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The More You Know: Pharmacy Law & Regulatory Updates 2023

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Clinical Management Fellow in Drug Information

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The More You Know: Pharmacy Law & Regulatory Updates 2023

A Presentation for HealthTrust Members

February 14, 2024

Samantha Triplett, PharmD

Clinical Management Fellow in Drug Information, HealthTrust

Preceptor: Kate Cook, PharmD, CAHIMS, BCMAS

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Learning Objectives

Pharmacists, Healthcare Executives, and Pharmacy Technicians

1. Recall recent legislation impacting pharmacy practice in the United States.
2. Recognize the impact of the removal of the X-waiver on prescribing requirements.
3. Identify the requirements of the Drug Supply Chain Security Act (DSCSA).

Commonly Used Abbreviations

- 3PL = Third-Party Logistic Providers
- ASP = Average Sales Price
- CMS = Centers for Medicare & Medicaid Services
- DEA = Drug Enforcement Administration
- DSCSA = Drug Supply Chain Security Act
- FDA = Food & Drug Administration
- FTC = Federal Trade Commission
- HHS = Department of Health and Human Services
- HP = Health Plan
- IRA = Inflation Reduction Act
- MFP = Maximum Fair Price
- OUD = Opioid Use Disorder
- PBM = Pharmacy Benefit Manager
- Rx = Prescription
- TI = Transaction Information
- TS = Transaction Statement

Agenda

- Inflation Reduction Act (IRA)
- Pharmacy Benefit Manager (PBM) Transparency Act
- Potential Marijuana Rescheduling
- Removal of the X-Waiver
- Drug Supply Chain Security Act (DSCSA)

Inflation Reduction Act (IRA)

IRA: Goals

IRA: Key Provisions

Medicare Price Negotiations

Medicare Part B and D Inflation Rebates

Medicare Part D Benefit Redesign

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IRA: Medicare Price Negotiations

Eligible Drugs

- Brand-name drugs without generic equivalents and account for the greatest Medicare spending
- Selected drugs must:
  - Be within the top 50 drugs with the highest total spending over the most recent 12-month period
  - Covered under Medicare Part D and/or Medicare Part B
  - Have had market approval for at least 7 years (drug products) or 11 years (biologics)

Ineligible Drugs

- Orphan drugs that are approved to treat only one rare disease or condition
- Plasma-derived products
- Drugs that account for <$200 million in annual Medicare spending (adjusted annually for inflation)
- Drugs that have already been selected

IRA: Medicare Price Negotiations

CMS-Manufacturer Agreement

- Agreement entered to negotiate pricing
  - Manufacturers must submit information relating to costs and other data as requested
- CMS may delay negotiations for biologics with pending biosimilar for up to 2 years upon manufacturer request

Failure to Comply

- Manufacturers that fail to comply are subject to civil penalties and/or excise taxes
- If a manufacturer declines to participate, they must either:
  - Pay an excise tax of up to 95% of its medication's U.S. sales; or
  - Pull all products from the Medicare and Medicaid markets

WAC = wholesaler acquisition cost

IRA: Medicare Price Negotiations

CMS-Manufacturer Agreement

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  upon manufa

A drug is removed from the program ≥9 months after the launch of generic/biosimilar competition

Failure to Comply

- Manufacturers that fail to comply are subject to civil penalties and/or excise

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  - Pull all products from the Medicare and Medicaid markets

