Diplomat, American Society for Pharmacy Law (DASPL) Candidate Capsule Summary Presentations

Inaugural Diplomat, ASPL Class

Saturday, November 5, 2022

Speaker Bio

Erin Albert is the Inaugural DASPL Program Developer, and a DASPL Candidate herself. She is also 2022 ASPL President, and the Vice President of Pharmacy Relations and Chief Privacy Officer at Mark Cuban Cost Plus Drug Company, PBC. She is both a pharmacist and an attorney.

Conflict of Interest Disclosures

- I declare that I currently have an affiliation or financial arrangement with Mark Cuban Cost Plus Drug Company, PBC and may have a direct interest in the subject matter of this presentation.
- I am discussing drug pipeline products that have not yet been FDA Approved in this presentation.
- This presentation is not and should not be construed as either legal nor pharmacy therapeutic advice.

Learning Objectives

1. List pharmacy & pharmacy law capsule projects analyzed during the inaugural Diplomat, ASPL Leadership Program during the year by each candidate.

2. Describe pharmacy and pharmacy law projects that may fit into the current and future practice of pharmacy.

3. Recognize pharmacy law innovations through DASPL candidates capsule projects, and integrate them into individual practice if relevant and applicable to the learner's area of pharmacy and/or pharmacy law practice.

Assessment Question

The Diplomat, ASPL program is focused on management and the future of pharmacy practice for early career professionals.

- True or False?

What is the Diplomat, ASPL Program?

- ASPL leadership and board has worked hard in recent years to deliver more options for early career and late career professionals.
- However, what about mid-career professionals?
  - What actions has ASPL been taking to bring along the next generation of potential pharmacy policy and pharmacy law leaders?
- The DASPL year-long leadership program was created for mid-career professionals.
- Application process began in late 2021 – recruiting professionals with at least 5 years of experience in their chosen fields.
- Eight inaugural candidates were selected.

Inaugural Diplomat, ASPL Candidates

Emily Do

Patrick Carpenter

Erin Albert

Eman Kirolos

Danielle Swenson

Michael DeBisschop

Frank North

Brett Barker

The Inaugural DASPL Year-Long Program Components

1. Participation in Zoom Subject Matter Expert Calls every other month (began in January 2022)
2. A Mentor Pairing
3. Attend an ASPL BOD Meeting.
4. A pharmacy-law based project, and capsule presentation at ASPL's Fall Conference Nov 3-6, 2022 in Naples, FL.
5. (Optional) consider participating in a Committee.

DASPL Candidate Year-Long Project

- **Choice of topic** – a topic germane to the area you would like to work within, or an area you're fascinated with but haven't had the time to dedicate to it yet in your current role.
  - Develop Hypothesis
- **Discuss topic –** with assigned mentor from ASPL and others throughout the year
- **Research topic** – what resources are available? What research has been conducted?
- **Present findings** – in this CE session.

My Topic: Value Based Ultra Orphan, Gene and Cellular Therapy Contracts (VBCs)

- Working in pharmacy benefits, some manufacturers has provided value based or outcomes-based contracts for more expensive therapies.
  - More expensive orphan and gene therapies coming to market.
    - 58% in 2020; 52% in 2021 => New Orphan FDA Therapy Approvals
  - But where should these be employed in the marketplace, by whom, and what have worked, if any?
  - **Working hypothesis:** that these VBCs may become standard in the future for high- cost therapies.

Why VBCs? Gene & Cellular Therapies in Development

Many are for rare genetic disease with high morbidity and few or no treatment options

Legend
- | Gene Therapy
- | CAR-T Therapy
- **Approved by FDA**

Cilta-cel (ciltacabtagene autoleucel) – Multiple Myeloma 9,000 adult patients (Approved as Carvykti™ in 2022)

PTC-AADC – AADC Deficiency 1-3:100,000 gene tested in newborns

Instiladrin (nadofaragene Firadenovec) – Bladder Cancer 56,000 patients

Eladocagene exuparvovec (AAVhAADC) "Upstaza" – L-amino acid decarboxylase deficiency 100 patients

Zynteglo (betibeglogene autotemcel) – Beta-thalassemia 1,450 patients $2;.8M WAC

Etranacogene desaparvovec – Hemophilia B in adults 1,800 patients

1Q
Fidanacogene elaparvovec – Hemophilia B
RPL201 – LAD-1 30,000 patients

2Q
Debcoemagene autoficel & EB101 - RDEB 400 patients
Lumevoq (lenadogene nolparvovec) – Optic neuropathy 4,500-7,500 patients
Olenasufligene relduparvovec – Sanfilippo Type A 240-1,840 patients
Resamirigene bilparvovec – X-linked myotubular myopathy 40 pts

4Q
Fordadistrogene movaparvovec – DMD 4,000 pediatric patients
Giroctocogene fitelparvovec – Hemophilia A

2024
ABO102 – Sanfilippo Type A
Generx – Refractory Angina 900K-1.2M patients
Ofranergene obadenovec – Ovarian cancer 15,000 patients
RPL102 – Fanconi anemia <1,000 pediatric patients
Tavo – Malignant melanoma subset of ~1.2M patients
ProstAtak – Prostate cancer 125,000 patients
Zolgensma – Type 2 & 3 SMA (new formulation) 8,000 pediatric patients

2022 | 2023 | 2024

2Q22: 23 Gene & Cell Therapies FDA-Approved
- 8 cord blood Therapies (organ transplant)
- 13 Cellular / CAR-T Therapies
- 2 Gene Therapies (Luxturna, Zolgensma)

LentiD (elivaldogene autotemcel) – cerebral adrenoleukodystrophy in males age <18 700 pediatric patients

Beremagene geperpavec – dystropic Epidermolysis bullosa (DEB) 900 patients

Roctavian (valoctocogene roxaparvovec) – Hemophilia A in adults 5,300 patients (BLA re-submission 9/22

Obecabtagene autoleucel lymphoblastic leukemia in adults 30,000 patients

PBCMA101 – Refractory multiple myeloma 9,000 adult patients

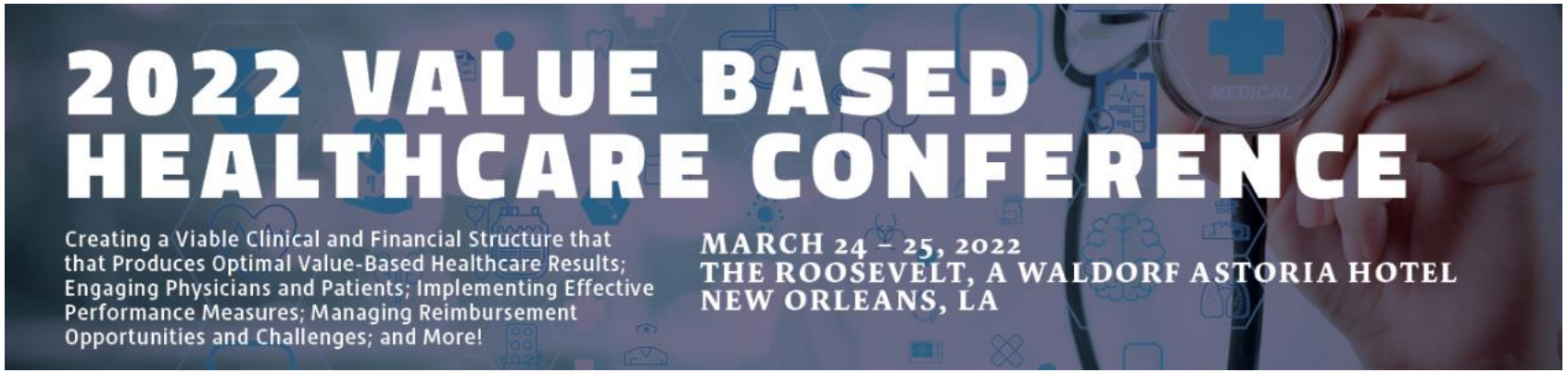
3Q
Engensis (donaperminogene seltoplasmid) - Diabetic peripheral neuropathy 7.1-13.5M adult patients
Atidarsagene autotemcel – metachromatic leukodystrophy 400-1,700 patients
JNJ64400141 – RSV prevention vaccine 34M patients
LentiGlobin – Sickle Cell Disease 58,000 patients

Hemophilia: New Gene Therapies Soon?

5 gene therapies are in clinical research:
- 3 for Hemophilia A (Pfizer, Spark/Roche, BioMarin)
- 2 for Hemophilia B (uniQure/CSL, Spark/Pfizer)

Research: VBCs

1. Teasing out VBCs for drugs and therapies vs. “Value Based Care” overall.

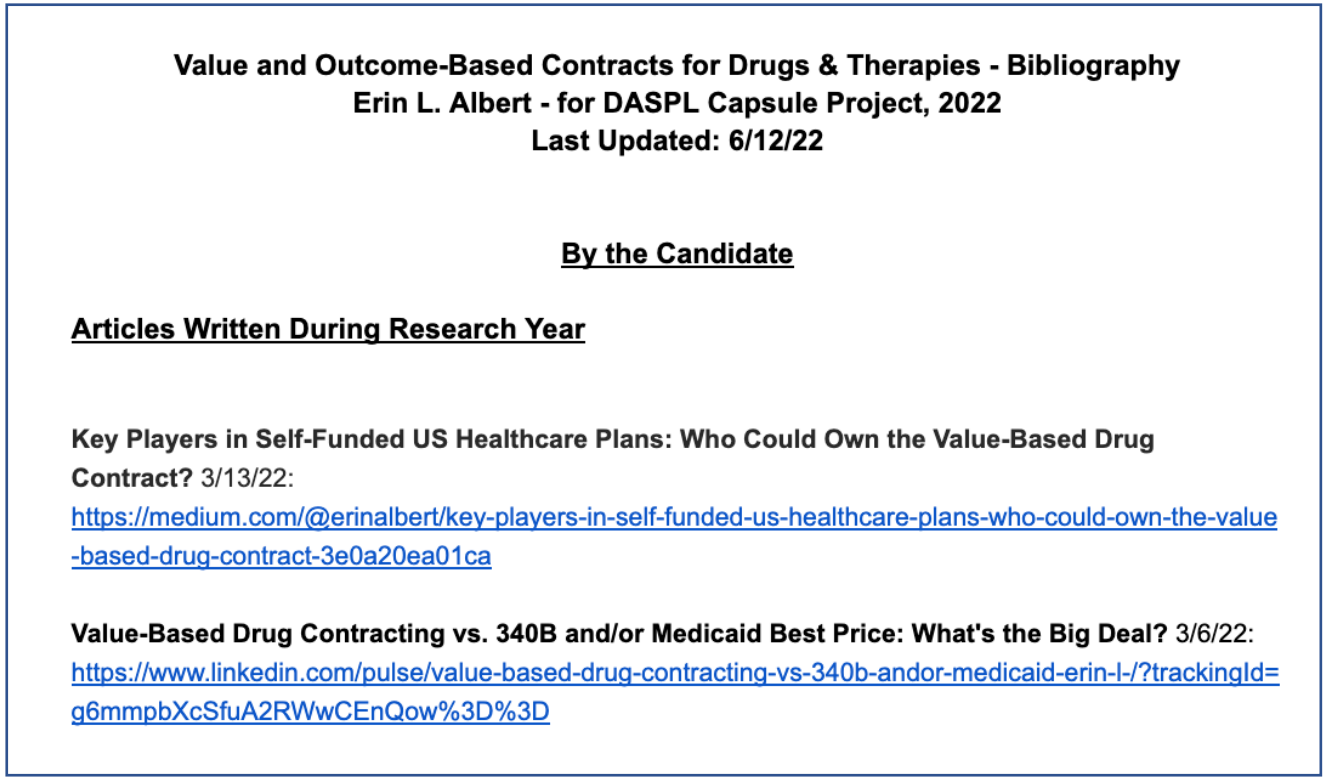


2. Understanding the background: Completed the AMCP Value Based Contracting e-learning program

Research: VBCs, cont.

