NABP
National Association of Boards of Pharmacy

Managing State Regulatory Challenges

FDA Compounding Quality Center of Excellence Annual Conference
September 12, 2023

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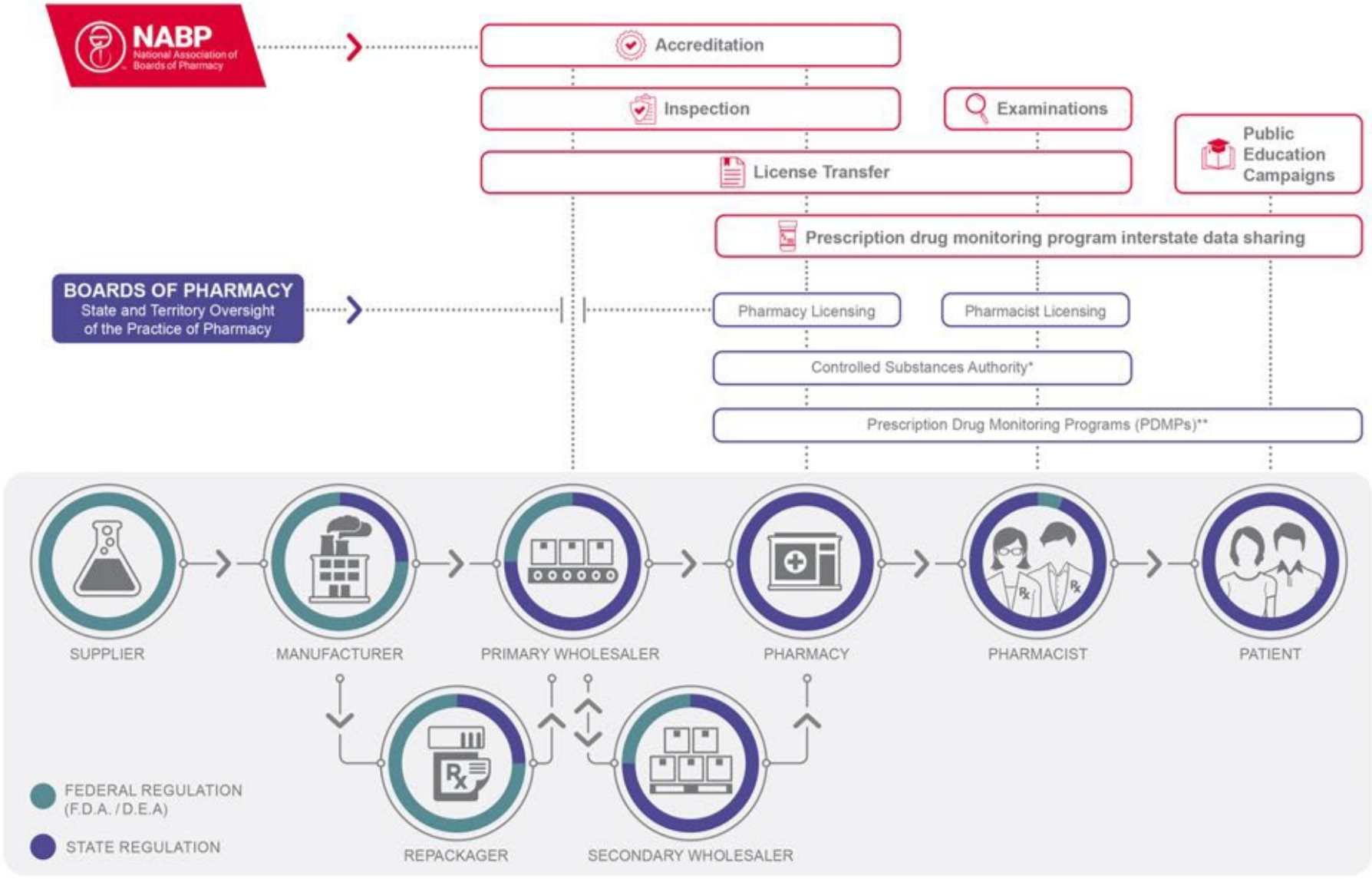
Who is NABP? National Association of Boards of Pharmacy

The National Association of Boards of Pharmacy® (NABP®) is a 501(c)(3) nonprofit organization founded in 1904.