WAC = wholesaler acquisition cost

IRA: Medicare Price Negotiations

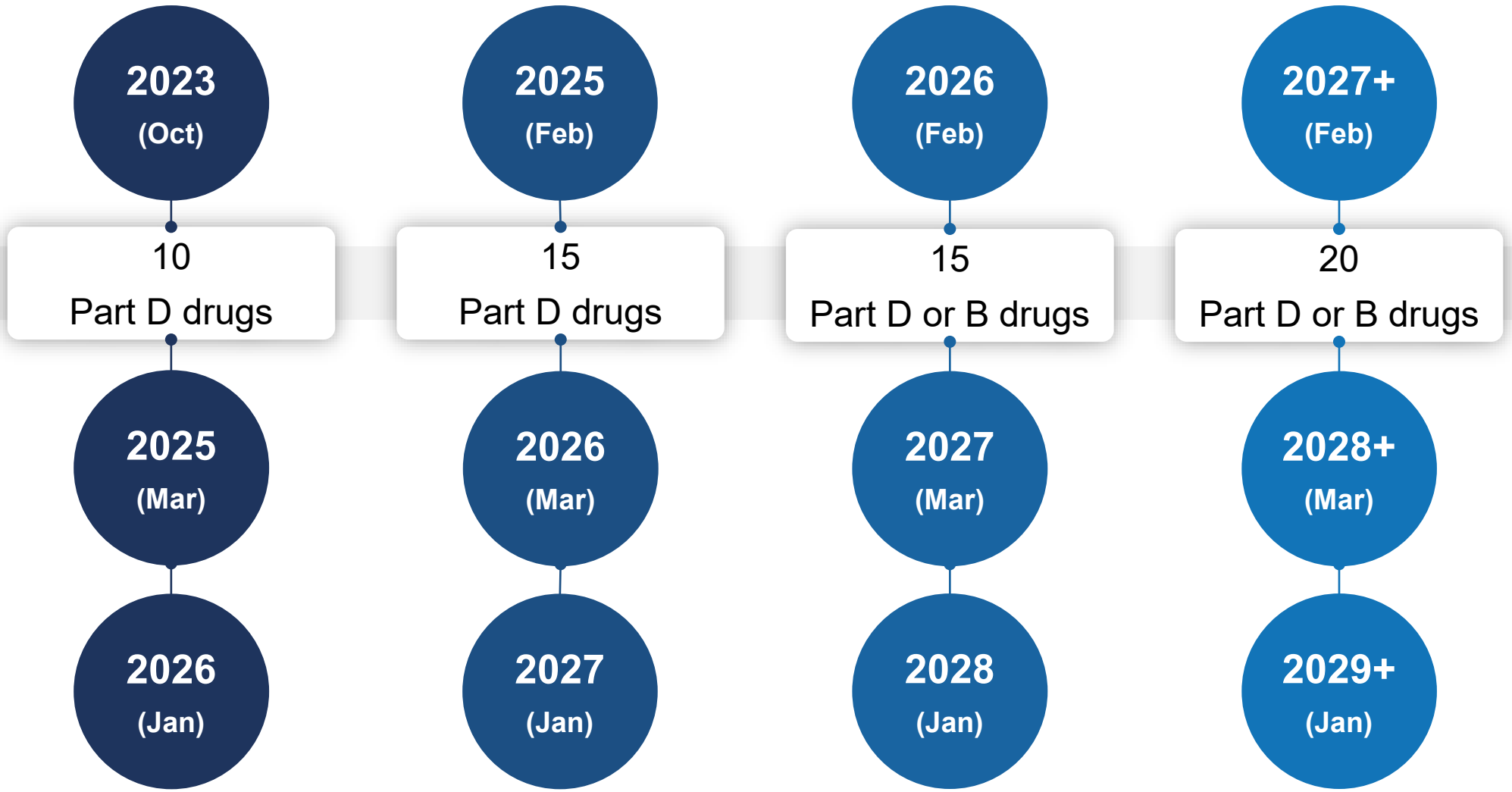
Maximum Fair Price (MFP) = Lower of…

Part B Drugs	Part D Drugs
ASP	Sum of enrollment-weighted cost to Part D plans
OR	
25-60% off the Non-FAMP; discount determined by years since drug approval	

Part B reimbursement for a selected drug is the MFP + 6% (not ASP + 6%)

Non-FAMP = Non-Federal Average Manufacturer Price

IRA: Effective Dates for Medicare Price Negotiations



IRA: Medicare Price Negotiations

MFP Effective January 2026

Manufacturer	Brand	Generic
AbbVie	Imbruvica	Ibrutinib
Amgen	Enbrel	Etanercept
AstraZeneca	Farxiga	Dapagliflozin
BMS	Eliquis	Apixaban
Boehringer Ingelheim	Jardiance	Empagliflozin
J & J	Stelara	Ustekinumab
	Xarelto	Rivaroxaban
Merck	Januvia	Sitagliptin
Novartis	Entresto	Sacubitril-valsartan
Novo Nordisk	Fiasp, Novolog	Insulin Aspart

BMS = Bristol Myers Squibb; J & J = Johnson & Johnson

IRA: Impact of Medicare Price Negotiations

Pricing

- Acquisition price: no change?
  - Will negotiated price spill-over into other negotiations, resulting in price decreases?
  - Will other markets subsidize the Medicare negotiated prices, resulting in price increases?
- Potential for higher future WAC at launch and more consistent price increases
  - Manufacturers will be limited to inflation-controlled price increases following launch

Reimbursement

- Potential for future significant decline in reimbursement rate
  - Medicare negotiated drugs will have lower MFP reimbursement (MFP + 6%)
  - Estimated 41.5-47.2% reduction in reimbursement on Part B drugs selected for negotiation (not effective until 2028)
  - Inflation-capped price increases may accelerate rate of ASP decline

WAC = wholesaler acquisition cost

IRA: Medicare Part B and D Inflation Rebates

2023

- Manufacturers are required to issue rebates to CMS for brand-name drugs, without generic equivalents, covered under Medicare Part B or D that:
  - Cost ≥$100 per year per individual
  - And/or in which prices increase faster than the rate of inflation

Impact

- Manufacturers may exit the market with regards to low-margin products due to inflationary rebate requirements
- Lower coinsurance rates for drugs subject to inflationary rebates

IRA: Medicare Part D Benefit Redesign

Potential impact for Medicare beneficiaries:

- Lower out-of-pocket costs (no charge in catastrophic phase)
- Capped out-of-pocket costs

Potential impact on health systems:

