

# Evidence Based Lawmaking: The Climb Towards Full Scope of Practice



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## Learning Objectives:

Pharmacists	Pharmacy Technician
Identify and recognize updates or changes to laws, regulations, and practice models in relation to scope of practice for various states across the country.	Recall updates to laws, regulations, and practice models in relation to pharmacy technician scope of practice for various states across the country.
Interpret and consider application of "full scope of practice" through an evidence-based analysis.	Examine and analyze "full scope of practice" for pharmacy teams through an evidence-based analysis.
Differentiate barriers to full scope and recognize how each prevents moving towards a higher level of practice.	Identify the barriers to full scope of technician practice and recognize how each prevents moving towards a higher level.

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## The 3 Big Ideas

- Pharmacy Practice is highly regulated which limits scope of practice
- Law and rule changes must be vetted using an evidenced based analysis
- The enforcement philosophy for laws and rules impacts scope of practice

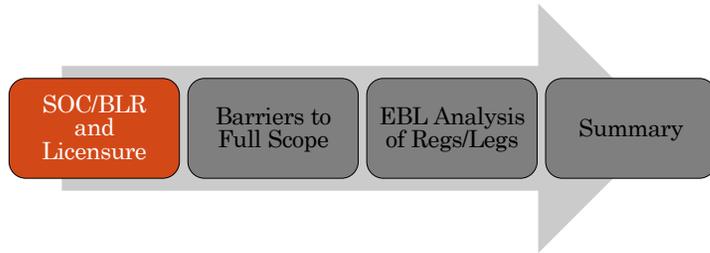
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## Pre-Learning Assessment Check #1

Name a pharmacy scope of practice advancement within the last 1-2 years outside of Michigan

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## Today's Agenda



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## Bright-Line Rules

- Clearly defined/objective
- Leaves little or no room for varying interpretation
- Defines forbidden and permissible conduct
- Can be punitive



**Pharmacy**

## Standard of Care

- Using skills, prudence, and diligence as similar professionals or licensees of similar education, training, and experience
- Assessed on a case-by-case basis to determine malpractice case rulings
- Room for interpretation/subjective
- Can be inclusive/wholistic



**Most other health professions**

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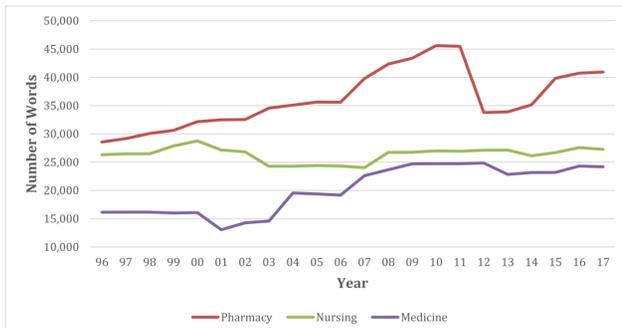


Fig. 4. Number of words in regulation by profession (1996-2017).

1 Adams AJ

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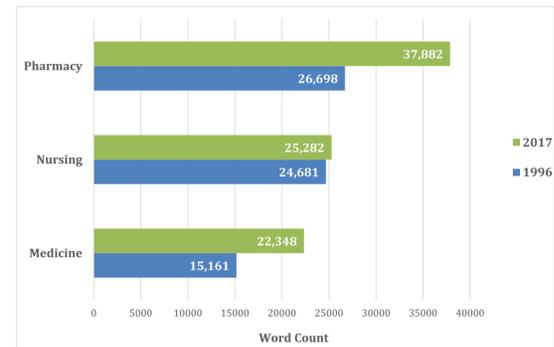
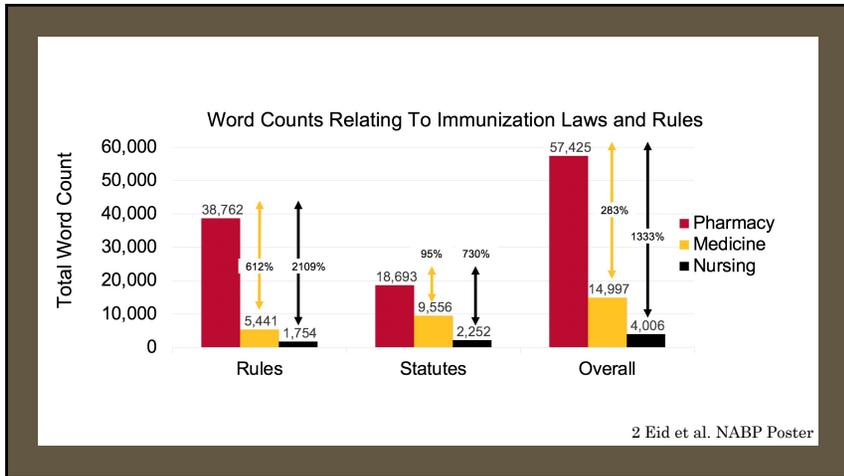


