

Time for a Road Trip: U.S. Law Review



UTAH SOCIETY OF
HEALTH-SYSTEM PHARMACISTS

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Disclosure

- Relevant Financial Conflicts of Interest
 - **CE Presenter, Samantha Relias**
 - No relevant conflicts of interest exist
 - **CE mentor, Erin Fox**
 - Has received complimentary meeting registration from ASHP for presenting on drug shortages
- Off-Label Uses of Medications
 - None



Learning Objectives

- Describe the impact of recent common law rulings on pharmacy practice.
- Discuss trends in pharmacy-related legislation in other states.
- Compare and contrast Utah practice with new laws and regulations in other states.
- Develop a plan to stay aware of ongoing legislative and regulatory issues.



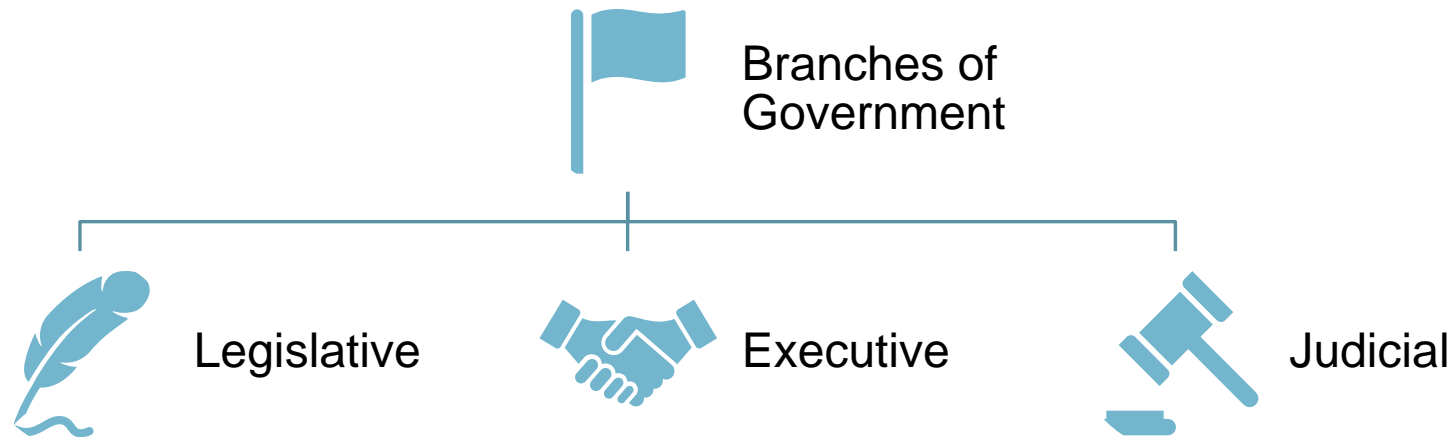
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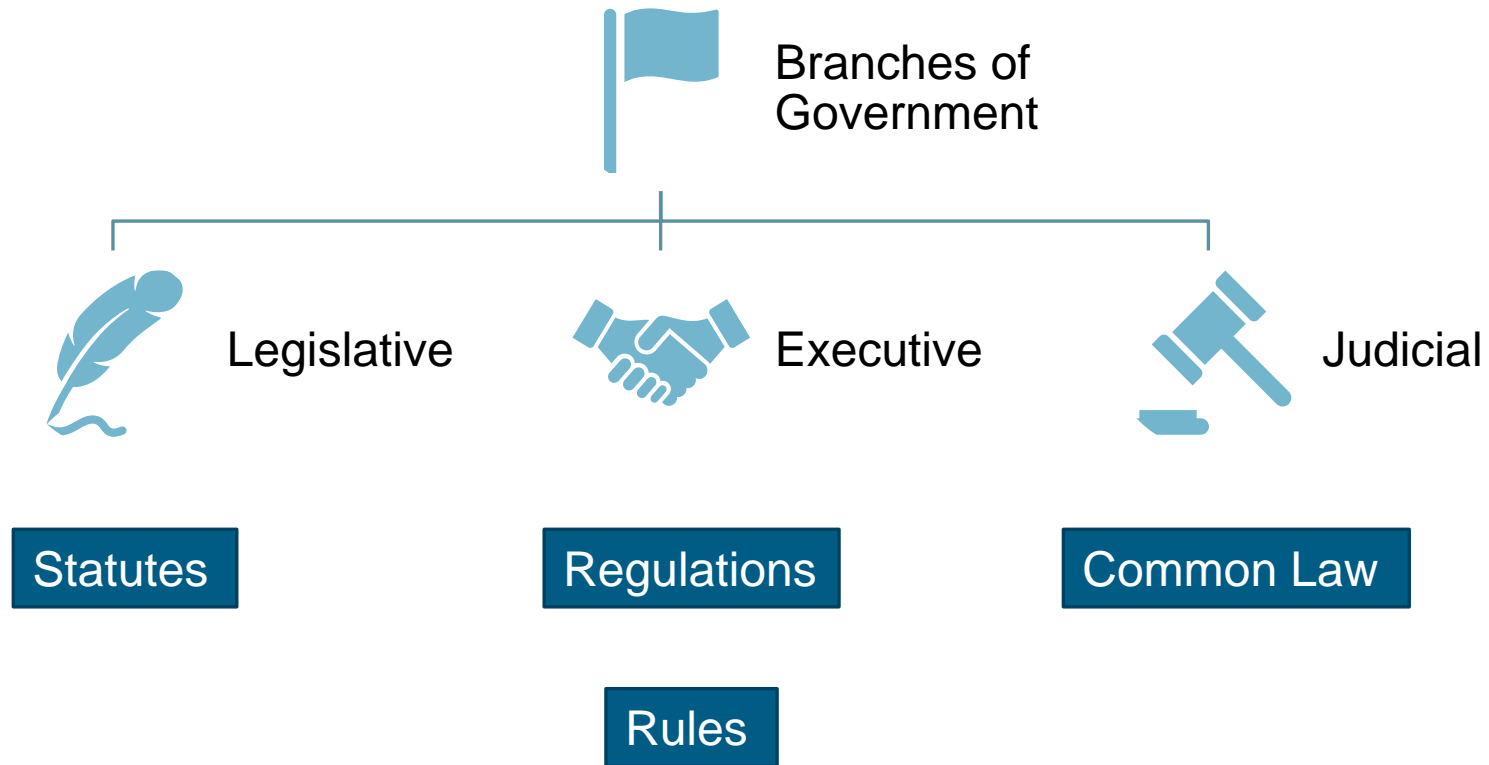


