From Crisis to Confidence: The Rise of 503B and Modern Standards

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Disclosures

The planner(s) and speaker(s) have indicated that there are no relevant financial relationships with any ineligible companies to disclose.

Learning Objectives

1. Discuss how the FDA Modernization Act of 1997, development of USP <797>, and 2012 New England Compounding Center (NECC) meningitis outbreak shaped modern sterile compounding standards

2. State the roles, requirements, and risk profiles of 503A traditional compounding pharmacies and 503B outsourcing facilities

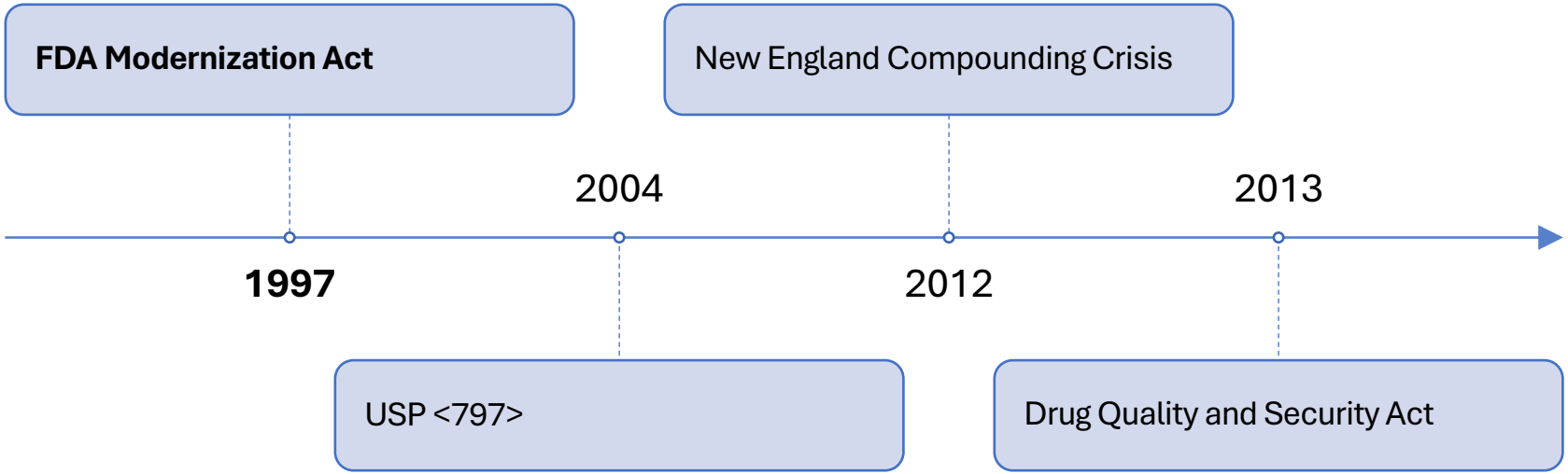
3. Explain how federal, state, and USP regulatory frameworks work together to govern compounding practice and prevent patient harm

4. Recognize a Group Purchasing Organizations (GPOs) influence on health-system purchasing decisions and quality expectations for 503B facilities

Abbreviations

- CSP: Compounded Sterile Product
- DH: Department of Health
- DHHS: Department of Health and Human Services
- DQSA: Drug Quality and Security Act
- FDAMA: Food and Drug Administration Modernization Act
- GPO: Group Purchasing Organization
- NECC: New England Compounding Center
- USP: United States Pharmacopeia

Timeline



FDA: Food and Drug Administration; USP: United States Pharmacopeia

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The Evolution of U.S. Compounding

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Introduction to Compounding Regulation

January 1, 1820

- 11 physicians meet in the Senate Chamber of the US Capitol to establish a pharmacopeia

