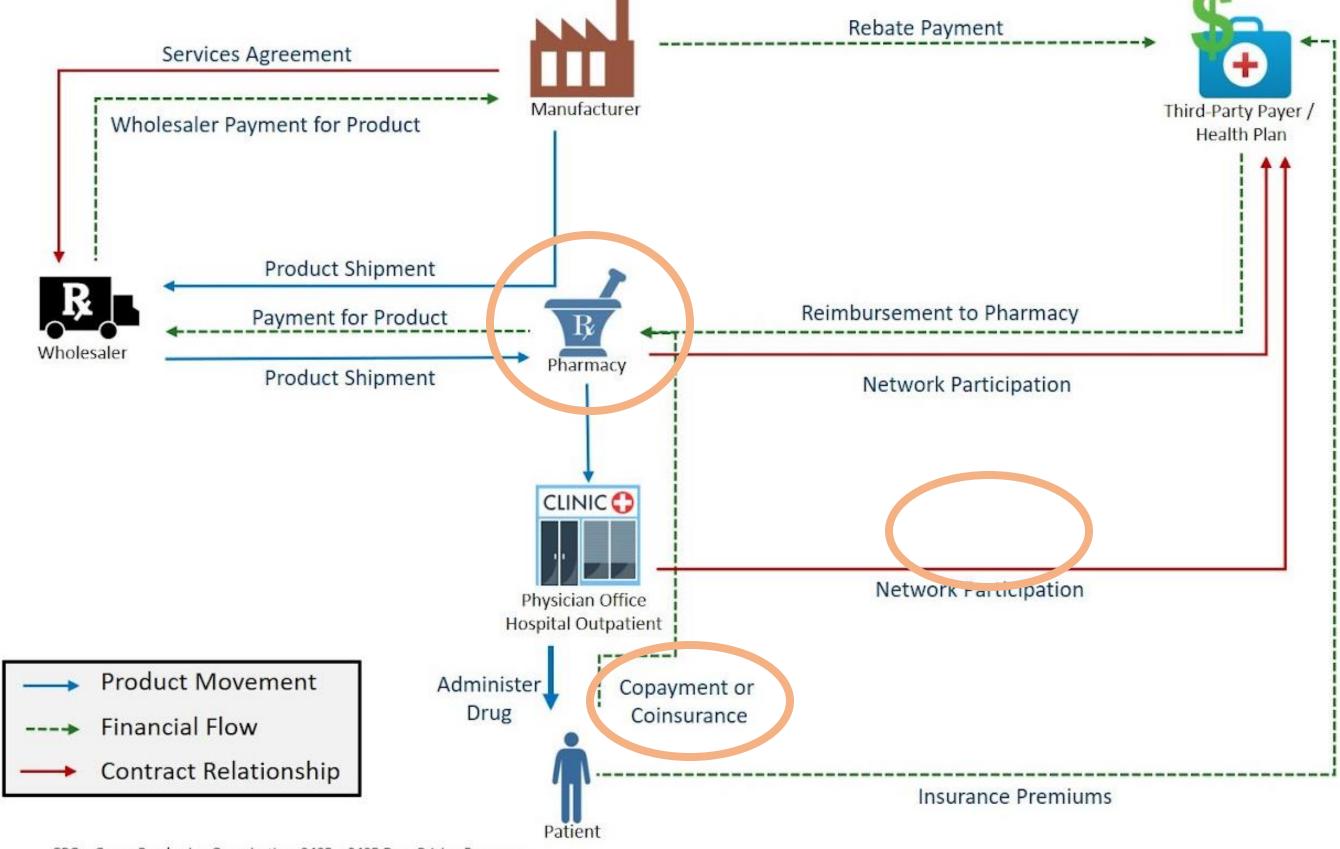




GPO = Group Purchasing Organization; 340B = 340B Drug Pricing Program DRUG CHANNELS Source: The 2021-22 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, Exhibit 38. Chart illustrates flows for Provider-Administered, Outpatient Drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.



#### White Bagging



GPO = Group Purchasing Organization; 340B = 340B Drug Pricing Program

Source: The 2022-23 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, Drug Channels Institute, Exhibit 44. Chart illustrates flows for **Provider-Administered, Outpatient Drugs.** Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.





