

# Evidence Based Law Making: The ABCs of Pharmacy Law

DEEB D. EID, PHARM.D., RPH  
SENIOR ADVISOR, REGULATORY AFFAIRS



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## DISCLOSURES

- Speaker has no financial disclosures.
- Opinions and perspectives presented are of the speaker themselves and not of any employer or affiliates.

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## LEARNING OBJECTIVES

Compare and contrast differences between federal and state legislatures, regulatory agencies, and how they impact pharmacy practice.

↓

Identify the barriers and challenges that exists in the political climate of pharmacy law.

↓

Recognize strategies, opportunities, and areas to push towards an evidence-based lawmaking philosophy for positive changes in pharmacy laws and rules.

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## THE BIG IDEA

Laws and rules have a critical importance to **impacting everyday practice**. **Understanding and contributing productively** to the process of changes to laws and rules **is indispensable**.

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## TODAY'S LESSON

Back to the basics

Rainy with a chance of politics

How to make an impact

Summary

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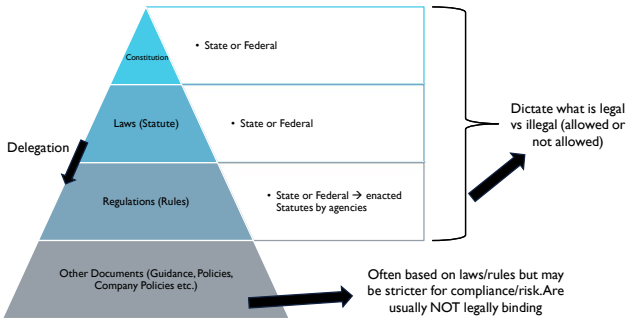
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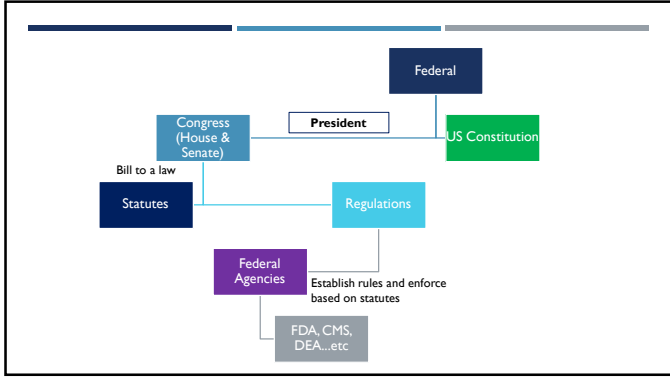
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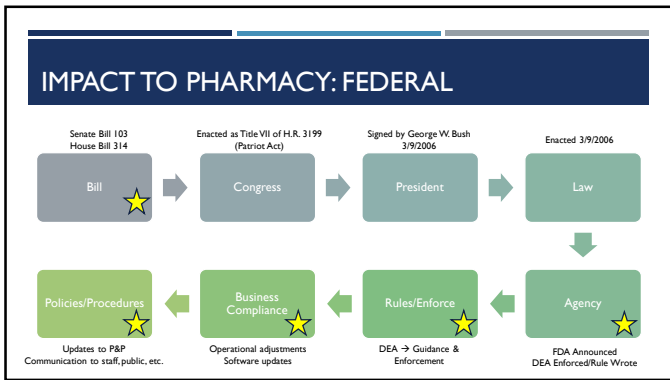
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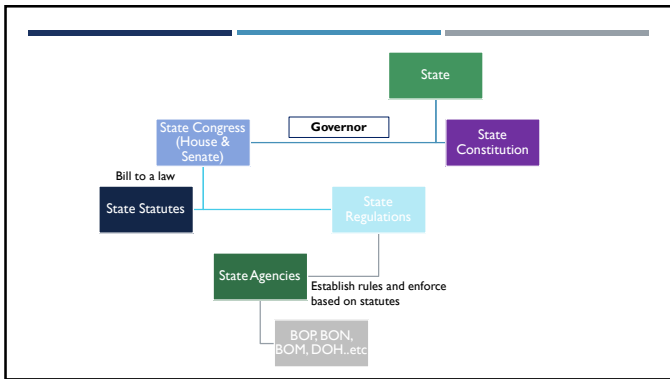
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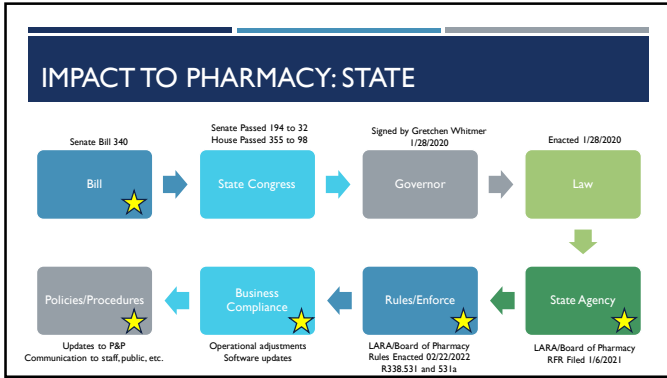
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### OVERALL IMPACT