December 15, 1820

- United States Pharmacopeia (USP) first published as a compendium of recipes

1820-1942

- USP published at 10-year intervals

Urick BY, Meggs EV. Towards a Greater Professional Standing: Evolution of Pharmacy Practice and Education, 1920-2020. *Pharmacy (Basel)*. 2019;7(3):98. Published 2019 Jul 20. doi:10.3390/pharmacy7030098

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Introduction to Compounding Regulation

1975 National Coordinating Committee on Large Volume Parenterals (NCCLVP)

- Addressed safety problems with parenteral solutions used in hospitals
- Focused on improving large volume parenteral product safety

1990 American Society of Health System Pharmacists Urgent Attention Letter

- Issued in response to sterile compounding quality failures in 1989-1990 causing microbial contamination and incorrect strength
- Called for more stringent sterile compounding practices

Kienle PC. *USP <797> Availability.* In: The Sterile Compounding Answer Book. American Society of Health-System Pharmacists; 2020. Accessed March 13, 2026.
Intravenous Admixture Systems: Pharmacy-Directed Programs. Studylib; Accessed March 13, 2026

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Introduction to Compounding Regulation

1995: USP <1206>

- Offers guidance on sterile compounding before standards established
- Later transformed into USP <797>

USP: United States Pharmacopeia

Okeke CC, Barletta F, Newton DW, Allen LV Jr. Evolution of the United States Pharmacopeia Chapter <1206>: *Sterile Preparations – Pharmacy Practices*. *International Journal of Pharmaceutical Compounding.* 2001; Jul/Aug:265-267

FDA Modernization Act of 1997

Added section 503A to the Food, Drug, and Cosmetic (FD&C) Act and established conditions for compounded products to be exempt:		
New drug approval requirements	Labeling with adequate directions for use	Current good manufacturing practice (cGMP) requirements

FDA: Food and Drug Administration; FD&C: Food,, Drug, and Cosmetics; cGMP: Current Good Manufacturing Practice

Buhay M, Wolfert M. *FDA Drug Topics: Regulatory Framework for Human Drug Compounding.* U.S. Food and Drug Administration; Accessed March 13, 2026.

FDA Modernization Act of 1997

Joint Explanatory Statement of the Congressional Committee of Conference explanation behind enacting 503A:

"It is the intent of the conferees to ***ensure continued availability*** of compounded drug products as a component of individualized therapy, while ***limiting the scope of compounding*** so as to ***prevent manufacturing under the guise of compounding***. Section 503A establishes parameters under which compounding is appropriate and lawful..."

FDA: Food and Drug Administration

Buhay M, Wolfert M. *FDA Drug Topics: Regulatory Framework for Human Drug Compounding.* U.S. Food and Drug Administration; Accessed March 13, 2026.

FDA Modernization Act of 1997

2002: Thompson v. Western States Medical Center

A group of licensed pharmacies specializing in compounded products argue the FDAMA violates the First Amendment

Restricts prescription from being "unsolicited," 21 U. S. C. § 353a(a)	"not advertise or promote the compounding of any particular drug, class of drug, or type of drug," § 353a(c)

Ruling

The FDAMA's prohibitions on soliciting prescriptions for, and advertising, compounded drugs amount to unconstitutional restrictions on commercial speech. Pp. 366-377.

FDA: Food and Drug Administration; FDAMA: Food and Drug Administration Modernization Act

Thompson v. Western States Medical Center, 535 U.S. 357 (2002)