What is common law?

- Law that is derived from *judicial decisions* instead of from statutes
- Impact beyond original case
 - New or modified statute
 - Precedent is established



How is pharmacy practice changed?



Common law. Legal Information Institute. https://www.law.cornell.edu/wex/common_law. Accessed February 12, 2022.

Recent Pharmacy Common Law Rulings

- 340B program enforcement
- Pharmacy Benefit Manager (PBM) regulation
- Direct and Indirect Remuneration (DIR) fees



Recent Pharmacy Common Law Rulings

- **340B program enforcement**
- Pharmacy Benefit Manager (PBM) regulation
- Direct and Indirect Remuneration (DIR) fees



Polling Question

- How familiar are you with 340B?
 - 1) What is 340B?
 - 2) I've heard of it.
 - 3) I understand the general idea.
 - 4) I know some of the specifics.
 - 5) I am a 340B expert.



340B Program Background

- Federal program allowing eligible safety net organizations to buy outpatient drugs at a discount
- Organization savings is used to support patient access to services
- Manufacturers participating in Medicaid agree to provide the discounts
- Organizations can contract with outpatient pharmacies to expand access
- Not all qualifying organizations have outpatient pharmacies of their own



340B Program Enforcement

- Manufacturers began refusing to honor the 340B discount for organizations who contract with outpatient pharmacies
- Health Resources & Services Administration (HRSA) sent violation letters to these manufacturers in May 2020, threatening civil fines
- Manufacturers then sued HRSA



340B drug pricing program. Health Resources & Services Administration. <https://www.hrsa.gov/opa/index.html>. Accessed February 12, 2022.

Program integrity. Health Resources & Services Administration. <https://www.hrsa.gov/opa/program-integrity/index.html>. Accessed February 12, 2022.

340B Program Lawsuits

- *Eli Lilly and Company v. HHS*
 - 340B statute does not allow manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications
- *Novartis Pharmaceuticals v. Espinosa; United Therapeutics v. Espinosa*
 - 340B statute does not explicitly prevent manufacturers from imposing conditions on the use of contract pharmacies
- *Sanofi-Aventis U.S. v. HHS; Novo Nordisk Inc. v. HHS*
 - 340B statute does not allow manufacturer restrictions on contract pharmacies



340B Program Enforcement Summary

- 340B program saves health organizations billions of dollars per year, allowing them to continue offering safety net services
- Agreements between eligible organizations and contract pharmacies are an important tool to capture this savings and reach patients
- Manufacturer restrictions on contract pharmacies undermine the intent of the 340B program
- HRSA continues to evaluate legal options for program enforcement



Recent Pharmacy Common Law Rulings

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- **Pharmacy Benefit Manager (PBM) regulation**
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PBM Background

- Controversial practices
 - Restrictive networks & vertical integration: requiring patients to fill at certain pharmacies, often those owned by the PBM
 - White bagging: requiring patients to fill clinician-administered drugs at certain pharmacies outside of the health system
 - Gag clauses: pharmacy unable to tell patient when it is cheaper to pay the cash price
 - Spread pricing: charging payer more than the amount reimbursed to the dispensing pharmacy, difference is kept by PBM as profit

Spread pricing 101. National Community Pharmacists Association. <https://ncpa.org/spread-pricing-101>. Accessed February 12, 2022.

PBM abuses. National Community Pharmacists Association. <https://ncpa.org/sites/default/files/2020-12/pbm-business-practices-one-pagers.pdf>. Accessed February 12, 2022.

White bagging jeopardizes patient care. American Society of Health-System Pharmacists. <https://www.ashp.org/-/media/assets/advocacy-issues/docs/White-Bagging-Infographic.pdf>. Accessed February 12, 2022.



PBM Regulation Lawsuits

- *Rutledge v. Pharmaceutical Care Management Association*
 - Arkansas Act 900 is not blocked by ERISA
- *Pharmaceutical Care Management Association v. Wehbi*
 - North Dakota PBM regulations are not blocked by ERISA and apply to Medicare Part D plans
 - Does not support prohibition against DIR fees

Rutledge v. Pharmaceutical Care Management Association. Oyez. <https://www.oyez.org/cases/2020/18-540>. Accessed February 12, 2022.