The National Association of Boards of Pharmacy (NABP) is the independent, international, and impartial Association that assists its member boards in protecting the public health.

Working with our members, the state and territorial boards of pharmacy, for over 100 years we help support patient and prescription drug safety, through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy and distributor accreditation programs.

Understanding New DSCSA Requirements and Common Diversion Schemes



* 29 states and territories house controlled substances authority in the board of pharmacy,10 in the Department of Health, 5 in professional licensing agencies, and 7 in law enforcement agencies.

** 24 PDMPs are housed within the board of pharmacy,18 in the Department of Health, 5 in professional licensing agencies, and 4 in law enforcement agencies.

OUTSOURCING FACILITIES (503Bs)

The Beginning: September 2012 - Framingham, MA

What is Compounding?

- Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved.
- Most states and pharmacy organizations have similar and modified definition that includes/implies individual patient need.

State Pharmacy Regulations – Compounding expanded from individual patient need to "office use" increasing the volume and distribution of unapproved new drugs.

NECC was not the only tragedy. There were many adverse events involving death before and after NECC. These included humans and other animals.

The Legislation – November 27, 2013 – Creation of an entirely new regulated entity.

From the start in 2012, states faced huge challenges.

State Board Facts (1 of 2)

State	First Enactment	Board Designation/ State Agency	Rules and Regulations Made by	Number Complia Officers/ Inspecto
Alabama	1887	B	B	13 RR
Alaska	1935	A	A	1
Arizona	1903	B	B	8
Arkansas	1891	B	B	5
California	1891	B	B	59
Colorado	1887	B, N	B	4
Connecticut	1881	C, L	C, L	11
Delaware	1883	B	B	1
District of Columbia	1906	A	A, T	6
Florida	1889	A, I	A	29
Georgia	1881	B, K	B	12 BB
Guam	1982	F, I	B	1 O
Hawaii	1949	B, M	B	EE
Idaho	1889	B, S	A, S	3
Illinois	1881	B, D	D	6
Indiana	1899	AA	A	7
Iowa	1880	A	A	8
Kansas	1885	B	B	6
Kentucky	1874	A	A	5
Louisiana	1888	A	A	7
Maine	1877	A, CC	A, CC	1
Maryland	1902	A	A	8 FF
Massachusetts	1885	E, P	E	13 OO
Michigan	1885	A, J	A, J	EE
Minnesota	1885	A	A	7
Mississippi	1892	A	A, QQ	5
Missouri	1881	A	A	9

State Board Facts (2 of 2)

Montana	1895	A	A	2
Nebraska	1887	A, GG	A, GG	3
Nevada	1901	B	B	7
New Hampshire	1875	A	A	3
New Jersey	1877	B	B	4
New Mexico	1889	A	A	7
New York	1884	B, G	U	EE
North Carolina	1881	A	A	13
North Dakota	1887	B	B	4
Ohio	1884	B	B	DD
Oklahoma	1907	B	B	6
Oregon	1891	B	B	6
Pennsylvania	1887	B, R, S	B, V	6
Puerto Rico	1906	A, I	A, I	II
Rhode Island	1870	A, I	A, I	1
South Carolina	1876	A, Y	A, V	5
South Dakota	1899	A	B	2
Tennessee	1893	A, I	B	5
Texas	1907	B	B	15
Utah	1892	A, S	S	EE
Vermont	1894	A	A	2
Virginia	1886	A	A	11 LL
Washington	1891	PP	NN	9 MM
West Virginia	1881	A	A, V	6
Wisconsin	1882	O, Q	O	1 H
Wyoming	1886	B	B	2

State Board of Pharmacy Organization

1. State Board of Pharmacy Funding
    a. State Board Account
    b. Special Fund in State's Treasury
    c. State General Revenue Fund
2. Board Member Composition
    a. Pharmacists
    b. Public Members
    c. Pharmacy Technicians
    d. Actively Practicing?
    e. Years of Practice Required
    f. Terms (in years)
3. State Law (Statutes)