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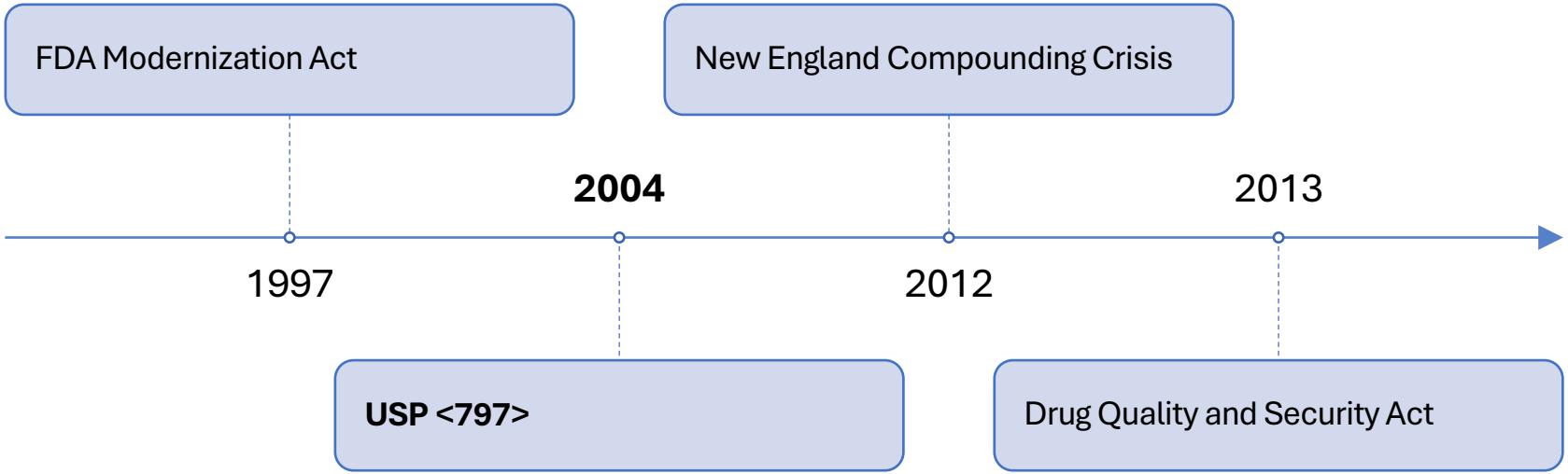
Timeline



FDA: Food and Drug Administration; USP: United States Pharmacopeia

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Compounding Concerns

Year	State	Description
1990	Nebraska	4 patients died of bacterial infection from non-sterile cardioplegia solution compounded in a hospital
1998	California	11 children became septic – 10 tested positive for *Enterobacter cloacae* bloodstream infections associated with contaminated prefilled saline syringes
2003	Missouri	Bacteria contamination with *Burkholderia cepacia* found in at least 2 batches of a compounded inhalant solution used by 19,000 patients with chronic lung disease

Buhay M, Wolfert M. *FDA Drug Topics: Regulatory Framework for Human Drug Compounding.* U.S. Food and Drug Administration; Accessed March 13, 2026.

USP <797>

Published on January 1st, 2004

First widely adoptable **national standard for sterile compounding practices**

USP: United States Pharmacopeia

United States Pharmacopeia. USP General Chapter <797>. USP. Published November 1, 2023. Accessed April 25, 2026.
https://www.usp.org/compounding/general-chapter-797

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USP <797> Sections

Responsibility of Compounding Personnel	Hazardous Drugs as Compounded Sterile Products	Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding	Compounded Sterile Product Microbial Contamination Risk Levels	Verification of Compounding Accuracy and Sterility
Finished Preparation Release Checks and Tests	Personnel Training and Evaluation in Aseptic Manipulation Skills	Environmental Quality and Control	Storage and Beyond-Use Dating	Immediate-Use Compounded Sterile Products
Suggested Standard Operating Procedures (SOPs)	Maintaining Sterility, Purity, and Stability of Dispensed and Distributed Compounded Sterile Products	Single-Dose and Multiple-Dose Containers	Elements of Quality Control	Quality Assurance (QA) Program

USP: United States Pharmacopeia

United States Pharmacopeia. USP General Chapter <797>. USP. Published November 1, 2023. Accessed April 25, 2026. https://www.usp.org/compounding/general-chapter-797

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Impact of United States Pharmacopeia Chapter 797: Results of a national survey (2006)