- More strict utilization management

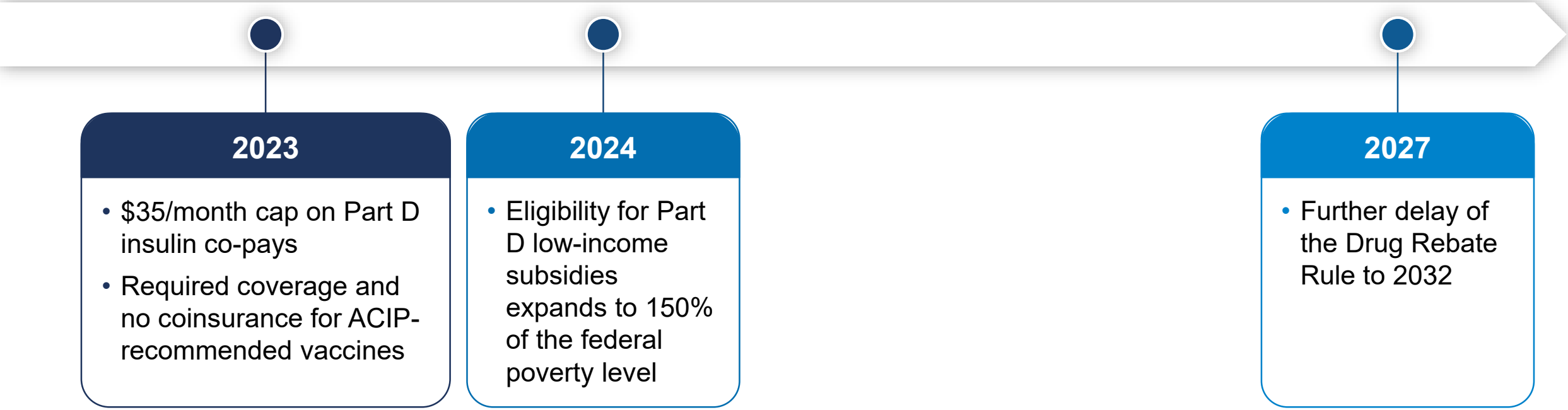
2024

- Medicare Part D 5% catastrophic coverage coinsurance eliminated
- Limit on Medicare Part D premium growth to ≤6% per year

2025

- Part D out-of-pocket spending cap of $2,000
- Manufacturer drug discount program replaces the Part D coverage gap program
- Option for Part D enrollees to opt in for max monthly caps on cost-sharing

IRA: Additional Programs Established by the IRA Related to Medicare Part D Coverage



2022-2027: Temporary increase in Part B payment for biosimilars (e.g., ASP + 8%)

ACIP = Advisory Committee on Immunization Practices

Assessment Question #1

Which of the following provisions is NOT part of the Inflation Reduction Act (IRA)?

1. Medicare Part D Benefit Redesign
2. Medicare Part B and D Inflation Rebates
3. Medicaid Price Negotiations
4. Medicare Price Negotiations

Assessment Question #1

Which of the following provisions is NOT part of the Inflation Reduction Act (IRA)?

1. Medicare Part D Benefit Redesign
2. Medicare Part B and D Inflation Rebates
3. **Medicaid Price Negotiations**
4. Medicare Price Negotiations

Pharmacy Benefit Manager (PBM) Transparency Act

PBM-Related Proposed Legislation in 2023

U.S. House of Representatives

- Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act
- Hidden Fee Disclosure Act
- Health Data Act
- Transparency Coverage Act