3. Created a bibliography on the topic:

Request access: https://docs.google.com/document/d/1IylqKMkAYSF0XCUyD5PvmwygNr8kghYsWx5EN4GDRVY/edit



Value and Outcome-Based Contracts for Drugs & Therapies - Bibliography
Erin L. Albert - for DASPL Capsule Project, 2022
Last Updated: 6/12/22

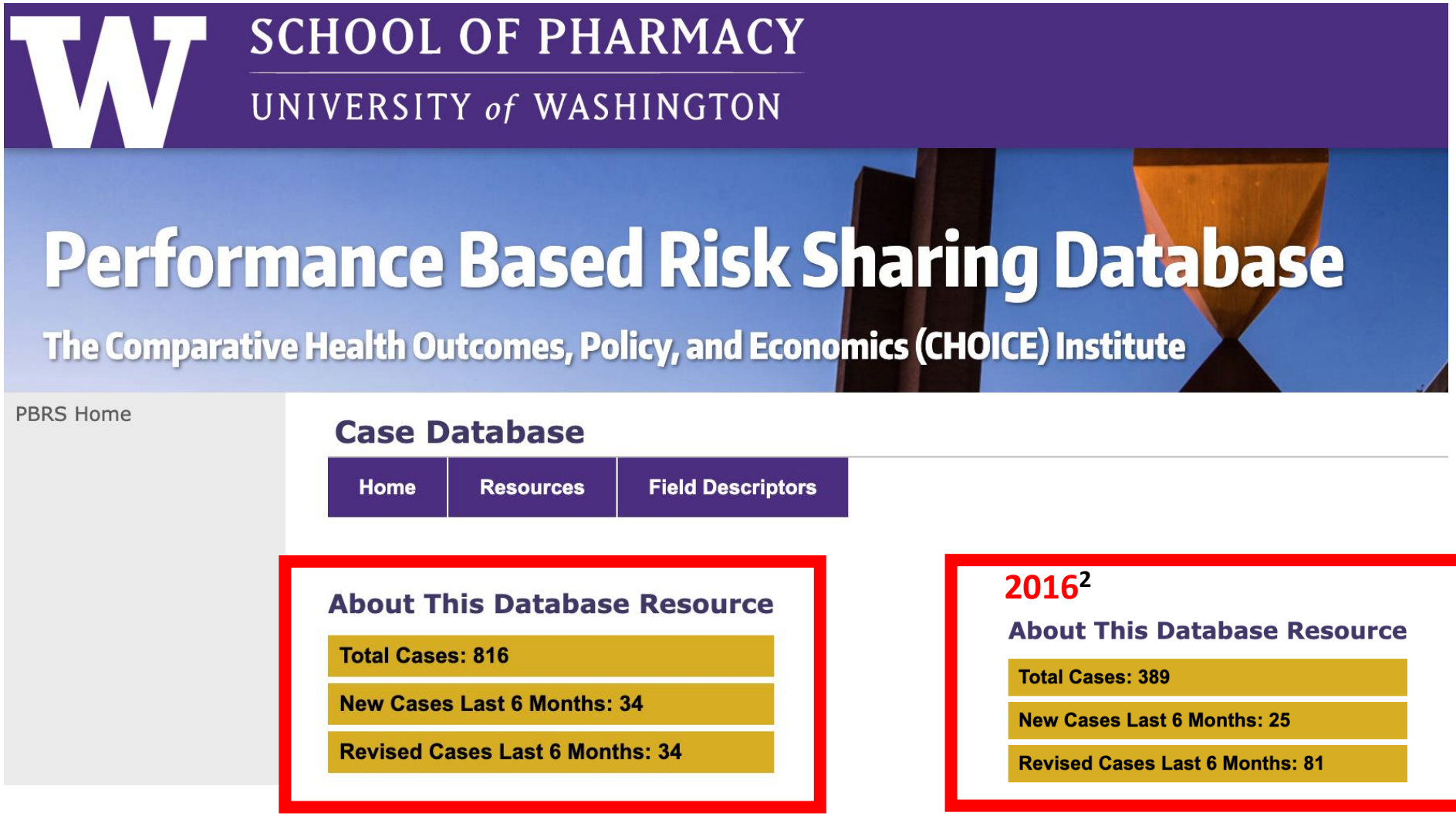
By the Candidate

Articles Written During Research Year

Key Players in Self-Funded US Healthcare Plans: Who Could Own the Value-Based Drug Contract? 3/13/22:
https://medium.com/@erinalbert/key-players-in-self-funded-us-healthcare-plans-who-could-own-the-value-based-drug-contract-3e0a20ea01ca

Value-Based Drug Contracting vs. 340B and/or Medicaid Best Price: What's the Big Deal? 3/6/22:
https://www.linkedin.com/pulse/value-based-drug-contracting-vs-340b-andor-medicaid-erin-l-/?trackingId=g6mmpbXcSfuA2RWwCEnQow%3D%3D

4. Database of VBCs[1]



1. 2022: https://depts.washington.edu/pbrs/index.php
2. 2016: https://web.archive.org/web/20160809065836/https://depts.washington.edu/pbrs/index.php

5. Reviewed top cost therapies

- Top 40 drug/gene therapy/cell therapy list – created from general list prices around the internet
  - Then analyzed how many of them offered VBCs:
    - 6 of the top 40 drugs/gene therapies/cell therapies offered at least one VBC.
    - 3 therapies offered 2 or more VBCs.
    - Both gene therapies on the market offered multiple VBCs.
- Who actually strikes VBCs with Manufacturers?
  - 1. Health Plans – ex. Harvard Pilgrim
  - 2. PBMs – ex. The big 3, Magellan
  - 3. Governments – OUS – ex. NHS (UK)
- Who <u>should</u> own the VBC?
  - *Article on Medium*

6. 5 Types of VBC Contracts[1]

- Adherence Based
- Outcomes Based
- Pay for Performance
- Indication-Specific Pricing
- Coverage with Evidence Generation

1. *AMCP Basic Training, Value-Based Contracting, 2022.*

How Are VBCs Produced?

1. Hospital Team (MassHealth) meet with manufacturers frequently, discuss pipeline
2. Contracting proposal submitted, team conducts clinical review and market trends/pricing
3. Team/others agree on proposed contract terms, MassHealth enters into negotiations with manufacturer
4. Agreement goes into place – implementation of criteria changes to drug list, communicating changes

Blum, K. "4 Value-Based Contracting Strategies," *Specialty Pharmacy Continuum*, May/June 2022 at 4.

7. Who is most advanced in VBCs?

- Europe – much like biosimilars.

8. What Types of Deals are Struck in VBCs?[1]

- Discounts
- Higher Rebates if Product Failure ("Warranty"?)
- Full Refund if Treatment Failure or Sentinel Event, like Death
- Lower Rebates if Positive Clinical Outcomes (like A1C goals achieved)

1. https://www.commonwealthfund.org/publications/issue-briefs/2017/sep/outcomes-based-pharmaceutical-contracts-answer-high-us-drug

In Conclusion

- More VBCs coming? Probably.
- Considering more gene / cell therapies and ultra orphan drugs are coming to market with higher price tags, more to come.
  - Current 2 gene therapies on the market have multiple VBC contracts at present, with health plans and PBMs.
- Further investigation:
  - What therapies should offer VBCs, and to whom?
  - Who should own these contracts?
  - What are the measurable outcomes?
  - What or how or through what mechanism should the savings be captured?

Assessment Question

The Diplomat, ASPL program is focused on management and the future of pharmacy practice for early career professionals.

- True or **False**?

Hatch-Waxman – for Pharmacist

Emily Do, PharmD, JD, MBA

Conflict of Interest Disclosure

I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

Learning Objectives

- At the completion of this activity, the participant will be able to describe how patents affect generic drug approvals and pricing.

Assessment Questions

1. A generic drug is immediately available the moment the patent for the branded drug expires
   - True
   - False
   - It depends

United States Patents

- Plant – 20 years from filing date of non-provisional
- Design – 15 years from date of grant
- Utility – 20 years from filing date
  - process
  - machine
  - article of manufacturer
  - composition of matter
  - “any new and useful improvement thereof”

https://www.uspto.gov

Hatch-Waxman Act (1984)

- Drug Price Competition and Patent Term Restoration Act (Orrin Hatch – UT, Henry Waxman – CA)
- Generic drug approval pathway
  - Innovation v. Affordability
  - Efficiency – safety and efficacy data
  - Exclusivity – 180 days for first generic to market
    - 5-year for brand
    - 3-year for improved version of brand
  - ”Safe harbor” provision

”Safe Harbor” Provision

- “Safe” for activities otherwise considered patent infringement
- Perform experiments needed to obtain FDA approval
- Challenges
  - REMS
  - Timing – Citizens Petition, labeling changes
  - ”Product hopping”

https://www.fdli.org/2017/07/fda-looks-improving-implementation-hatch-waxman-amendments/

Impacts

	Before	After
Generic prescriptions	19%	90%
Generic version available after patent expired	35%	80%
Time to enter market after patent expired	3 to 5 years	Immediately

https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf

Takeaways for Pharmacists

- Why is the first generic as expensive as the brand?
- Why is there only one generic for 180 days (6 months)?
- Why do we see delay in generic release?
- What about biosimilars?