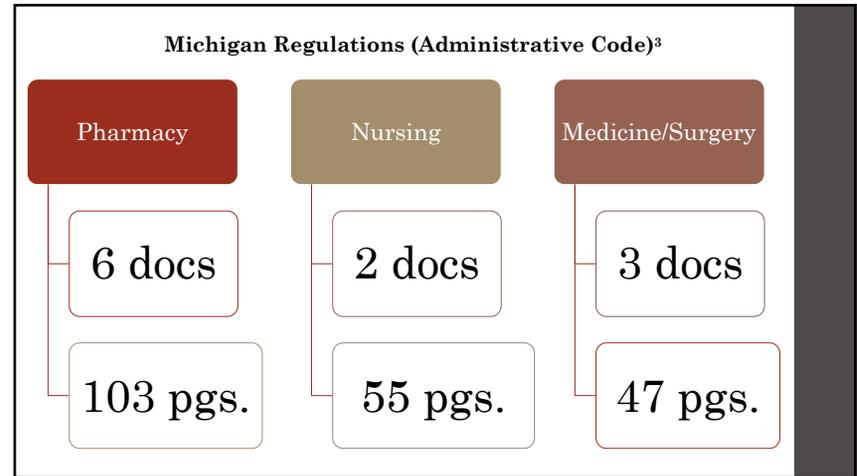
Fig. 2. Total word count of regulations by health profession (1996 vs. 2017).

1 Adams AJ

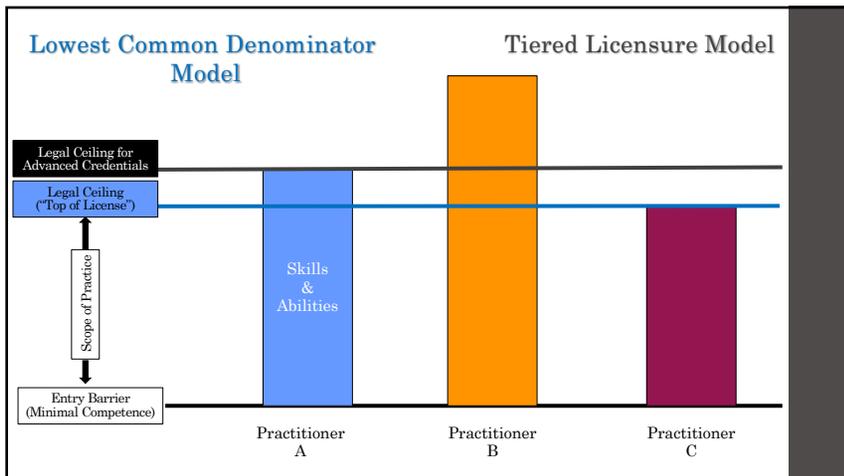
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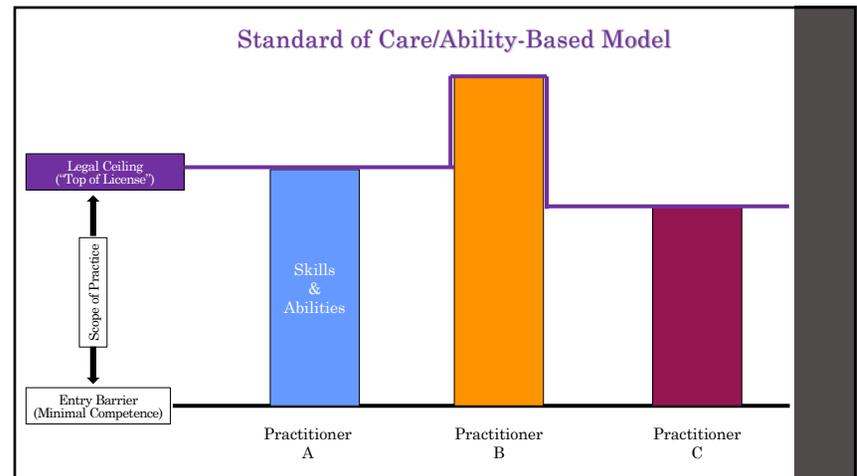
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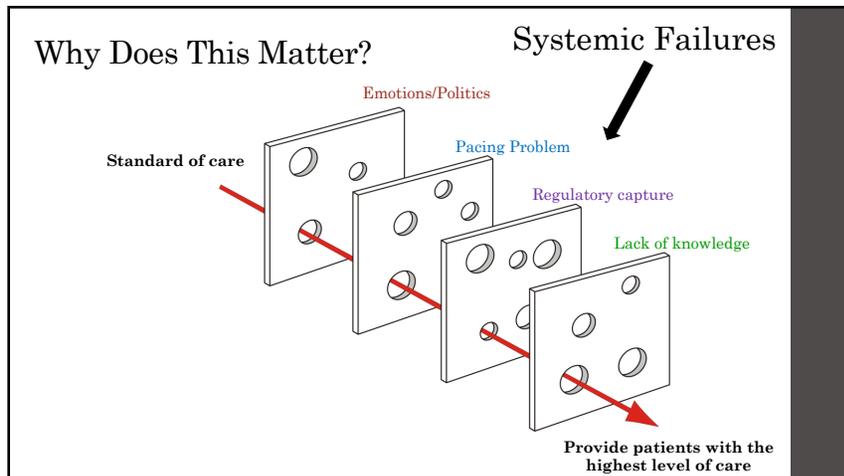
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## Learning Assessment Case

**Background:** Patient M.K. presents to pharmacy for the first time seeking an albuterol inhaler to be given to them without a prescription because they have had it before from another pharmacy in the past and there is an emergency need for it. Pharmacist provides M.K. with an inhaler to help alleviate potential emergency, then calls the patient's physician to seek a prescription for documentation afterwards.

