

Collaborative Approach to Patient Safety

Lemrey "Al" Carter, PharmD, MS, RPh Executive Director/Secretary, NABP January 2022



NABP Mission Statement

NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

Vision Statement

Innovating and collaborating today for a safer public health tomorrow

NABP Purpose

Founded in 1904, the purpose of the Association is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensure, and practice by cooperating with state, national, and international government agencies and associations having similar objectives.

> Farm Hosp. 2021 Feb 22;45(2):89-95. doi: 10.7399/fh.11652.

How COVID-19 has impacted the role of pharmacists around the world

Dominique Jordan ¹, Josep M Guiu-Segura ², Gonçalo Sousa-Pinto ³, Lin-Nam Wang ⁴

Affiliations + expand

PMID: 33709893 DOI: 10.7399/fh.11652

Free article

Abstract in English, Spanish

All over the world pharmacists are standing up to the challenge of COVID- 19 and showing their commitment to the communities they serve. As the COVID-19 pandemic has tested global health systems to their limits, pharmacy professionals have shown themselves to be an integral part of them. Community pharmacists have supported government initiatives to control the pandemic and have ensured patients continued to receive their medicines. Hospital pharmacists have been moving beyond their specialties to help provide critical care to patients while dealing with ICU drug shortages. Pharmaceutical scientists have been involved in finding effective vaccines and identifying effective treatments. In short, the pharmacy profession has been demonstrating expertise, strength, courage and dedication to care at the highest level. The International Pharmaceutical Federation (FIP), which



Agenda:

- 1. How Do We Address Burn-Out, Working Conditions, Mental Health
- 2. The Forgotten Epidemic Opioid Addiction and Substance Use Disorders
- 3. Drug Supply Chain Integrity
- 4. New Pharmacy Model



How Do We Address Burn Out, Working Conditions, Mental Health

NABP Task Force on Workplace Safety and Well-Being

 Participants included Boards of Pharmacy ED, Pharmacist Representatives (Chain and Independent), and Technicians

Task Force Charge:

- Examine the topics of pharmacy workplace safety and pharmacist well-being and their effects on patient safety.
- 2. Review existing guidelines and objective tools that address these issues and make recommendations regarding their use.
- 3. Amend NABP Model Rules, if necessary.



Preliminary Findings of this Task Force

- CQI Programs
 - Lack of utilization
 - Confidentiality and PSO organizations
 - Instrumental in illuminating workplace safety issues
- Regulatory model limitations contribute to staff issues and on the job stress.
- Collaboration with pharmacies, associations, and industry specialists is necessary for improvements.
- Collaborate with health and wellness organizations to focus on mental well-being through trainings.
- Evaluate the regulatory changes made by states to address working conditions and burnout



The Forgotten Epidemic



Mainstreaming Addiction Treatment (MAT) Act

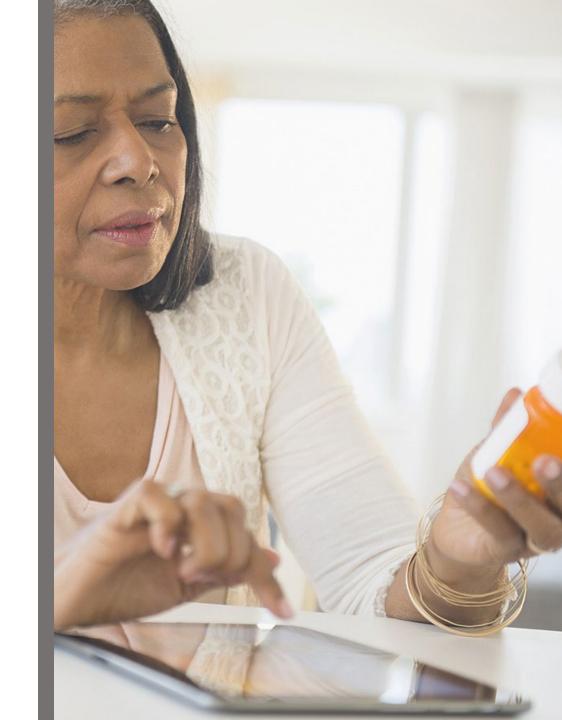
- NABP Chairperson Tim Fensky's Presidential Initiative
- Serving as one of the lead stakeholders in support of the MAT Act
 - Letters to leadership
 - Recruiting sponsors in House and Senate
 - Press releases/social media/Op-Ed
 - Briefings before Addiction, Recovery and Treatment Caucus
- Advocating for expansion of access to treatment

- HR 1384 and S 445 were introduced in February 2021
- The MAT Act is bipartisan legislation that would remove a federal requirement for practitioners to obtain a special waiver from the DEA.
- MAT act does not explicitly enable pharmacists to prescribe MAT



