Who is NCSL?

NCSL
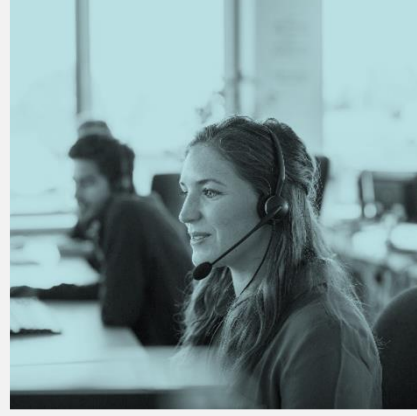NATIONAL CONFERENCE OF STATE LEGISLATURES

Policy Research

NCSL provides trusted, nonpartisan policy research and analysis
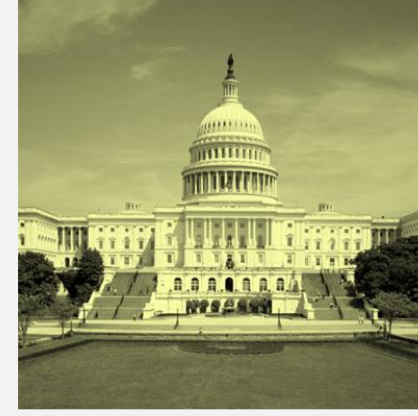
Connections

NCSL links legislators and staff with each other and with experts

Training

NCSL delivers training tailored specifically for legislators and staff

State Voice in D.C.

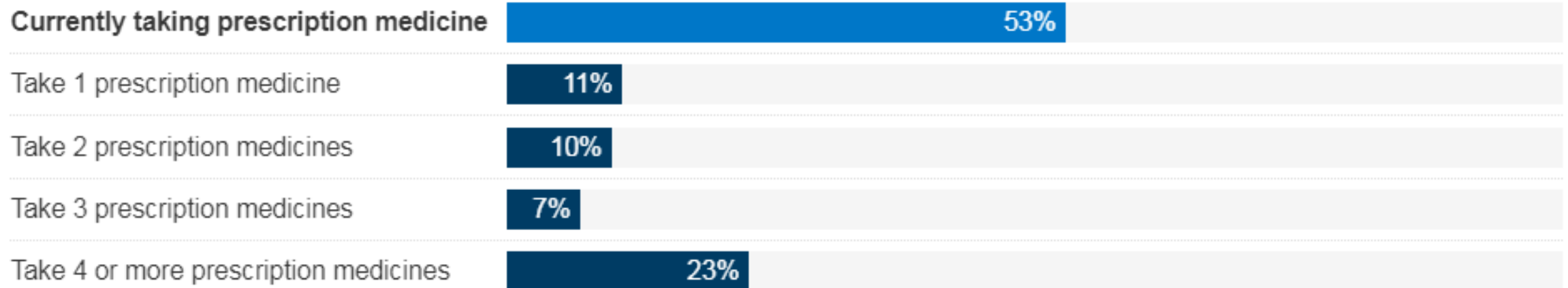NCSL represents and advocates on behalf of states on Capitol Hill

Meetings

NCSL meetings facilitate information exchange and policy discussions

Roadmap

Background → Pharmacy Supply Chain → State Policy Trends

Figure 1

Half Of Adults Report Currently Taking At Least One Prescription Medicine; About One In Four Say They Take Four Or More

Percent who say they take the following number of prescription drugs:

Currently taking prescription medicine	53%
Take 1 prescription medicine	11%
Take 2 prescription medicines	10%
Take 3 prescription medicines	7%
Take 4 or more prescription medicines	23%

NOTE: See topline for full question wording.
SOURCE: KFF Health Tracking Poll (May 18-25, 2021) • PNG

KFF

Figure 4

About Three In Ten Say They Haven't Taken Their Medicine As Prescribed Due To Costs

Percent who say they have done the following in the past 12 months because of the cost:

Not filled a prescription for a medicine

19%

Taken an over-the-counter drug instead

18%

Cut pills in half or skipped doses

12%
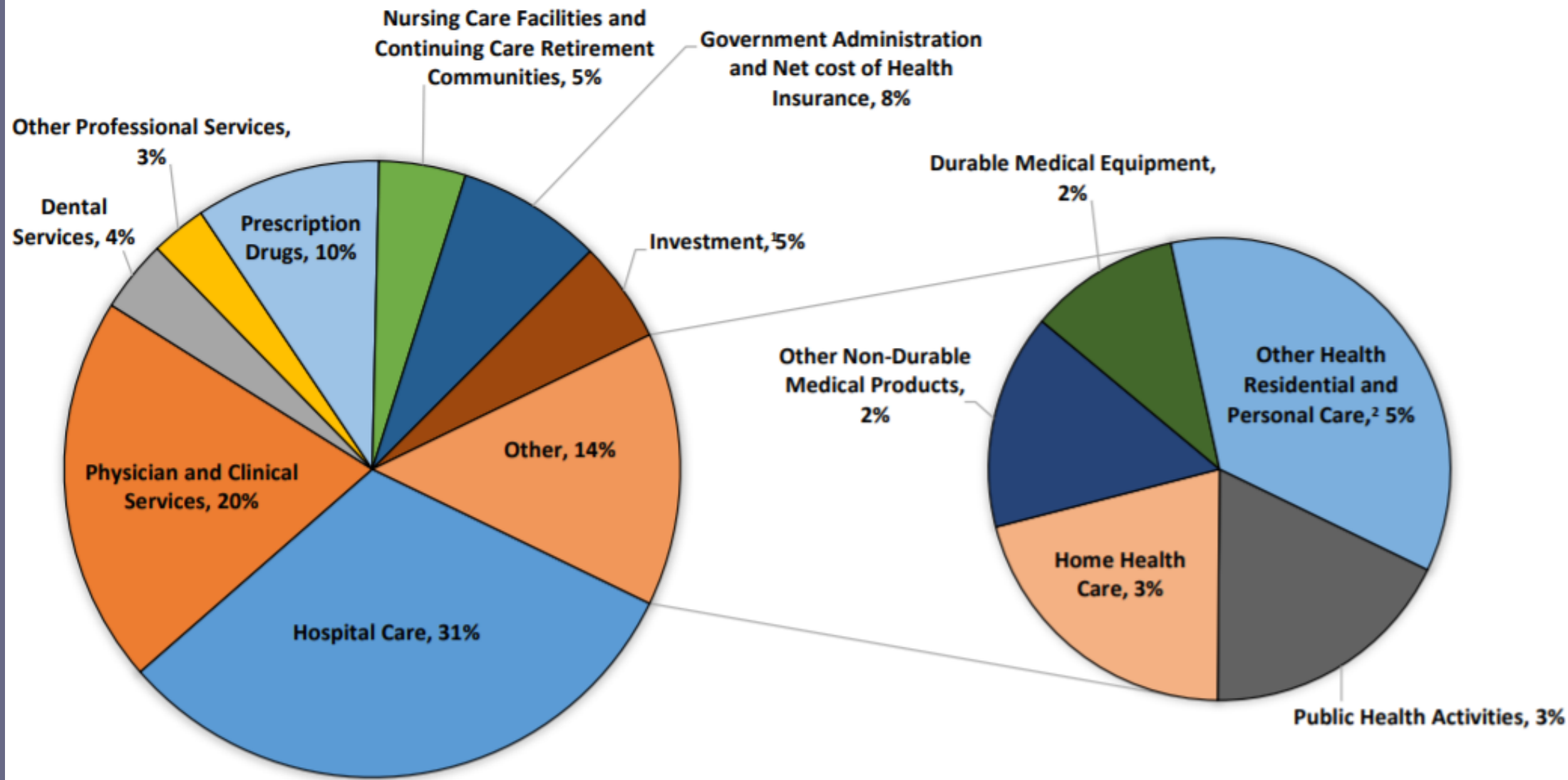
Did at least one of the above

29%

NOTE: See topline for full question wording.
SOURCE: KFF Health Tracking Poll (February 14-24, 2019) • PNG

KFF

Nursing Care Facilities and Continuing Care Retirement Communities, 5%

Government Administration and Net cost of Health Insurance, 8%

Other Professional Services, 3%

Dental Services, 4%

Prescription Drugs, 10%

Investment,[1] 5%

Durable Medical Equipment, 2%

Other Non-Durable Medical Products, 2%

Other Health Residential and Personal Care,[2] 5%

Physician and Clinical Services, 20%

Other, 14%

Home Health Care, 3%

Hospital Care, 31%

Public Health Activities, 3%

[1] Includes Noncommercial Research and Structures and Equipment.
[2] Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid.
Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Spending

States

- All 50 states participate in the Medicaid Drug Rebate Program (MDRP) for federal rebates

    - Generally, 23.1% for brand-name; 13% for generic
    - Must cover all drugs from participating manufacturers

- 5% of state Medicaid dollars spent on prescription drugs (KFF, PhRMA)

- States purchase drugs for:

    - State employee health plans/Retirees

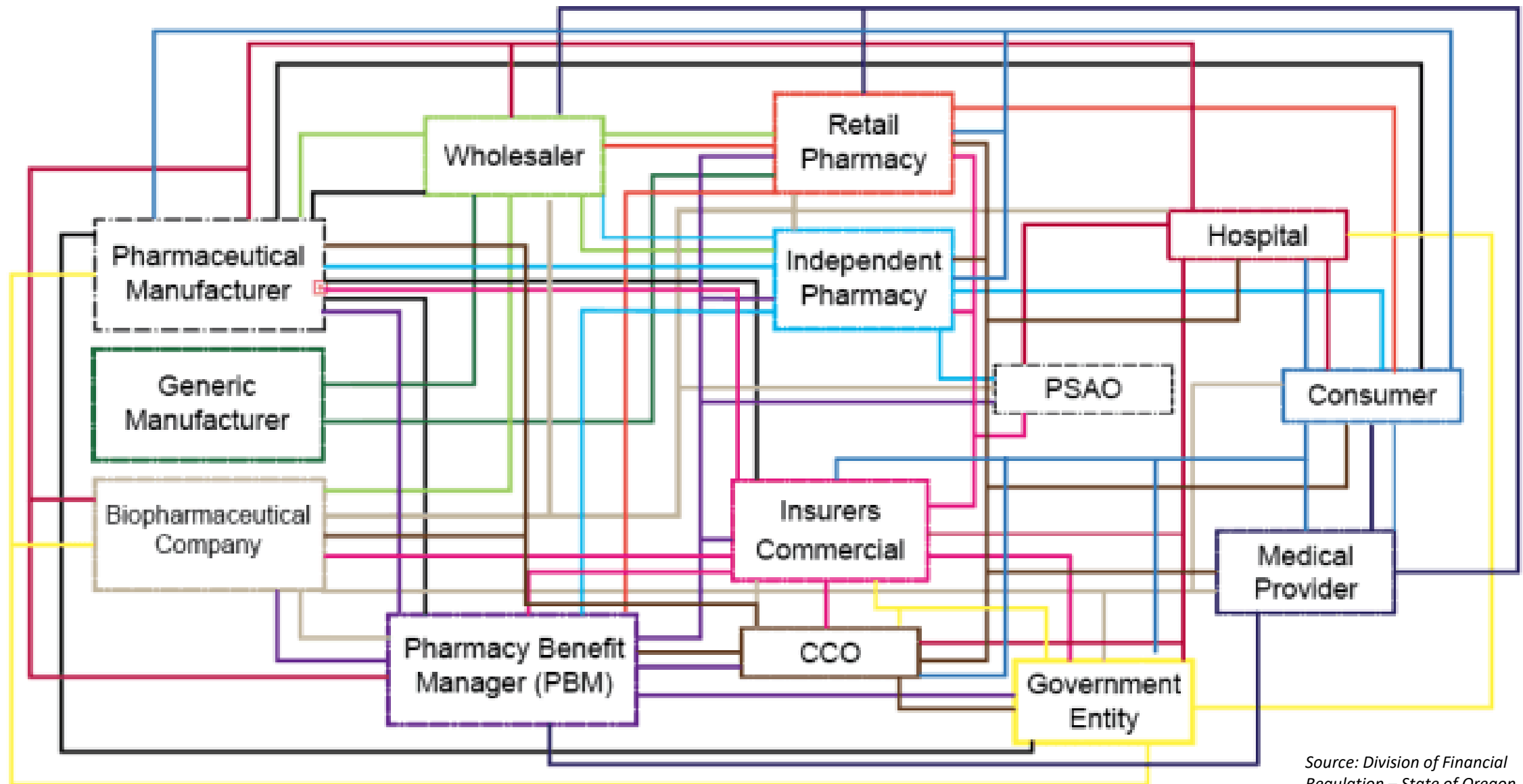   - Teachers/Universities

    - Corrections

Consumers

- Overall personal health care spending on prescription drugs averages 12-15% (KFF, GAO)

- Average patient spend = $1200/year (Bloomberg)

- 53% of retail spending on specialty drugs (IQVIA)

- States regulate plans for:

    - Fully insured

    - Marketplace

Products

- US Food and Drug Administration (FDA) approved products

  - 20,000 prescription drug products approved for marketing (dosages; delivery method)

  - 400 FDA-approved biologics products

    - Includes insulin, vaccines

    - 31 FDA-approved biosimilars

      - First biosimilar insulin approved July 2021

- Generics = 90% of filled Rx, brand = 10% of filled Rx (IQVIA)

  - Significant spending goes to brand-name specialty medicines

    - Treatments for complex or chronic conditions, rare diseases

    - Require special administration, handling and storage

    - High monthly cost = $1000/30-day supply (MagellanRx)

- Analysis often does not account for increased hospitalizations, nursing facility utilization, societal and individual costs
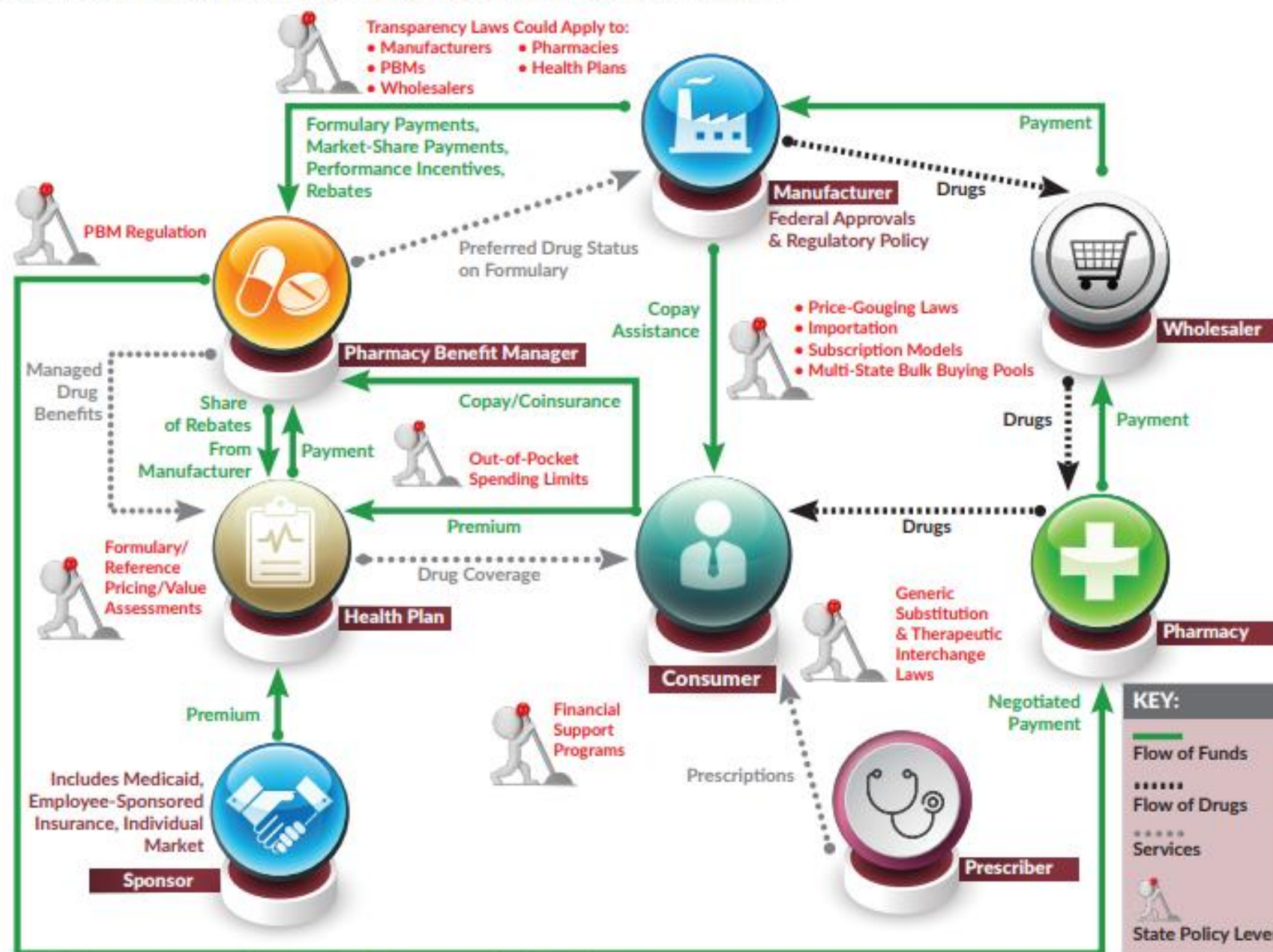
Figure 1: Pharmaceutical Supply Chain: All Direct Transactional Relationships.

Figure 1. State Policy Levers in the Retail Prescription Drug Supply Chain

Transparency Laws Could Apply to:
- Manufacturers
- PBMs
- Wholesalers
- Pharmacies
- Health Plans

Manufacturer
Federal Approvals & Regulatory Policy

Formulary Payments, Market-Share Payments, Performance Incentives, Rebates

Payment

Drugs

PBM Regulation

Preferred Drug Status on Formulary

Pharmacy Benefit Manager

Copay Assistance

- Price-Gouging Laws
- Importation
- Subscription Models
- Multi-State Bulk Buying Pools

Wholesaler

Managed Drug Benefits

Share of Rebates From Manufacturer

Payment

Copay/Coinsurance

Out-of-Pocket Spending Limits

Drugs

Payment

Formulary/Reference Pricing/Value Assessments

Premium

Drug Coverage

Drugs

Health Plan

Consumer

Generic Substitution & Therapeutic Interchange Laws

Pharmacy

Premium

Financial Support Programs

Prescriptions

Negotiated Payment

Includes Medicaid, Employee-Sponsored Insurance, Individual Market

Sponsor

Prescriber

KEY:
— Flow of Funds
····· Flow of Drugs
····· Services
State Policy Lever

Note: Model represents non-specialty prescription drugs covered by health insurance.
Source: Adapted by the Kansas Health Institute from "Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System," Health Affairs Blog, June 13, 2017.