Pharmacy orgs cheer eighth circuit decision supporting state PBM regs. American Pharmacists Association. <https://www.pharmacist.com/APhA-Press-Releases/pharmacy-orgs-cheer-eighth-circuit-decision-supporting-state-pbm-regs>. Accessed February 12, 2022.

Court upholds most sections of North Dakota PBM law. Minnesota Pharmacists Association. <https://www.mpha.org/news/587669/Court-Upholds-Most-Sections-of-North-Dakota-PBM-Law.htm>. Accessed February 12, 2022.



PBM Regulation Summary

- *Rutledge v. Pharmaceutical Care Management Association* was a landmark decision by the Supreme Court in favor of PBM regulation
- Many states are working on PBM regulation legislation
- More legal cases may be in the future



Recent Pharmacy Common Law Rulings

- 340B program enforcement
- Pharmacy Benefit Manager (PBM) regulation
- **Direct and Indirect Remuneration (DIR) fees**



Polling Question

- How familiar are you with DIR fees?
 - 1) What is a DIR fee?
 - 2) I've heard of it.
 - 3) I understand the general idea.
 - 4) I know some of the specifics.
 - 5) I am a DIR fee expert.



Direct and Indirect Remuneration (DIR) Fees

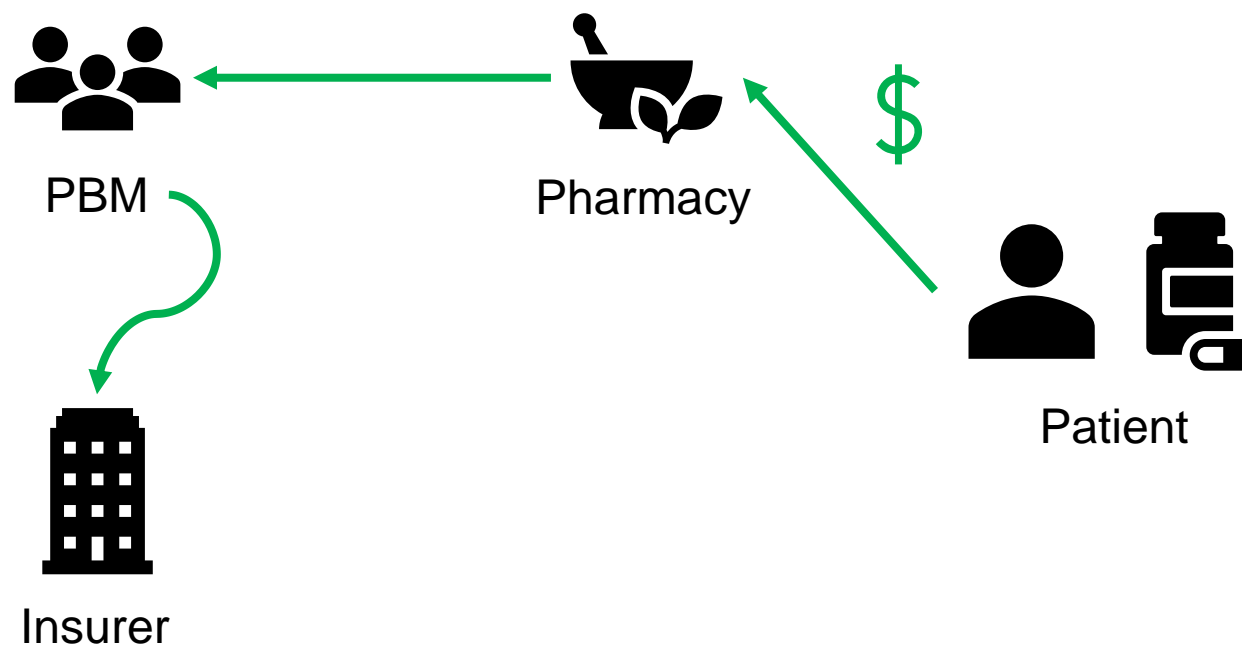
- DIR = compensation to part D sponsor or PBM after point-of-sale to patient
 - Rebates from manufacturers and fees paid by pharmacies
- Patient cost sharing is calculated based on drug cost at point-of-sale
- Increased DIR fees may decrease total program expenses, but do not reduce drug cost for patients

Federal lawsuit challenging retroactive DIR fees: *NCPA V Becerra*. American Pharmacists Association. <https://www.pharmacist.com/Advocacy/Issues/Federal-Lawsuit-Challenging-Retroactive-DIR-Fees>. Accessed February 12, 2022.