**Issue:** The physician's nurse notifies them of the scenario and the physician decides to call the board of pharmacy to file a report of breach of law on behalf of the pharmacist who issued the inhaler without a valid prescription.

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## Learning Assessment Case

**Facts of the case:**

- Patient suffers from asthma, which they treat with prescription albuterol
- When M.K. went to the pharmacy for the first time, she pleads to the pharmacist she was suffering from an acute asthmatic attack and had run out of her inhaler
- Patient did not have a valid prescription for the Rx only product
- Pharmacist, using their professional judgement, provided patient with the product
- Pharmacist called the prescriber to pursue a valid prescription for dispensing after the fact the product had already left the store
- As a result, patient did not suffer damage to her breathing, nor did she require hospitalization
- Physician filed a report with the state board of pharmacy ensuing a breach of law requiring the board to investigate

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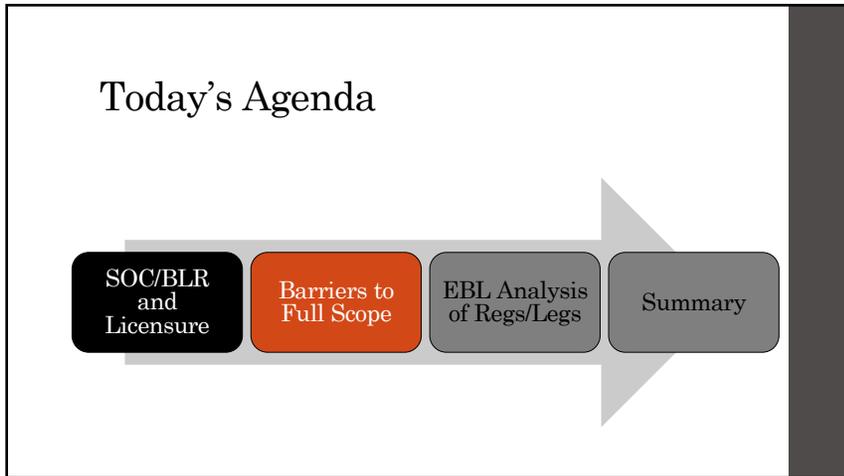
## Learning Assessment Case

**Case Analysis:**

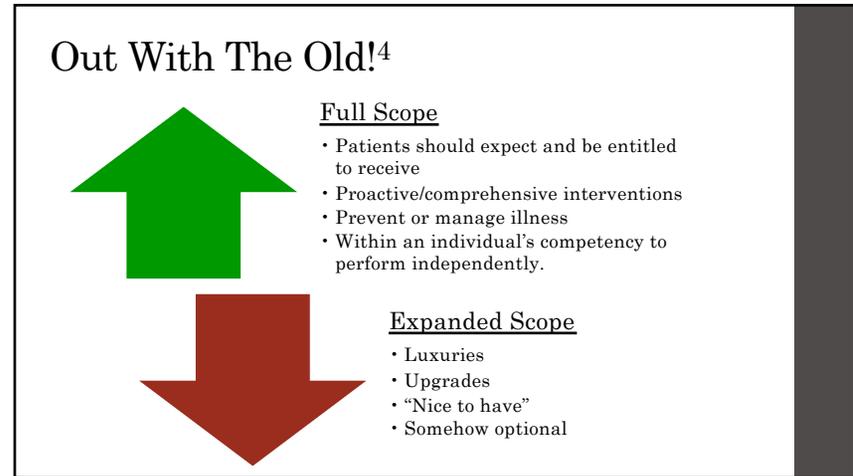
1. Compare and contrast using **bright line rules** VS **standard of care** enforcement strategies.

How might the state board of pharmacy handle the report/breach of law?