- Changing one sentence, even one singular word in the laws/rules can have positive or negative impact on practice.
  - "may" vs "shall"
- Testimonies, comment letters, calls, and more can impact any proposed bill, rule change, or policy changes.
  - Anyone can be involved at any level
- If you are not at the table, you are on the menu

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### ADMINISTRATIVE PROCEDURES ACT

The Administrative Procedure Act (APA) governs the process by which federal/state agencies develop and issue regulations.

It includes requirements for publishing notices of proposed and final rulemaking in the registers and provides opportunities for the public to comment on notices of proposed rulemaking.

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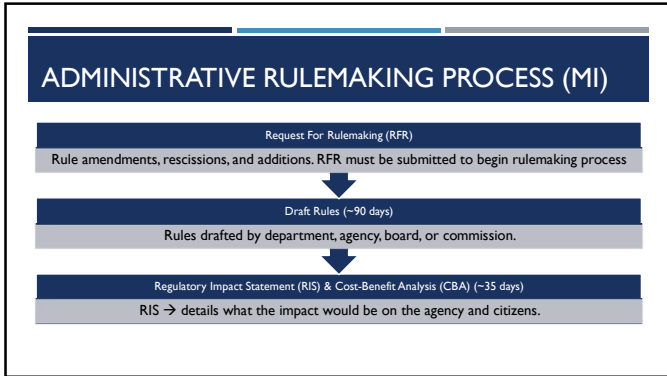
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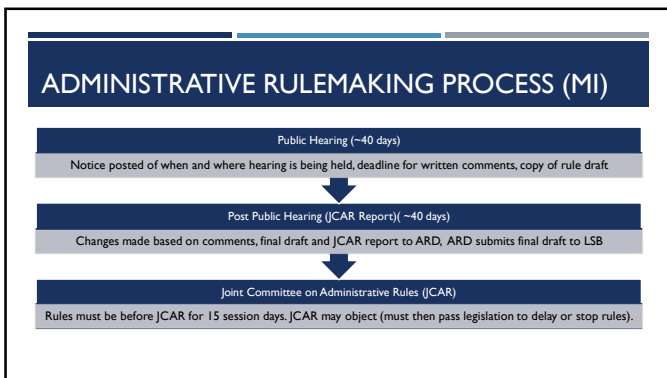
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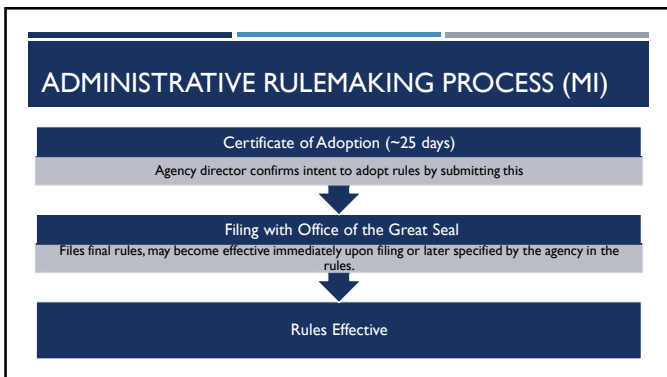
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Pursuant to MICHIGAN Administrative Hearing Standard 2022.1, administrative proceedings will by default be conducted remotely, unless (i) an administrative law judge, hearing officer, or Tax Tribunal Member determines in their discretion that all or part of a proceeding should be in person or (ii) a party submits a written request demonstrating good cause for why all or part of the proceeding should be in person and the administrative law judge, hearing officer, or Tax Tribunal Member finds the request should be granted because of accessibility limitations, specific evidentiary issues, or other unique circumstances. For further social remote hearing participants, MICHIGAN has developed a **Standards and Guidelines for Remote Hearings** manual. This manual contains useful information and best practices relevant to the conduct of remote hearings for all practice areas within MICHIGAN, except for the Corrections area and the Michigan Tax Tribunal, the latter of which has its own **MTT Video Hearing Guides for Participants**.