#### Vertical Integration



- 1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. IN Dec. 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was rebranded as AllianceRx Walgreens Pharmacy. 2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy Services.
- 3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
- 4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
- 5. Previously known as Evernorth Care Group and Cigna Medical Group.
- 6. In 2021, Cigna's Evernorth business acquired MDLive.
- in 2021, Cigna is evernoren business acquired widelive.
   In 2022, Cigna invested \$2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
- 8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023.
- 9. Previously known as IngenioRx.
- 10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
- 11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations. Source: The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 234. Companies are listed alphabetically by companies are listed alphabetically by companies.



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WYOMING STATE ONCOLOGY SOCIETY

# Impacts



# Patients













Increased cost

Confusion coordinating refills

Delays

Restricts Choice

Lower Premiums?

Safety



# Provider



Loss of Revenue



Increased
Administrative
Burden & Cost



Mandates

Providers be

"agent-of-the-patient"



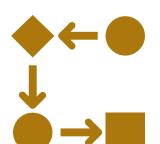
Liability



# Payer



**Increased Control** 



Increased Coordination



Savings



Increased Revenue



#### Professional Organization Recommendations

#### Association of Community Cancer Centers (ACCC)

• Cancer care providers should not be required to accept or administer drugs supplied via white or brown bagging

#### American Medical Association (AMA)

Brown-bagging can only be accepted if physician responsible approves

#### American Hospital Association (AHA)

- No brown bagging. Policies should prohibit white bagging when the dosage or compounding of a pharmaceutical product is dependent upon the results of lab tests
- Should be permissible in instances where the provider and health plan agree through their standard negotiations process. May be instances where white bagging policies are necessary to ensure patient access to a medication

#### American Society of Clinical Oncology (ASCO)

• Recommends against "brown bagging" and "white bagging" medications prepared by an outside entity

#### National Comprehensive Cancer Network (NCCN)

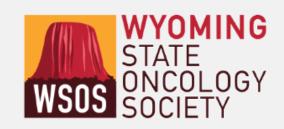
Recommends to standardize methods of communication

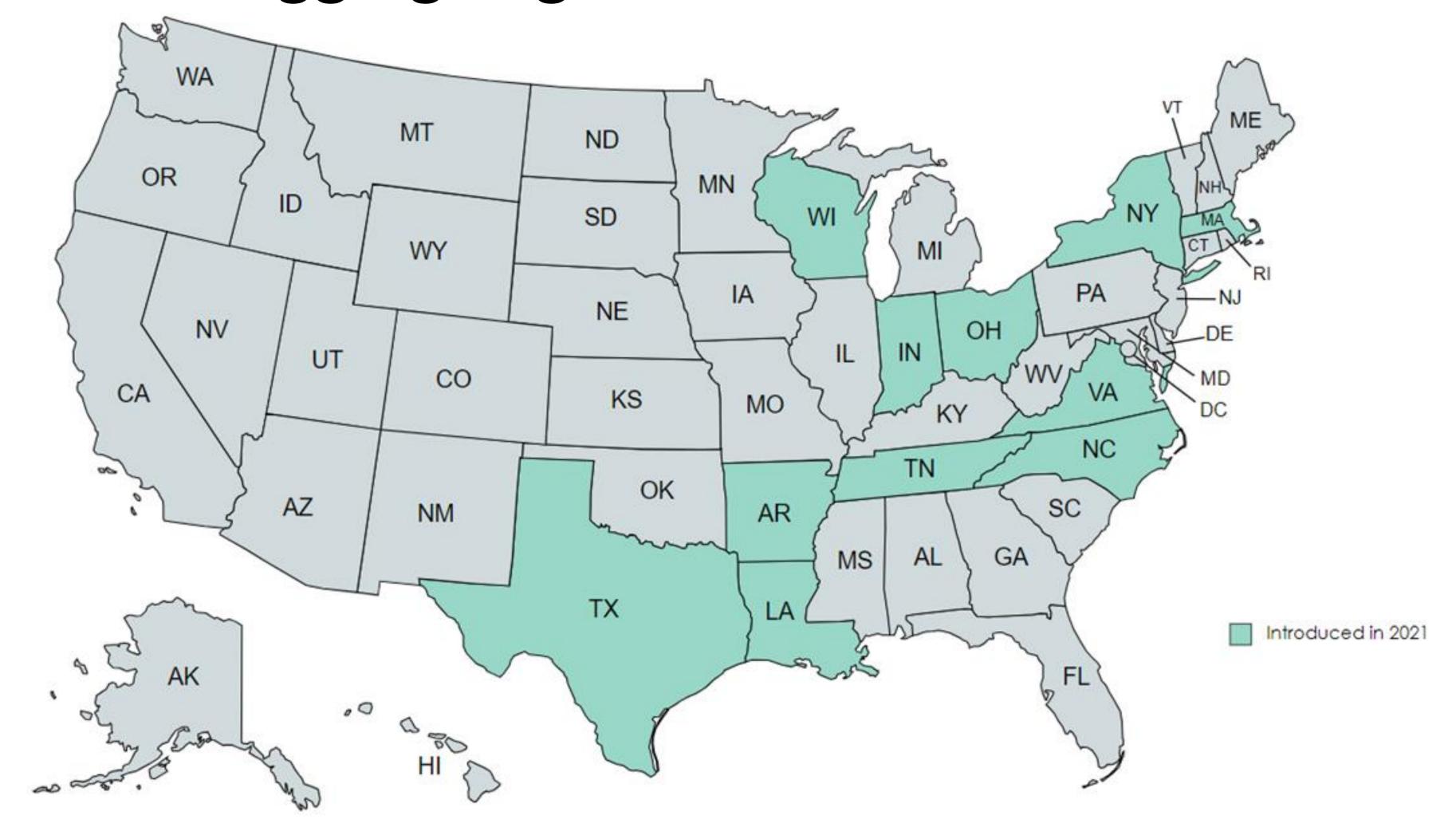
#### National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)