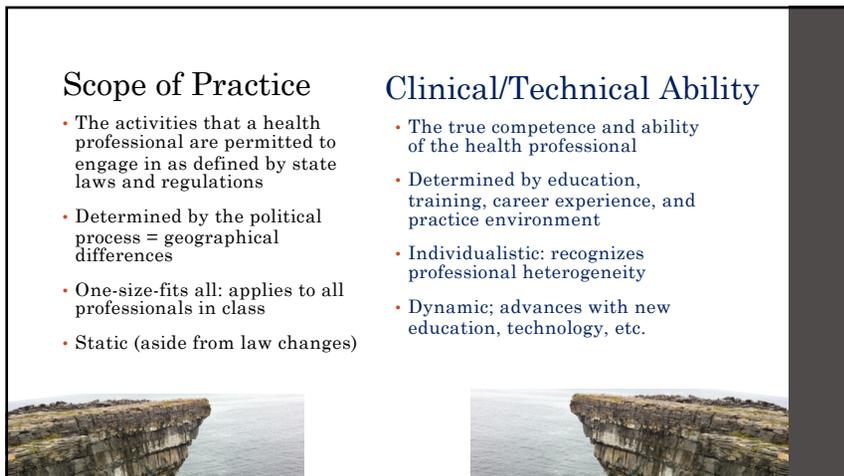
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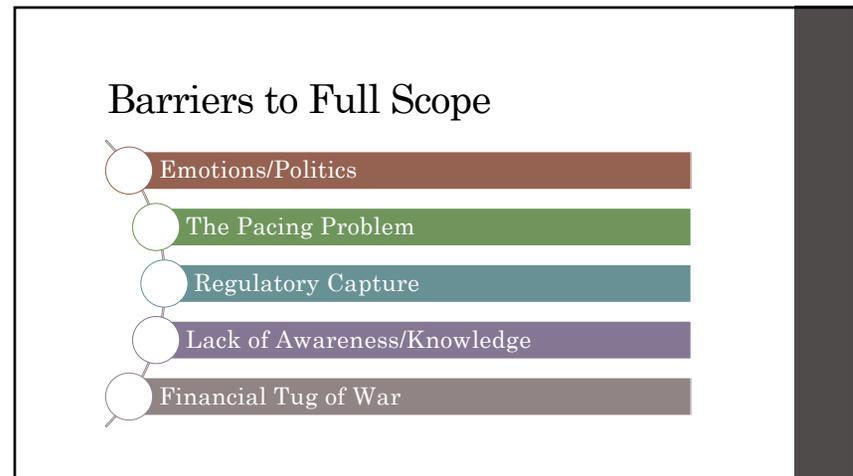
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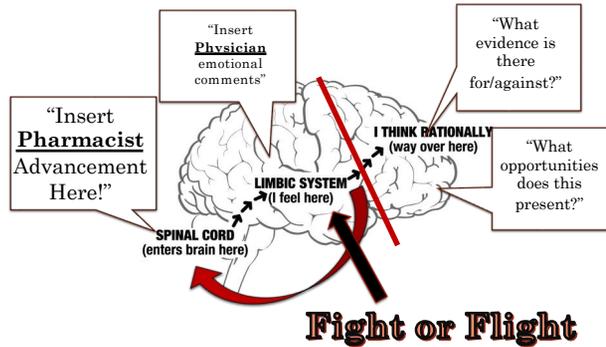


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## Emotions<sup>5</sup>



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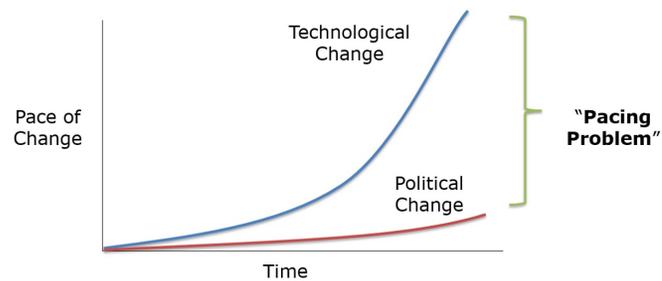
## Barriers to Full Scope

We are taught to use evidence-based decision making in clinical practice, but often use emotion-based decision making in law/policy making.

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## The Pacing Problem<sup>6</sup>

Technology changes *exponentially*; political systems change *incrementally*



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## Regulatory Capture<sup>7</sup>

- Economic theory: regulatory agencies come to be dominated by the interests they regulate and not by the public interest.
- Who seeks to gain or monetize by capturing the marketplace and regulating.

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### Regulatory Capture Examples



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### Today's Agenda



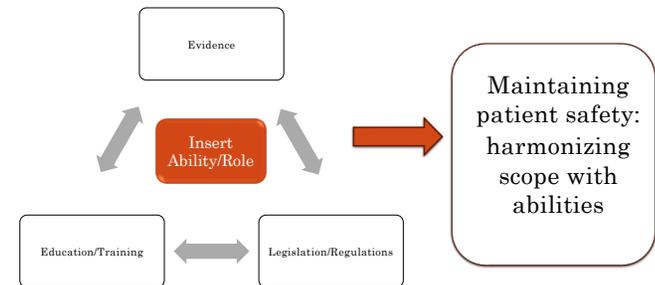
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*“Shouldn't the **full scope** of pharmacist practice be **defined by evidence**, **not outdated and restrictive legislation and policy** that differ across provinces and workplaces?”*

4 Ross et al.

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### Evidence Based Law Analysis



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## Disclaimer: Common Issues To Consider

- A few of the most common issues pharmacy faces:
  - Working conditions
  - Burnout
  - COVID
  - Not enough time/too busy
  - Not enough resources or help (lack of hours/staffing)
  - Not receiving reimbursement for services
  - Less autonomy than other professions
  - Drug pricing issues
  - Heavily overregulated
  - Over saturation