The Administrative Rules Division is charged with overseeing the administrative rulemaking process for each department in the State of Michigan.

You may filter your search for administrative rules by a department name and, if desired, then a bureau. The Michigan Administrative Code can be filtered by subject numbers or range numbers.

[Administrative Rules Search](#)

**Explore Administrative Rules Topics**

[Current Emergency Rules](#) [Pending Rules Activity](#) [Publications](#) [Education](#)

[Rules Currently Pending in the Rulemaking Process](#)  
[Michigan Administrative Code](#)

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ARS - Administrative Rulemaking System  
Department of Licensing and Regulatory Affairs

MI Admin Code

**Home**

Pending/Recent Rulemaking Transactions

Show 10 entries Search:

Rule Set #	Department - Bureau	Rule Set Title	Filing Date	Effective Date
2019-39 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Board of Pharmacy - General Rules	12/22/2020	12/22/2020
2019-22 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Pharmacy - Continuing Education	12/22/2020	12/22/2020
2019-86 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Board of Pharmacy - Animal Euthanasia and Sedation Rules	10/28/2021	10/28/2021
2020-29 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Pharmacy Technicians	10/19/2021	10/19/2021
2020-82 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Pharmacy - Controlled Substances	1/6/2022	1/6/2022
2020-128 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Pharmacy - General Rules	2/22/2022	2/22/2022
2021-51 LR	Licensing and Regulatory Affairs - Bureau of Professional Licensing	Pharmacy - Pharmacist Continuing Education	Pending	Pending

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ARS - Administrative Rulemaking System  
Department of Licensing and Regulatory Affairs

Rule Set #  
2022-028 LR

Department:  
Licensing and Regulatory Affairs

Bureau:  
Bureau of Professional Licensing

Title of Rule Set:  
Pharmacy - General Rules

Rule Number(s) or rule set range of numbers:  
# 000001 - 000001

Filing date:  
02/22/2022

Effective date:  
02/22/2022

Click on the links below to download

ARS Form: [ARS Form](#)

ARS Form Attachment: [ARS Form Attachment](#)

Draft Rule Language: [Draft Rule Language](#)

ARS Form: [ARS Form](#)

Notice of Public Hearing: [Notice of Public Hearing](#)

Final Rule Language: [Final Rule Language](#)

Final Rule Attachment: [Final Rule Attachment](#)

JCAR Package: [JCAR Package](#)

JCAR Package Attachment: [JCAR Package Attachment](#)

JCAR Report Affidavit: [JCAR Report Affidavit](#)

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**Board Information**

- [Michigan Board of Pharmacy Members](#)
- [Pharmacy 2022 Board Meetings](#)
- [Pharmacy 2021 Board Meetings](#)
- [Pharmacy Board Meeting Agendas and Minutes](#)
- [Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain](#)
- [Pharmacy Rules Committee Work Group](#)