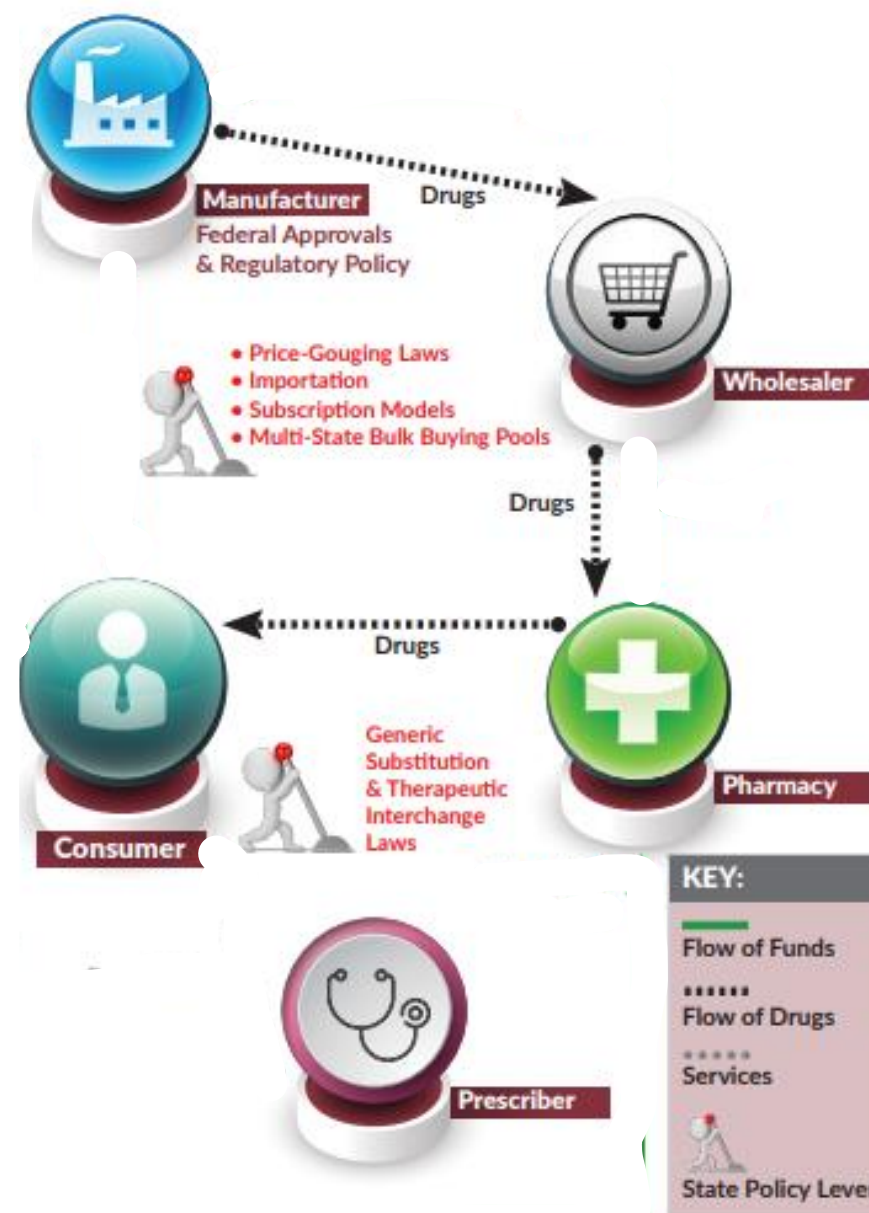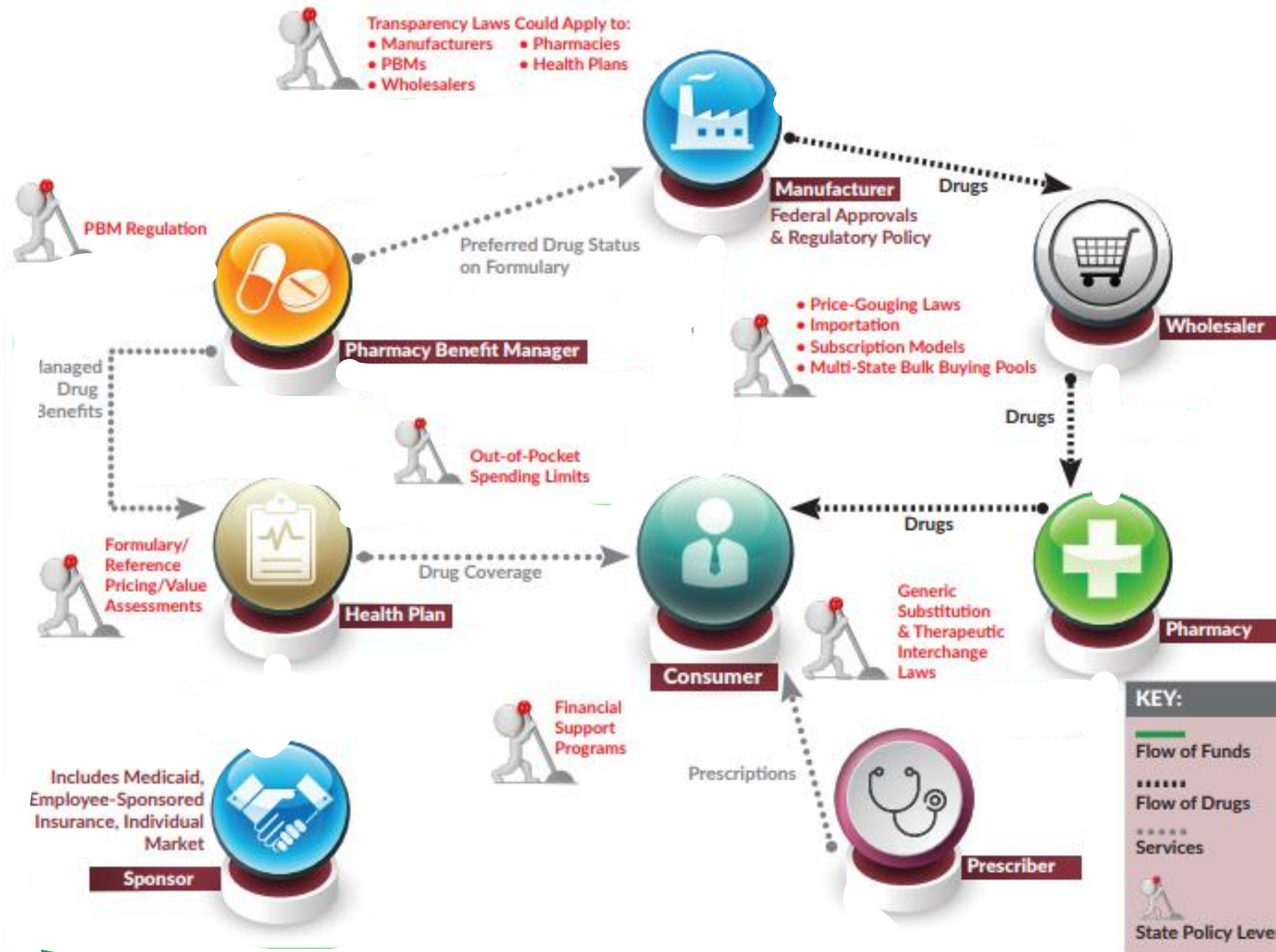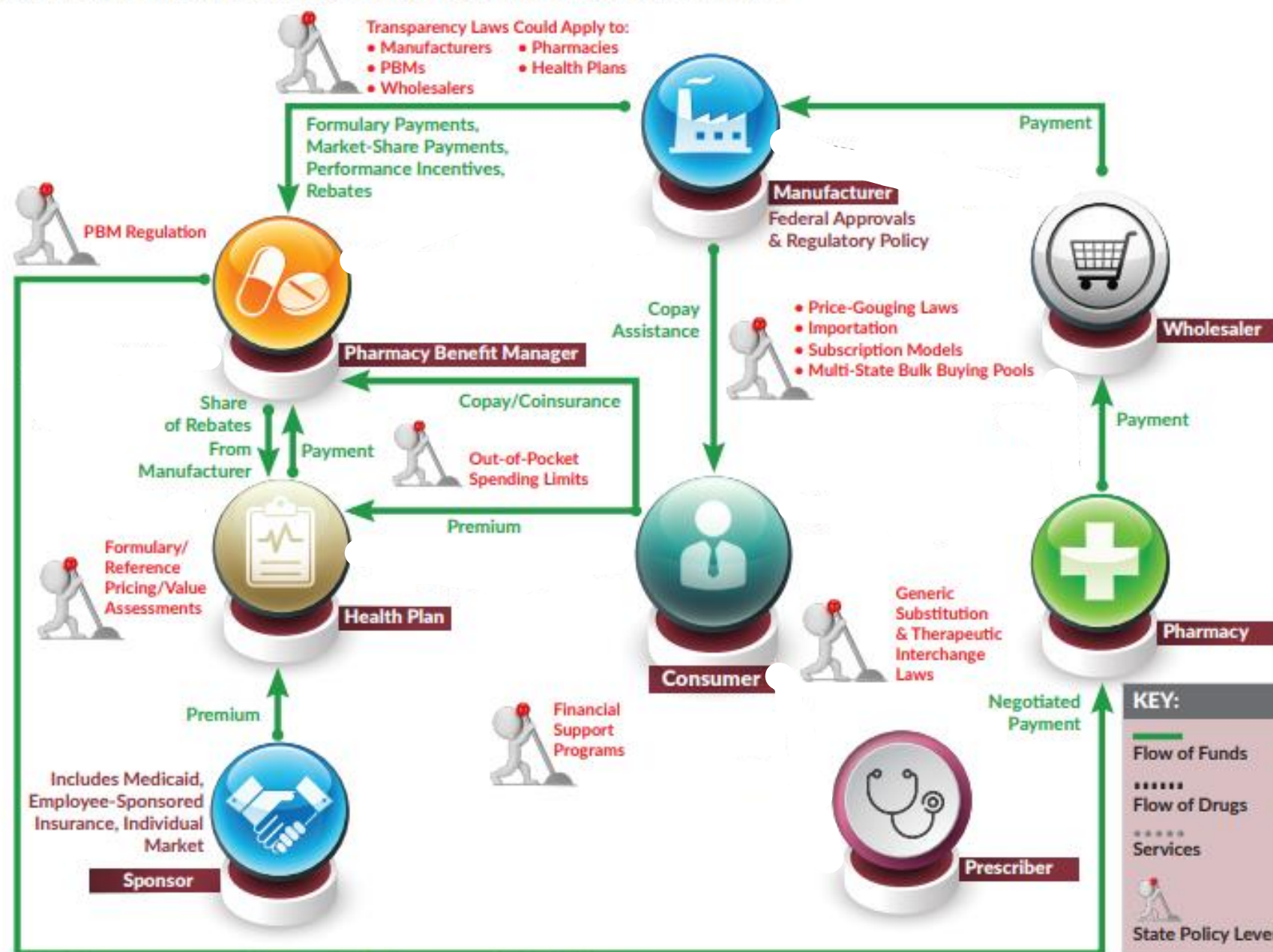**Figure 1.** State Policy Levers in the Retail Prescription Drug Supply Chain