Methods

- Survey sent to 600 hospital pharmacy directors
- 251 surveys returned

45.3%	21.3%	42.3%
Planned to build a clean room	Planned to obtain new equipment for compliance	Decreased quantity of high-risk compounding

Candy TA, Schneider PJ, Pedersen CA. Impact of United States Pharmacopeia chapter 797: results of a national survey. *Am J Health Syst Pharm*. 2006;63(14):1336-1343. doi:10.2146/ajhp050447

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USP <797> 2008 Revision

Risk Classification of CSPs

- USP classifies sterile preparations into four risk levels guiding compounding controls and beyond-use dates

Environmental Quality Controls

- Strong engineering controls require Class 5 environments with HEPA filtration and strict cleanroom standards

Personnel Training and Aseptic Technique

- Mandated training and competency testing ensure aseptic techniques minimize contamination risks in sterile compounding

Enhanced Cleaning and Monitoring

- Expanded cleaning protocols and environmental monitoring safeguard against microbial and endotoxin contamination

USP: United States Pharmacopeia

U.S. Pharmacopeial Convention. USP general chapter <797> pharmaceutical compounding—sterile preparations. In: USP 31–NF 26, Second Supplement. Rockville, MD: U.S. Pharmacopeial Convention; 2008. Official June 1, 2008.

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Adoption Concerns

By 2011, 15/50 states had specific regulatory language incorporating USP <797>

30/50 states & DC had regulations addressing compounded sterile preparations

30% of states (15 of 50) had formally adapted USP <797> by the end of 2011

USP: United States Pharmacopeia

U.S. Pharmacopeial Convention. USP general chapter <797> pharmaceutical compounding—sterile preparations. In: USP 31–NF 26, Second Supplement. Rockville, MD: U.S. Pharmacopeial Convention; 2008. Official June 1, 2008.

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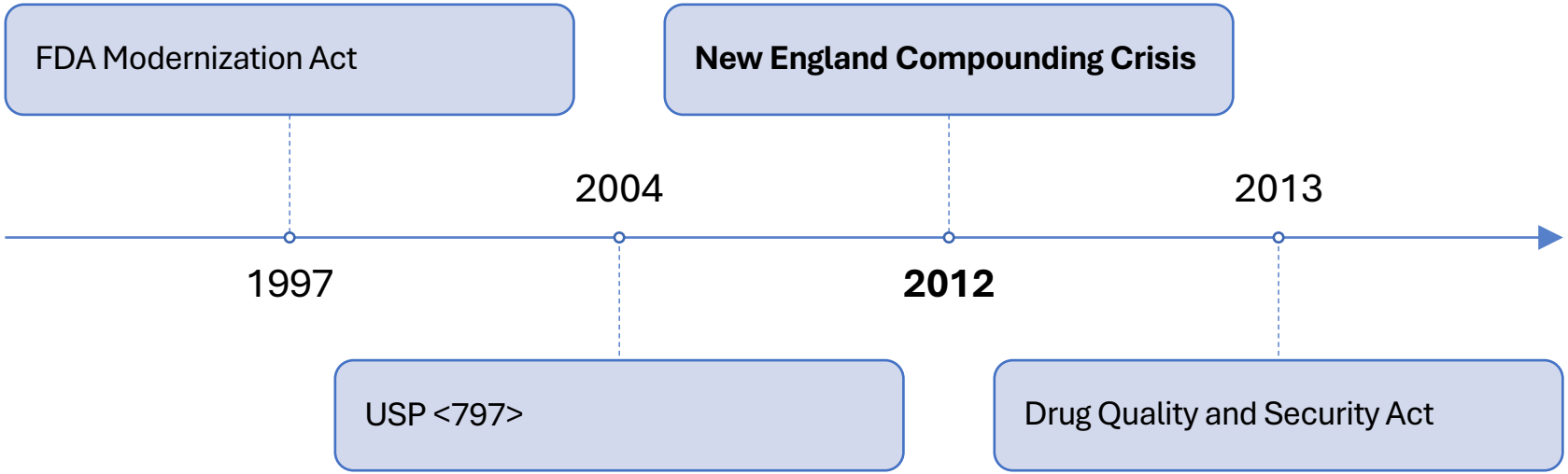