Assessment Questions – Answers

1. A generic drug is immediately available the moment the patent for the branded drug expires
   - **It depends**

FDA 483 Observation Frequency Analysis

Patrick M. Carpenter, MS, PharmD, RPh

Saturday, November 5, 2022

Speaker Bio

- Patrick Carpenter was granted a B.S. in pharmacy from Albany College of Pharmacy, an M.S. in Drug Regulatory Affairs and Health Policy, and a PharmD from Massachusetts College of Pharmacy and Health Sciences. He is currently in his second year as a law student at Lewis and Clark Law School in Portland, OR with an anticipated graduation date of August 2024. Patrick is the Regional Director of Operations for Option Care Health covering Oregon, Idaho, Montana, Colorado, and Utah. His professional interests include the the regulation of compounding pharmacies and outsourcing facilities.

Conflict of Interest Disclosures

- I am an employee of Option Care Health.
- I am a consultant for APS/Belmar pharmacy.
- I am a consultant for MenMD.

- The opinions expressed in this presentation about the data collected are my own and in no event are affiliated with and/or represent the opinions of the above referenced entities.

Assessment Question

The most common deficiency cited by the FDA in inspections of 503A sterile compounding pharmacies in 2021 through May 17, 2022 was?

1) Inadequate smoke studies
2) Media fill not worse case
3) Inadequate aseptic technique
4) Failure to monitor pressure differentials

FDA 483 Observation Frequency Analysis

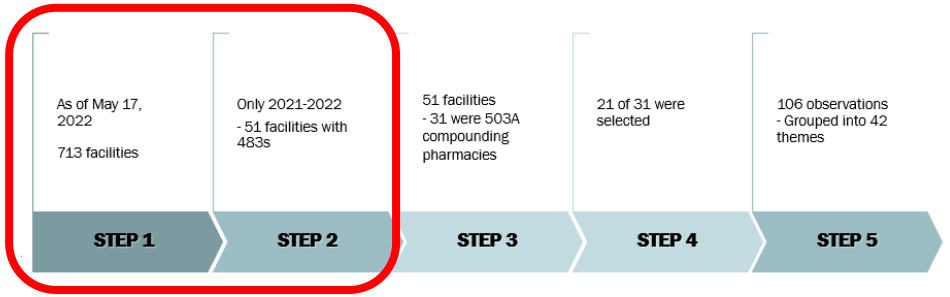
- My background in compounding pharmacy regulatory compliance and prior work as a compounding pharmacist made me curious about commonalities among FDA inspections at 503A sterile compounding pharmacies.

- I believed the analysis would show clear areas rising to the top of the list rather than scattered, random, or inconsistent observations. I further believed that the observations would reflect an evolution of 503A compounding pharmacy showing fewer egregious violations as compared to 8-9 years ago.

FDA 483 Observation Frequency Analysis - Methodology

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

- As of May 17, 2022, the Compounding: Inspections, Recalls, and other Actions link within the FDA Human Drug Compounding page displayed:
  - 713 facilities with inspection documentation
  - To further narrow the sample for analysis only 2021 through May 17, 2022 (the start date of the analysis) were included.
    - Within this time period there were 51 responsive 483s
    - From there 483's were analyzed to separate manufacturer, 503B facilities, and 503A facilities.

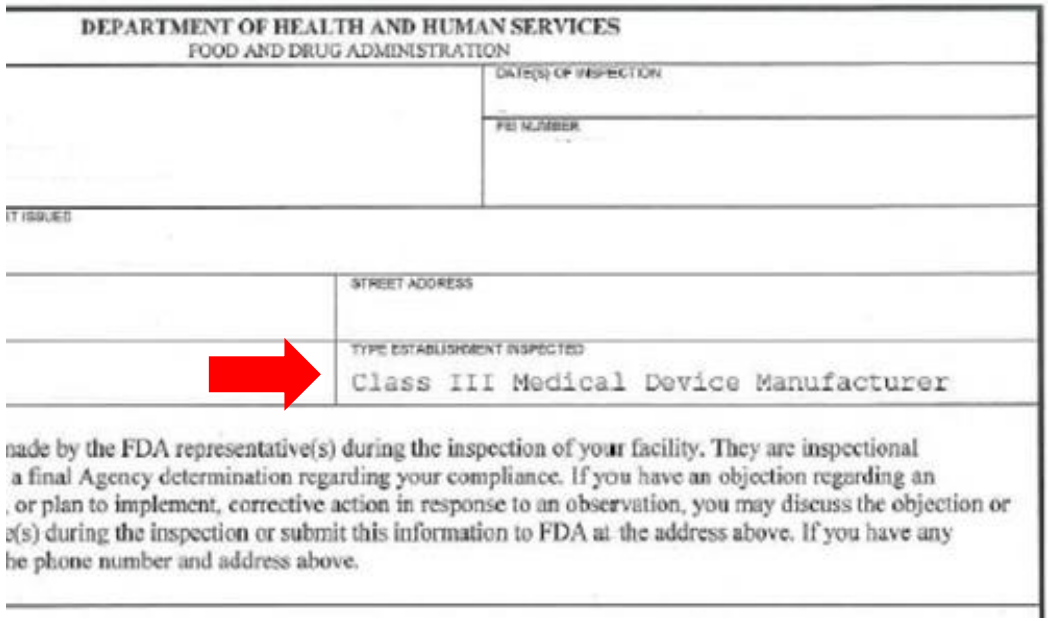


FDA 483 Observation Frequency Analysis - Methodology

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

- Checks of the following were used to determine the regulatory classification of the entity:
  - 483 itself
  - Company website
  - State Board of Pharmacy license verifications

- 31 facilities were 503A compounding pharmacies


DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE(S) OF INSPECTION

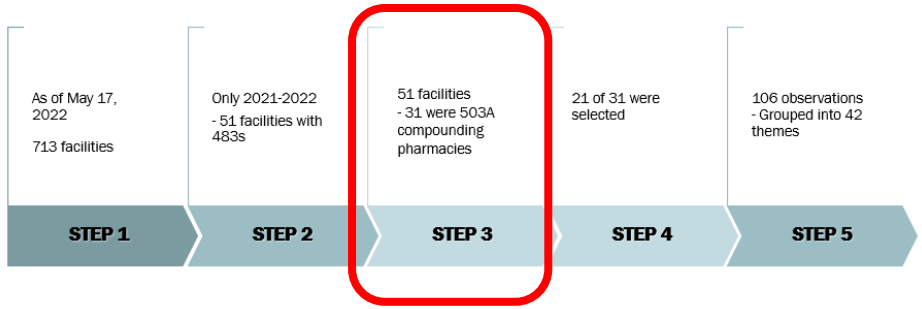
FEI NUMBER

IT ISSUED

STREET ADDRESS

TYPE ESTABLISHMENT INSPECTED
Class III Medical Device Manufacturer

nade by the FDA representative(s) during the inspection of your facility. They are inspectional
a final Agency determination regarding your compliance. If you have an objection regarding an
, or plan to implement, corrective action in response to an observation, you may discuss the objection or
(s) during the inspection or submit this information to FDA at the address above. If you have any
he phone number and address above.

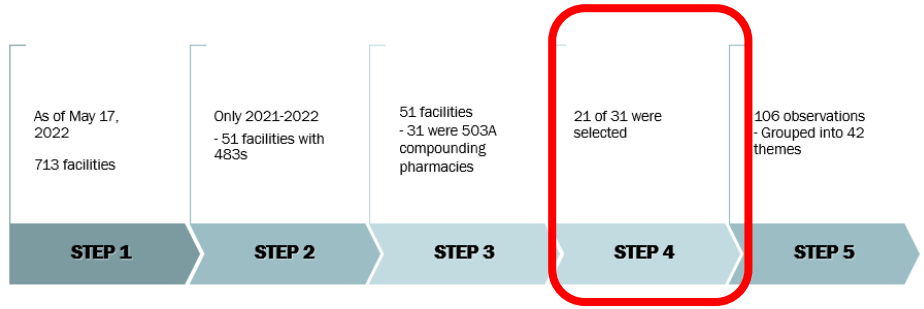


FDA 483 Observation Frequency Analysis - Methodology

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

- Of the thirty one 503A compounding pharmacies:
  - 21 facility 483s were selected for analysis

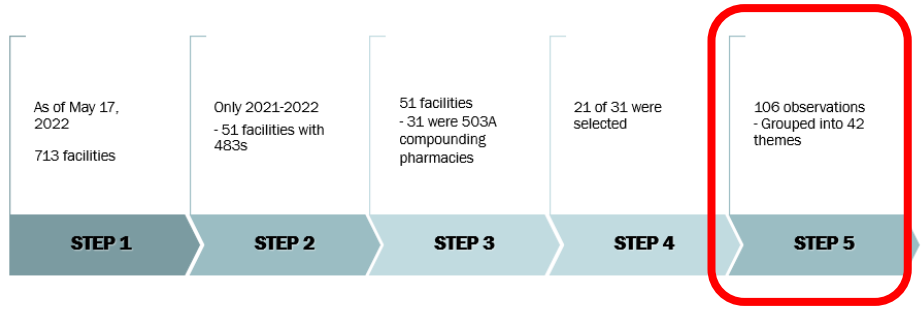
  - Reasons for exclusion were:
    - Non sterile compounding only
    - Broken link or improper 483 uploaded



FDA 483 Observation Frequency Analysis - Methodology

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

- The specific observations from the 483s of the twenty one 503A compounding pharmacies engaged in sterile compounding were then individually analyzed with deficiencies grouped into themes.
- The 483s from the 21 facilities contained 106 observations in total.
- These 106 observations were able to be grouped into 42 themes.



FDA 483 Observation Frequency Analysis – Examples of Theme Placement

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

OBSERVATION 2
Your facility design allowed the influx of poor-quality air into a higher classified area.

Specifically,

a) You replaced the condenser and air handler to the sterile suite on the human side on June 25, 2021 and loss pressure beginning Friday, 6/25/21 in (b) (4) room at 11:38 am until 06/27/21 at 14:00. You performed cleaning with (b) (4) on Monday, 6/28/21 after the installation but did not recertify the human side and continued to produce and distribute sterile drugs.

b) Doors between rooms are not fully closed to prevent air flow between classified areas.

- **This observation fell into the theme of "Classified/non classified air mixing."**

FDA 483 Observation Frequency Analysis – Examples of Theme Placement

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

OBSERVATION 4
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, media fills do not include the most challenging process performed. For example, your media fill records indicate filling (b) (4) ml vials; however, I reviewed sterile production records that demonstrate more challenging operations such as filling (b) (4) ml vials for S-Ascorbic Acid (NON-CORN) 500MG/ML MDV, lot S03042021DH@09 and/or filling (b) (4) ml syringes for S-Glutathione 200MG/3ML (PF) INHALATION, lot S03172021DH@04.