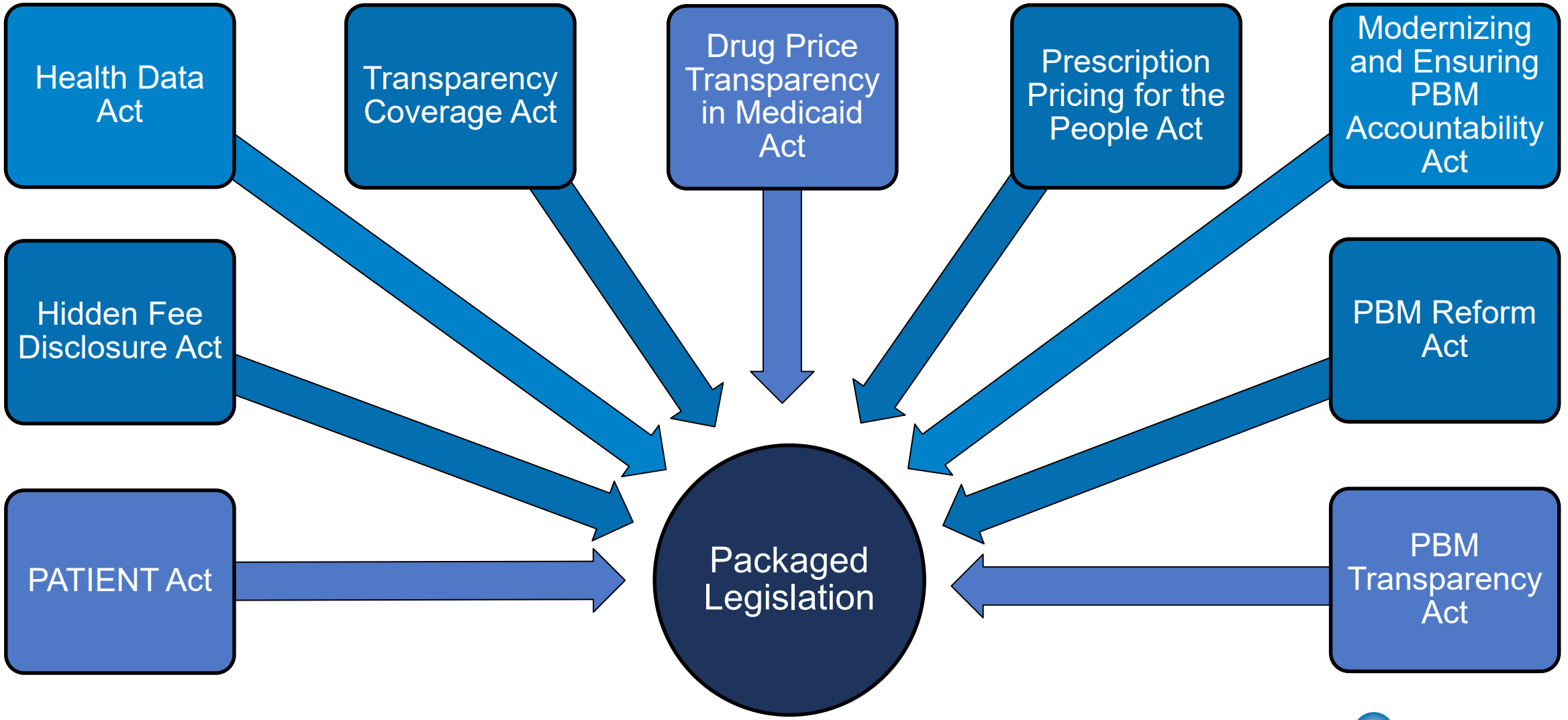
U.S. Senate

- Prescription Pricing for the People Act
- Modernizing and Ensuring PBM Accountability Act
- PBM Reform Act

Bipartisan House and Senate

- Drug Price Transparency in Medicaid Act
- PBM Transparency Act

PBM-Related Proposed Legislation in 2023



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PBM Transparency Act: Goals

Prohibit Unfair or Deceptive Pricing Practices

Incentivize Fair and Transparent PBM Practices

Mandate Transparency

PBM Transparency Act

Makes it illegal for PBMs to engage in “spread pricing”

Prohibits PBMs from arbitrarily, unfairly, or deceptively:

- Clawing back payments made to pharmacies; or
- Increasing fees/lowering reimbursements to offset reimbursement changes in federally-funded HPs

A PBM would NOT be in violation of the Act if it:

- Passes 100% of any rebate to the HP or payer; and
- Provides full and complete disclosure of:
  - The cost, price, and reimbursement of Rx drugs to HPs and pharmacies;
  - All fees, mark-ups, and discounts the PBM charges or imposes on HPs and pharmacies; or
  - The aggregate remuneration fees it receives from manufacturers to HPs, payers, and any federal agency

PBM Transparency Act: Reporting Requirements

PBMs must file an annual report to the FTC disclosing the following:

1. The aggregate difference between how much each HP paid for Rx drugs and how much the PBM paid each pharmacy on behalf of HPs for such drugs;
2. The aggregate total amount of fees the PBM charged to pharmacies and the total amount of reimbursements clawed back from pharmacies;
3. Why the cost, copay, coinsurance, or deductible for a consumer increased, or why the reimbursement rate to a pharmacy decreased for a Rx drug; and
4. For PBMs that control or are affiliated with a pharmacy, a description of differences between what is reimbursed or charged for affiliated and non-affiliated pharmacies

PBM Transparency Act: Enforcement & Accountability

Enforcement

- Enforced by the FTC and State Attorneys General
- Each violation results in civil penalties plus an additional penalty of up to $1 million