**Frequently Asked Questions**

- [Laws, Rules & Other Resources](#)
- [Link to the FDA Purple Book \(Pursuant to Public Act 41 of 2018\)](#)
- [Pharmacist FAQs](#)
- [Pharmacy FAQs](#)
- [Pharmacy Technician FAQs](#)

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**Professional Licensing Resources**

Home > Bureau > Professional Licensing > Professional Licensing Resources

**Professional Licensing Resources**

- [Administrative Rules](#)
- [BPL Legislative Reports](#)
- [Consent to Service of Process](#)
- [Contact the Bureau of Professional Licensing](#)
- [Declaratory Rulings](#)
- [Michigan Occupational Code \(Act 299 of 1980\)](#)
- [Michigan Public Health Code \(Act 368 of 1978 - Article 15\)](#)
- [Social Security Number Affidavit](#)

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You can Google indexes and it should take you to the wording of the rule or statute.

Rule 338.479, MCL 333.17755(1), 333.17756

The first 3 numbers indicate the statute chapter

"Rule" means it will be within the Board of Pharmacy Rules or Federal Rules

Numbers indicate the index of where it can be found within the rules

"MCL" (Michigan Compiled Laws) means it can be found within statutes or the public health code

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ARS - Administrative Rulemaking System  
 Department of Licensing and Regulatory Affairs

### MI Administrative Code

MI Administrative Code(s) for Licensing and Regulatory Affairs - Bureau of Professional Licensing

Show 6 entries

Title	Start	End	Admin Code File	Last Updated On
Board of Pharmacy - Animal Euthanasia and Sedation Rules	R 338.3501	338.3523	R 338.3501 to R 338.3523.pdf	11/10/2021 2:44:44 PM
Board of Pharmacy - Continuing Education	R 338.3041	338.3045	R 338.3041 to R 338.3045.pdf	12/22/2020 10:48:02 AM
Board of Pharmacy - Controlled Substances	R 338.3101	338.3199a	R 338.3101 to R 338.3199a.pdf	1/6/2022 12:18:15 PM
Board of Pharmacy - General Rules	R 338.471	338.590	R 338.471 to R 338.590.pdf	2/22/2022 11:59:39 AM
Centralized Prescription Processing Pharmacies	R 338.3051	338.3056	5472_2014-139L_R_AdminCode.pdf	N/A
Pharmacy Technicians	R 338.3651	338.3660	R 338.3651 to R 338.3660.pdf	10/18/2021 10:14:16 AM

Showing 1 to 6 of 6 entries (filtered from 50 total entries)

Search Administrative Code

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368-1978-15

Legislature

Public Health Code (Excerpt)  
 Act 368 of 1978  
 Article 15  
 OCCUPATIONS

Document	Type	Description
368-1978-15-114	Division	PART 161 GENERAL PROVISIONS (333.16501...333.16349)
368-1978-15-144	Division	PART 164 CHIROPRACTIC (333.16401...333.16431)
368-1978-15-165	Division	PART 165 Acupuncture (333.16501...333.16529)
368-1978-15-166	Division	PART 166 DENTISTRY (333.16601...333.16699)
368-1978-15-168	Division	PART 168. AUDIOLOGY (333.16801...333.16811)
368-1978-15-169	Division	PART 169 MARRIAGE AND FAMILY THERAPY (333.16901...333.16915)
368-1978-15-170	Division	PART 170 MEDICINE (333.17001...333.17097)
368-1978-15-171	Division	PART 171. MIDWIFERY (333.17101...333.17123)
368-1978-15-172	Division	PART 172 NURSING (333.17201...333.17242)
368-1978-15-173	Division	PART 173 (333.17301...333.17319)
368-1978-15-174	Division	PART 174 OPTOMETRY (333.17401...333.17437)
368-1978-15-175	Division	PART 175 OSTEOPATHIC MEDICINE AND SURGERY (333.17501...333.17556)
368-1978-15-176	Division	PART 176. SPEECH-LANGUAGE PATHOLOGY (333.17601...333.17613)
368-1978-15-177	Division	PART 177 PHARMACY PRACTICE AND DRUG CONTROL (333.17701...333.17780)