- **This observation fell into the theme of "Media fill not worse case."**

FDA 483 Observation Frequency Analysis – Results

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

Row Labels	Count of Summary of problem
Inadequate smoke studies	9
Media fill not worst case	9
Hazardous cross contamination	7
Inadequate disinfectant contact time	7
non microbial contamination in production area	6
Classified/Non classified air mixing	5
Failure to disinfect sterile gloves	5
Improper garbing	4
Inadequate remediation following environmental sampling	4
non pharmaceutical grade ingredients	4
Difficult to clean equipment and surfaces	3
Failure to disinfect materials/supplies	3
Inadequate aseptic technique	3
Lack of biological indicators in equipment prep	3
Product released not matching release specs	3
Inadequate bubble test	2
Inadequate environmental monitoring	2
Use of items that have become non sterile in the classified production space	2
Vermin adjacent to compounding area	2
Adjacent construction with inadequate controls	1
Equipment callibration	1
Failure to monitor pressure differentials	1
HEPA filter not sealed around perimiter	1
Improper drug storage conditions	1
Inadequate Container/Closure sterile practices	1
Inadequate personell monitoring	1
Inadequate pressure differential	1
Inadequate sterilization	1
ISO 5 hood in non classified space	1
Lack of batched sterility testing	1
Lack of sporicidal cleaning agent	1
Lack of stability studies	1
No release testing	1
Non pharmaceutical grade detergent	1
non pharmaceutical grade equipment	1
Non sterile garb in sterile production	1
Non sterile stock solutions	1
Product intended to be sterile exposed to less than iso 5 air	1
Use of non sterile cleanig wipes in ISO 5	1
Use of non sterile cleaning wipes in ISO 5	1
Use of non sterile equipment during sterile production	1
visibly dirty utensils for non sterile production	1

FDA 483 Observation Frequency Analysis – Results

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

1. **Inadequate smoke studies**
2. **Media fill not worst case**
3. **Hazardous cross contamination**
4. **Inadequate disinfectant contact time**
5. **Non microbial contamination in production area**

FDA 483 Observation Frequency Analysis – Conclusion

An analysis of FDA post inspection observations and their frequency at 503A sterile compounding pharmacies in 2021 and 2022.

- There were commonalities among the 503A sterile compounding pharmacies.
- Although I do not have an actual prior analysis from 2013/2014 to compare these results to, my impression is that these violations are less egregious than the violations seen at 503A sterile compounding pharmacies shortly after the implementation of DQSA.

Assessment Question

The most common deficiency cited by the FDA in inspections of 503A sterile compounding pharmacies in 2021 through May 17, 2022 was?

1) Inadequate smoke studies
2) Media fill not worse case
3) Inadequate aseptic technique
4) Failure to monitor pressure differentials

Pharmacists Prescribing: Strategies for Scope Expansion

Brett Barker, PharmD

Saturday, November 5, 2022

Speaker Bio

- VP Operations, NuCara Pharmacy
- Senior Policy Advisor, Iowa Pharmacy Association
- PharmD from the University of Iowa
- Mayor, City of Nevada, IA

Conflict of Interest Disclosures

- Brett Barker has no conflicts of interest to disclose.

Assessment Question

Pharmacists can prescribe drugs in the United States.

- True or False?

My Topic: Pharmacists Prescribing: Strategies for Scope Expansion

- Why this topic?
  - IPA work
  - Student Exchange experience
- Hypothesis: States have implemented a variety of strategies to expand pharmacist prescriptive authority.

Research: How did you research your project?

- Review of relevant literature
- Review of professional association resources (NABP, NASPA, etc)
- Review of current state code / agency rules

What is “prescribing?”

- AACP defines prescribing as selecting, initiating, monitoring, continuing, discontinuing, modifying, and / or administering drug therapy.
- Initiating therapy is more widely understood as core of “prescribing” and means writing an order or prescription, including an initial dose and a dosing schedule.
- Scope of practice is under purview of state governments and commonly regulated by state boards of pharmacy.

Adams, A. J., & Weaver, K. K. (2016). The continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy*, *50*(9), 778–784.

History

- 1970s – US collaborative practice agreements
- 1980s – US statewide protocols
- 2003 – UK Independent prescribing
- 2007 – Canadian independent prescribing (provincial)
- 2017 – NABP / NASPA Workgroup Report on Statewide Protocols
- 2018 – HHS Urges States to Ease Scope-of-Practice Rules
- 2021 – FDA EUAs for COVID therapeutics
- 2023 – Scotland's goal for all patient-facing pharmacists being independent prescribers

1. Guirguis, L. M., & Adesanoye, D. T. (2018). Pharmacist prescribing: An overnight success, decades in the making. *Journal of the American Pharmacists Association*, *58*(6), 589–590.
2. Adams, A. J., & Weaver, K. K. (2016). The continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy*, *50*(9), 778–784.
3. Jebara T, Cunningham S, MacLure K, Awaisu A, Pallivalapila A, Stewart D. Stakeholders' views and experiences of pharmacist prescribing: a systematic review. Br J Clin Pharmacol. 2018 Sep;84(9):1883-1905.
4. Frieden, J. (2018, August 9). HHS chief urges states to ease scope-of-practice rules. Medical News. Retrieved August 23, 2022, from https://www.medpagetoday.com/practicemanagement/reimbursement/74505
5. NASPA / NABP. (n.d.). *Pharmacist statewide protocols key elements for legislative and regulatory authority*. Retrieved August 23, 2022, from https://naspa.us/wp-content/uploads/2017/03/Pharmacist-Statewide-Protocols-Key-Elements-for-Legislative-and-Regulatory-Authority.pdf

Stats

- More than 90% of US population lives withing 5 miles of a community pharmacy
- Patients visit their pharmacist more than 12 times more frequently than their primary care provider
- More than 10,000 pharmacies already perform CLIA-waived tests

1. Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic. Prev Chronic Dis 2020;17:200317

Benefit

- Pharmacist prescribing is beneficial to address gaps in care in rural communities
- Pharmacist prescribing associated with positive patient outcomes
- Other health care providers and patients experience with a pharmacist prescribing have a favorable view
- Pharmacists play a key role among underserved populations

1. *McKeirnan KC, MacLean LG. Pharmacist, physician, and patient opinions of pharmacist-treated minor ailments and conditions. J Am Pharm Assoc (2003). 2018;58(6):599e607.*
2. Guirguis, L. M., & Adesanoye, D. T. (2018). Pharmacist prescribing: An overnight success, decades in the making. *Journal of the American Pharmacists Association*, *58*(6), 589–590.
3. Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic. Prev Chronic Dis 2020;17:200317
4. Jebara T, Cunningham S, MacLure K, Awaisu A, Pallivalapila A, Stewart D. Stakeholders' views and experiences of pharmacist prescribing: a systematic review. Br J Clin Pharmacol. 2018 Sep;84(9):1883-1905.
5. Poh, E. W., McArthur, A., Stephenson, M., & Roughead, E. E. (2018). Effects of pharmacist prescribing on patient outcomes in the hospital setting: A systematic review. JBI Database of Systematic Reviews and Implementation Reports, 16(9), 1823–1873

Opposition and Barriers

- Opposition
  - Fragmentation of care
  - Level of pharmacist training
  - Conflict of interest
  - Evidence

- Barriers
  - Politics / protectionism
  - Access to patient records
  - Organizational / financial support
  - Governmental policy

1. *Tsuyuki RT. FAQs (frequent asinine questions) on pharmacists' scope of practice. Can Pharm J (Ott). 2018 Jun 4;151(4):212-213.*
2. Jebara T, Cunningham S, MacLure K, Awaisu A, Pallivalapila A, Stewart D. Stakeholders' views and experiences of pharmacist prescribing: a systematic review. Br J Clin Pharmacol. 2018 Sep;84(9):1883-1905

Uses

- Acute illness / test to treat
- Chronic condition monitoring
- Preventative care / vaccines
- Prescription adaptation
- Prescription renewals

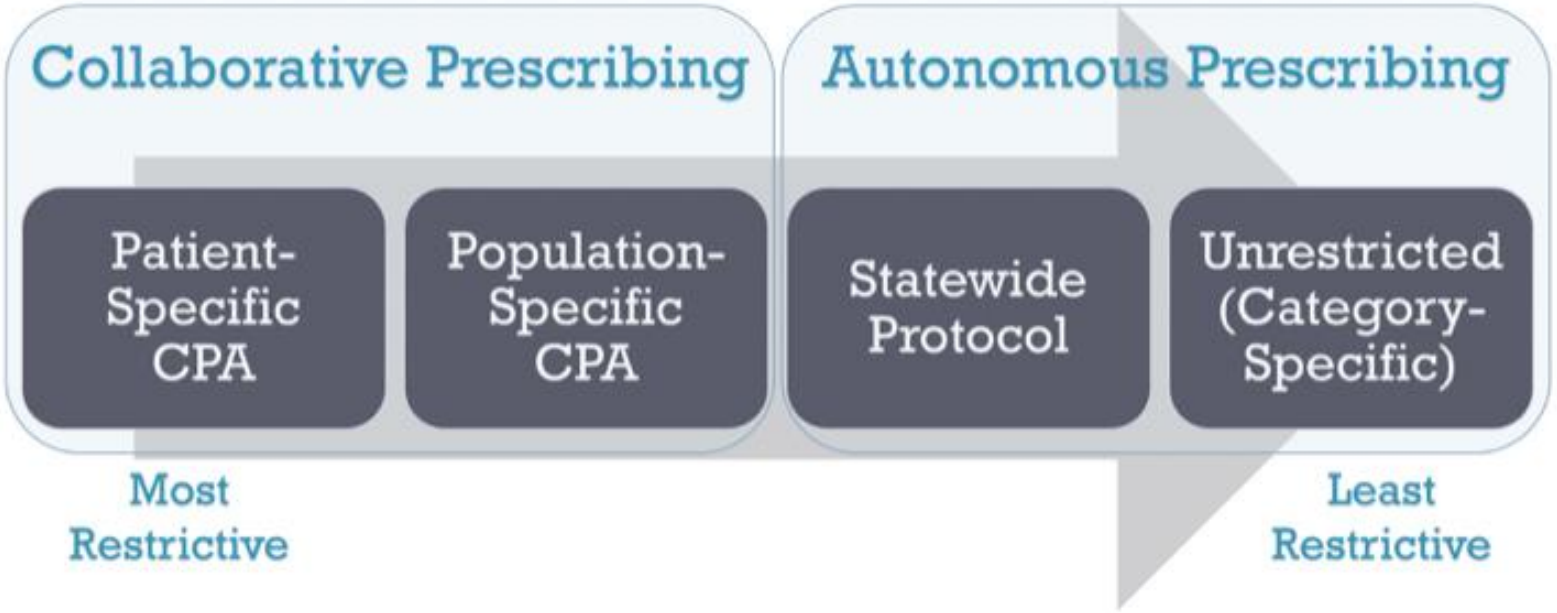
1. Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic. Prev Chronic Dis 2020;17:200317