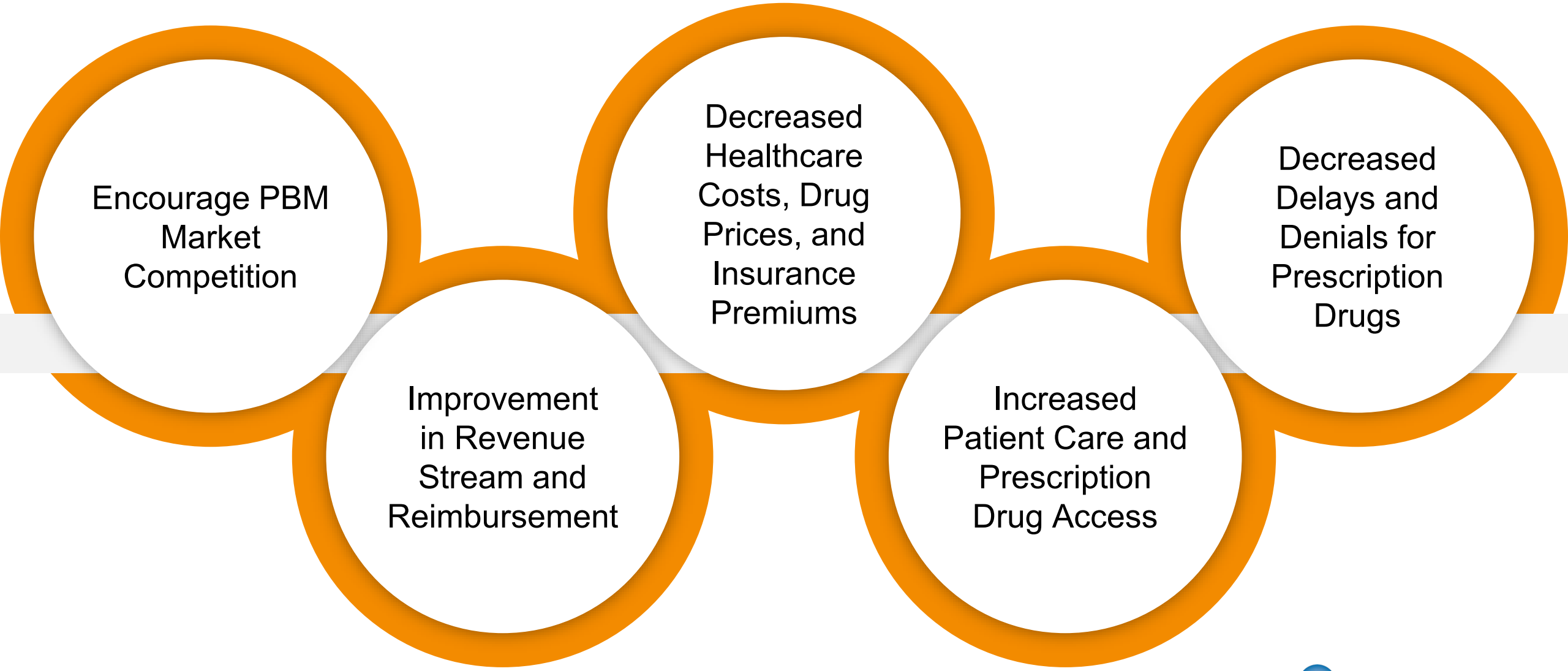
Accountability

- Whistleblower protection against termination or reprimanding

Accountability Provisions Added in 2023

- U.S. Government Accountability Office is required to submit to various committees (within 1 year of bill's enactment) a report that addresses at least the following:
  - The role of PBMs in the pharmacy supply chain;
  - The state of competition within the PBM industry and the market share of the 10 largest PBMs;
  - The use of rebates and fees by each PBM (10 largest PBMs), including whether and the amount of rebates collected for each drug on each PBM's formulary that is passed to patients and/or payors;
  - Whether PBMs structure formularies in favour of high-rebate Rx drugs over low-cost alternatives;
  - Details surrounding prior authorization step-therapy practices; and
  - A summary of the extent of spread pricing practices of which PBMs are participating

PBM Transparency Act: Potential Impact



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Assessment Question #2

According to the PBM Transparency Act, once enacted, who would receive 100% of any rebates received by the PBM?

1. The patient
2. The PBM
3. The health plan/payer
4. The pharmaceutical company

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Assessment Question #2

According to the PBM Transparency Act, once enacted, who would receive 100% of any rebates received by the PBM?

1. The patient
2. The PBM
3. **The health plan/payer**
4. The pharmaceutical company

Potential Rescheduling of Marijuana

Marijuana Reform Events of 2023

- State Specific Marijuana Legislation
- Marijuana Opportunity, Reinvestment and Expungement (MORE) Act
- States Reform Act (SRA)
- Secure And Fair Enforcement Regulation (SAFER) Banking Act
- Potential Rescheduling of Marijuana

Background: Drug Schedules

Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
• Drugs with no currently accepted medical use and a high potential for abuse	• Drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence	• Drugs with a lower potential for abuse than Schedule I and II and a moderate-to-low potential for physical and psychological dependence	• Drugs with a low potential for abuse and low risk of dependence	• Drugs with a lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics

Background: Drug Schedules

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Background: History and Future?