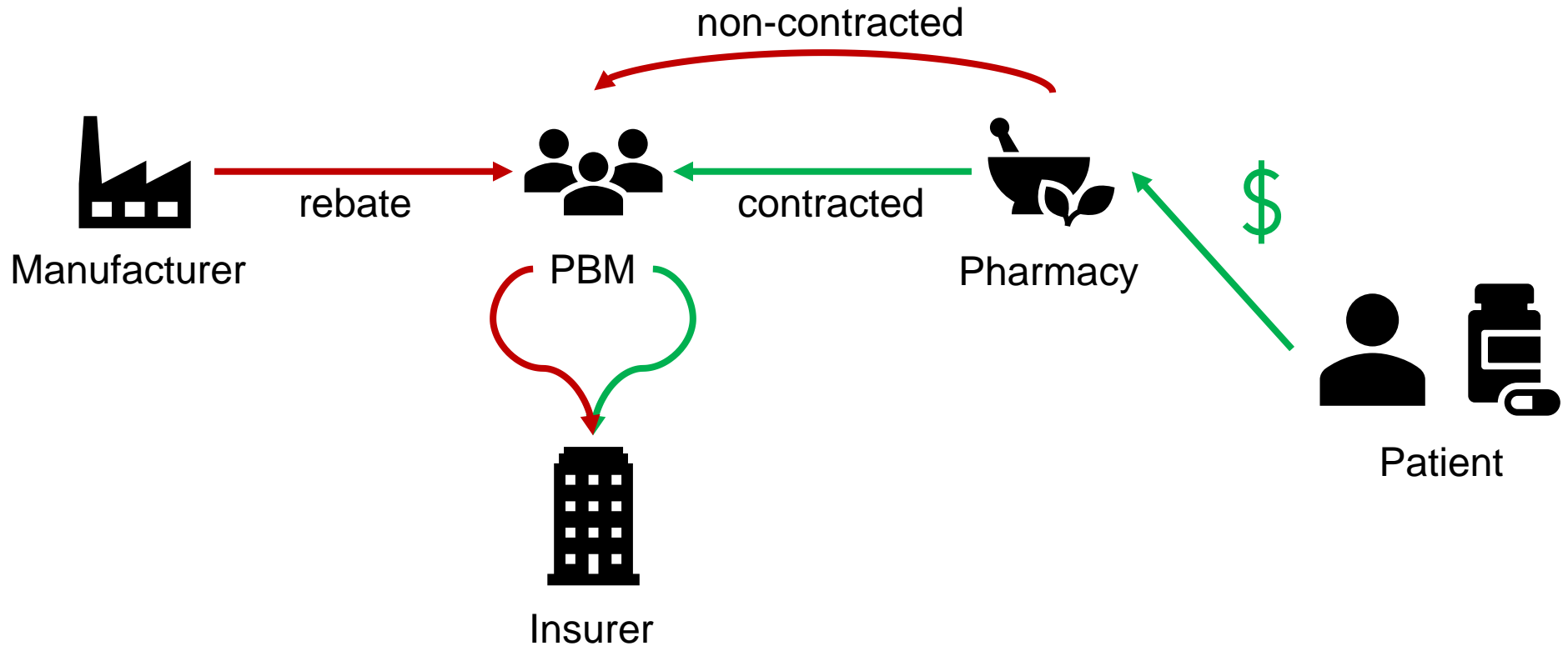
Medicare part D – direct and indirect remuneration (DIR). Centers for Medicare & Medicaid Services. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>. Accessed February 12, 2022.



Money Flow (No DIR Fees)



Money Flow (DIR Fees)



Direct and Indirect Remuneration (DIR) Fees

- *NCPA v Becerra*
 - Challenges current HHS rule allowing DIR fee loophole
 - Would not eliminate all DIR fees, just requires PBMs to assess them at the point-of-sale

Federal lawsuit challenging retroactive DIR fees: *NCPA V Becerra*. American Pharmacists Association. <https://www.pharmacist.com/Advocacy/Issues/Federal-Lawsuit-Challenging-Retroactive-DIR-Fees>. Accessed February 12, 2022.

Medicare part D – direct and indirect remuneration (DIR). Centers for Medicare & Medicaid Services. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>. Accessed February 12, 2022.



Direct and Indirect Remuneration (DIR) Fees

- DIR fee impacts:
 - No decrease in patient cost sharing
 - Decreased revenue for pharmacies
 - Increased cost for public payers (Medicaid, Medicare)
 - Increased profits for PBMs
- *NCPA v Becerra*
 - Ongoing lawsuit focused solely on DIR fees

Federal lawsuit challenging retroactive DIR fees: *NCPA V Becerra*. American Pharmacists Association. <https://www.pharmacist.com/Advocacy/Issues/Federal-Lawsuit-Challenging-Retroactive-DIR-Fees>. Accessed February 12, 2022.

Medicare part D – direct and indirect remuneration (DIR). Centers for Medicare & Medicaid Services. <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>. Accessed February 12, 2022.



Assessment Question

- Which of the following is the definition of common law?
 - a) A court decision considered the authority for later similar cases
 - b) Law that is derived from judicial decisions instead of from statutes
 - c) Arranging laws or rules into a systematic code
 - d) Law enacted by a legislature



Assessment Question

- Which of the following describes the potential impact of *Rutledge v. Pharmaceutical Care Management Association* and *Pharmaceutical Care Management Association v. Wehbi*?
 - a) DIR fee prohibition in North Dakota
 - b) Protection of contract pharmacy agreements
 - c) Enforcement of manufacturer discounts
 - d) Increased state legislation on PBM regulation