Definitions

- **Statewide protocol**: A framework that specifies the conditions under which pharmacists are authorized to prescribe a specified medication or category of medications when providing a clinical service
- **Pharmacist Collaborative Practice Agreement (CPA):** A formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.
- **Independent prescribing**: Independent prescribers are responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about the clinical management required, including prescribing. Different professional groups may hold different prescribing rights, for example

1. Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic. Prev Chronic Dis 2020;17:200317
2. CDC. (n.d.). Collaborative practice agreements and pharmacists' patient care services. Retrieved August 23, 2022, from https://www.cdc.gov/dhdsp/pubs/docs/Translational_Tools_Pharmacists.pdf
3. Prescribing by non-medical healthcare professionals. Health. (2022, July 29). Retrieved August 23, 2022, from https://www.health-ni.gov.uk/articles/pharmaceutical-non-medical-prescribing

The continuum of pharmacist prescriptive authority



1. *Pharmacist prescribing: Statewide protocols and more*. NASPA. (2020, July 7). Retrieved August 22, 2022, from https://naspa.us/resource/swp#unique-identifier-support
2. American Pharmacists Association. (n.d.). Scope of Practice. Retrieved August 23, 2022, from https://www.pharmacist.com/Practice/Practice-Resources/Scope-of-Practice

The landscape

- All states and DC enable pharmacist prescribing via some mechanism

1. *Pharmacist prescribing: Naloxone*. NASPA. (2022, March 31). Retrieved August 22, 2022, from https://naspa.us/resource/naloxone-access-community-pharmacies/

Did You Find any Literature or Resource(s) to Share On Your Topic?

Share what you learned on several slides – good framework includes:

-Who should care about this topic, or who are the key players
-What do the key players do with your topic?
-When did your topic start, stop or change?
-Where is the topic most robust or developed (for example, US, Europe, somewhere else?)
-Why – you already set up – but you should bring the why back in your conclusion slide.
-Share why or how this is important to the overall practice in the future (learning objective #3)

In Conclusion

- Hypothesis: States have implemented a variety of strategies to expand pharmacist prescriptive authority.
- Why is this an important topic to keep an eye on?
  - Health care costs
  - Primary care shortage
  - Patient preference
  - State initiatives
  - Third party coverage adoption
  - Ultimately, what is best for the patient?

Assessment Question

Pharmacists can prescribe drugs in the United States.

- **True** or False?

Central Fill-Is It for You?

Danielle A. Swenson, JD

Saturday, November 5, 2022

Danielle Swenson is a Sr. Associate General Counsel at IngenioRx, Inc. where she supports multiple PBM areas, including licensing, prior authorization, pharmacy networks and collaborates with public affairs/compliance to review and implement legislation. She is a graduate from Muhlenberg College and while working at the Bergen County Prosecutor's Office, she attended Seton Hall University School of Law. Starting her legal career in private practice, she transitioned back to government work as a regulatory analyst within the Division of Consumer Affairs of the NJ Attorney General's Office. After eight years in the public sector, she then joined Medco Health Solutions, Inc. where she held various corporate positions, assisted in the Express Scripts/Medco merger, and continued her career with Express Scripts, Inc. for seven years. She holds a Pharmacy Technician Certification, sits on the Board of Directors for the George Washington Memorial Park, and has been appointed by the NJ Supreme Court to serve on the District Fee Arbitration Committee. She previously served as an elected official for the Wyckoff Board of Education and a member of Women Lawyers in Bergen County. In addition to volunteering in her community, Dani enjoys spending time at Long Beach Island, NJ and Miami Beach, FL with her two children who attend THE Ohio State University.

Conflict of Interest Disclosures

I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

What is Centralized Prescription Handling/Processing (Central Fill/Shared Services)?

Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription: intake, processing, fulfillment and dispensing. *NJAC 13:39-4.19*

Central prescription processing means the dispensing of an order when more than one registered prescription drug outlet (pharmacy) is involved in the transaction. It is the processing by one pharmacy of a request from another pharmacy to fill or refill an order or to perform one or more dispensing functions, such as preparation, mixing, labeling, initial interpretation, and refill authorizations. *3 CCR 719-1:20.00.10*

Centralized Prescription Processing means the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
Tenn. Comp. R. & Regs. 1140-01-.01

Centralized prescription filling means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. “Centralized prescription filling” includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations. *IL ST CH 225 § 85/25.5*

Assessment Question

Central Fill Pharmacy Automation market size was valued at USD 493.44 Million in 2020 and is projected to reach USD 968.93 Million by 2028.

TRUE OR FALSE?

Is Central Fill the Solution?

Why was this topic chosen:

- Building a retail, non-dispensing, closed-door pharmacy that will utilize Central Fill services
- Seeking application approval for the newly built retail, non-dispensing, closed door pharmacy
- In NJ, there are four component functions of handling a prescription: intake/originating, processing, fulfillment and dispensing.
- This newly built pharmacy responsible for intake/originating and processing; contracting with other pharmacies to perform fulfillment and dispensing.

Is Central Fill the Solution?

Hypothesis:

When building a pharmacy, servicing patients in all 50 states*, the Central Fill model can provide benefits to multiple stakeholders (patients, staff, pharmacy, providers and payors):

- Increase efficiency and technological accuracy;
- Reduce pharmacy and start up costs;
- Increase staff clinical training and evaluations;
- Increase patient contact;
- Improve patient outcomes and safety;
- Increase provider satisfaction; and
- Lower overall costs

*Vast majority of states allow Central Fill; however, some states have restrictions such common owner only; not allowed (MS); Board approval prior to engaging (NJ/KY); patient notification or choice not to have centrally filled (GA/MT).

Evolution of Central Fill

- Automated dispensing began in the 1990s. The goal was to save time and reduce human-caused errors. Generally, automated dispensing meets those goals; however, automation also can introduce opportunities for error.
- Central Fill is a strategy pharmacies can use to create the environment pharmacists need to practice at the level they are trained; spend valuable time to patient care services.
  - Vaccinations
  - Medical Treatment Management
  - Certain Prescriptive Authority (Paxlovid)
- COVID-19 pandemic acted as a catalyst to allow pharmacists deliver what they are trained to deliver—patient facing services and care. Central Fill automation and technology can assist pharmacies to accelerate the pace of patient care and delivery.

Central Fill Pros

- Speed:
  Automation is faster than humans.
- Safety:
  Automation does not mix up different formulations or make counting errors.
- Security/Less Risk for Diversion:
  Medications are locked inside the automated machine, with access being limited to specific, identifiable staff. Thus, opportunities for diversion or human error are reduced.
- Service:
  Automation can reduce fill and wait times, which can improve service levels and customer satisfaction. Automation dispensing also frees up pharmacists and technicians to spend more time with patients to provide additional non-prescriptive services and expand areas such as immunizations, health screening, diagnostic testing, and prescribing.
- Lower costs:
  Automation efficiencies can lower costs which ultimately benefit patients, payors, pharmacies

Central Fill Cons

- Human Error:

  Automation is computer-based technology; if a human inputs the wrong information or fills a cell with the wrong medication, or makes some other mistake, safety is compromised.

- Downtime:

  Automated machines can break down, so a backup plan is needed if there is an equipment failure.

- Glitches:

  Software failures can happen with any computer-based technology.

- Refills:

  Automated machines can not refill stock, so inventory management is crucial.

Implementing the Central Fill Process

- Licenses/Registrations/Applications
  - Resident state and non-resident state licensure, incl. DEA and NPI
- Contractual agreement or share a common owner
- Share Common Electronic File
- Joint Policies and Procedures
- Prescription transmission; not transfer
  - Retail pharmacy is the one directly responsible to the patient, as contrasted with a transferred prescription where the new pharmacy becomes responsible

Implementing the Central Fill Process

- Responsibilities
  - Valid Prescription/Accuracy
  - Recordkeeping
  - Audit trail
  - Labeling
  - Disclosure

- Controlled substances are permissible, with DEA registration (Federal Register.: June 24, 2003, Volume 68, Number 121)
  - Limitations: prepared prescription back to the originating pharmacy
  - Transmission is not a transfer: prescription can be filled by a central-fill pharmacy as many times as there are refills on the prescription
  - In an emergency, a central-fill pharmacy is not allowed to prepare a Scheduled II controlled substance prescription upon an oral order from another retail pharmacy or an individual practitioner

In Conclusion

Central Fill can:

- Create a more streamlined, cost effective and efficient/accurate workflow
- Improve patient care through personalized, high touch care
- Simplify or eliminate administrative tasks that do not involve direct contact with the patient
- Allows for pharmacists and pharmacy technicians to focus on being caregivers:
  - Patient monitoring;
  - Vaccination immunizations;
  - Chronic disease management;
  - Adherence;
  - Compliance packaging; and
  - Patient education

In Conclusion

- Better patient outcomes with high value care and efficiency with no capital investment/expense
- Focus on delivering superior patient care
- Manage medications to improve:
  - Patient safety;
  - Provider satisfaction;
  - Financial results;
  - Efficiency; and
  - Compliance
- Technology increases contactless healthcare, allowing for an increase in medications being prescribed and an increase in prescriptions causes an increase in the demand for pharmacist services

Assessment Question: Answer

TRUE

Central Fill Pharmacy Automation market size was valued at USD 493.44 Million in 2020 and is projected to reach USD 968.93 Million by 2028.

QUESTIONS

Efforts and Initiatives to Address Pharmacy Work Environment / Conditions

Eman Kirolos, PharmD, RPh, MS

Saturday, November 5, 2022

Speaker Bio

- Dr. Kirolos has practiced as a pharmacist for over 15 years at different practice settings. She is currently a Walgreens Pharmacist and recipient of the *2022 Pharmacy Appreciation Award* from Arizona Pharmacy Association. She recently obtained a Master of Science in Pharmaceutical Outcomes and Policy with dual concentrations; Pharmaceutical Regulations and Patient Safety from University of Florida. She earned her Doctor of Pharmacy from Howard University and obtained a Bachelor of Pharmaceutical Sciences from Assiut University, Egypt where she graduated summa cum laude and received multiple recognition awards and scholarships.

Disclaimer

- I work for Walgreens. However, this is my independent work that has not received any financial arrangement from any source.
- This presentation was developed independently and not in collaboration with any pharmacy owner or operator. Any views or opinions expressed are strictly my own and should not be attributed to my employer, current or previous.