• Recommends to standardize processes to prevent error-prone aspects of the medication use process

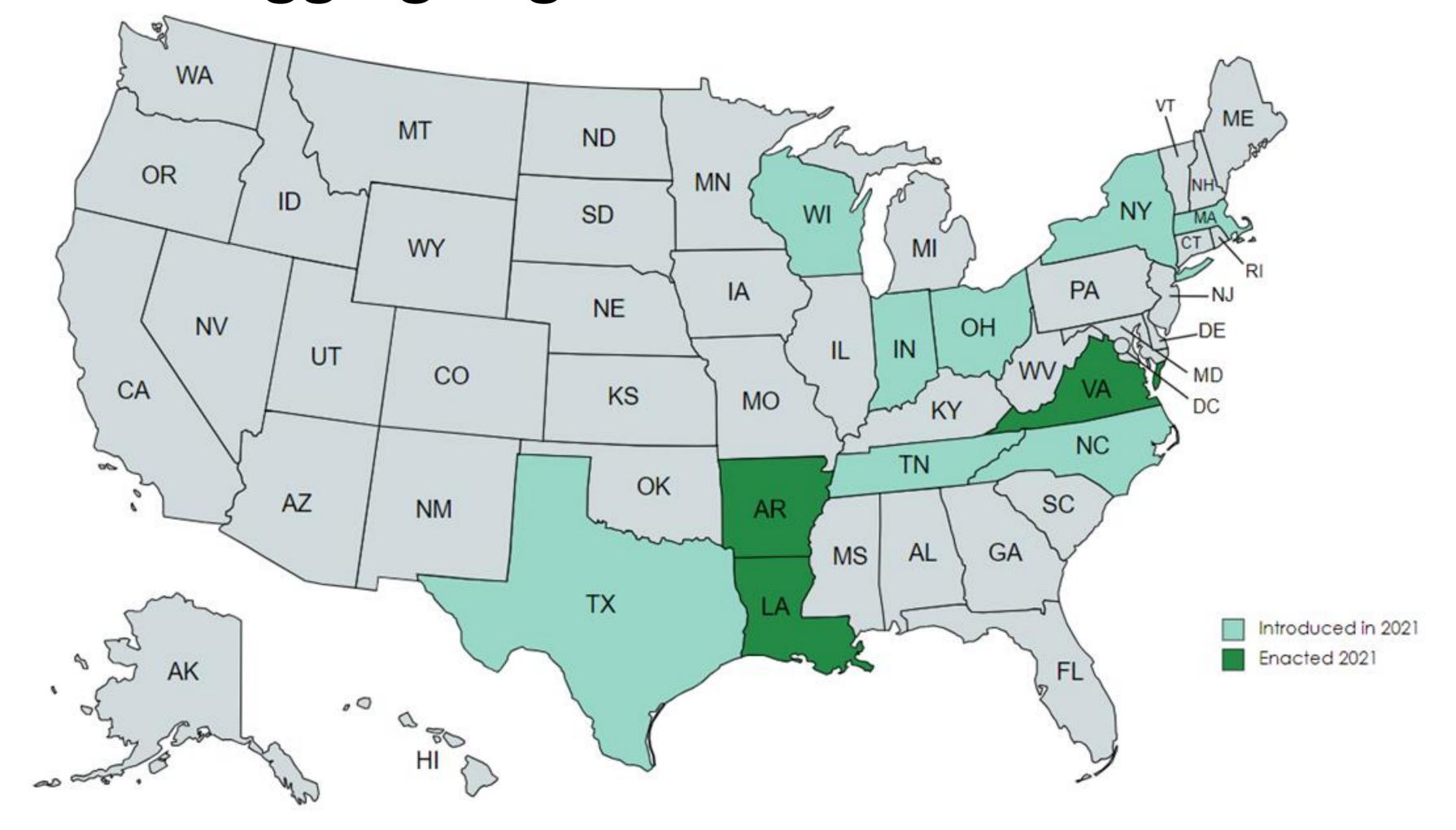


# Action

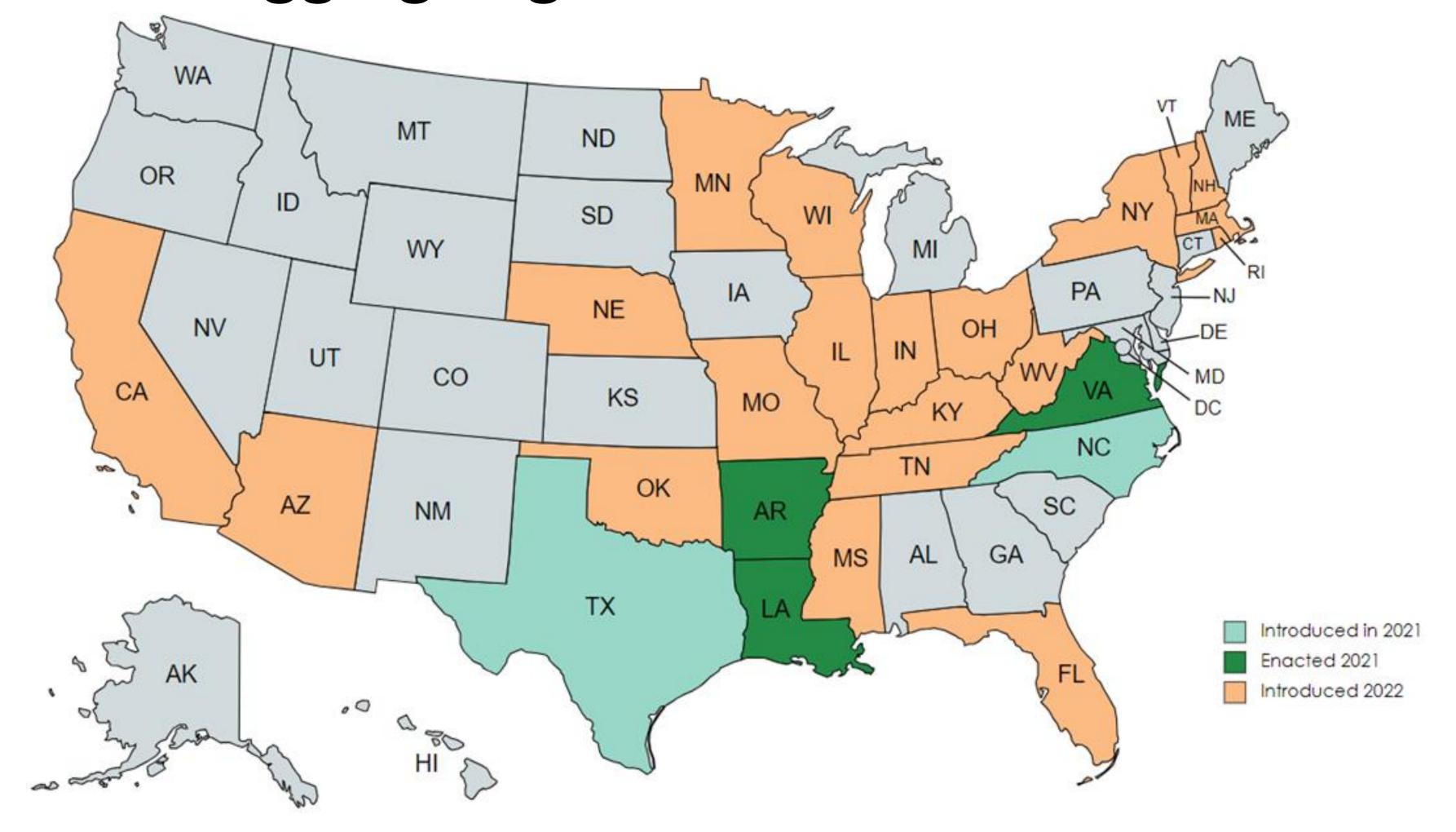




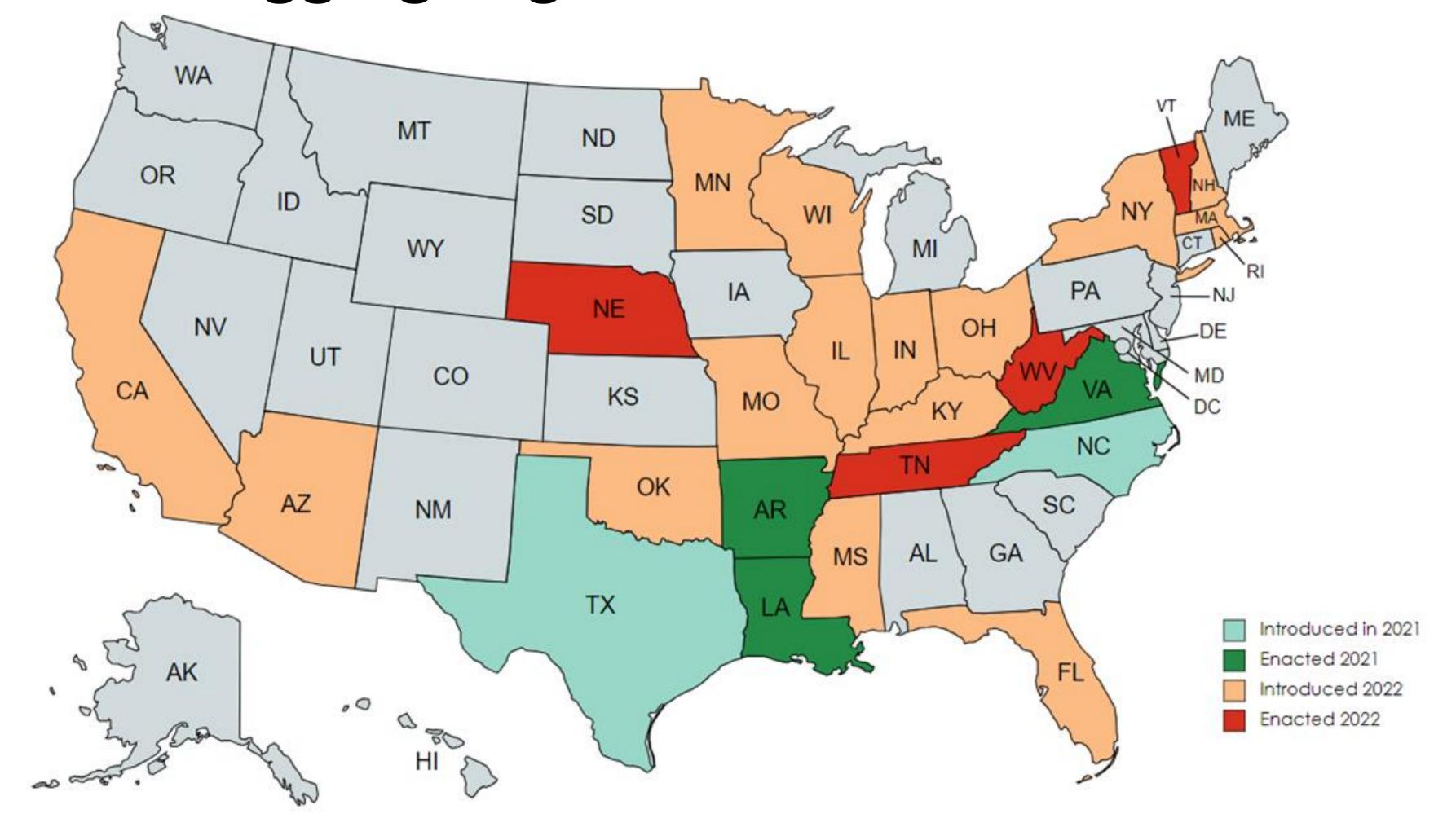




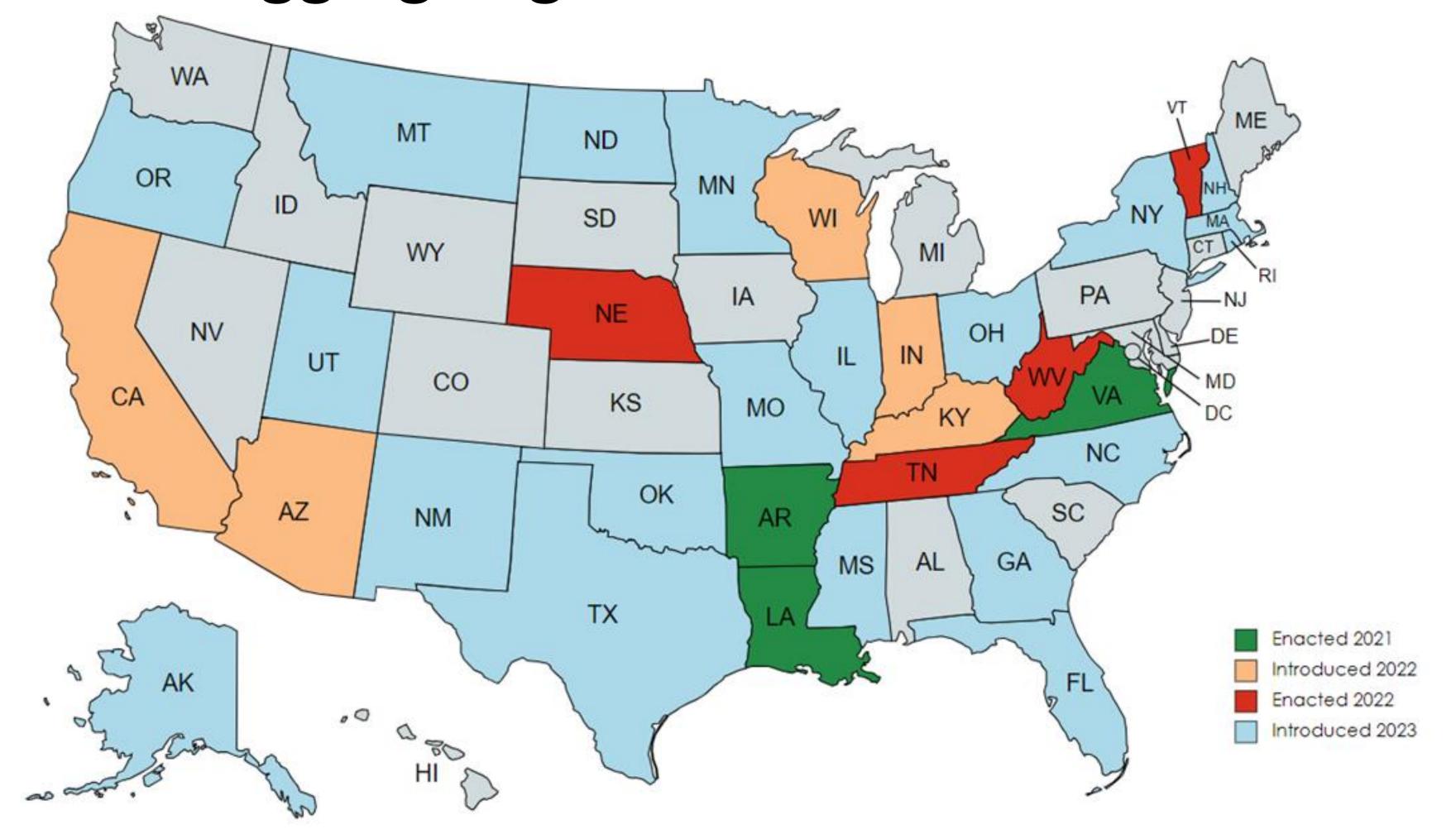




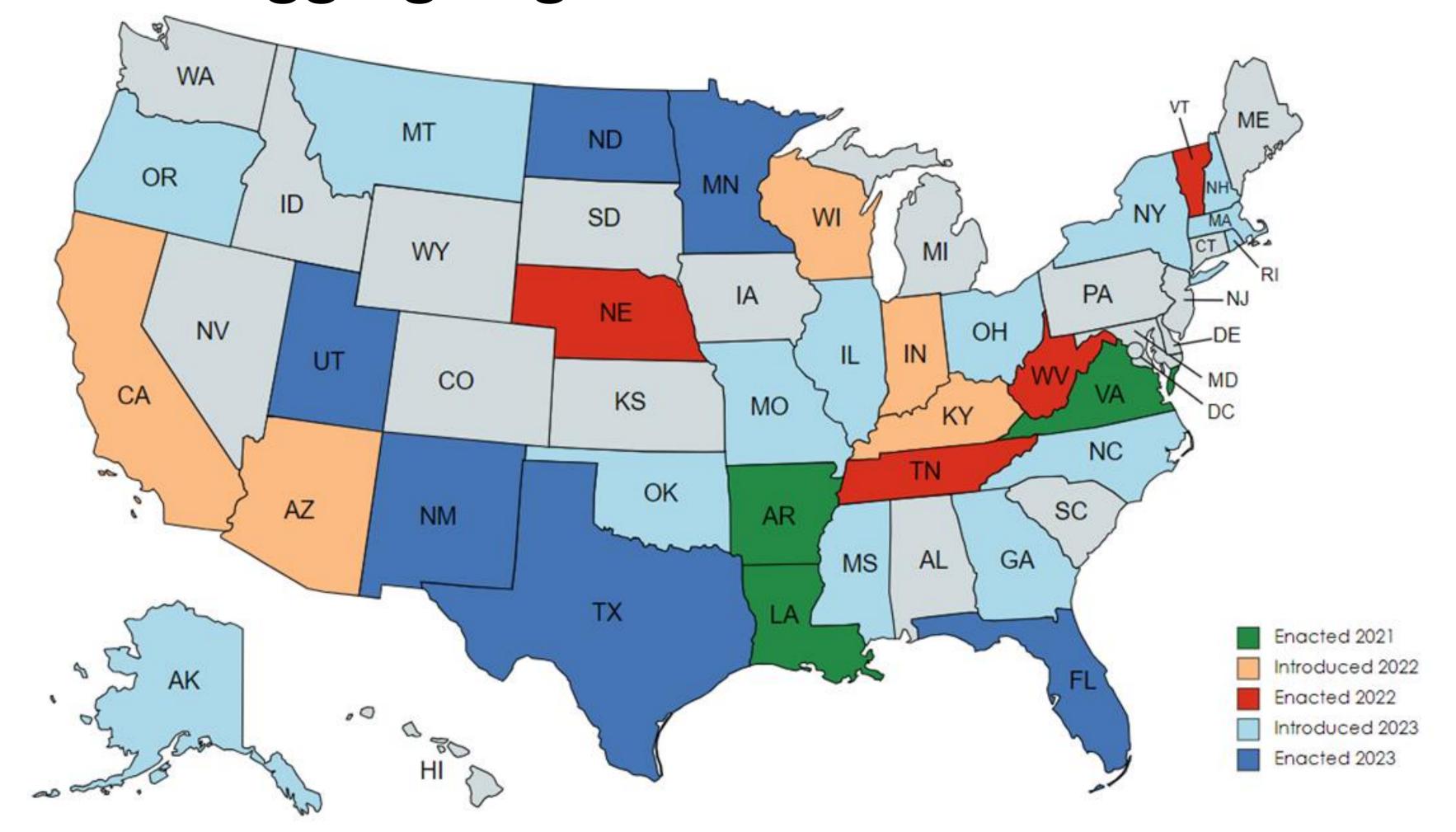














# Legislation Approaches

- 1. Brown Bagging
- 2. Choice Patient
- 3. Choice Provider
- 4. Competition
- 5. Clinical
- 6. Coordination
- 7. Checks and Balances



# Brown Bagging

•Ban the practice\* CA,GA,IL,MA,MN,NE,NH,NY,RI,UT,VA,VT,WI