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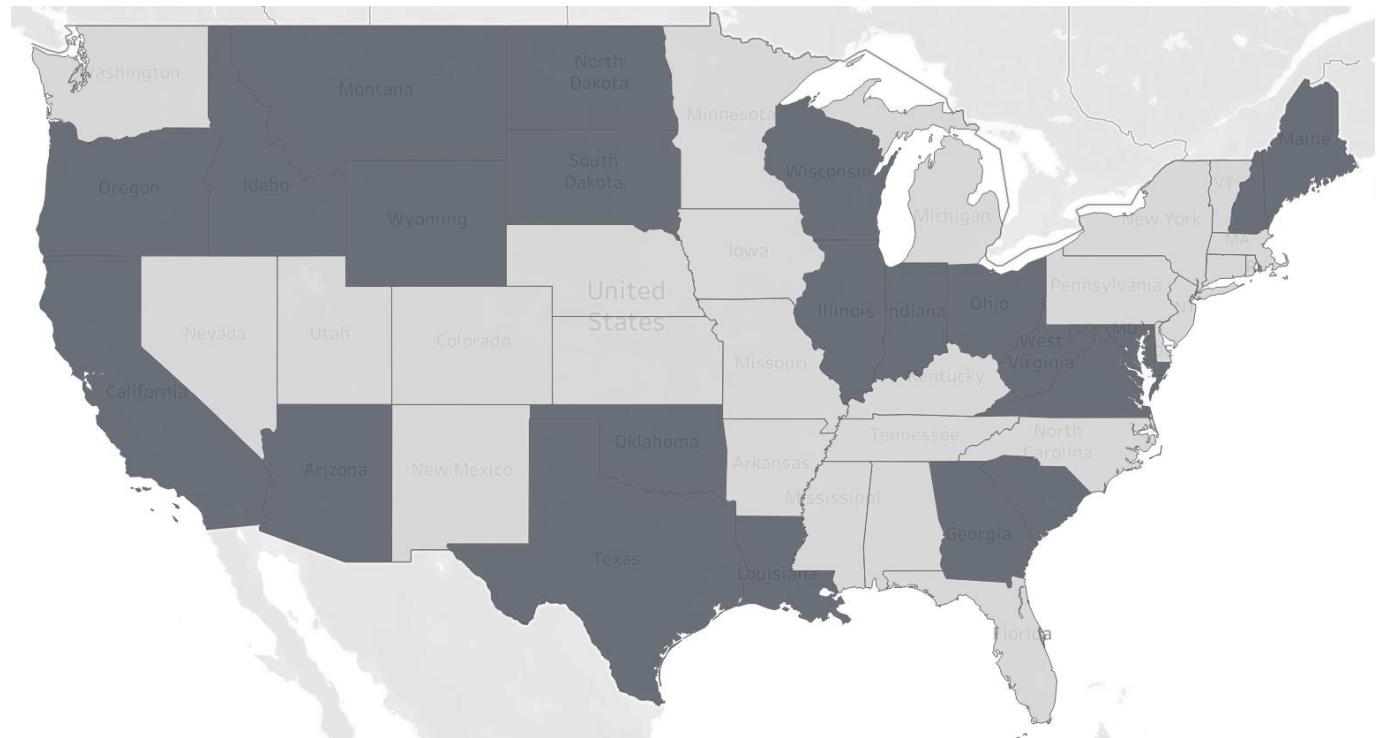
Hot Topics

- Clinical Decision Making
 - Immunization
 - Testing
 - Hormonal contraceptives
 - HIV PEP & PrEP
- Product Administration
 - Long-acting injectable administration
- Payment