Assessment Question

Efforts and recommendations to address pharmacy work conditions include:

a. Professional autonomy
b. Pharmacist input for resource allocation and performance metrics; replacing revenue metrics with quality metrics.
c. Staffing plan
d. Evidence-based organizational practices focus on implementing interventions that matter the most to all stakeholders and align with organizational priorities to simultaneously improve clinician well-being and patient experience.
e. Employing Just Culture principles in medication error analysis
f. Mandated breaks and limiting daily shifts to 12 hours to promote RPh well-being
g. Advocacy for scope of practice, PBM regulation, and service reimbursement.
h. All of the above

Efforts and Initiatives to Address Pharmacy Work Environment/Conditions

- They do not only impact the well-being and retention of pharmacy workforce, but also patient safety.
- Pharmacy work conditions are the product of job demands and resources.
- They are affected by multiple factors; organizational and extra-organizational, which means a multi-faceted approach is required from various stakeholders rather than employers alone.
- Stakeholders: pharmacists, employers, payers, government (regulators/legislators), professional associations, and ***patients.***

Objectives

1. Illustrate how work environment can impact patient safety
2. Identify pharmacists' perceptions of work conditions and potential solutions.
3. Explore the efforts and recommendations made by various professional organizations that **directly and indirectly** impact different pharmacy practice settings.
4. Recognize the initiatives taken by state boards of pharmacy to address the issue.

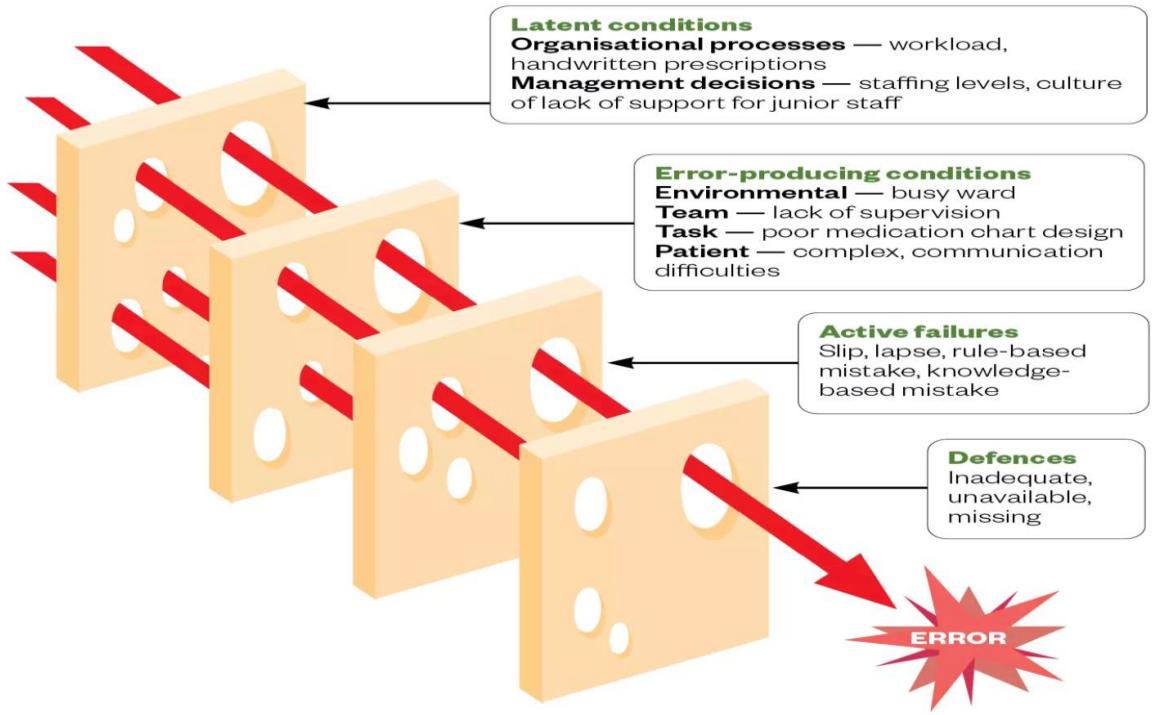
Impact of Work Conditions on Patient Safety

- "Humans are fallible" - 1999 IOM *To Err is Human: Building a safer Health System".*
- "Poor work conditions lead to medications errors" (ISMP – *Medication Errors* book 1999 edition*).*
- "Trying harder will not work. Changing systems will." 2001 *IOM – Crossing the Quality Chasm* Report
- Safety culture, safe system design, and confidential voluntary reporting of errors with protections against legal proceeding (PSQI Act of 2005)
- Safe system design: fitting work conditions and job demands into the workforce capabilities (human strengths and limitations) – *Human Factors Engineering (Ergonomics).*
- OSHA: good fit results in increased safety, quality of care, workforce satisfaction, and productivity.

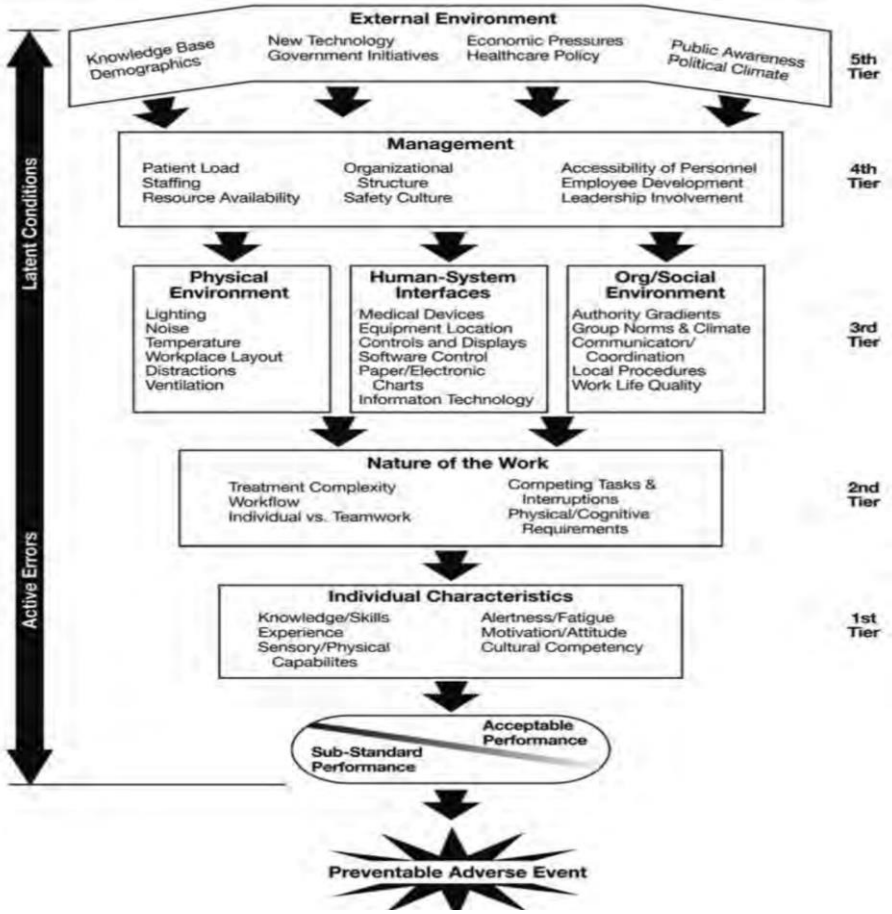
WHO 10 Patient Safety Facts:

- Risk of dying due to airplane accident is 1 in 3 million vs.1 in 300 due to a ***preventable*** medical accident.
- Global annual cost of medication errors is $42 billion (1% global health expenditure)

Reason's Model of Error Causation- *1990*
(Swiss Cheese Model)
RCA vs. System Analysis
Just Culture

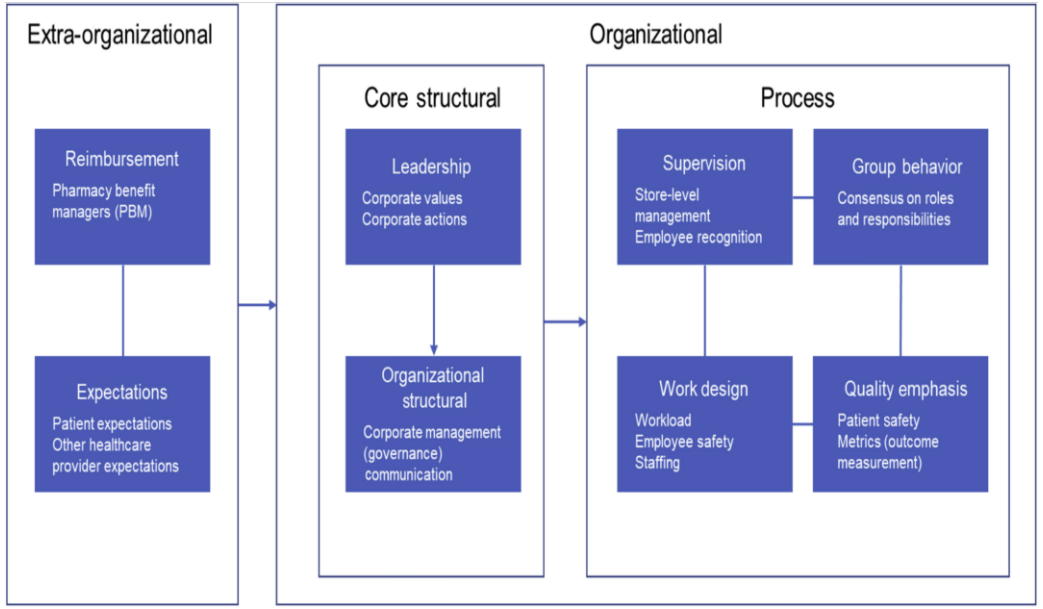


JC -Improving Patient and Worker Safety Monograph (2013)