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MICHIGAN LEGISLATURE  
 Michigan Compiled Laws Complete Through PA 31 of 2022  
 House: Adjourned until Tuesday, June 21, 2022 10:00:00 AM  
 Senate: Adjourned until Thursday, June 23, 2022 10:00:00 AM

368-1978-15-177

Public Health Code (Excerpt)  
 Act 368 of 1978  
 Part 177  
 PHARMACY PRACTICE AND DRUG CONTROL

Document	Type	Description
Section 333.17701	Section	Meanings of words and phrases; general definitions and principles of construction.
Section 333.17702	Section	Definitions: A to C.
Section 333.17703	Section	Definitions: D, E.
Section 333.17704	Section	Definitions: F to L.
Section 333.17705	Section	Definitions: M.
Section 333.17706	Section	Definitions: M, Q.
Section 333.17707	Section	Definitions: R.
Section 333.17708	Section	Definitions: P to R.
Section 333.17708a	Section	Definitions: P to R; limitation on prescription of pharmaceutical agents.
Section 333.17709	Section	Definitions: S to X.
Section 333.17711	Section	Practice of pharmacy or pharmacy technician; license or authorization required; use of words, titles, or letters.
Section 333.17713	Section	Temporary resolutions of pharmacists and prescriptions during qualified order or declaration.

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**Executive Orders**  
**Executive Reports**  
**Historical Documents**  
**MC Tables**  
**Other Real Laws**  
**Req Outdated Acts**

**More**  
 Archives  
 Email Notifications  
 Legislative Directory  
 Michigan Manuals  
 Michigan Color Themes  
 Publications  
 Related Sites

**Syndication**

**Rss**

**Meetings**

**Laws**

**Recently Viewed**  
 mdl chap333

**Compiler's Notes:** For transfer of the Department of Insurance and Office of the Commissioner on Insurance from the Department of Licensing and Regulation to the Department of Commerce, see E.R.O. No. 1991-9, compiled at MCL 338.3501 of the Michigan Compiled Laws for transfer of powers and duties of certain health-related functions, boards, and commissions from the Department of Licensing and Regulation to the Department of Commerce, see E.R.O. No. 1991-9, compiled at MCL 338.3501 of the Michigan Compiled Laws for transfer of powers and duties of licensing of substance abuse programs and certification of substance abuse workers in the division of program standards, evaluation, and data services of the center for substance abuse services, from the department of public health to the director of the department of commerce, see E.R.O. No. 1996-1, compiled at MCL 330.3101 of the Michigan Compiled Laws.  
**Popular Name:** Act 368

The People of the State of Michigan enact:

Document	Type	Description
368-1978-1	Division	ARTICLE 1 PRELIMINARY PROVISIONS (333.1101...333.1299)
368-1978-2	Division	ARTICLE 2 ADMINISTRATION (333.2201...333.3625)
368-1978-5	Division	ARTICLE 5 PREVENTION AND CONTROL OF DISEASES AND DISABILITIES (333.5101...333.5955)
368-1978-6	Division	ARTICLE 6 SUBSTANCE ABUSE (333.6101...333.6528)
368-1978-7	Division	ARTICLE 7 CONTROLLED SUBSTANCES (333.7401...333.7545)
368-1978-8	Division	ARTICLE 8 PHARMACEUTICAL-GRADE CANNABIS (333.8101...333.8511)
368-1978-9	Division	ARTICLE 9 SUPPORTIVE PERSONAL HEALTH SERVICES (333.9101...333.9709)
368-1978-10	Division	ARTICLE 10 ANATOMICAL GIFTS AND DISPOSITION OF HUMAN BODY PARTS (333.10101...333.11191)
368-1978-12	Division	ARTICLE 12 ENVIRONMENTAL HEALTH (333.12101...333.13832)
368-1978-15	Division	ARTICLE 15 OCCUPATIONS (333.16101...333.18838)
368-1978-17	Division	ARTICLE 17 FACILITIES AND AGENCIES (333.20101...333.22340)
368-1978-18	Division	ARTICLE 18 SURPRISE MEDICAL BILLING (333.24501...333.24517)
368-1978-19	Division	ARTICLE 19 REPEALS, SAVINGS CLAUSES, AND EFFECTIVE DATES (333.25101...333.25211)

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## LEARNING ASSESSMENT #1

A state agency such as a board of pharmacy can impact the practice of pharmacy in which of the following methods?