# Patient Choice

- Cannot result in higher cost\*
  AZ,CA,FL,GA,KY,LA,MS,MO,NE,NM,ND,OH,OR,RI,TN,VA,VT
- Payer cannot interfere with right to choose\* MA,TN,RI
- Only allow if consent by patient CA,TX



# Provider Choice

- Determine which billing pathway in patient's best interest AR
- Must consent to be "agent-of-thepatient" CA,NY,TX
- Negotiate terms ahead MA,MN
- Autonomy to determine if medication clinically appropriate for white bagging AR,OK,OR



# Competition

- Cannot require white bagging as condition of coverage\* CA,FL,IL,KY,MN,OH,VT
- Cannot limit to only their affiliated pharmacies; "any-willing-pharmacy" verbiage\* AZ,GA,FL,IL,KY,LA,MN,MO,NE,NC,OH,RI,TN,VA,VT
- Cannot refuse authorization to participating providers or pharmacies if otherwise covered\* GA,MN,MO,ND,OK,OR,RI
- Must reimburse provider for administrative coordination MA



# Clinical

- Identify "clinically appropriate" medications for white bagging MA,NY,WV
- Establish patient safety and quality assurance measures NY,OR
- Require Board of Pharmacy to write rules regarding preparation, dispensing and administration <sup>IN</sup>
- Medication arrives in ready-toadminister form MA