FDA: Food and Drug Administration; USP: United States Pharmacopeia

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NECC Meningitis Outbreak

September 18, 2012

- Tennessee Department of Health alerted by a clinician regarding a culture-confirmed *Aspergillus fumigatus* meningitis case
- Diagnosed 46 days after epidural steroid injection

September 27, 2012

- Tennessee DH and North Carolina DHHS identify seven cases in Tennessee and one case in North Carolina
- All cases received an injection of preservative-free methylprednisolone acetate solution (MPA) from New England Compounding Center (NECC)

Centers for Disease Control and Prevention (CDC). Multistate outbreak of fungal infection associated with injection of methylprednisolone acetate solution from a single compounding pharmacy—United States, 2012. *MMWR Morb Mortal Wkly Rep.* 2012;61(41):839-842. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6141a4.htm

NECC Meningitis Outbreak

- Fungal Meningitis
- Basilar Stroke
- Spinal osteomyelitis
- Septic arthritis of peripheral joint

NECC: New England Compounding Center

Centers for Disease Control and Prevention (CDC). Multistate outbreak of fungal infection associated with injection of methylprednisolone acetate solution from a single compounding pharmacy—United States, 2012. *MMWR Morb Mortal Wkly Rep.* 2012;61(41):839-842. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6141a4.htm

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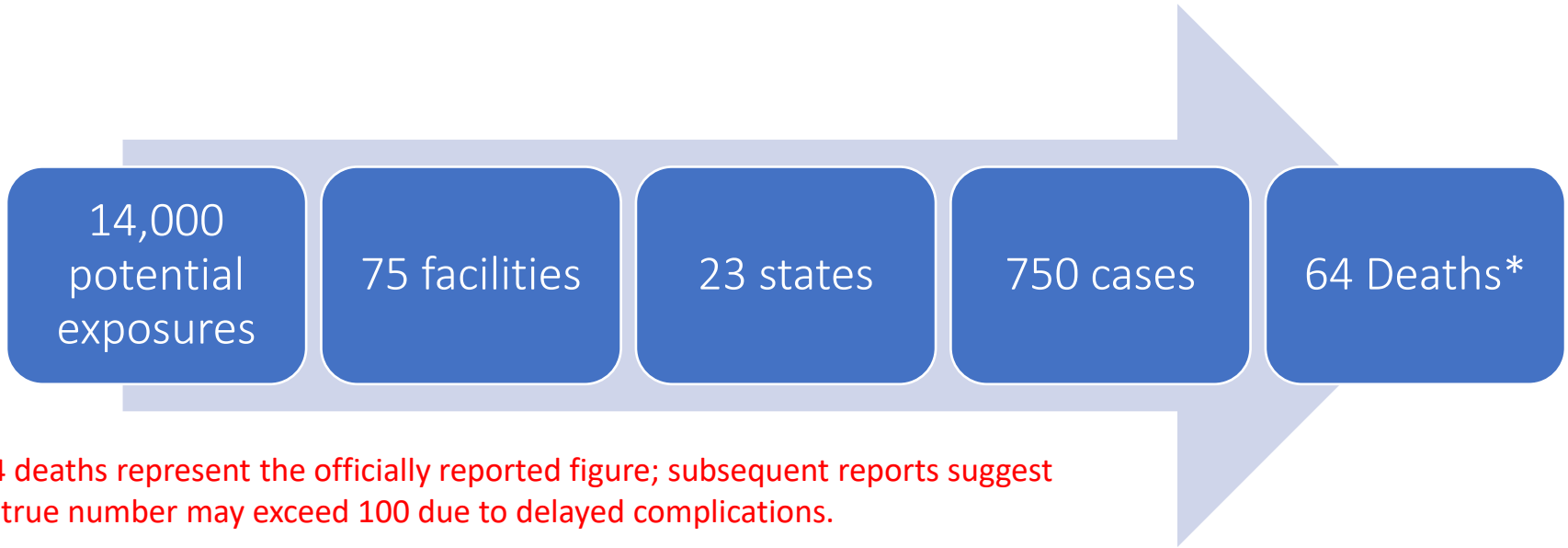
NECC Meningitis Outbreak