Manufacturer
Federal Approvals & Regulatory Policy

Drugs

Wholesaler

- Price-Gouging Laws
- Importation
- Subscription Models
- Multi-State Bulk Buying Pools

Drugs

Drugs

Consumer

Generic Substitution & Therapeutic Interchange Laws

Pharmacy

Prescriber

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Out-of-Pocket Spending Limits

Formulary/ Reference Pricing/Value Assessments

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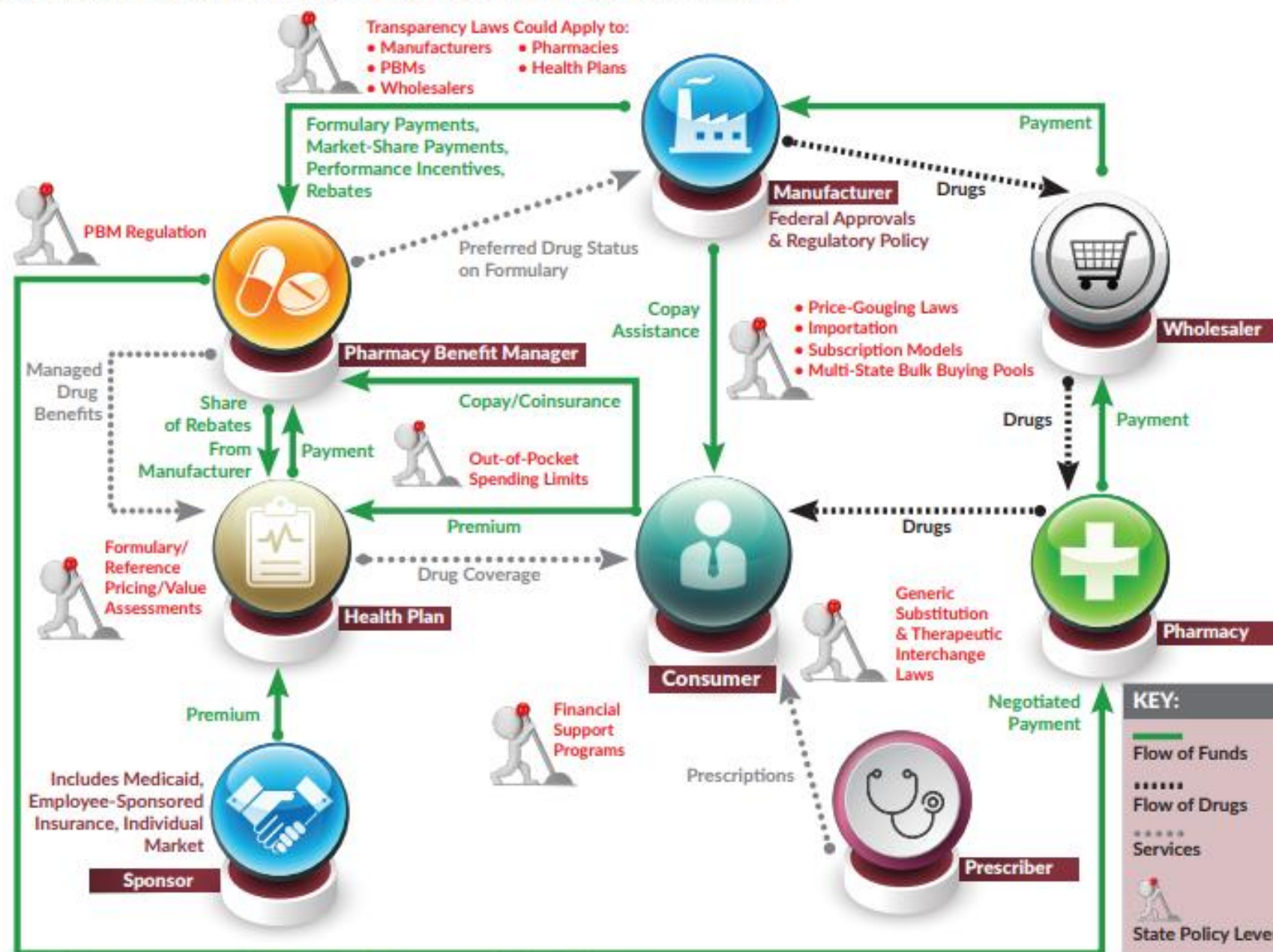
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Formulary Payments, Market-Share Payments, Performance Incentives, Rebates

Manufacturer
Federal Approvals & Regulatory Policy

Payment

PBM Regulation

Pharmacy Benefit Manager

Copay Assistance

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Wholesaler

Share of Rebates From Manufacturer

Copay/Coinsurance

Payment

Out-of-Pocket Spending Limits

Premium

Payment

Formulary/ Reference Pricing/Value Assessments

Health Plan

Consumer

Generic Substitution & Therapeutic Interchange Laws

Pharmacy

Premium

Financial Support Programs

Negotiated Payment

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Flow of Drugs

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Source: Adapted by the Kansas Health Institute from "Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System," Health Affairs Blog, June 13, 2017.

NCSL Prescription Drug Policy Database

- Spans six years and tracks legislation in all 50 states, D.C. and the territories.

- Search over **7,000 pieces of introduced and enacted** legislation in 13 categories.

- More than **750 bills** tracked across 49 states in 2021!
  - 114 enacted in 36 states.

https://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx

Statewide Prescription Drug State Bill Tracking Database | 2015–Present

10/1/2021
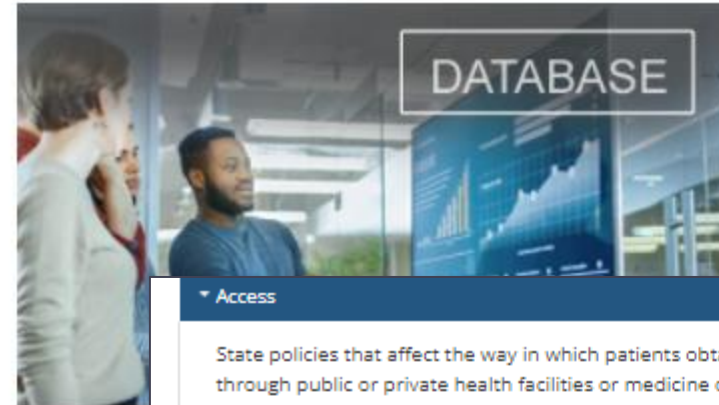
DATABASE

Welcome to the Prescription D

Search approximately 7,000 pi
keyword, status, and/or prima
to-try, compounding pharmacy
coverage, pharamcy benefit m
safety and errors, utilization m
database, please see the guide

▼ Access

State policies that affect the way in which patients obtain prescription drugs, including their availability through public or private health facilities or medicine outlets and pharmacies.

▸ Biologics and Biosimilars

▸ Clinical Trials and Right to Try – Rx Drugs

▸ Compounding Pharmacy Regulation

▸ Cost Sharing and Deductibles

▸ Coverage in Insurance – Rx Drugs

▸ Medicaid Use and Cost – Rx Drugs

▸ Other Prescription Drug Measures

▸ Pharmacy Benefit Managers (PBM)

▸ Pricing and Payment - Industry

▸ Prescription Drug Safety and Errors

▸ Specialty Pharmaceuticals

▸ Utilization Management – Rx Drugs

▸ Excluded Topics - Not in this Database

Prescription Drug Policy: A Bipartisan Remedy

Recommendation One: Determine the True Cost of Drugs

- Require price and cost transparency throughout the supply chain.
- Establish a prescription drug affordability board.
- Prohibit excessive price increases.

Recommendation Two: Streamline procurement processes and create new purchasing models

- Procure pharmaceuticals through purchasing pools and alternative payment models.
- Leverage savings and prevent duplicate discounts under the federal 340B program.
- Pursue importation agreements with other countries.