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## Analysis Focus Areas

Technician  
Admin of  
Vaccines

Independent  
Prescriptive  
Authority

Telepharmacy

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## Technician Administration of Vaccines/Medications

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## Evidence: Vaccines<sup>8-11</sup>

12/16 to 06/17:

- 953 immunizations administered-0 **adverse events reported**

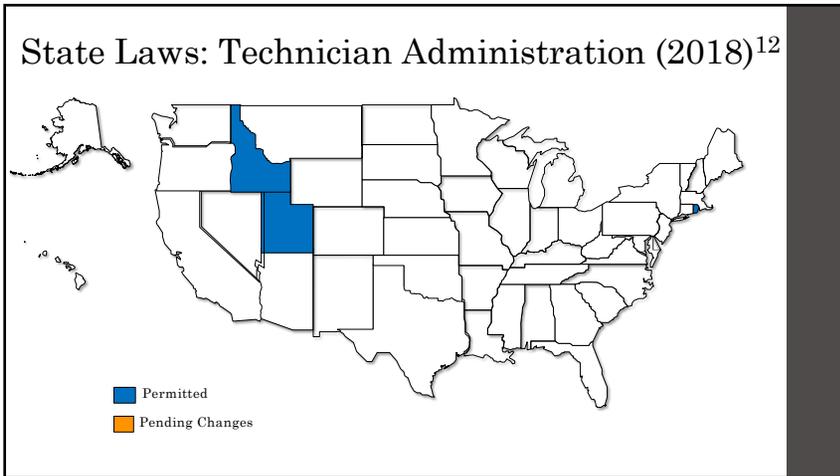
Several studies:

- **Unlicensed laypersons** can safely and effectively self-administer vaccines
- Perceptions studies

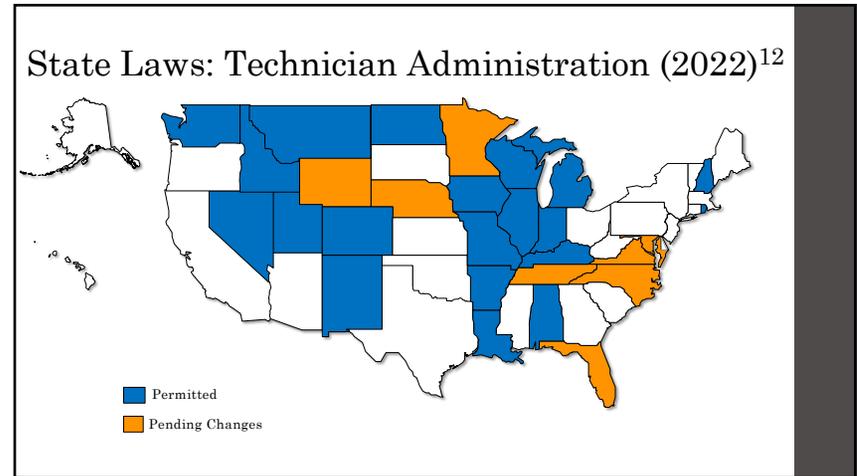
Jurisdictional  
Success:

- Tens of thousands of vaccines administered since 2017
- HHS PREP Act (COVID-19)
- Eid et al. law review

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### Training and Education<sup>13-15</sup>

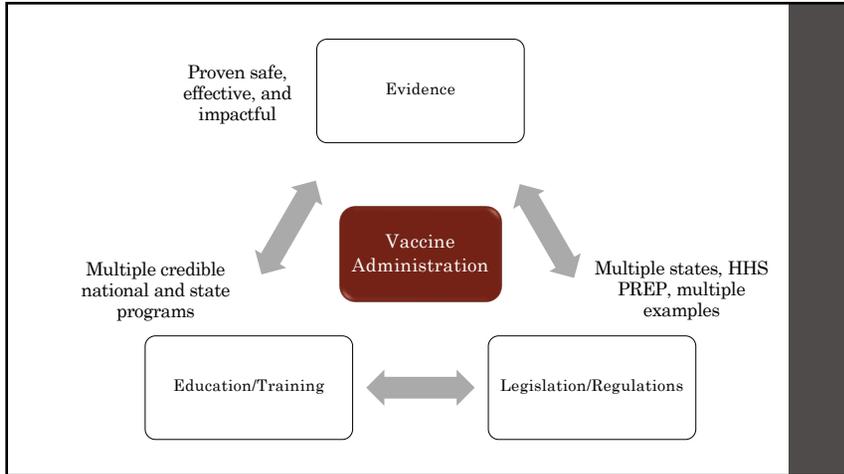
- Pharmacists have recognized certificate training programs for immunizations...and so do pharmacy technicians

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### Federal Laws: HHS PREP ACT Amendments<sup>16</sup>

- Created a united pathway for:
  - COVID POCT
    - by pharmacists, technicians, students
  - Administration of COVID vaccine
    - by pharmacists, technicians, students
  - Interstate practice
    - by pharmacists (possibly technicians)
  - RPh Ordering/Administration of COVID therapeutics
  - Immunity from state laws/rules