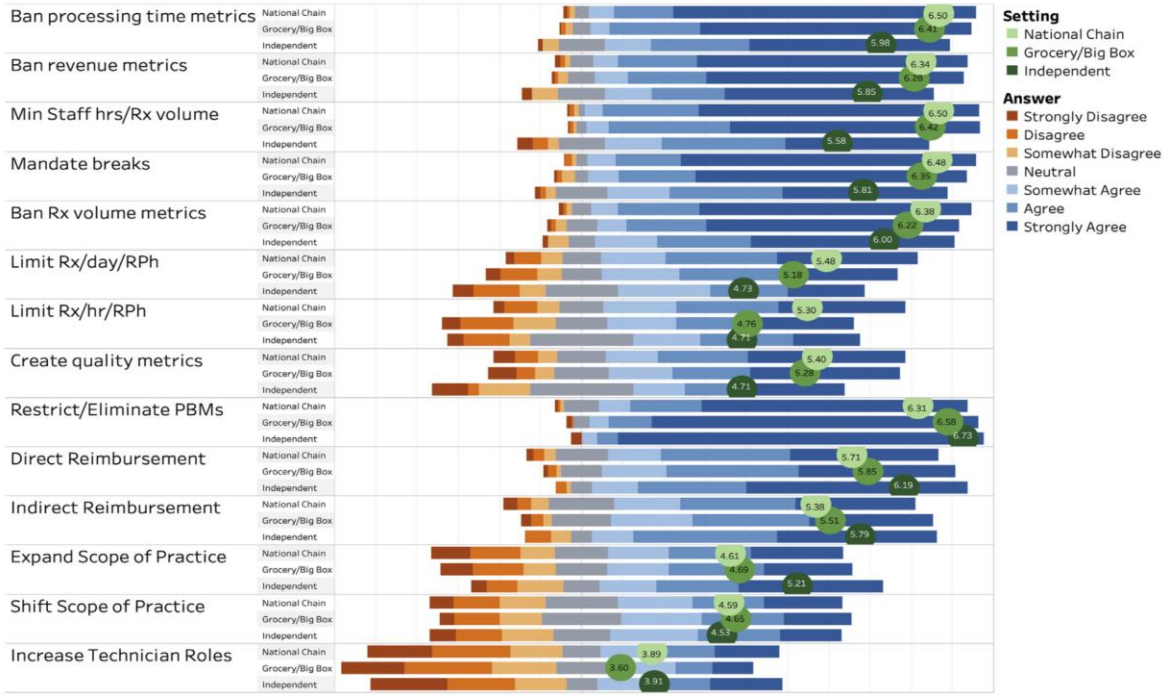
Purdue University: COP

Perception of Working Conditions and Safety Concerns in Community Pharmacy (*June 2021)*



Stone et al.[14] original integrative model of organizational climate and safety was adapted to add the extra-organizational domain and remove the outcomes subdomain, based upon the findings of this study. Extra-organizational factors both directly and indirectly affect outcomes.

Pharmacist Perceptions Of Potential Policy Solution (Feb 2021)

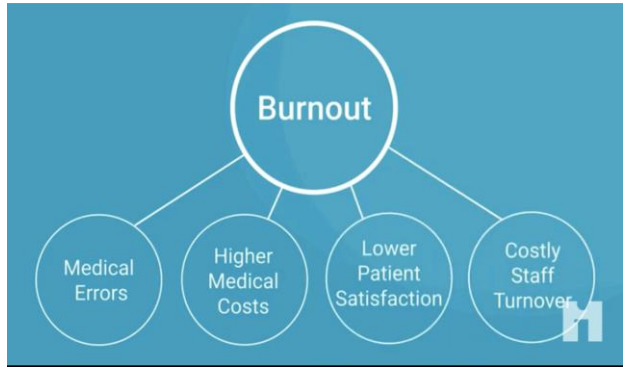


Institute of Healthcare Improvement (IHI)

- Framework for Improving Joy in Work–White Paper 2017 (resilient systems result in fewer errors, better patient experience, and better financial performance)

- Organizational Evidence-based and Promising Practices for Improving Clinician Well-being. *NAM Nov 2020. (target 6 domains, interventions that simultaneously improve clinician well-being and patient experience, measure well-being, leadership reports, efficiency of environment, culture/trust, cost of workforce burnout, recruitment, and retention)*

- Joy in Work Results-Oriented Learning Global Network (Kaiser, Mass General, Mayo Clinic, and others) – *case studies*



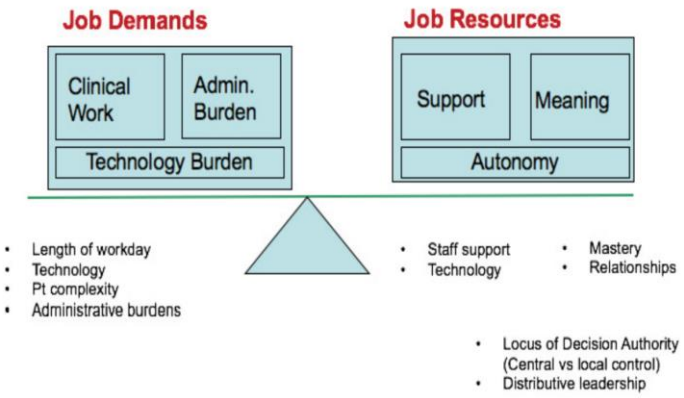


Figure 1 | Job Demands and Job Resources Conceptual Model of Clinician Well-Being
SOURCE: Developed by Christine Sinsky and Mark Linzer.

National Consensus Conference : (APhA, AACP, ACPE, NASPA,NABP) Enhancing Well-being and Resilience Among Pharmacy Workforce –

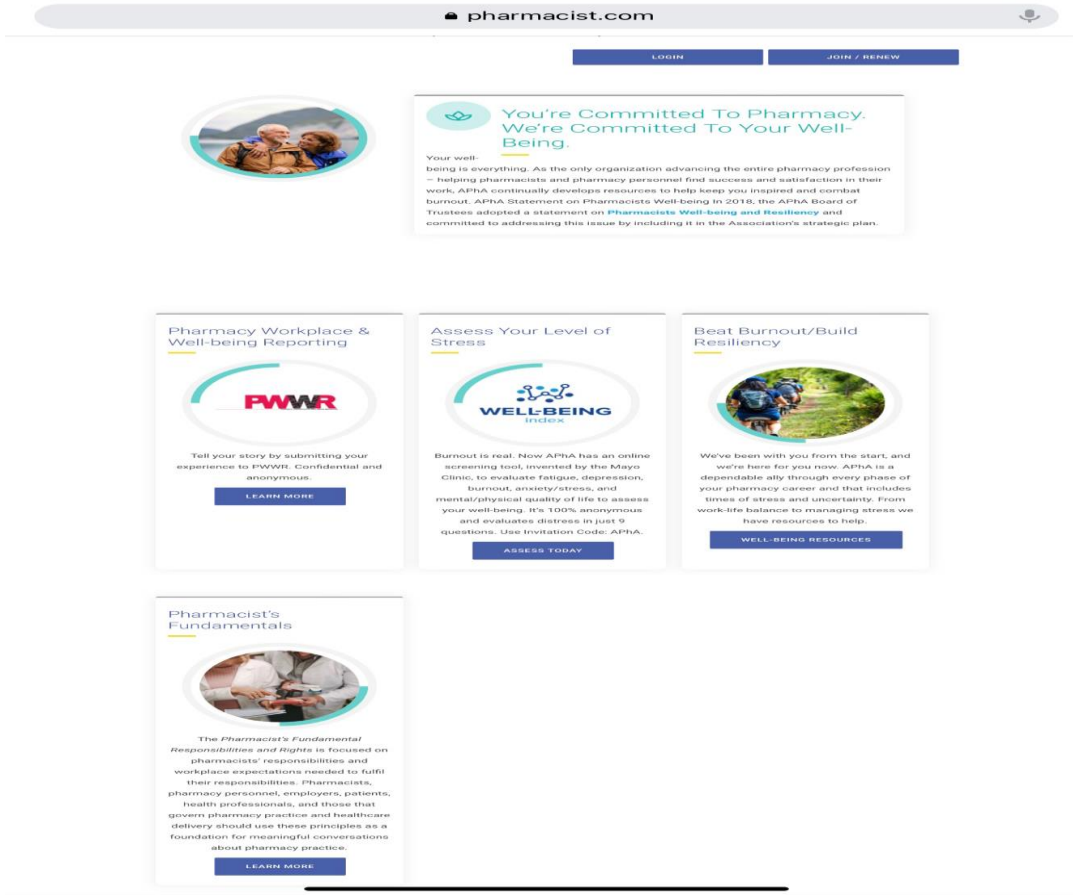
July 2019

- Impact of working conditions on patient safety, quality of care, and RPh well-being

- Comprehensive recommendations:
  - Workload, staffing, professional autonomy, open communication, team input, technological solutions
  - Quality metrics
  - Mandated breaks, regulatory and administrative burdens
  - Advocacy for scope of practice, PBM transparency, and service reimbursement.
  - Education, assessment surveys, and research on burnout, resilience, and work conditions.

American Pharmacist Association (APhA)

- Resources: WBI, Beat Burnout/Build Resilience
- Pharmacist's Fundamentals (APhA & NASPA)
- Pharmacy Workplace and Well-being Report (PWWR) Dec 2021. www.pharmacist.com/PWWR (APhA & NASPA)
- Pharmacy Workplace Survey Apr 2022 (APhA & NASPA)
- APhA Community Pharmacy Workplace Summit – Feb 2022.



www.pharmacist.com/wellbeing

NAM - Clinician Well-being & Resilience National Action Plan

- **Health ecosystem** that serves patients & health workers
- Network of 200 organizations (HCOs ,educational institutions, policymakers, health IT companies, payers, regulators, associations, and others) - ***ASHP***
- Goal: reverse health worker burnout crisis + optimize well-being & resilience + address shortages (especially post-pandemic)
- June 2022: issue a call to action for all actor groups to unify to advance this national movement.

"It is critical to hear the perspectives of all who have a stake in health to make progress toward a health ecosystem that better serves patients and health workers."

-Victor Dzau, NAM President

NABP: Taskforce – Workplace safety and Well-being (Nov 2021)

- Standardized CQI program (AHRQ, ISMP, PQA).
- Platform of de-identified aggregate data on medication errors (AHRQ) to provide stakeholders for further analysis.
- Medication Safety Training Academy and “Just Culture” principles.
- Webinars on burnout, stress management, and the correlation between a poor well-being index and increased medication errors.
- Model Act review: align definitions of error, AE, and near misses with those used by CMS; add provisions for mandated breaks and whistleblower protection
- In Jan 2022, endorsed “Pharmacist’s Fundamental Rights and Responsibilities” in preserving patient safety and acknowledged that business-related provisions are outside the regulatory purview

State Boards of Pharmacy (BOPs)

❑BOPs: Reference to Resources

- *AR: reference to* "Pharmacists Fundamental Rights and Responsibilities"
- KY: reference to "Pharmacy Personnel Well-being" "PWWR and WBI"
- ID**:** reference to "Safety Culture" and "Just Culture**"** approach to pharmacy practice

❑ BOPs: Position Statement

- TX & SC : *"Working Conditions and Communication in Pharmacies" (encourage meal breaks, empowering PIC in decision making, peer review committees, prioritizing pt. safety when setting workload expectations, discourage working conditions that increase stress, metrics and quotas)*
- *OR:* "Safe Pharmacy Practice for Licensees" …sufficient staffing
- MO*:* "Board Statement on Pharmacy Working Conditions" – April 2021 .. three pages yet comprehensive ISMP "risk mitigation strategies", Just culture principle, "system designs", and pharmacist well-being as part of patient safety.