Recommendation Three: Encourage or introduce competition into the supply chain.

- Increase state oversight of market competition.
- Reform pharmacy benefit management (PBM) practices.

https://www.ncsl.org/research/health/prescription-drug-policy-a-bipartisan-remedy.aspx

Policy Options

States and Taxpayers

APMs

Bulk purchasing/pools

Leveraging 340B

Reference pricing

Preferred drug lists (PDLs)

States can negotiate:
- *Medicaid—Supplemental Rebate Agreement (SRAs)*
- *Corrections contracts*
- *State employee health plans (SEHP)*

Both

PBM reform

Price and cost transparency

PDABs

Importation

Utilization management

Generic and biosimilar uptake

Patients

Cost-sharing limitations

Consumer protections

Patient accessibility

Patient assistance programs

And can regulate:
- *Fully-insured plans*
- *Individual market*

Utilization Management Processes

Tools pharmacy benefit managers (PBMs), health plans and other payers use to influence patterns of prescribing.

Step Therapy

When a patient is required to try certain treatments or prescription drugs before switching to a more expensive or non-generic alternative.

Prior Authorization

Provider seeks preapproval from the health plan or PBM for a drug or treatment before it can be administered to the patient.

Non-Medical Switching

Non-medical switching occurs when a patient who is stable on one medicine is switched to another for reasons other than clinical purposes.

Uniform Prior Authorization

NEW MEXICO

KNOW THE LAW

Prior Authorization (Chapter 187 2019 Laws)

What the Law Says

Submitting a Prior Authorization Request

Prior authorizations will frequently require documentation supporting the request for coverage. Establishing processes in your practice that identify and document information required for prior authorizations will streamline submission and maximize chances of success.

Chapter 187 of the 2019 Laws (SB 188) requires use of a standard prior authorization form by health insurers,

In addition, insurers must provide for electronic submission and auto-adjudication of electronic prior authorization requests by January 1, 2021.

Response Timeframe

A determination must be issued within 7 days or within 24 hours when exigent circumstances exist. If the health plan fails to abide by these timelines the request for prior authorization is considered granted.

Denial of a prior authorization request must include grounds for the denial and a notice of the right to appeal.

https://csro.info/non_cms_pages/legislation-in-your-state.php
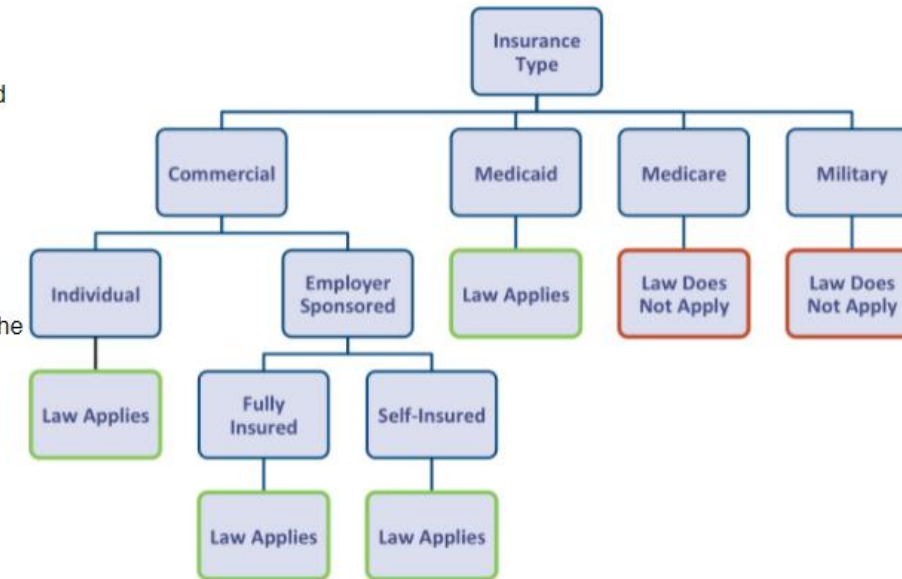
Step Therapy (Chapter 9, Sections 1 – 6, Laws 2018)

What the Law Says

Submitting an Exception Request

Under Chapter 9 of New Mexico's 2018 laws, a health plan must provide enrollees and prescribing practitioners to a clear, readily accessible, and convenient process to request a step therapy exception. A plan may use its existing medical exceptions process to satisfy this requirement. The process must be made available on the plan's website.

The process for submitting a step therapy exception request may vary from payer to payer. To maximize your chances of receiving a favorable determination it is important to familiarize yourself with the specific payer's process and requirements. Exception requests that are insufficiently documented or do not follow the payer's procedure may be denied or result in additional time expenditure.

Establishing processes in your practice that identify and document information required for each payer's exceptions process will streamline this process for your practice. Regardless of the process be sure document the content, date, and time of your communications.

Here's what you should know before initiating an exception request:

- What forms & documentation of medical necessity are required
- How the payer expects to receive the information
- How the payer will communicate their determination
- Relevant timelines

Exceptions Criteria

New Mexico state law requires certain health plans to expeditiously grant an override of a step therapy protocol if at least one of the following conditions is established to exist based on medical necessity and a clinically valid explanation*:

- The required drug is contraindicated or will likely cause and adverse reaction by or physical or mental harm;
- The required drug is expected to be ineffective;
- The patient has tried the required drug or another drug in the same pharmacologic class or with the same mechanism of action as the required drug, and the drug was discontinued due to lack of efficacy, diminished effect, or an adverse event;
- The required drug is not in the best interest of the patient because the required drug would:
  - Cause a significant barrier to adherence or compliance with a plan of care;
  - Worsen a comorbid condition
  - Decrease the patient's ability to achieve or maintain reasonable functional ability performing daily activities.

*The exceptions criteria outlined above are a summary of state law. Please consult the full text of the legislation found via the button below to determine whether a patient is eligible for a step therapy protocol override, or to view any documentation requirements.

Timeframes

A plan must make a determination within 72 hours of receipt, or within 24 hours when exigent circumstances exist. If a plan does not respond to a request within the given timeframe the request is considered granted.
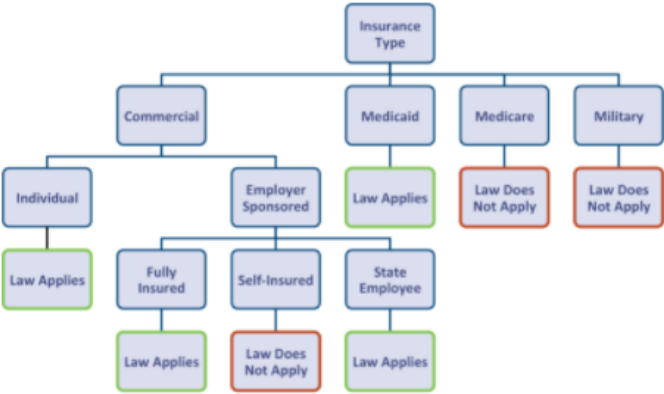
Applicability