2016

- DEA denied a petition to reschedule marijuana from a Schedule I to a Schedule II drug
  - HHS had recommended marijuana remain a Schedule I drug

2022

- President Biden mandated HHS and the Attorney General's Office to initiate the administrative process to review how marijuana is Scheduled under federal law

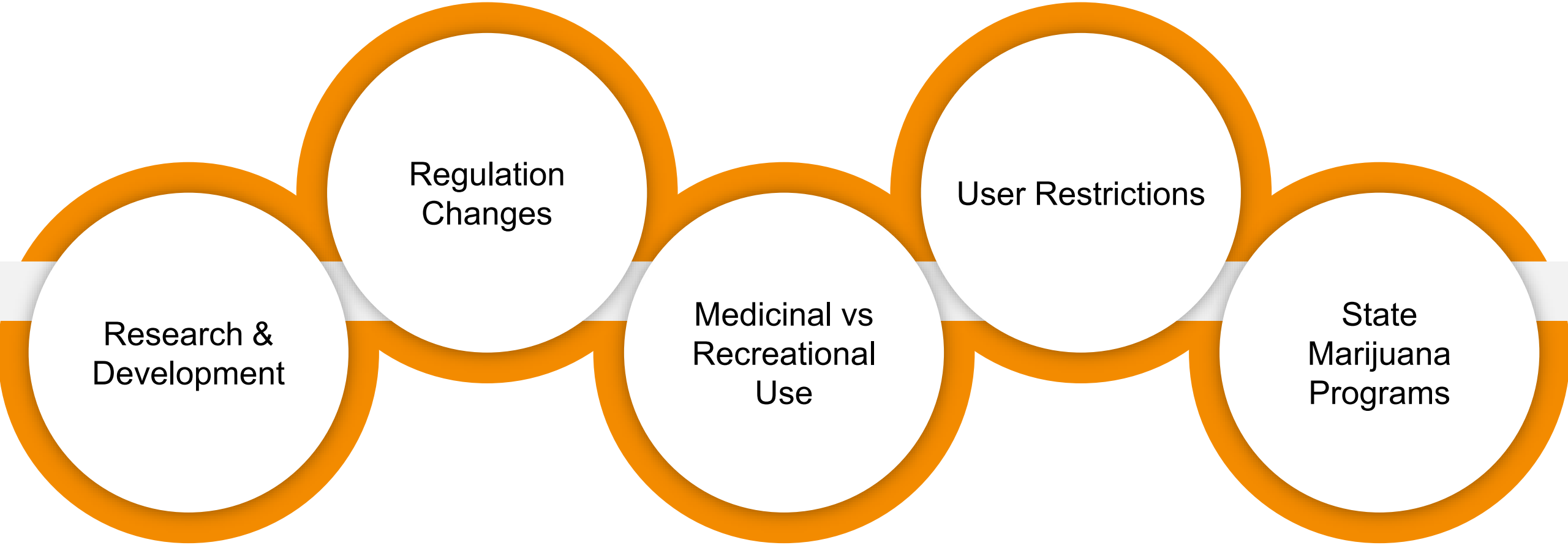
2023

- After receiving the FDA's review, HHS recommended marijuana be rescheduled from a Schedule I to a Schedule III drug
  - Recommendation has sent to the DEA
- DEA began reviewing the recommendation

2024

- Public notice-and-comment period
- DEA internal review
  - Re-evaluation or rejection

Marijuana Rescheduling: Potential Implications



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Assessment Question #3

What is the proposed rescheduling of marijuana?

1. Schedule I to Schedule II
2. Schedule I to Schedule III
3. Schedule I to Schedule IV
4. Schedule I to Schedule V

Assessment Question #3

What is the proposed rescheduling of marijuana?

1. Schedule I to Schedule II
2. **Schedule I to Schedule III**
3. Schedule I to Schedule IV
4. Schedule I to Schedule V

Removal of the X-Waiver

Removal of the X-Waiver: Background

DATA 2000

- DATA-waiver ("X-waiver") required for buprenorphine prescribing
  - 45 days from application to approval
  - "X" number required on each buprenorphine prescription written
- Training required in addition to DEA registration
- Patient limits

Consolidated Appropriations Act

- December 29, 2022: eliminated the X-wavier
- Practitioners with a current DEA registration may prescribe buprenorphine for OUD if permitted by state law
- Training required as part of DEA registration (for all registrants)
- No patient limits

DATA = Drug Addiction Treatment Act

Consolidated Appropriations Act of 2023

New or renewing DEA registrants, starting June 27, 2023, upon submission of their application, to have ≥1 of the following:

- A total of 8 hours of training from certain organizations on opioid or other substance use disorders;
- Board certification in addiction medicine or addiction psychiatry (American Board of Medical Specialties, American Board of Addiction Medicine, or the American Osteopathic Association); or
- Graduation within 5 years and status in good standing from medical, advanced practice nursing, or physician assistant school in the US that included successful completion of an opioid or other substance use disorder curriculum of ≥8 hours