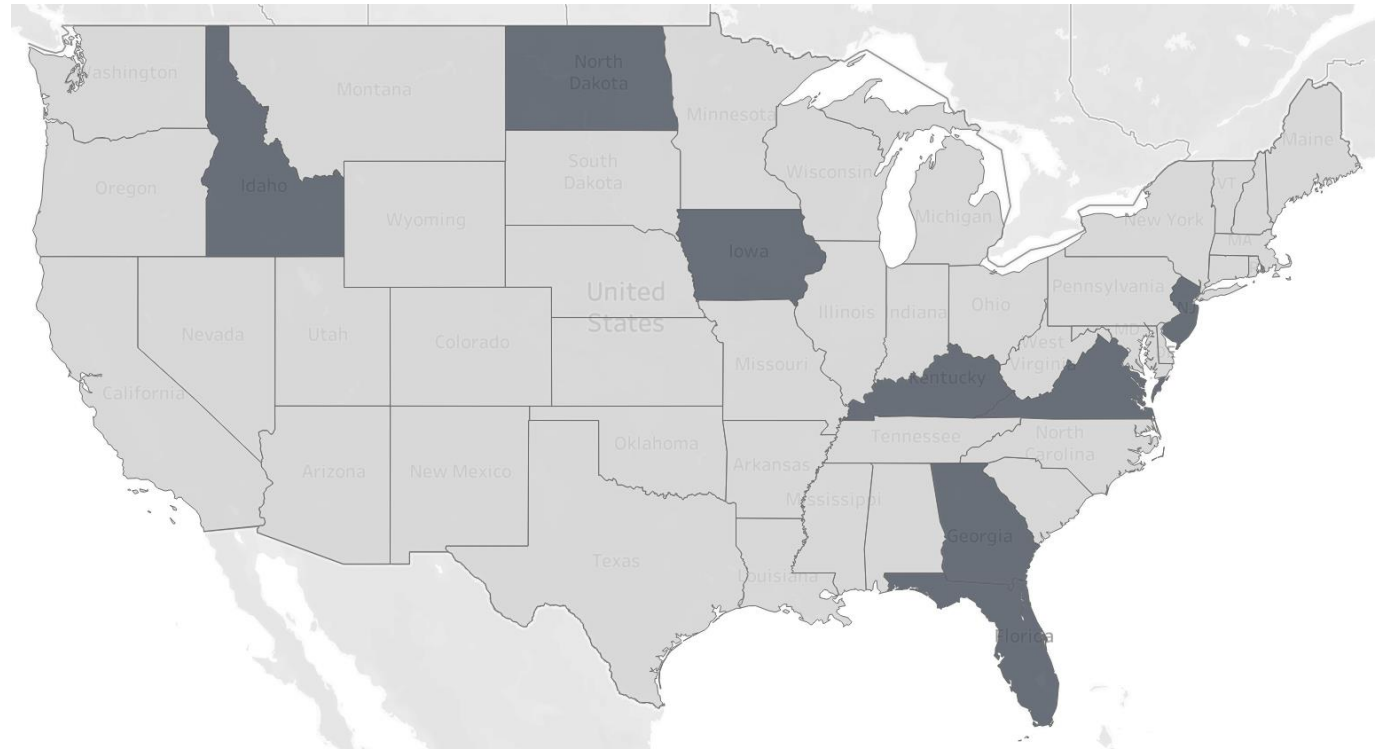
Clinical Decision Making: Immunization

- Pharmacists able to order & administer all ACIP recommended vaccines
- Pharmacy technicians able to administer vaccines



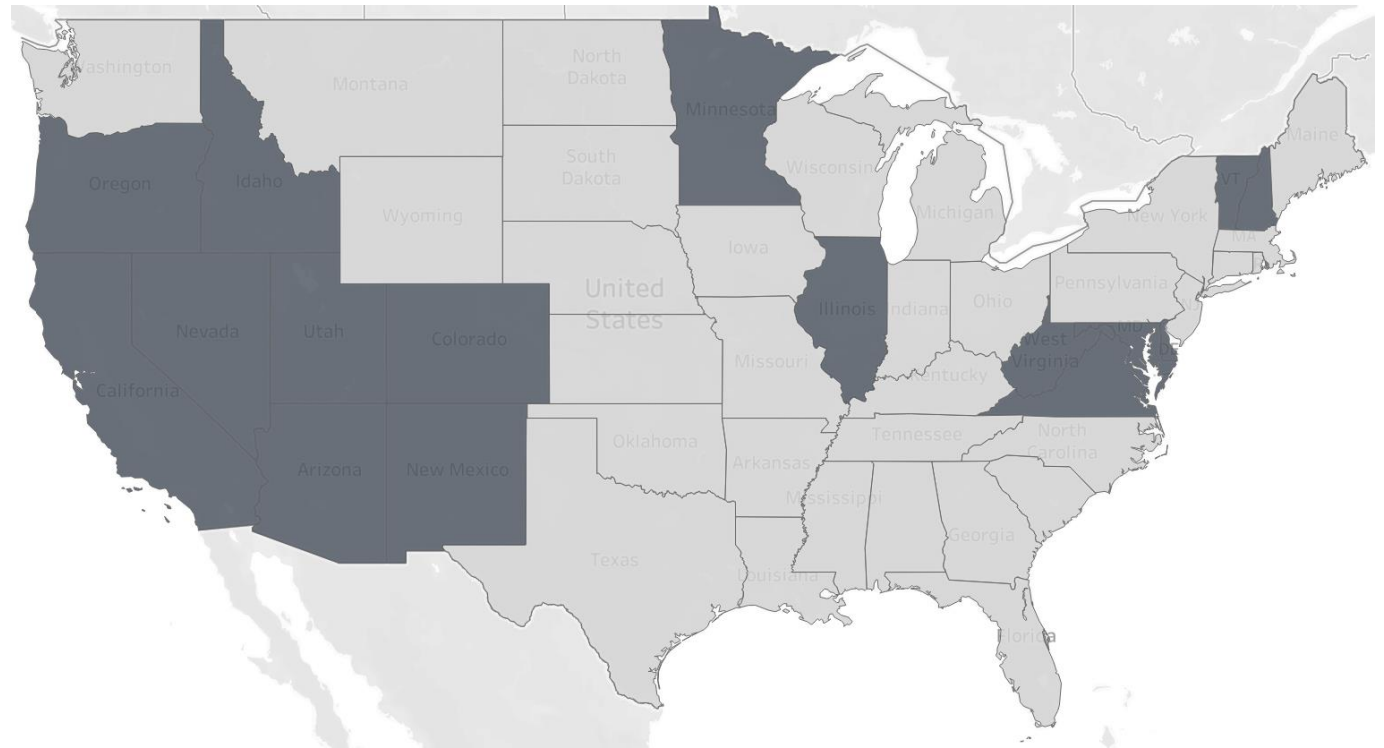
Clinical Decision Making: Testing

- Pharmacists able to administer & interpret all COVID-19, influenza, strep A, and/or TB tests