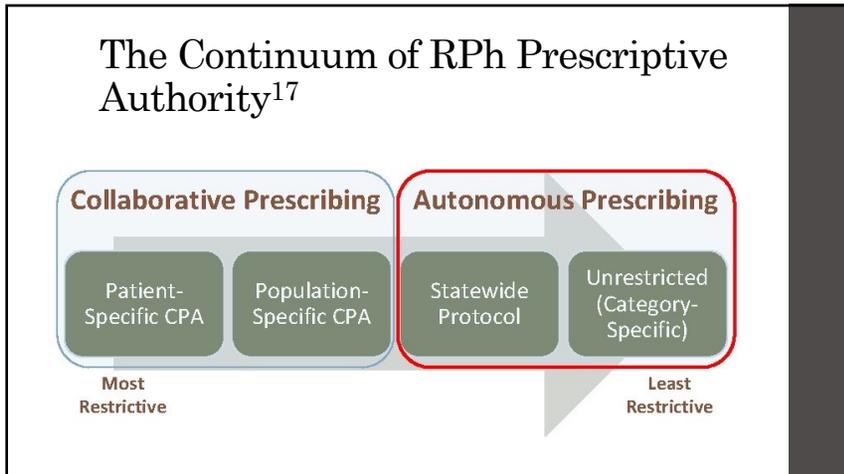
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# Independent Prescriptive Authority

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## State Laws: Independent Prescribing<sup>18-21</sup>

Alberta (Canada), ID

**\*Recently Passed Bills: CO, UT, ID**

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## Evidence: Independent Prescribing<sup>22</sup>

**Effects of pharmacist prescribing on patient outcomes in the hospital setting: a systematic review (15 studies)**

RPh	Author Conclusion:
<ul style="list-style-type: none"> <li>• Better cholesterol levels</li> <li>• Blood sugar</li> <li>• Adherence to warfarin dosing/therapeutic range</li> <li>• Decreased ADRs</li> <li>• Less prescribing errors (20-25X less)</li> <li>• Less omissions</li> <li>• Patient satisfaction</li> </ul>	<p><i>"Pharmacists are better at adhering to dosing guidelines when prescribing by protocol and make significantly fewer prescribing errors when charting patients' usual medications on admission to hospital."</i></p>

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## Evidence: Independent Prescribing<sup>23-28</sup>

**RxING (26 wks.):**

- 100 patients, diabetes
- A1c reduced from 9.1% to 7.3%
- FBG reduced from 198 to 124

**RxACTION (24 wks.):**

- 248 patients, blood pressure
- Systolic reduced 18.3 mm/Hg, diastolic 8 mm/Hg

**RxEACH (12 wks.):**

- 723 patients, CV risk reduction
- 21% greater relative reduction in estimated risk for CV events

**RxOUTMAP:**

- 750 patients, UTIs
- RPh arm → 88.6% clinical cure rate

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> J Manag Care Spec Pharm. 2018 May;24(5):423-429. doi: 10.18553/jmcp.2018.24.5.423.

**The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home**

Jared Prudencio <sup>1</sup>, Timothy Cutler <sup>2</sup>, Stephanie Roberts <sup>2</sup>, Stephanie Martin <sup>3</sup>, Machele Wilson <sup>2</sup>

Affiliations + expand  
PMID: 29694290 DOI: 10.18553/jmcp.2018.24.5.423  
Free article

> Eur J Hosp Pharm. 2018 Mar;25(e1):a2-e6. doi: 10.1136/ehp-2017-001267. Epub 2017 Aug 9.

**Pharmacist prescribing in critical care: an evaluation of the introduction of pharmacist prescribing in a single large UK teaching hospital**

Verity J Cross <sup>1</sup>, James T Parker <sup>2</sup>, Marie-Christine Y L Law Min <sup>2</sup>, Richard S Bourne <sup>2</sup>

Affiliations + expand  
PMID: 31157059 PMCID: PMC6457156 DOI: 10.1136/ehp-2017-001267  
Free PMC article

Review > Curr Probl Cardiol. 2019 Sep;44(9):276-293. doi: 10.1016/j.cpcardiol.2018.07.003. Epub 2018 Aug 4.

**Risk Reduction to Disease Management: Clinical Pharmacists as Cardiovascular Care Providers**

Katherine E Di Palo, Khusbu Patel, Troy Kish  
PMID: 30173910 DOI: 10.1016/j.cpcardiol.2018.07.003

**The role of the pharmacist in hypertension management**

Katherine E Di Palo <sup>1</sup>, Troy Kish <sup>2</sup>

Affiliations + expand  
PMID: 29697544 DOI: 10.1097/HCO.0000000000000527

Comparative Study > JBI Database System Rev Implement Rep. 2018 Sep;16(9):1823-1873. doi: 10.11124/JBISIR-2017-003697.