❑BOPs: Assessment Surveys and Tools

- NV: "Workplace Assessment Tools"
- OH: "Workload Survey" to help inform "Pharmacist Workload Advisory Committee"
- ID: a survey to assess in-house and PSO "medication safety incident reporting"

BOPs: Rules and Guidance

- **NC** (2007), **MN** (2017), **IL** (2020): mandate breaks (14 states) & shifts NTE 12 hrs
- **CA**: *bans quotas (RXs or services) in chain pharmacies .*
- **MO**: reviews pharmacy working conditions during inspections (e.g., allotted **breaks**, **interruptions**, assigned **staffing**, prescription **volume**/vaccinations, and other clinical cognitive patient services)
- **OR:** sufficient staffing, adequate time to complete professional tasks & responsibilities.
- **OH**: "Pharmacist Workload Advisory Committee" 2020 using workload survey >> draft recommendations July 2022 (open door and dark hours, tech career pathway, *staffing plan).*
- **VA**: "Pharmacy Working Conditions Guidance and Well-being" Guidance document 110-26 effective May 2022. PIC professional judgment.
- **OK, VA, and OH:** staffing reporting.

BOPs: PBM Regulation

- **LA**: PBM -Monitoring Advisory Council
- **MS**: PBM -A Pharmacy Benefit License is required to do business as a Pharmacy Benefit Manager (PBM). PBMs must also file certain financial statements with the Mississippi Board of Pharmacy (due March 1st annually). The site offers PBM complaint form and reimbursement appeals
- **AR** –Rutledge (not through BOP): adequate reimbursements (pharmacy may decline dispensing if reimbursement is lower than acquistion cost), frequently updated MAC list, reimbursement appeal

Conclusion

- Poor pharmacy work conditions are detrimental to staff and patient safety. They are associated with costs of medication errors, workforce burnout, recruitment, and retention (staff shortages complicate the issue).
- A multifaceted approach is needed from all stakeholders to create a resilient health ecosystem that serves staff well-being and quality patient experience.

Assessment Question

Efforts and recommendations to address pharmacy work conditions include:

a. Professional autonomy
b. PIC input for resource allocation and performance metrics; replacing revenue metrics with quality metrics.
c. Employing “Just Culture” principles in medication error analysis
d. Mandated breaks and limiting daily shifts to 12 hours to promote RPh well-being
e. Advocacy for scope of practice, PBM regulation, and service reimbursement.
f. All of the above


Thank
You

To MPJE or not to MPJE?

Michael DeBisschop, Pharm.D.

Frank North, Pharm.D., M.P.A

Saturday, November 5, 2022

Michael DeBisschop

- PharmD, University of Michigan
- Primary Care Residency, Buffalo VAMC
- Taught pharmacy school:
  - University of Wyoming
  - St. John Fisher College
  - Manchester University
  - Medical College of Wisconsin

- Current areas of teaching/practice:
  - Pharmacy law
  - Calculations
  - Leadership
  - Community Engagement

Frank North

- B.S. Biology, Texas Southern University
- Cert. business Entrepreneurship – Technology Transfer,
  California State University – San Bernardino
- PharmD, Texas Southern University
- M.P.A., Texas Southern University
- ABD, Urban Higher Education (Ph.D.),
  Jackson State University

- President, National Pharmaceutical Association

- Current areas of teaching/practice:
  - Pharmacy law
  - Health Systems
  - Sterile Compounding
  - Social and Behavioral Aspects of Patient Care
  - Interprofessional Education & Practice
    - Integrated Practice of Dentistry

Conflict of Interest Disclosures

- DeBisschop: operates an online MPJE review course in Wisconsin.

- North: No financial or other conflicts to disclose

Learning Objectives

1. State 3 reasons why the MPJE should be kept as a requirement for licensure and transfer of license.
2. State 3 reasons why the MPJE should no longer be a requirement for licensure or license transfer.
3. Decide which side you support.

Assessment Question

- Passing the MPJE as it currently stands should CONTINUE TO BE a requirement for licensure in each state, or transfer of licensure between states.

- True or False?

PRO: Keep MPJE as licensure requirement

Legally Pharmacy…

- Pharmacy is:
  - Highly-regulated
  - Detailed
  - Consistently changing
  - State specific

PRO: Keep MPJE as licensure requirement

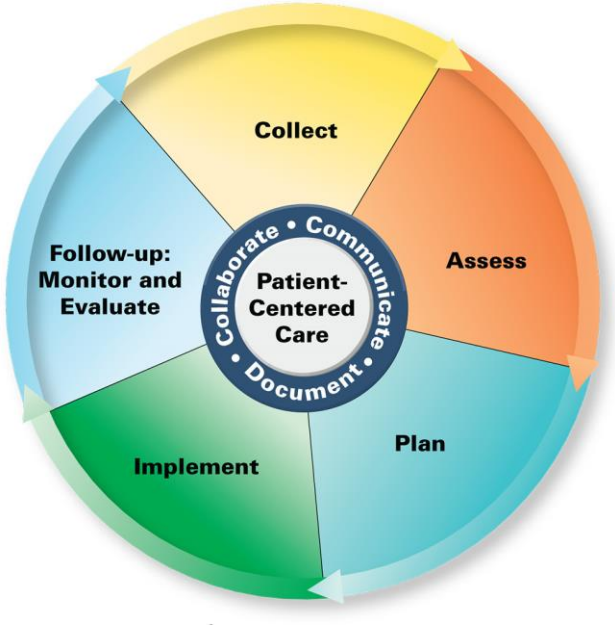
What is Pharmacy Law?

- Regulation of the practice of pharmacy
  - Labeling
  - Recordkeeping
  - Location
    - Security
  - How drug/medications are handled
  - And MORE

PRO: Keep MPJE as licensure requirement

Why is this important to me?

- States regulate pharmacies and pharmacists practice in their state.
- MPJE
- Regulations vary state to state
  - Controversial, but why?
- PPCP



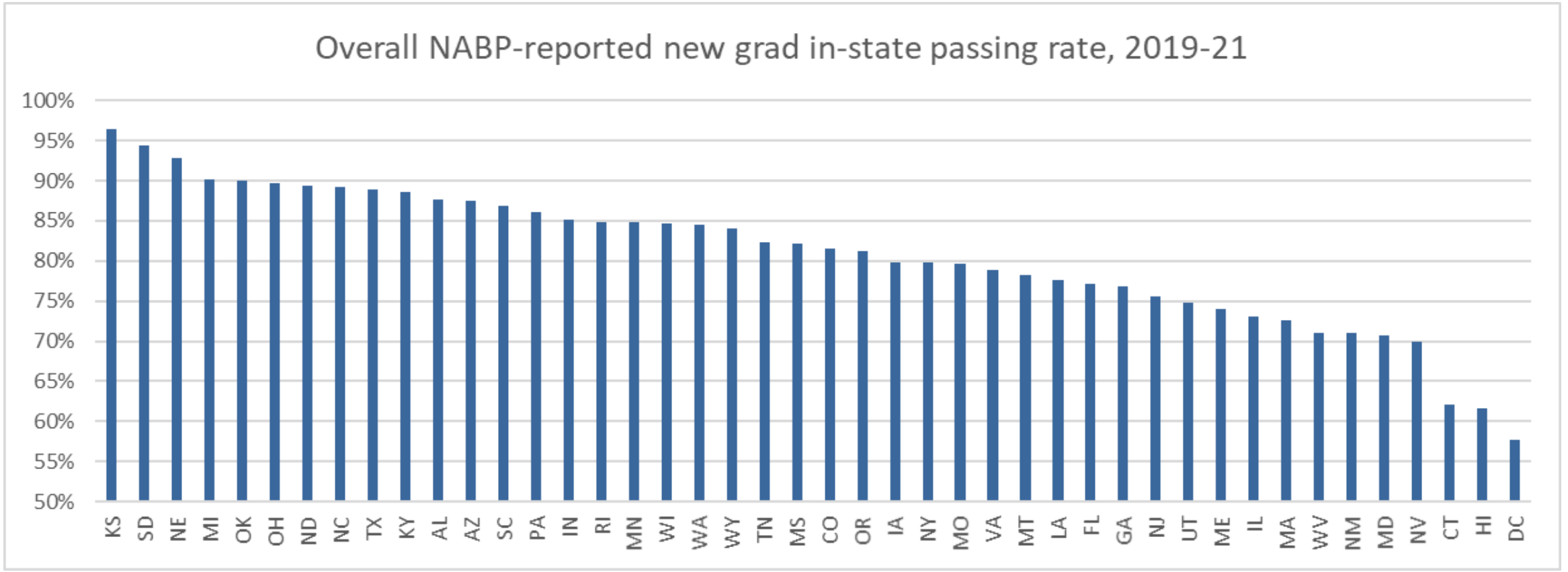
PRO: Keep MPJE as licensure requirement

- Federalism
  - Decision Founders made to split power between state and national governments
    - Passport vs. Driver's license
    - Pharmacy licenses

CON: Eliminate state-specific MPJE as licensure requirement

- Problems with the exam itself
- Recent experience with waiving MPJE
- Resolutions from pharmacy organizations
- Potential alternatives

Exam results highly variable by state



Source: NABP MPJE Passing Rates for 2019-21 Graduates. April 29, 2022. https://nabp.pharmacy/wp-content/uploads/2021/03/MPJE-Pass-Rates-2021.pdf. Accessed 7-29-2022.

More exam problems

- Question quality
  - Writing good MC questions is very difficult
- Slow to update for changes in law
- One-time assessment of pharmacy law knowledge
- Causes delays and anguish for new grads/licensees
- We have less info about the actual exam than ever

Life without MPJE

- Idaho, Vermont no longer require law exam for licensure
  - Ohio no longer requires law exam for licensure transfer
- Many states waived MPJE requirement for licensure transfer during pandemic
- 30/50 states do not require licensing of non-resident pharmacists

  (per 2021 Survey of Pharmacy Law)

Pharmacy organization resolutions

- AACP House of Delegates, July 2022:
  - "**AACP recommends the removal of a stand-alone examination of federal and/or state pharmacy law as a requirement for licensure.**"

- NABP, June 2022:
  - **"THEREFORE BE IT RESOLVED that NABP examine the development of a national standardized pharmacy jurisprudence examination for the state boards of pharmacy to assess competence for licensure."**

Alternatives

- Pharmacists still need to know law, including course taught in schools
  - Greater range of teaching/assessment methods possible without MPJE
- Periodic law continuing education requirements (10 states already have)
- Employer training?
- Periodic audits/inspections?
- Not better: national law exam on Federal only (either stand-alone or rolled into NAPLEX)

Assessment Question

- Passing the MPJE as it currently stands should CONTINUE TO BE a requirement for licensure in each state, or transfer of licensure between states.

- True or False?