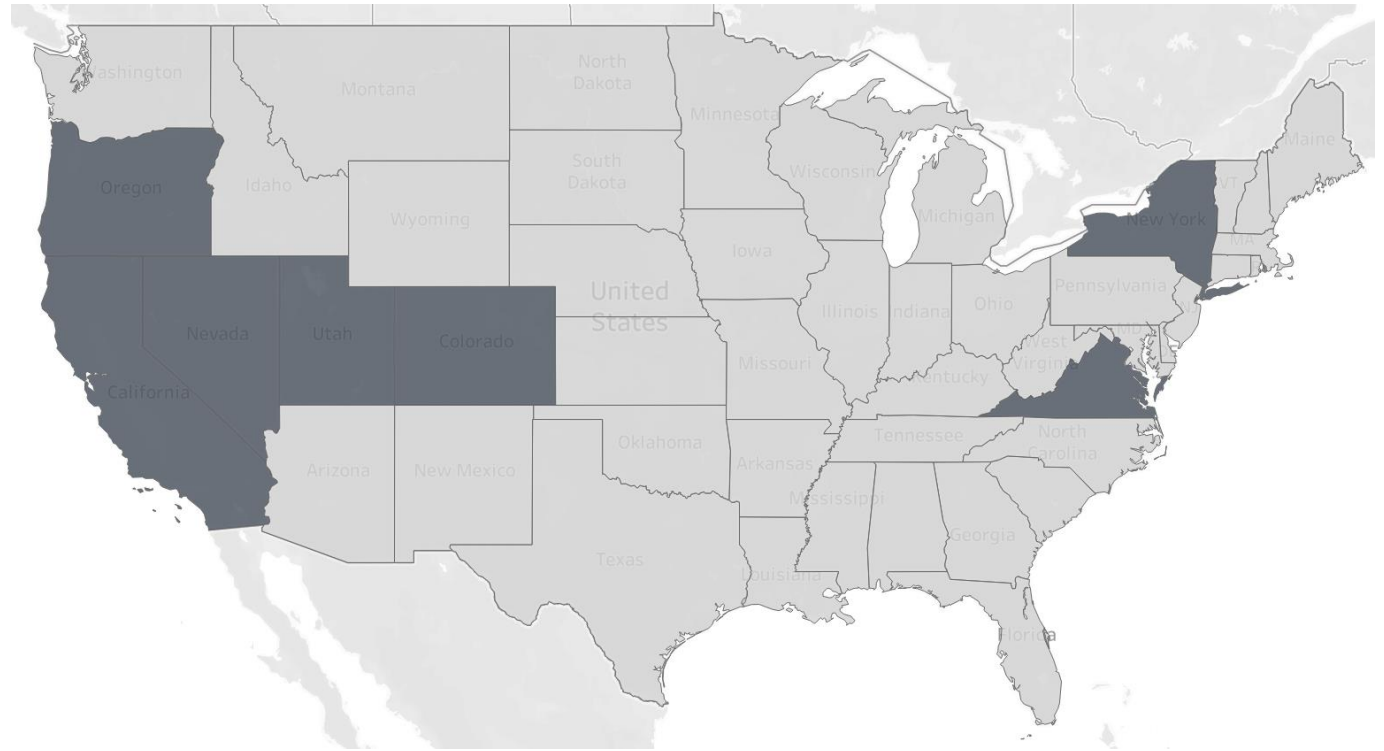
Clinical Decision Making: Hormonal Contraceptives

- Pharmacists able to prescribe and furnish hormonal contraceptives



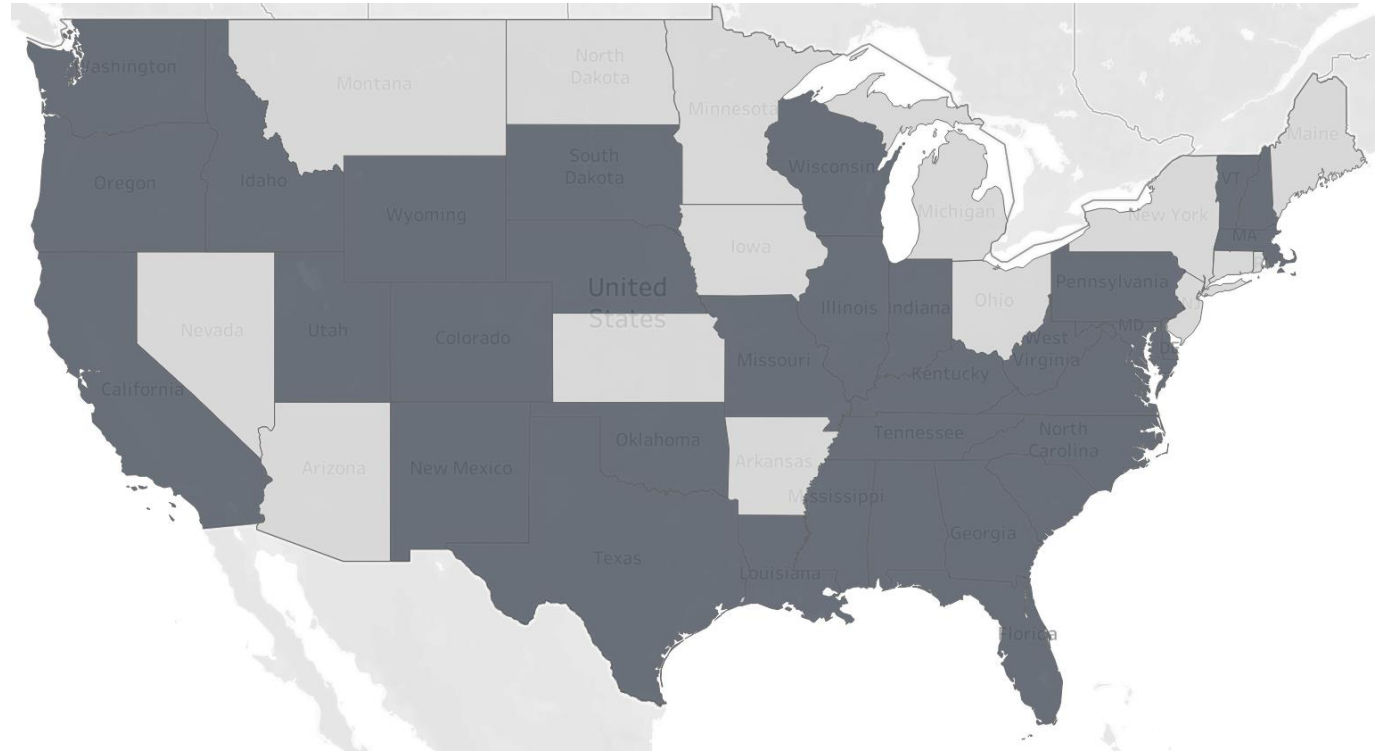
Clinical Decision Making: HIV PEP & PrEP