- a) Develop and enforce regulations
- b) Vote on and enact statutes
- c) Overturn state court rulings
- d) Issue executive orders

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## TODAY'S LESSON

Back to the basics

Rainy with a chance of politics

How to make an impact

Summary

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# POLITICS

*Politics (from Greek: politiká, 'affairs of the cities') is the set of activities that are associated with making decisions in groups, or other forms of **power relations** among individuals, such as the **distribution of resources** or status.*

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## CHARACTERISTICS OF POLITICS

<p><b>Typical Governmental</b></p> <ul style="list-style-type: none"> <li>▪ Choosing a "party" or being part of a group</li> <li>▪ Having certain beliefs or views on various topics based on perspectives</li> <li>▪ Creating, changing, or striking rules, laws, court decisions or other areas</li> <li>▪ Resource allocation and power distribution</li> <li>▪ Financial tug of war</li> <li>▪ Emotions</li> </ul>	<p><b>Pharmacy</b></p> <ul style="list-style-type: none"> <li>▪ Choosing a "sector"</li> <li>▪ Having perspectives based on our everyday working environments OR past experiences</li> <li>▪ Creating, changing, or striking rules and laws within the profession</li> <li>▪ Turf wars with others and ourselves</li> <li>▪ Financial tug of war with healthcare and ourselves</li> <li>▪ Emotions</li> </ul>
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## EMOTIONS

**Fight or Flight**

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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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**LET'S BE HONEST**

- What % of pharmacists, technicians, or students have firsthand experience in the political or legal process?
- How many pharmacists...etc. have an above average understanding of how to actually change or impact laws and rules within the profession?
- What number of pharmacists...etc. rely on associations and other "groups" to do the advocacy for them?
- How many can recognize and implement effective advocacy changes that better most patients AND the profession VS operational/clinical knowledge?
- What quantity have undergone formal or informal education or training in this area?

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**LET'S BE HONEST**

Raise your hand if you have thought to yourself "if it does not impact my day-to-day job, I don't really care that much"

Raise your hand if you have ever read an article or a headline or overheard someone talking about a topic you do not TRULY understand but you "felt" like you agreed with the stance

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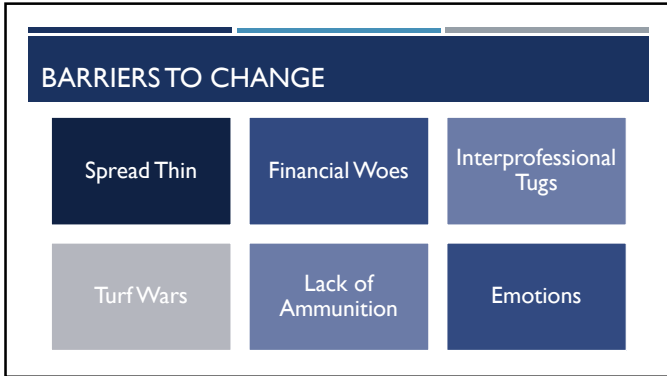
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**LEARNING ASSESSMENT #2**

Which of the following could assist with alleviating the political barrier in pharmacy of being "spread thin"?