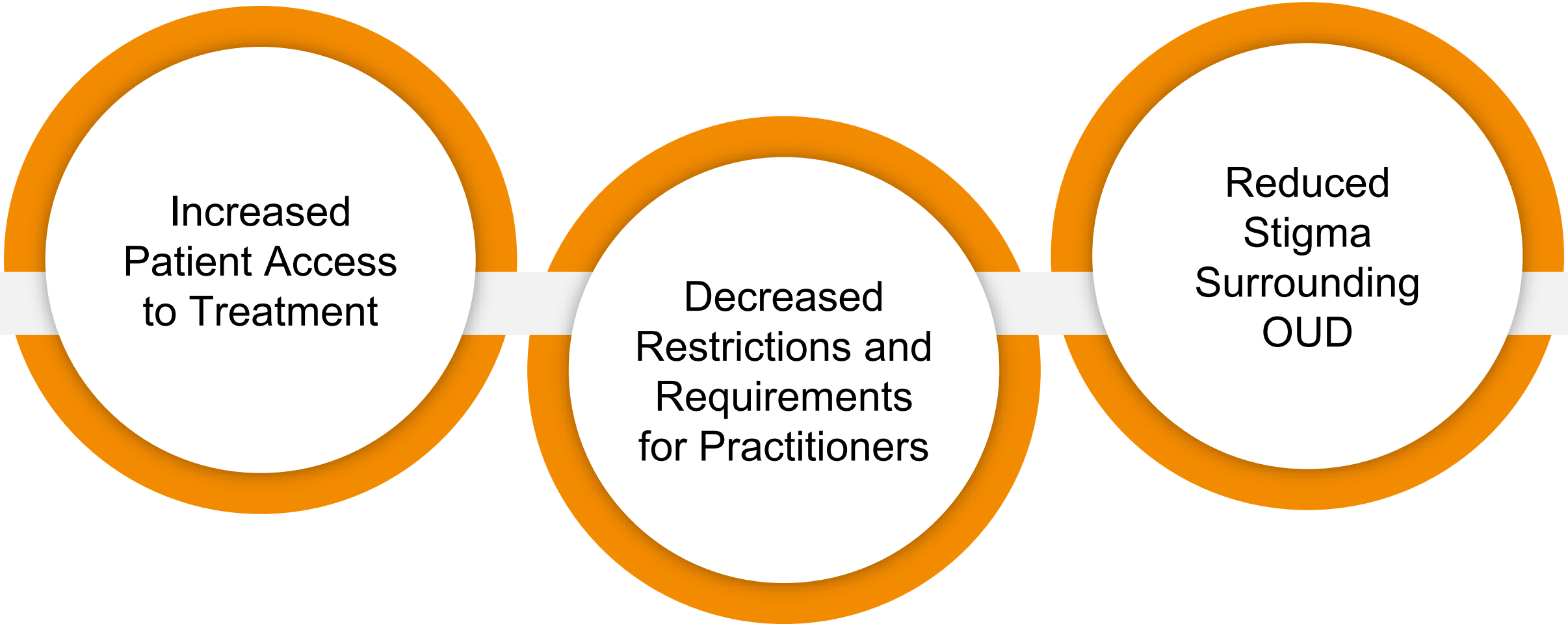
Approved Organizations for Training Requirements

American Society of Addiction Medicine	American Academy of Addiction Psychiatry	American Medical Association	American Osteopathic Association	American Dental Association
American Association of Oral and Maxillofacial Surgeons	American Psychiatric Association	American Nurses Credentialing Center	American Association of Nurse Practitioners	American Academy of Physician Assistants

- Any other organization accredited by:
  - The American Council for Continuing Medical Education or the Commission;
  - A State medical society accreditor that is recognized by the ACCME or the CCEPR; or
  - The American Osteopathic Association to provide continuing medical education
- Any organization approved by the ACCME, or the CCEPR

ACCME = Accreditation Council for Continuing Medical Education;
CCEPR = Commission for Continuing Education Provider Recognition

Removal of the X-Waiver: Impact



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Assessment Question #4

Removal of the X-waiver has resulted in which of the following changes in regards to prescribing requirements?

1. Pharmacists are now allowed to prescribe buprenorphine
2. DEA registration is no longer required
3. Buprenorphine is no longer a scheduled medication
4. Patient limits are no longer enforced

Assessment Question #4

Removal of the X-waiver has resulted in which of the following changes in regards to prescribing requirements?

1. Pharmacists are now allowed to prescribe buprenorphine
2. DEA registration is no longer required
3. Buprenorphine is no longer a scheduled medication
4. **Patient limits are no longer enforced**

Drug Supply Chain Security Act (DSCSA)

DSCSA: Goals

Achieve interoperable, electronic tracing of product at the package level to identify and trace certain prescription drugs as they are distributed in the U.S.