* 64 deaths represent the officially reported figure; subsequent reports suggest the true number may exceed 100 due to delayed complications.

NECC: New England Compounding Center

Centers for Disease Control and Prevention (CDC). Multistate outbreak of fungal infection associated with injection of methylprednisolone acetate solution from a single compounding pharmacy—United States, 2012. *MMWR Morb Mortal Wkly Rep.* 2012;61(41):839-842. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6141a4.htm

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NECC Meningitis Outbreak

Non-sterile powder for sterile compounding

- Methylprednisolone powder to compound preservative-free injectable MPA had no documented sterility

Contaminated equipment

- Steam autoclaves used to sterilize product were found to have "greenish yellow discoloration"

Sterile environment not up to standards

- FDA inspectors noted mold, bacteria, and foreign particulate matter in clean rooms where MPA was compounded

NECC: New England Compounding Center; MPA: Methylprednisolone Acetate

U.S. Senate Committee on Health, Education, Labor, and Pensions. *The New England Compounding Center and the Meningitis Outbreak of 2012: A Failure to Address Risk to the Public Health*. Published November 15, 2012. Accessed March 17, 2026. https://www.help.senate.gov/imo/media/doc/11_15_12%20HELP%20Staff%20Report%20on%20Meningitis%20Outbreak.pdf

NECC Inspection Results

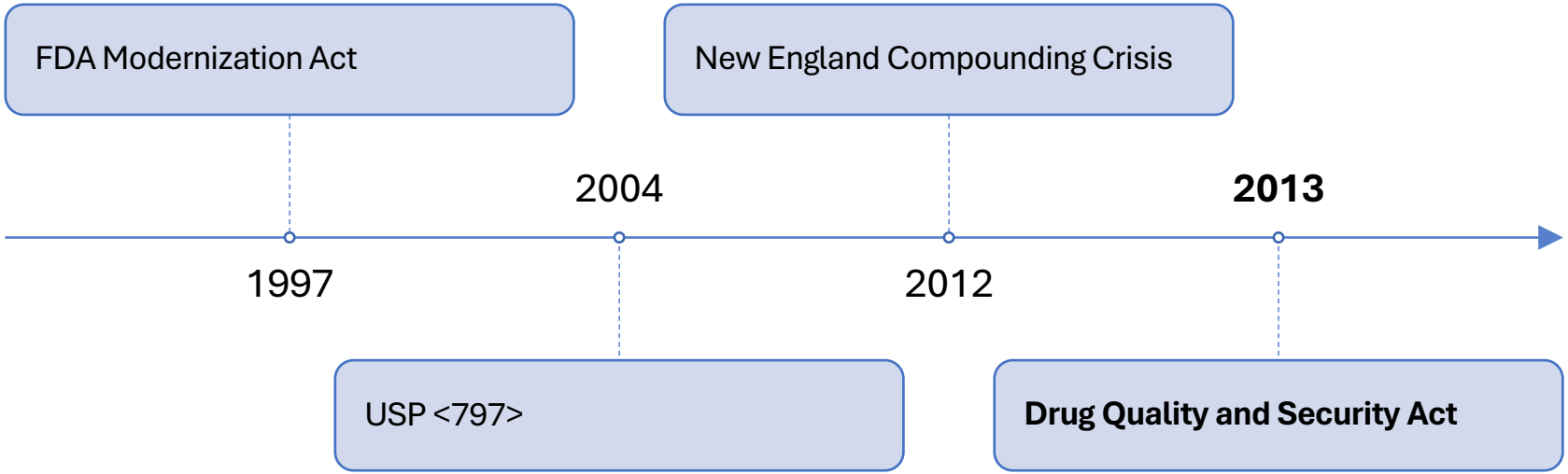
"On 10/02/2012, we observed approximately eighty-three (83) vials of methylprednisolone acetate... a sterile injectable drug... to contain ***what appeared to be greenish black foreign matter.***