- Pharmacists able to prescribe and furnish PEP & PrEP



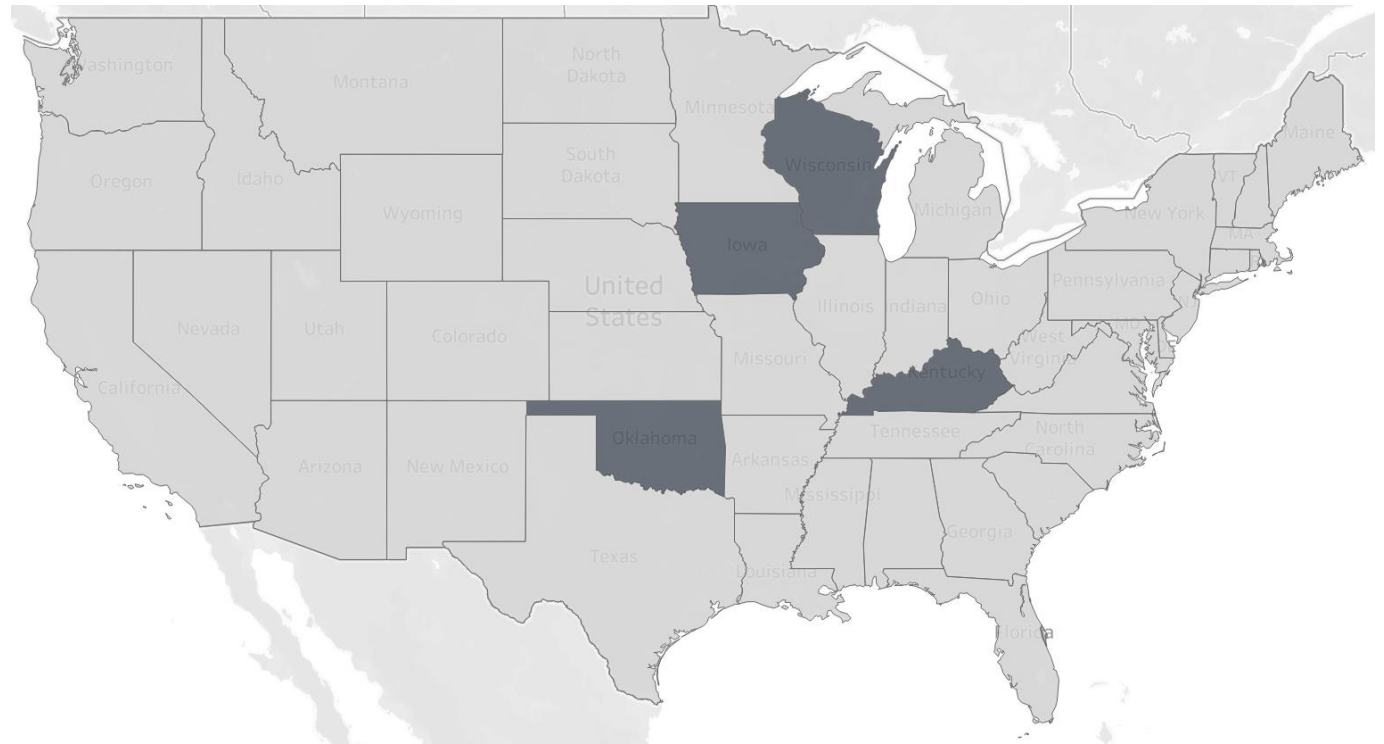
Product Administration: Long-Acting Injectables

- Pharmacists able to administer non-vaccine, long-acting injectable medications



Payment for Pharmacist Services

- Pharmacists able to bill third parties for clinical services provided



Assessment Question

- Which of the following was NOT a trend in pharmacy-related legislation?
 - a) Immunization
 - b) Genetic screening
 - c) Hormonal contraceptives
 - d) Payment for clinical services



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Compare & Contrast

Hot Topic	Trend	Utah
Immunization	Administer entire ACIP schedule	Yes!
Testing	Test & treat	Yes!
Payment for clinical services	Bill third party payers independently	Not quite
Hormonal contraceptives	Prescribe & furnish	Yes!
HIV PEP & PrEP	Prescribe & furnish	Yes!
Long-acting injectables	Administration	Yes!



2021 state provider status mid-year legislative update. National Alliance of State Pharmacy Organizations. <https://naspa.us/resource/2021-state-provider-status-mid-year-legislative-update/>. Accessed February 12, 2022.

Assessment Question

- Utah is the only state in which pharmacists have authority to provide hormonal contraception.
 - a) True
 - b) False



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Why should I stay aware?

- *I will embrace and advocate changes that improve patient care.*



What resources are available?

- Professional Organizations
 - APhA, ASHP, state, and specialty organizations
 - Conferences
 - Email updates
- Board of Pharmacy meetings



Assessment Question

- Which of the following resources would be most helpful to you in your practice?
 - a) Legislative email updates
 - b) Attending a national conference
 - c) Attending a Board of Pharmacy meeting
 - d) Attending a state pharmacy advocacy day



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