**Effects of pharmacist prescribing on patient outcomes in the hospital setting: a systematic review**

Eng Whui Poh <sup>1</sup>, Alexa McArthur <sup>2</sup>, Matthew Stephenson <sup>2</sup>, Elizabeth E Roughead <sup>3</sup>

Affiliations + expand  
PMID: 30204671 DOI: 10.11124/JBISIR-2017-003697

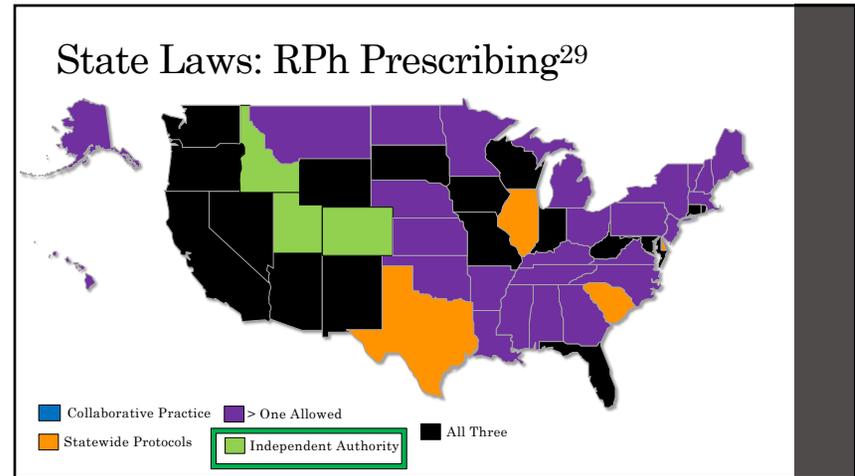
> J Clin Pharm Ther. 2016 Dec;41(6):645-649. doi: 10.1111/jcpt.12436. Epub 2016 Aug 31.

**Patient satisfaction with the clinical pharmacist and prescribers during hepatitis C virus management**

M T Martin <sup>1</sup> <sup>2</sup>, D M Faber <sup>3</sup>

Affiliations + expand  
PMID: 27578276 DOI: 10.1111/jcpt.12436

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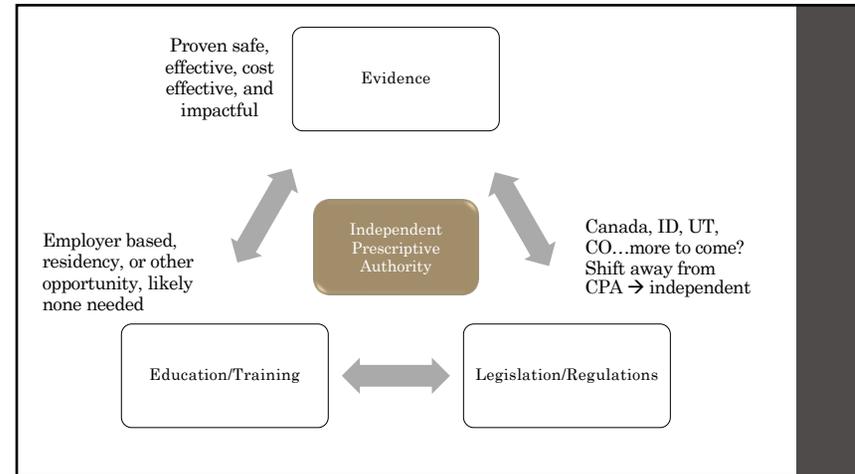


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## Education & Training

Element	Pharmacy Technician; Reasonable Activity with Training	Pharmacist; Graduated from accredited college and passed NAPLEX
Document during patient assessment	Yes	Yes
Collect vital signs or perform POCT	Yes	Yes
Interpret laboratory tests	Maybe	Yes
Develop a differential diagnosis	No	Yes
Independently select a drug regimen to treat a condition	No	Yes

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## Telepharmacy

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## State Laws: Barriers



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### State Laws: Head-to-Head

<p><b>Michigan-SB340 (01/20)</b></p> <ul style="list-style-type: none"> <li>• 10-mile radius restrictions</li> <li>• Avg. &lt; 150 Rx per day</li> <li>• Limit of 3 supervisee pharmacies at a time</li> <li>• Pharmacy technician → 1,000 hours of work experience, licensure, certification...etc.</li> </ul>	<p><b>Idaho</b></p> <ul style="list-style-type: none"> <li>• No milage restrictions</li> <li>• No Rx quantity restrictions</li> <li>• No pharmacy technician restrictions</li> <li>• Video surveillance must be maintained for 90 days</li> <li>• Audio-video → HIPAA compliant</li> </ul>
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### Evidence: Telepharmacy<sup>31-33</sup>

ND Telepharmacy Project	Systematic Reviews	Jurisdictional Success
<ul style="list-style-type: none"> <li>• 22 publications dating back to 2004</li> <li>• Proven safe and effective</li> <li>• Rural, community, health system</li> </ul>	<ul style="list-style-type: none"> <li>• Strnad et al. 2018</li> <li>• Pathak et al. 2021</li> </ul>	<ul style="list-style-type: none"> <li>• 20+ years of success in ND</li> <li>• Multiple years of success in various states (without added restrictions)</li> </ul>