- a) Decreasing the number of colleges of pharmacy
- b) Decreasing the number of special interest groups, associations, and sector dividers
- c) Increasing the amount of education pharmacist receive on political science and advocacy impact
- d) Increasing the amount of dollars spent on lobbying against other healthcare professionals

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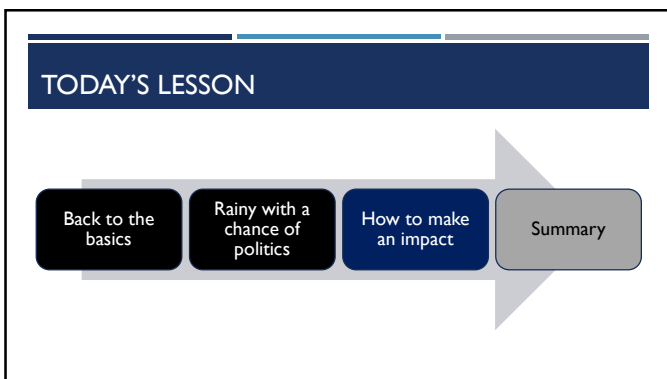
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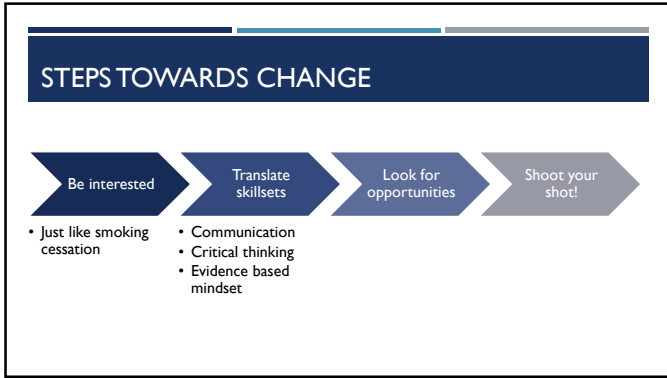
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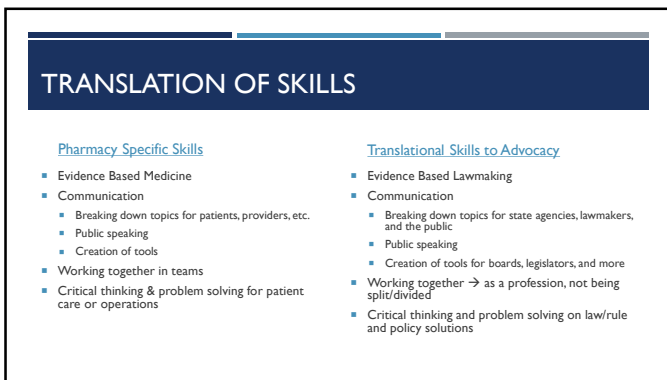
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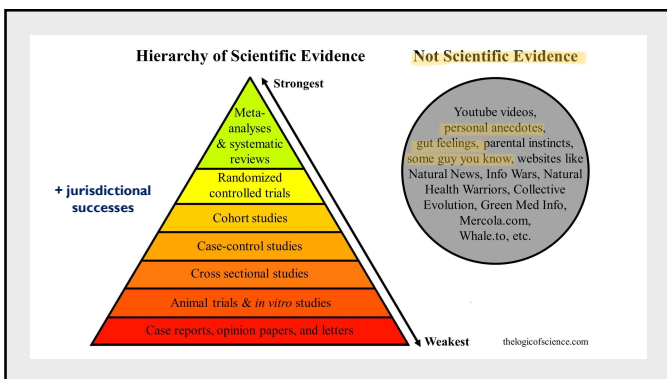
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## OPPORTUNITIES & SHOTS

- Board of Pharmacy meetings (every other month)
  - Sending in evidence based public comments
  - Sending in research articles
  - Advocating for an evidence-based philosophy
- Legislative sessions/meetings (online recorded)
- Planned visits to legislators' offices (local or Lansing)
- Identifying gaps and creating evidence/research to be utilized for future efforts
- Volunteer on political campaigns or other community-based boards
- Run for local, state, or federal office

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## BARRIERS: POLITICS & TURF WARS

AMA RECOVERY PLAN  
FOR AMERICA'S PHYSICIANS

Fighting  
scope creep

**SCOPE OF PRACTICE**

**Inside the AMA's wide-ranging fight against scope creep**

JUN 13, 2022 • 8 MIN READ

**Andri Robeznieks**  
Senior News Writer

[Bookmark](#) [Print](#)

An AMA-led coalition of 198 national, state and specialty medical societies, has been active in dozens of states this year, working to block legislation that would provide inappropriate expansion of the medical services and procedures nonphysician health professionals are allowed to perform.