Consumers Are Moving Online

- In 2021, 42% of Americans used an online pharmacy to buy medicines for themselves or someone in their care up seven points from 2020
- <u>59% of patients</u> who have purchased prescription medicines online <u>believe that the websites have</u> <u>been approved by FDA or state regulators</u>





Illegal Pharmacy Landscape

- There are between 30,000 and 35,000 illegal online pharmacies operating at any one time, and 20 new illegal online pharmacy sites are launched every day.
- Drugs sold by illegal online pharmacies often contain too much, too little, or no active ingredient; are manufactured in unsafe conditions; and/or contain unsafe materials.
- When shown an illegal website, <u>17.5% of pharmacists</u>
 <u>believe the website is legal</u> based on the look of the web page.





BUY SAFELY

Beware of fraudulent and unsafe prescription medication sold on websites and social media platforms. Only buy prescription medication from legitimate, verified pharmacies and pharmacy websites.

Search for a website to see if it is safe or not recommended:

www.example.com



Download an Excel list of safe pharmacy websites, or email custserv@safe.pharmacy to request the list in another format.









How can your pharmacies best protect patients?

- Share information with NABP
- Direct patients to safe.pharmacy
- Ensure that your pharmacy is .Pharmacy Verified
- Support S.3339/HR.6352 Domain Reform for Unlawful Drug Sellers Act or "DRUGS Act"





BUY SAFELY

Beware of fraudulent and unsafe prescription medication sold on websites and social media platforms. Only buy prescription medication from legitimate, verified pharmacies and pharmacy websites.

Search for a website to see if it is safe or not recommended:

www.example.com



Download an Excel list of safe pharmacy websites, or email custserv@safe.pharmacy to request the list in another format



Drug Supply Chain Integrity



State Regulator & Industry Alignment Why is NABP engaging in DSCSA?

Key Questions from State Regulators

- When might regulators request transaction information from trading partners within the secure, electronic, interoperable system?
 - When conducting illegitimate, suspect product investigations
 - When inspecting suspected fraudulent activity
 - When investigating product recalls
 - When conducting compliance audit inspections
- How will regulators assess trading partner compliance with the Drug Supply Chain Security Act (DSCSA)?
 - Inspect for Policies and Procedures and best practices documentation
 - Inspect wholesaler/supplier licensure



DSCSA Regulator Workshop Summary

- Develop education and training for regulators and trading partners (focused on dispensers)
- Develop uniform guidelines and tools for assessing DSCSA compliance
- Develop a system to facilitate regulator requests for information from trading partners
 - Consistent with DSCSA Uniform National Policy and FDA Guidance
- Leverage tools being used widely by the industry to make change management and compliance easier for all.

Sec. 585. Uniform National Policy

- (a) Product Tracing and Other Requirements
- (b) Wholesale
 Distributor and 3PL
 Standards



State Regulator & Industry Alignment

Primary Goal:

Create a network to facilitate regulator requests for transaction information from trading partners.

The network will:

- Be consistent with the Uniform National Policy (Sec. 585) and FDA guidance
- Create a uniform request/response standard for state regulators incorporating DSCSA requirements and FDA Guidance
- Create a consolidated source for state regulator/trading partner communication
- Ensure that only authorized regulators are able to access and make requests of authorized trading partners
- Protect confidential/proprietary information
- Focus on the most critical patient safety use cases

 Confidential contact for further distribution

Network Outcomes:

- Increase efficiency of inspections and investigations
- Rapid disposition of suspicious or illegitimate products
- Reduce manual requests/responses for information
- Leverage existing standards and industry work whenever possible



State Regulator & Industry Alignment How might regulators engage?

Regulator Authentication

- NABP currently maintains a platform accessed and used daily by state boards of pharmacy
- Expanded use to other state and federal regulatory agencies (including the FDA)
- NABP can limit access to only authorized state/federal government officials
- NABP can restrict access to the system based on user function and responsibility

Pilot

- Tabletop exercises will run from January-March 2022
- Participants will include state regulators, manufacturers, distributors and dispensers
- Outputs will inform ongoing industry efforts and development of solutions
- Focus on ensuring that the state regulator and dispenser perspectives are incorporated into solutions



New Pharmacy Model



New Pharmacy Model For Patient Safety

Considerations

- Practice of pharmacy is faced with numerous challenges (e.g., regulatory requirements, reimbursement, workforce, others)
- Response to COVID-19 included emergency orders that <u>temporarily</u> enabled and improved patient access to care (e.g., interstate practice, expanded technician role such as immunization administration, etc.)
- COVID drove the proliferation of Digital solutions (e.g., Virtual medical office visit, Telepharmacy, Telehealth, Virtual regulatory inspections, accreditation surveys, etc.)
- Need to enable Pharmacists authority to provide clinical services matching their education and training
- Future of Pharmacy The Pharmacy of 2030