To best determine what type of health plan a patient is enrolled in and whether it is subject to the law, use the contact information found of the insurance card issued to the patient.
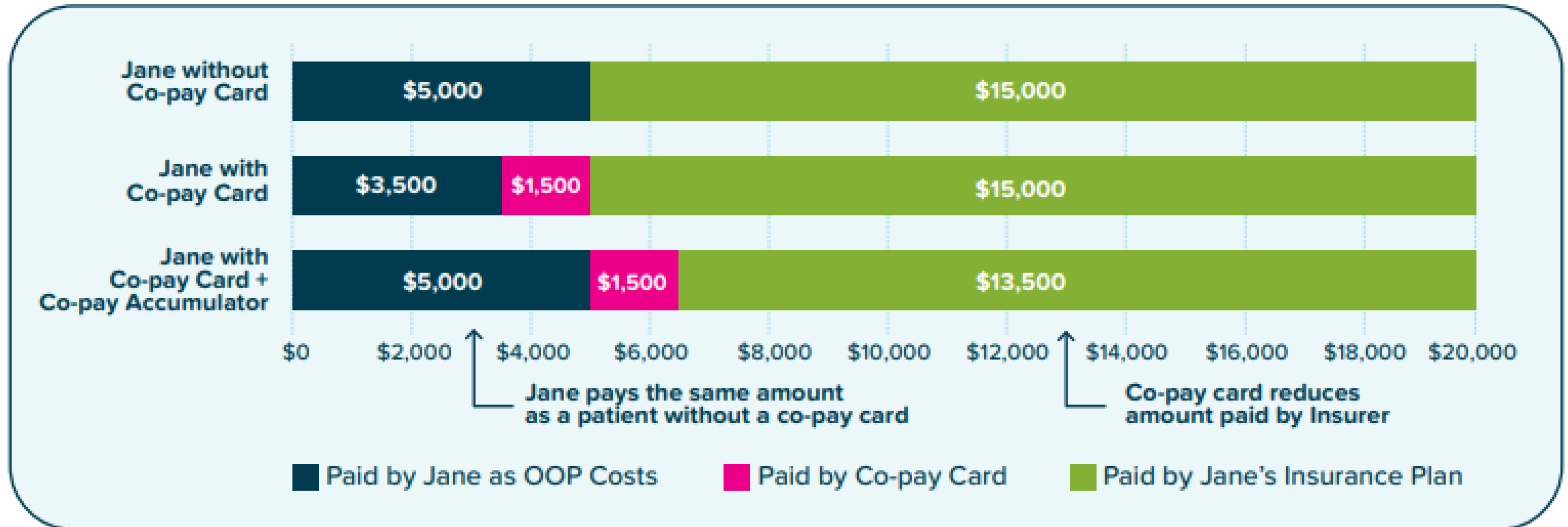
Helpful tip: if the card says the policy is "underwritten by" the insurer, then the plan is likely an individual or group insurance policy regulated by the state. If the card says the policy is "administered by" the insurer or "administrative services only" (ASO), then the plan is likely a self-funded plan not subject to state insurance laws.
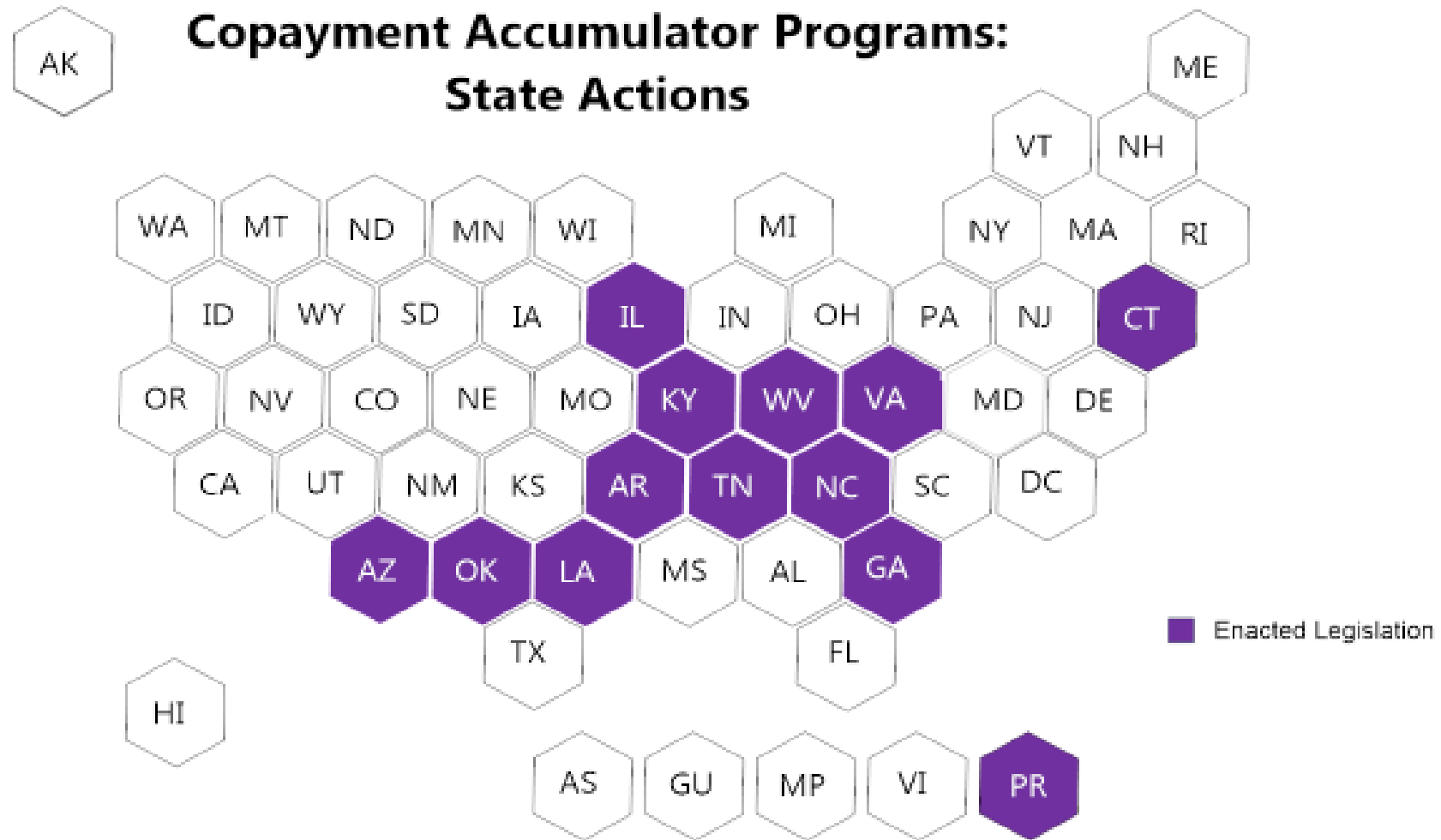
Further Appeals

Denial of a step therapy exception request is subject to further appeal under New Mexico's Patient Protection Act.

Copayment Adjustment Programs

Jane without Co-pay Card
$5,000 (Paid by Jane as OOP Costs) | $15,000 (Paid by Jane's Insurance Plan)

Jane with Co-pay Card
$3,500 (Paid by Jane as OOP Costs) | $1,500 (Paid by Co-pay Card) | $15,000 (Paid by Jane's Insurance Plan)

Jane with Co-pay Card + Co-pay Accumulator
$5,000 (Paid by Jane as OOP Costs) | $1,500 (Paid by Co-pay Card) | $13,500 (Paid by Jane's Insurance Plan)

Axis: $0, $2,000, $4,000, $6,000, $8,000, $10,000, $12,000, $14,000, $16,000, $18,000, $20,000

Jane pays the same amount as a patient without a co-pay card

Co-pay card reduces amount paid by Insurer

Legend: Paid by Jane as OOP Costs | Paid by Co-pay Card | Paid by Jane's Insurance Plan

Example from Patient Access Network Foundation

Copayment Accumulator Programs: State Actions

(c) NCSL - Updated October 2021

https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx

Insulin

Nineteen states cap consumer copayments ranging from $25-$100 per 30-day supply

Arkansas

No copay cap but prohibits the use of manufacturer coupon for insulin products.

Minnesota

Establishes copay cap, and patient assistance and emergency access programs both paid for by manufacturers.

State Legislation Capping Insulin Copayments

Enacted states: WA, MN, IL, OR, CO, KY, WV, VA, DE, UT, NM, OK, TX, AL, NY, VT, NH, ME, RI

LEGEND
■ Enacted

(c) NCSL - Updated Sept. 30, 2021

https://www.ncsl.org/research/health/diabetes-health-coverage-state-laws-and-programs.aspx
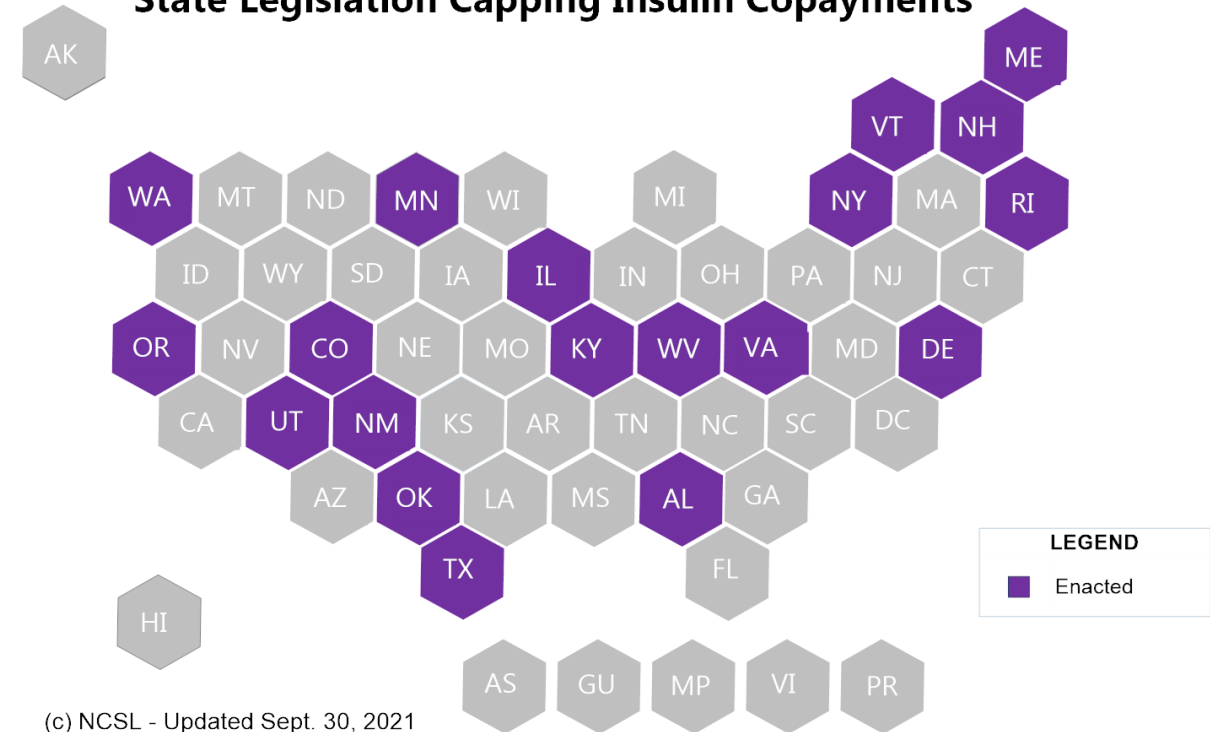
Limits on copayments

- At least 11 states have limits on patient copayments.

- California (HSC § 1342.71)

  - State regulated plans = $250/mo. and up to $500/mo. on some high deductible plans.

- Specialty drugs – $150/30-day supply

  - Delaware

  - District of Columbia

  - Maryland

  - Louisiana

Research suggests caps on specialty drugs may ease financial burden on patients who have high prescription drug costs with minimal impact on overall premiums.