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## BARRIERS: POLITICS & TURF WARS\*

Professional Association	2018 Cycle Total Lobbying Expenditures
American Medical Association	\$41,962,000
American Academy of Family Physicians	\$6,813,354
American College of Cardiology	\$4,050,000
National Community Pharmacists Association	\$2,790,000
American College of Physicians	\$2,317,140
American Society of Health System Pharmacists	\$1,930,000
American Pharmacists Association	\$264,000

\*Data reworked from article "Provider Status Explained: What Pharmacists can do to advocate for Provider Status"

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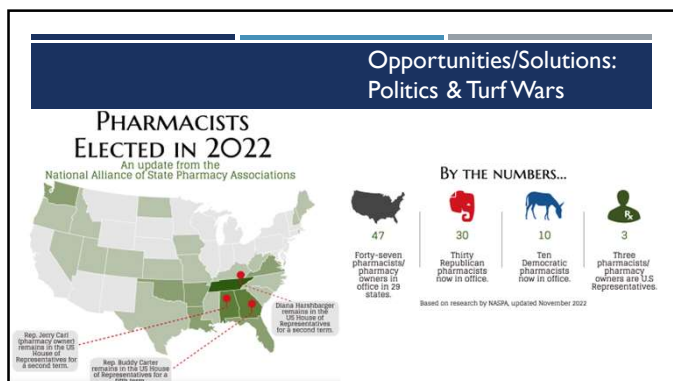
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### LEARNING ASSESSMENT #3

Which best describes moving towards "Evidence Based Lawmaking"?

- a) Using examples found on social media to assist state agencies in rule writing
- b) Providing personal testimonials of patient care examples to legislators
- c) Developing a flyer that describes a pharmacy staff's feelings towards a political topic
- d) Sharing and summarizing peer reviewed publications for regulators and legislators

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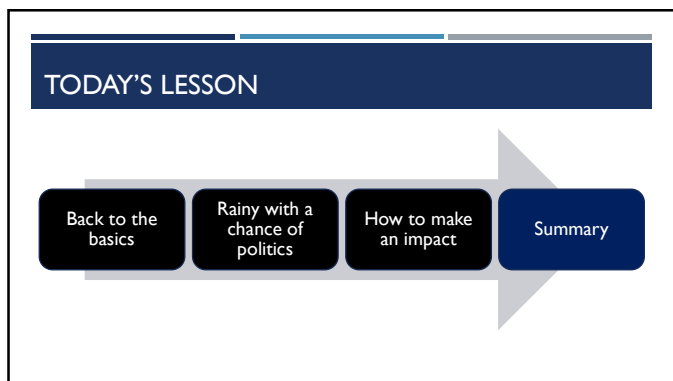
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## THE BIG IDEA

Laws and rules have a critical importance to **impacting everyday practice**. **Understanding and contributing productively** to the process of changes to laws and rules **is indispensable**.

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## SUMMARY

1. Educate yourself and others on the fundamental process of law/rulemaking and how/where you can get involved.
2. Utilized evidence-based lawmaking as a leading philosophy to productively impact the process.
3. Neutralize emotions and politics whenever possible.
4. Pick ANY spot in the process and get involved sooner rather than later!
5. Do not rely on others, groups, to do the advocacy for you.
  - a) If you not at the table, you are on the menu!

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## LEARNING ASSESSMENT #4

Select which best defines an Administrative Procedures Act:

- a) Governs the process by which federal/state agencies develop and issue regulations
- b) An economic theory in which regulatory agencies come to be dominated by the interests they regulate
- c) The act which allows state agencies to supersede federal rules and laws
- d) A fiscal analysis of the cost and risk to the public when a new rule is in consideration

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QUESTIONS | INQUIRIES | FEEDBACK | COMMENTS

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Senior Advisor, Regulatory Affairs  
deeb.eid@gmail.com



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