NABP Working Group To Consider Extending COVID Waivers

Work Group Charge:

- 1. Review all provisions waived by state boards of pharmacy during public health emergency
- 2. Advise which waivers could safely remain in effect beyond COVID-19
- 3. Amend NABP Model State Pharmacy Act to reflect recommendations by group

Recommendations for State Boards of Pharmacy to consider:

- 1. Expansion of pharmacists' scope (CLIA, therapy substitutions, emergency dispensing, change in counseling requirements)
- 2. Expansion of pharmacy technician role and authority



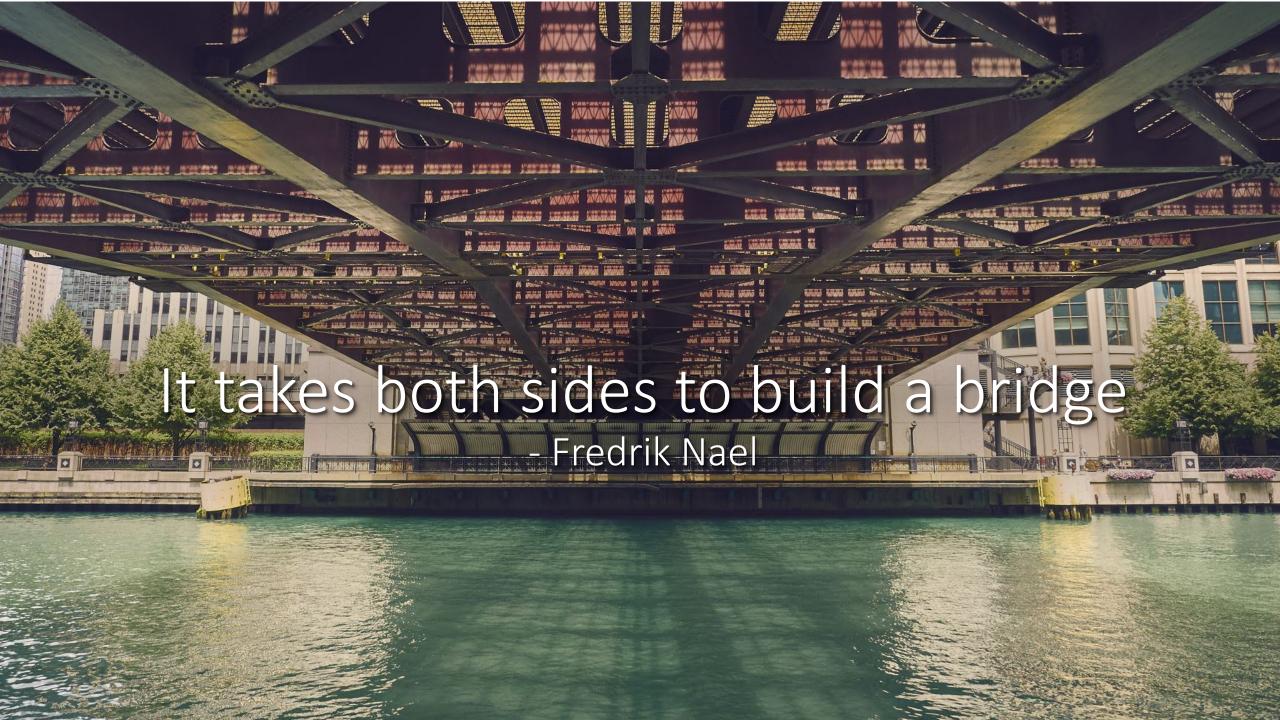
Create an Environment to Enable Pharmacists to Provide Clinical Services Matching Their Education and Training

- Digital intra/interstate practice models
 - Central fill and processing models have moved all or part of dispensing functions outside of community practice site
 - Remote work ability for pharmacists and technicians
 - Clinical and dispensing functions completed outside of a pharmacy allows more bandwidth for patient facing activities
- Expansion of pharmacy technician role and authority
 - Immunization administration e.g., Prep Act permanent authority by the states
 - Technician Product Verification
 - Technology assisted model in long term use in institutional settings
 - Iowa Board of Pharmacy- rules to allow in community practice



NABP Verify Program (Q2-2022 Launch)

- Based on the success of the NABP Passport program
- NABP Verify credential is evidence of initial verification and ongoing monitoring of licensure in good standing
- Practice authority will be described in state statute or regulation
- Intent of this program is to decrease state BOP administrative burdens while maintaining, and possibly increasing, patient safety through enabling regulatory channels
- Provides additional state insight/oversight of pharmacists working within a digital interstate practice model
- Subscription based; Annual fee





Thank you