State Pharmacy Benefit Manager (PBM) Reform

247 bills introduced in 49 states!

Meaning…

43% of enacted laws are PBM related

Prohibit Gag-Clauses

Licensure/Registration

Network Adequacy/Mail Order

Utilization Management

Reverse Auctions

Fiduciary Requirements

Data transparency and reporting

Pricing contract revisions
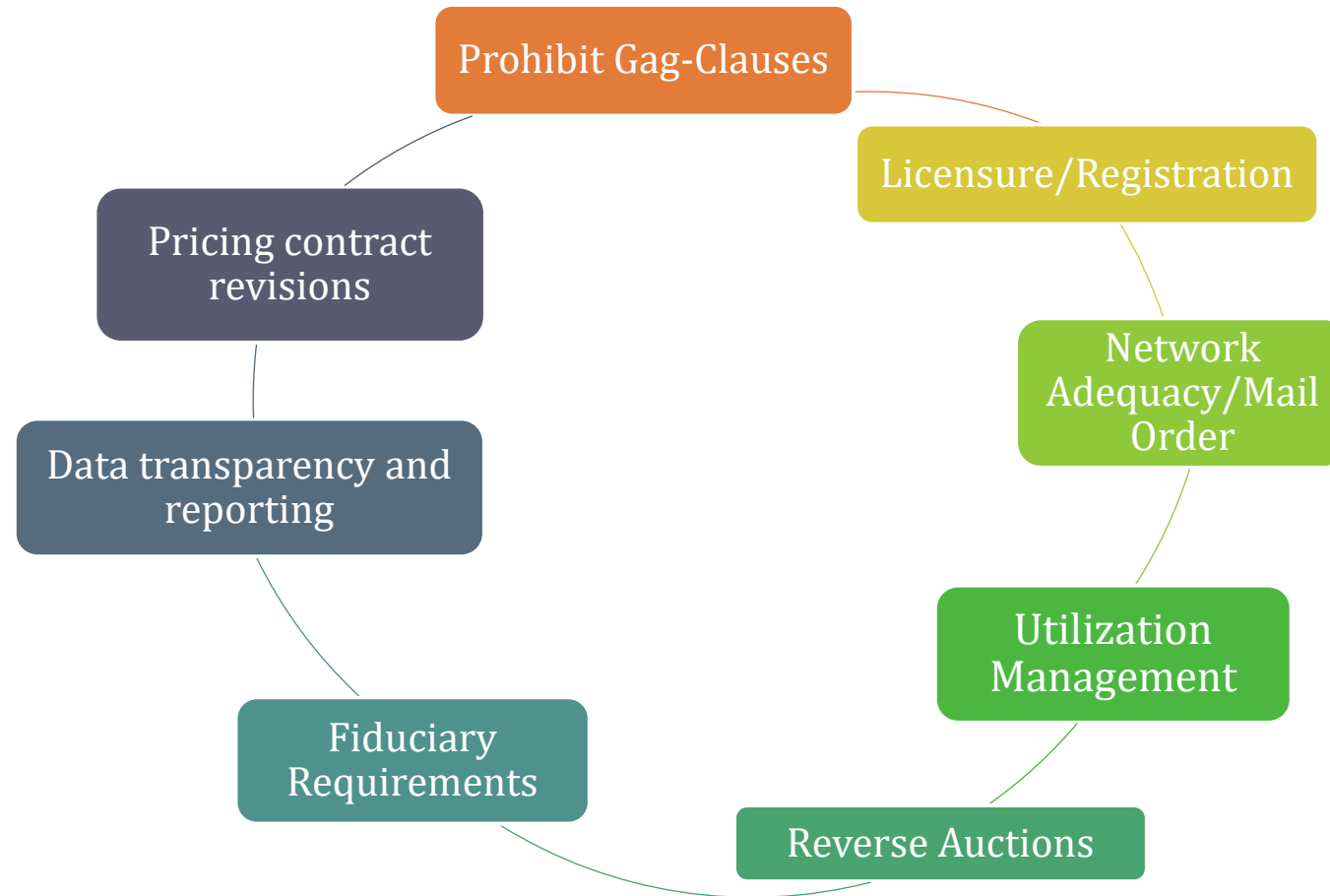
New Mexico

Provision	Statute
Cost-Disclosure/Gag-Clause	59A-61-5E(3)(b)
Fiduciary	
Maximum Allowable Cost (MAC) or Reimbursement Lists	59A-61-4
Network Adequacy	59A-61-5(H)
Patient Steering	
Pharmacy Reimbursement Clawbacks	59A-61-4(B) 59A-61-7
Pharmacy Auditing Standards Appeals Process	59A-61-4(D)(4)
Registration/Licensure	59A-61-3
Regulatory Agency/Enforcement	59A-61-3
Reporting/Transparency Requirements	
Spread Pricing	
Utilization Management Tools	59A-22B-4 59A-22B-5 59A-22-53.1

https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx

Price Transparency

	Manufacturer Price Increases	Manufacturer Launch Prices	Pharmacy benefit managers (PBMs)	Health Plans
California (2018)	●	●		●
Connecticut (2018)	●	●	●	●
Maine (2019)	●	●	●	●
Minnesota (2020)	●	●	●	
Nevada (2018 and 2019)	●		●	
North Dakota (2021)	●		●	●
Oregon (2018 and 2019)	●	●		●
Texas (2019)	●		●	●
Utah (2020)	●		●	●
Vermont (2018)	●	●		●
Virginia (2021)	●		●	●
Washington (2019)	●	●	●	●

Prescription Drug Multi-State Bulk Purchasing Pools 2021

LEGEND
- NMPI
- TOP$
- SSDC
- NPDC (non-Medicaid)