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### Evidence: Telepharmacy

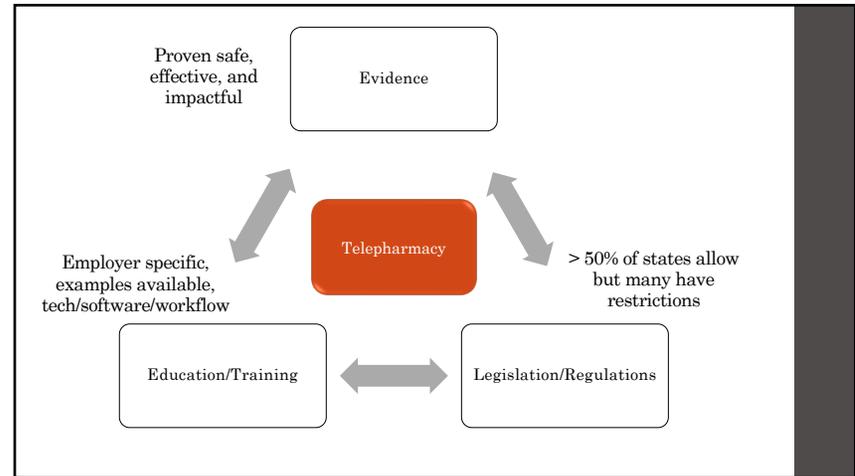
**Non-Evidence Based Restrictions**

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## Education/Training: Telepharmacy

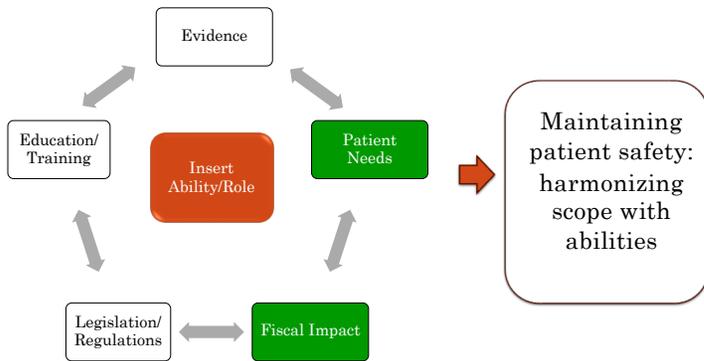


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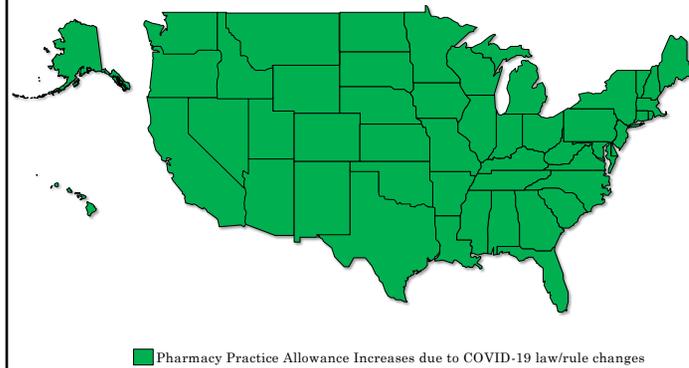
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## Full Evidence Based Law Analysis



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## The COVID MAP



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## Today's Agenda



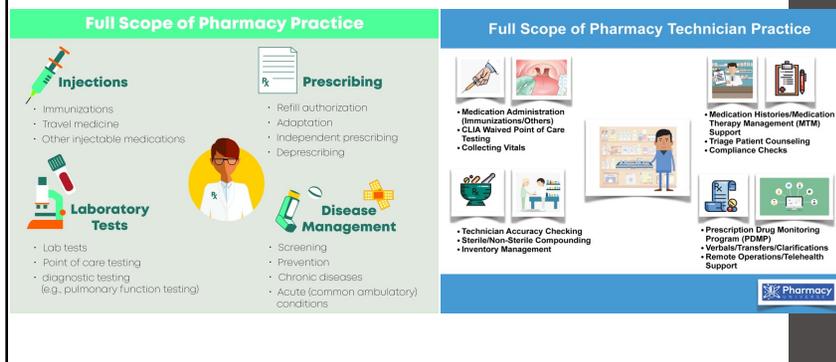
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## The Big Question

How might we maintain patient safety while harmonizing scope of practice with clinical/technical abilities?

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## Evidence Based Law Analysis<sup>4</sup>



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## What Can We Do?

- **Laws:**
  - Remove the "RED TAPE"
    - *Just because you won't/can't, doesn't mean others won't/can't*
  - Work with State Associations, BOP, Legislators, Stakeholders
- **Evidence:**
  - Educate and disseminate studies, evidence, and historical successes
  - Learn from other states/models
  - Evidence based decisions > Emotional
- **Education/Training:**
  - Tools/Resources available
  - Appropriate, but not "shackling"

**Instead of fighting each other let's work together!**

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## What Can You Do?

- Work to expand your practice sites based on other successful models
- Utilize pilot programs, research projects, or other experimental opportunities
- Be conscious of emotions and don't let the emotions overtake evidence in decision making
- Advocate and support for evidenced based legislation/rule changes → **no matter the sector in pharmacy**

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*“You don't run a race  
for the journey, you run  
it to arrive.”*

-Tim Grover

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