State Board of Pharmacy Organization (1 of 2)

1. Board of Pharmacy Rules – Promulgation, Approval
2. Examinations and Licensure of Pharmacists
3. Registration of Interns, Preceptors, Training Sites
4. Licensure of Pharmacies
5. Continuing Education Requirements
6. Controlled Substance Registrations
7. 40 States Regulate Wholesale Distributors, Manufacturers, Repackagers, Third Party Logistic Providers, Reverse Distributors, any location handling prescription drugs.
8. Some regulate OTC Drugs and Medical Devices

State Board of Pharmacy Organization (2 of 2)

NABP Model Act

Model Rules for Outsourcing Facilities

1. Purpose – Consistency with Federal Law
2. Registration
3. Notification – Biannual reports of compounded drugs
4. Requirements
    a. Supervision under a Licensed Pharmacist
    b. cGMPs
    c. Education, training, experience
    d. Labeling
    e. Bulk substance requirements
    f. Shortage requirements

OUTSOURCING FACILITIES (503Bs) (1 of 2)

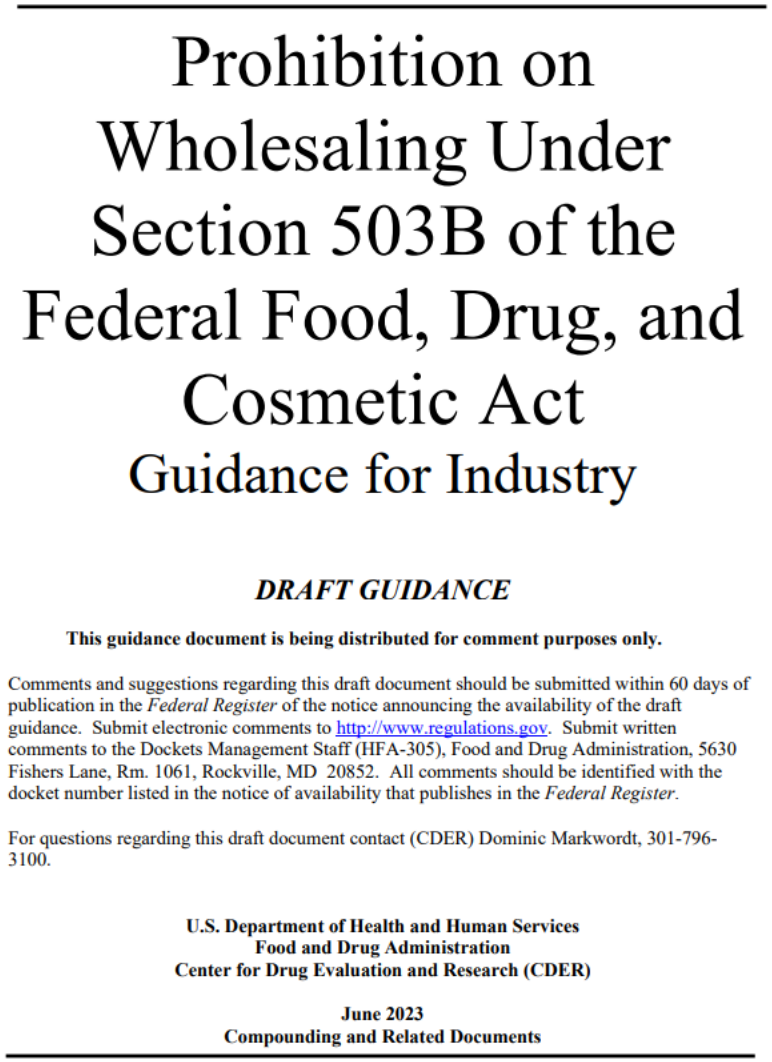
Examples of Board Challenges

1. One Legal Entity with Multiples Licenses (Mfr, WD, Pharmacy, OF)
    1. Same address
    2. Address in close proximity
2. Several related Legal Entities under same ownership operating as OF, WD, and Pharmacy
3. Drugs compounded by a Pharmacy and transferred to OF
4. Assessing not just the quality of compounded drugs, but also the legality (ex. Semaglutide in 503A pharmacies)
5. Assessing Certificates of Analysis
6. Wholesale Distribution by 503Bs

OUTSOURCING FACILITIES (503Bs) (2 of 2)

SEC. 503B. o**21 U.S.C. 353b**. **OUTSOURCING FACILITIES.**

(8) PROHIBITION ON WHOLESALING.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance With section 503(b)(1).



Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Dominic Markwordt, 301-796-3100.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2023
Compounding and Related Documents

OUTSOURCING FACILITIES (503Bs) – State License (1 of 2)

State	Does State Issue Separate Licenses for Sterile Compounding Pharmacies?	Does State Issue Separate Licenses for Sterile Compounding Facilities That Are Registered With FDA as Outsourcing Facilities?
Alabama	No	Yes
Alaska	No	No
Arizona	No	Yes JJJ
Arkansas	No	No
California	Yes	Yes GGG
Colorado	No	No TT
Connecticut	No	No
Delaware	No	No
District of Columbia	No	No Y
Florida	Yes	Yes
Georgia	No	No
Guam	No	No
Hawaii	No	No
Idaho	No	Yes
Illinois	No	No W
Indiana	No	No
Iowa	No	Yes X5
Kansas	No	Yes
Kentucky	No	Yes
Louisiana	No	No
Maine	Yes	No
Maryland	No	No EEE
Massachusetts	No Z	Yes
Michigan	No	No
Minnesota	No III	No JJJ
Mississippi	Yes	Yes
Missouri	Yes	Yes

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OUTSOURCING FACILITIES (503Bs) – State License (2 of 2)

State	Does State Issue Separate Licenses for Sterile Compounding Pharmacies?	Does State Issue Separate Licenses for Sterile Compounding Facilities That Are Registered With FDA as Outsourcing Facilities?
Montana	No AA	No AA
Nebraska	No	No W
Nevada	No	No
New Hampshire	No	Yes
New Jersey	No	No LL
New Mexico	Subcategory	Yes
New York	No	Yes
North Carolina	No	FFF
North Dakota	No	No OOO
Ohio	No	Yes
Oklahoma	PPP	Yes QQQ
Oregon	No	Yes W
Pennsylvania	No	YY
Puerto Rico	No	R
Rhode Island	No	No OOO
South Carolina	No	Yes
South Dakota	No	Yes
Tennessee	Yes MMM	NNN
Texas	Yes	No LL
Utah	No	No
Vermont	Yes E5	Yes
Virginia	No	Yes Y4
Washington	No	Yes Z5
West Virginia	Yes	Yes G6
Wisconsin	No	No
Wyoming	No	No BBB

STATES ISSUING “OUTSOURCING FACILITY LICENSE”

Alabama
California
Delaware
Florida
Idaho
Iowa
Kansas
Kentucky
Massachusetts
Mississippi
Missouri
Nevada
New Hampshire
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
South Carolina
South Dakota
Tennessee
Vermont
Virginia

STATES LICENSING OF OUTSOURCING FACILITIES

Arizona -- Manufacturer

Arkansas – Wholesaler

Colorado – Manufacturer

Georgia – Manufacturer

Illinois -- Manufacturer

Indiana – Pharmacy

Louisiana – Pharmacy

Michigan – Pharmacy

Minnesota – Manufacturer

Montana – Pharmacy

New Jersey – Manufacturer

Oregon – Manufacturer

Pennsylvania – Manufacturer

Texas -- Manufacturer, Wholesaler OOS

Washington -- Manufacturer, Wholesaler OOS

West Virginia – Manufacturer

Wyoming -- Wholesaler

Reported State Statistics on 503B Facilities

1. Number of States issuing an Outsourcing Facility License
2. Number of States not issuing Outsourcing Facility Licenses
3. Number of States Licensing Outsourcing Facilities as Manufacturers
4. Number of States Licensing Outsourcing Facilities as Pharmacies
5. Number of States Licensing Outsourcing Facilities as Distributors
6. Number of Resident Outsourcing Facilities
7. Number of Non-Resident Outsourcing Facilities
8. Number Reporting “0” Resident Outsourcing Facilities with numerous Non-Resident Facilities

THANK YOU

QUESTIONS?