- Enhances FDA's ability to protect consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Ensures the safety and security of the pharmaceutical supply chain
- Aims to deter, detect, and remove potentially dangerous drugs from the supply chain

DSCSA: Products

Covered under DSCSA

- Prescription drugs in finished dosage form for administration to a patient without further manufacturing
  - Capsules, tablets, lyophilized products prior to reconstitution

Exempt from DSCSA

- Blood or blood components intended for transfusion
- Radioactive drugs or radioactive biological products
- Imaging drugs
- Certain intravenous products
- Any medical gas
- Homeopathic drugs
- Drugs compounded in compliance with sections 503A or 503B

FD&C = Food, Drug, & Cosmetic Act

DSCSA: Key Requirements

Authorized Trading Partners

Product Identifiers

Product Tracing

Verification

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DSCSA: Key Requirements

Authorized Trading Partners

- **All trading partners** must be authorized
- **Trading partners** must either be appropriately licensed or hold a valid registration
- **Wholesale distributors** and **3PLs** must report licensure and other information to FDA annually

Product Tracing

- **Manufacturers**, **repackagers**, **wholesale distributors**, and **dispensers** (primarily pharmacies) must provide, capture, and maintain TI

Product Identifiers

- **Manufacturers** and **repackagers** must add a product identifier to certain Rx drug packages and homogenous case of product

Verification

- **Manufacturers** and **repackagers** must establish systems and processes to respond to requests for verification of product identifier
- **Manufacturers**, **repackagers**, and **wholesale distributors** must establish systems and processes to be able to verify the product identifier on saleable return product
- **Manufacturers**, **repackagers**, **wholesale distributors**, and **dispensers** (primarily pharmacies) must establish systems and processes to:
  - Determine whether product is suspect
  - Conduct an investigation into whether product is illegitimate
  - Promptly notify FDA when suspect product is determined not to be illegitimate
  - Quarantine and dispose of illegitimate product
  - Notify FDA and other stakeholders if an illegitimate drug is found or if product with a high risk of illegitimacy is identified

DSCSA: Background

2013

- Signed into law by President Obama on November 27, 2013
- 3PLs and wholesale distributors required to report to the FDA

2015

- Trading partners required to provide purchaser with product TI when engaged in transactions involving certain Rx drugs
  - Information must be maintained for >6 years after date of transaction

2018

- Each package within the pharmaceutical distribution supply chain must have a product identifier (human- and machine-readable)
  - Standardized numerical identifier
  - Lot number
  - Expiration date

2019

- Wholesale distributors required to verify the product identified upon receipt of a returned product if intended to further distribute

2023

- Implementation of electronic, interoperable system

DSCSA: Enforcement

Until November 27, 2024, the FDA does not intend to take action to enforce the requirement:

- That the TI and the TS be exchanged in a secure, interoperable, electronic manner
- That systems and processes for verification of product, are in accordance with established standards
- For systems and processes to promptly respond with the TI and TS for a product upon request by the Secretary, or other appropriate Federal or State official
- For systems and processes to promptly facilitate gathering information necessary to produce the TI for each transaction going back to the manufacturer
- That those accepting saleable return products have systems and processes in place to allow acceptance of such product

Considerations for Hospitals, Health Systems, Retail Pharmacies, and Dispensing Physician Practices

- Obtain and begin using Global Location Numbers
- Create protocols so products lacking serial numbers are not accepted
- Fine tune processes for investigating suspect and illegitimate products
- Determine and establish how products will be stored in case a return is necessary
- Consider how to store and access data

Assessment Question #5

Which of the following are key requirements of DSCSA?

1. All trading partners must be authorized
2. Products must be tracked
3. Products must be verified
4. Products must have identification packaging
5. All of the above

Assessment Question #5

Which of the following are key requirements of DSCSA?

1. All trading partners must be authorized
2. Products must be tracked
3. Products must be verified
4. Products must have identification packaging
5. **All of the above**

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Thank you!

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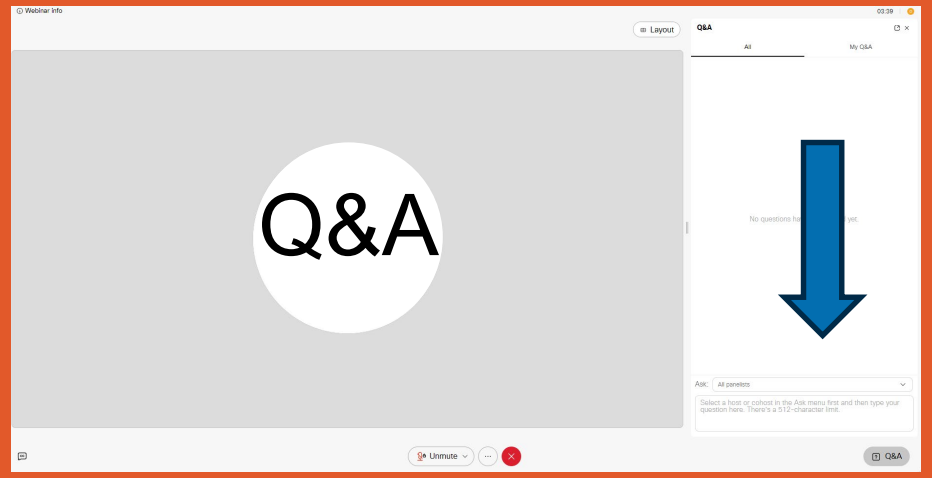

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