# Coordination

- Transparency of Chain of Custody
  - DSCSA IL,LA,MA,MN,OR
  - USP<800> MN
  - Other MA
- Exception process established MA,MN,NH
- Payer must provide 24/7 support MA,MN
- Notification to providers and/or patients prior to enacting <sup>CA,MA,NY</sup>
- Banning use of shifting medications to pharmacy benefit for clinician administered medications KY
- Requiring coverage on both medical and pharmacy benefit AR
- Removing providers from liability for any harm resulting from practice OK



# Checks and Balances

- General PBM statutes:
  - Protection from audits and fees
  - Prohibiting spread pricing
  - Transparency
- Cannot apply more stringent requirements to non-affiliated MO,VT,OR
- Cannot pay non-affiliated less\* FL,GA,LA,MA,MS,MO,NE,NH,OH,OR,RI,WV,WI



# Legislative Strategy

- Review and understand current state statutes and rules
- Assess and understand:
  - >State white bagging impacts
  - ➤ Political mood
- Begin building coalition (Providers are a MUST)
- Educate, educate, educate
  - > Lawmakers
  - ➤ Board of Pharmacy
  - > Chamber of Commerce





# References

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# Legislation Links

- 1. Arkansas
- 2. Arizona
- 3. California
- 4. Florida
- 5. Georgia
- 6. Illinois
- 7. Indiana
- 8. Kentucky
- 9. Louisiana
- 10. Massachusetts
- 11. Minnesota

- 12. Mississippi
- 13. Missouri
- 14. Montana
- 15. Nebraska
- 16. New Hampshire
- 17. New Mexico
- 18. New York
- 19. North Carolina
- 20. North Dakota
- 21. <u>Ohio</u>
- 22. Oklahoma

- 23. Oregon
- 24. Rhode Island
- 25. Tennessee
- 26. Texas
- 27. <u>Utah</u>
- 28. Virginia
- 29. Vermont
- 30. West Virginia
- 31. Wisconsin



# THANK YOU

# Questions

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