All 50 states participate in MMCAP
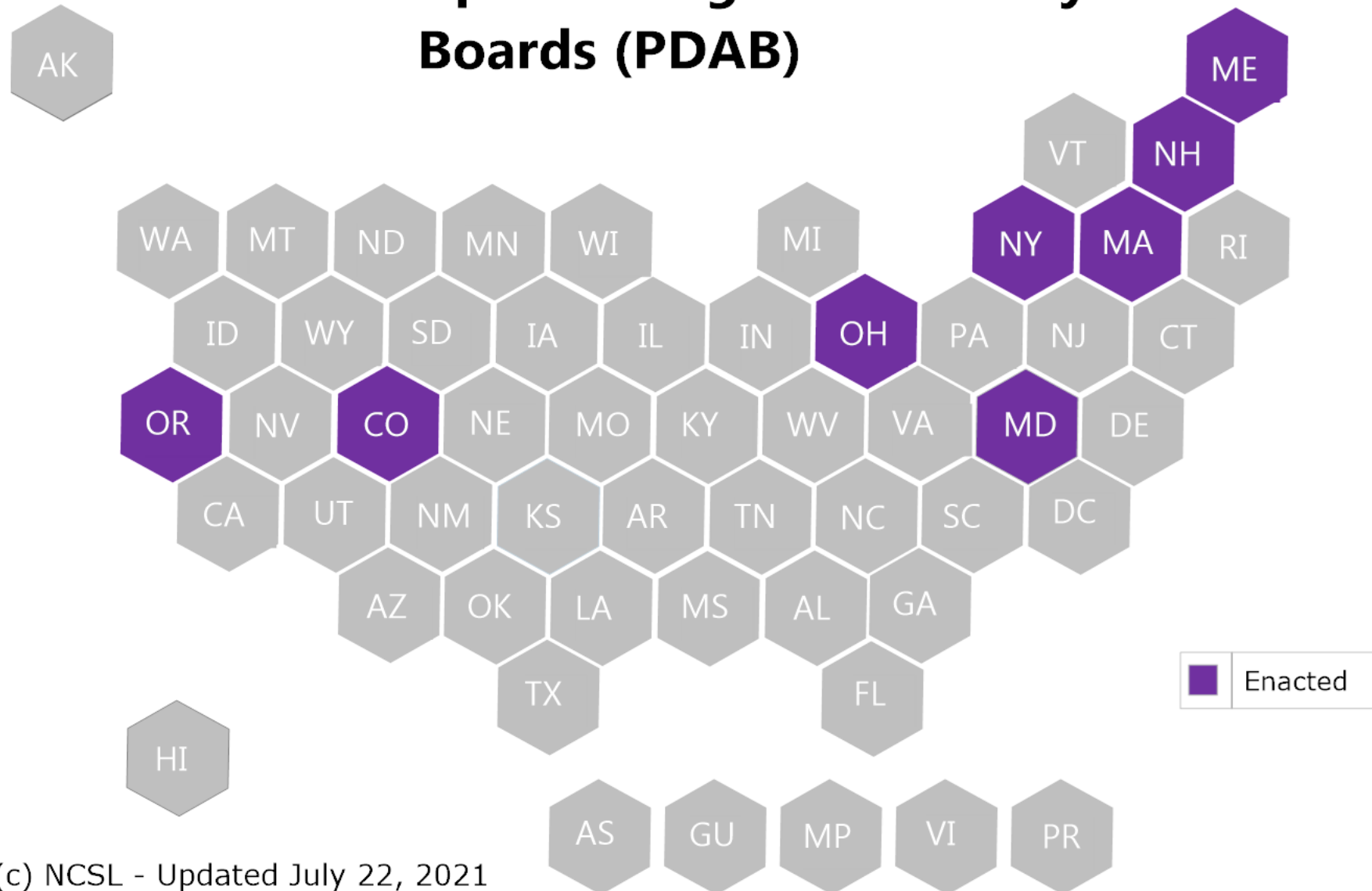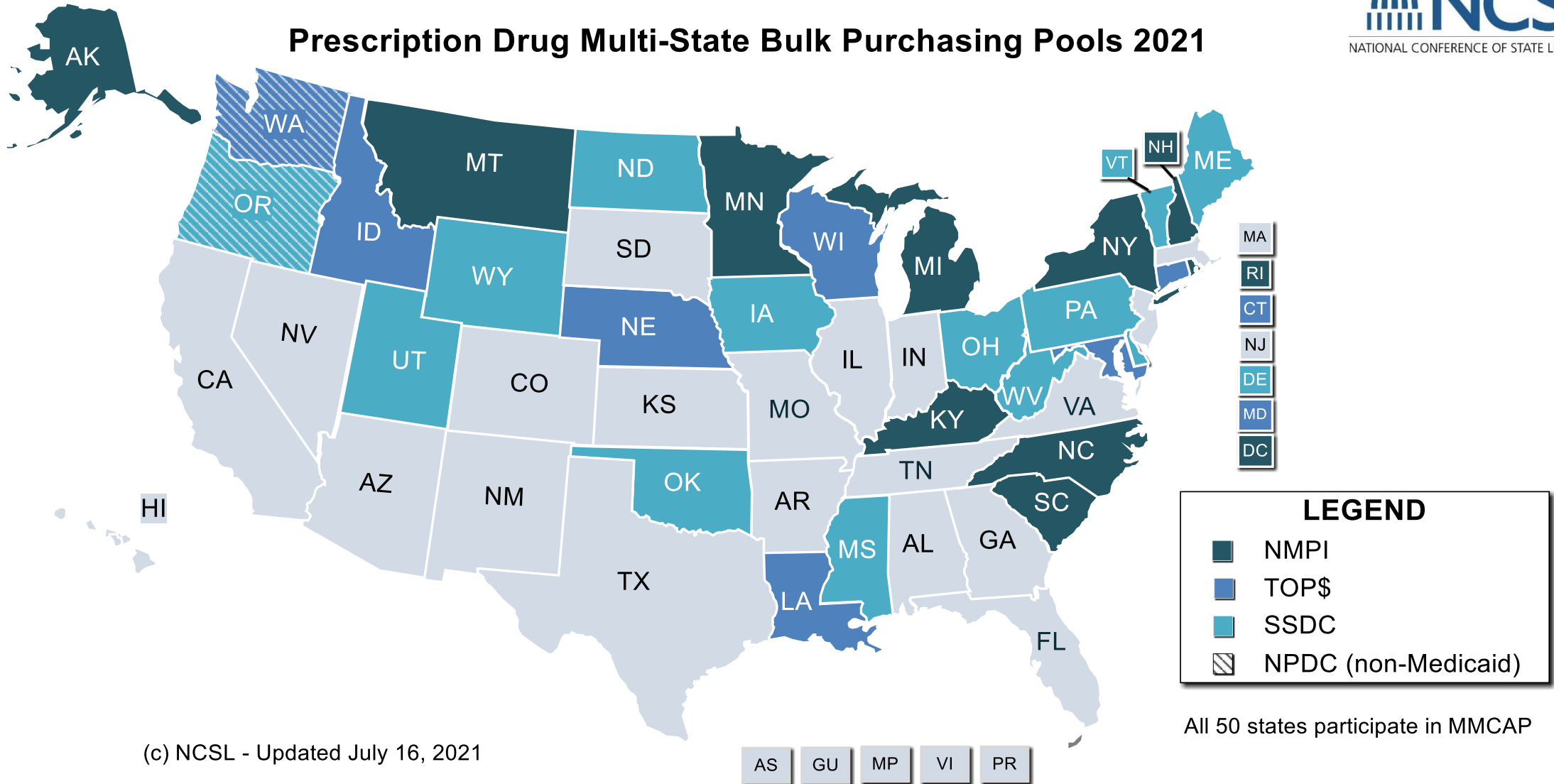
(c) NCSL - Updated July 16, 2021

https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx

Alternative Payment Models (APMs)

Performance-Based

- Five states approved by CMS for state plan amendments: CO, MA, MI, OK, WA
  - Ties payment to certain metrics, outcomes
  - Oklahoma has contracts with four manufacturers

Spending Targets/Caps

- Maine, Massachusetts, New York
- May be linked to medical rate of inflation, spending targets
- If projected spending exceeds cap, drugs identified for additional supplemental rebates

Subscription-Based

- Three states approved by CMS: LA, MI, WA
  - Broader state strategies to eliminate Hepatitis C
  - Multi-year contract; state receives a certain amount of drug for a flat fee, then receives doses over this amount for discounted rate.

Annuity

Reinsurance

Risk-Pools

- Medicaid will have to cover cell and gene therapies in pipeline.
- Massachusetts and Michigan have pay-over-time+performance
- Tennessee waiver for closed formulary approved Oct 2021

States with Drug Importation Laws
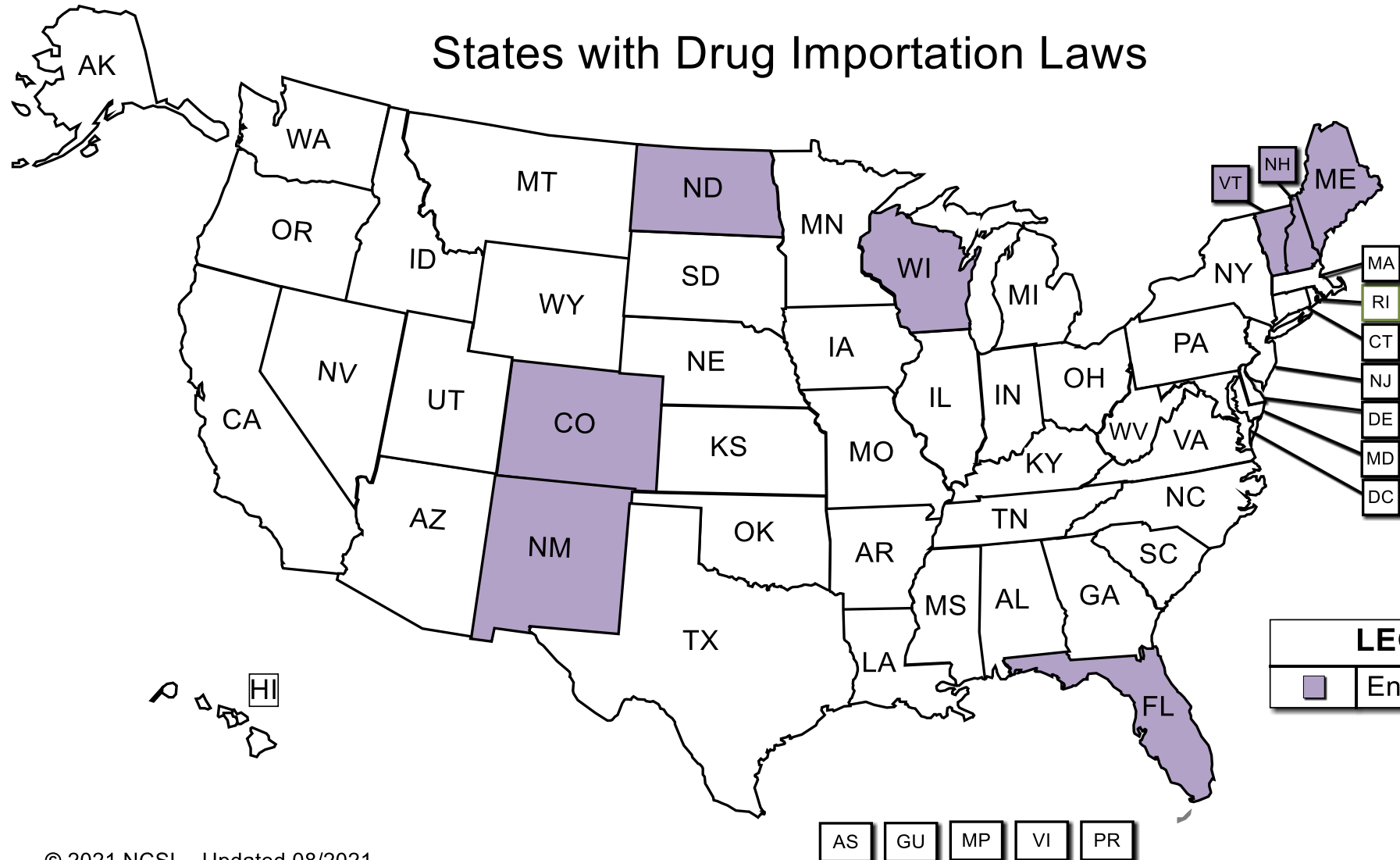
© 2021 NCSL - Updated 08/2021
See NCSL Prescription Drug Law Database for details at www.ncsl.org

LEGEND
Enacted

What can we expect in 2022?

- https://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx

- https://www.ncsl.org/research/health/prescription-drug-policy-a-bipartisan-remedy.aspx

- https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx

- https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx

- https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx

- https://www.ncsl.org/research/health/diabetes-health-coverage-state-laws-and-programs.aspx

NCSL Resources

Outside Resources

Slide four and five

- https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

Slide six

- https://www.cms.gov/files/document/highlights.pdf

Slide seven

- https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/
- https://www.phrma.org/policy-issues/medicaid
- https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/
- https://www.gao.gov/prescription-drug-spending
- https://www.bloomberg.com/quicktake/drug-prices
- https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us

Outside Resources

Slide eight

- https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance
- https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
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