"The sterility sample taken by the firm consisting of one 5ml vial of bulk formulated methylprednisolone acetate... confirmed the presence of ***viable microbial growth in 50/50 vials tested. One vial... showed fungal morphological features."***

NECC: New England Compounding Center

U.S. Senate Committee on Health, Education, Labor, and Pensions. *The New England Compounding Center and the Meningitis Outbreak of 2012: A Failure to Address Risk to the Public Health*. Published November 15, 2012. Accessed March 17, 2026. https://www.help.senate.gov/imo/media/doc/11_15_12%20HELP%20Staff%20Report%20on%20Meningitis%20Outbreak.pdf

Timeline



FDA: Food and Drug Administration; USP: United States Pharmacopeia

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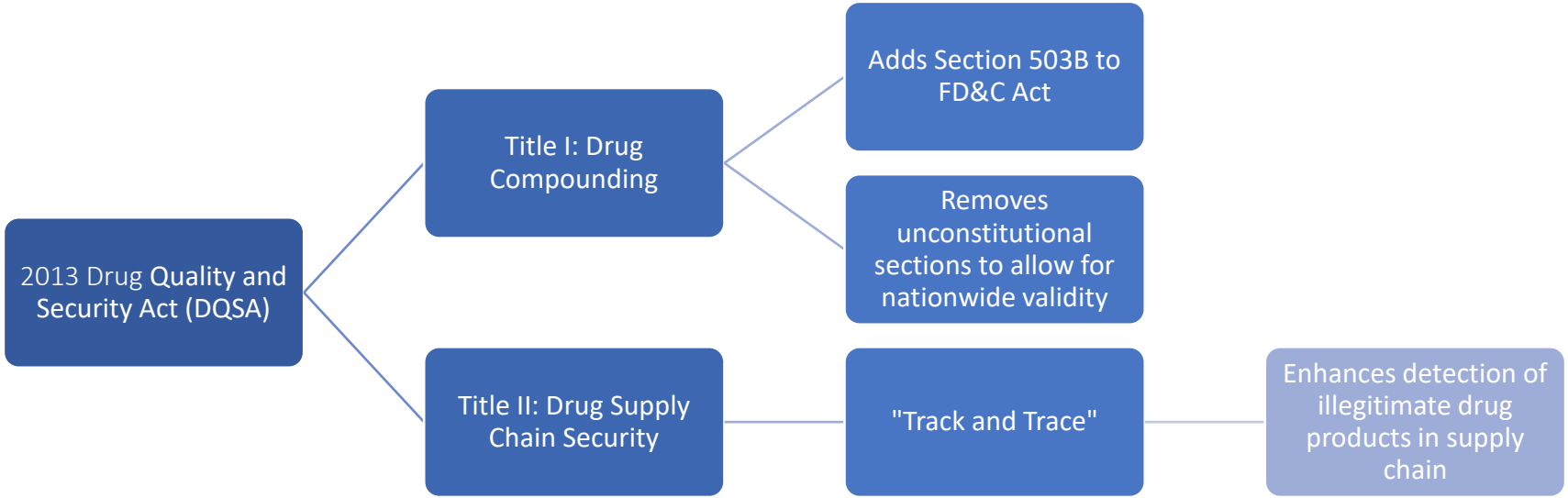
Post-NECC Regulatory Reform



NECC: New England Compounding Center; FD&C: Food, Drug, and Cosmetics

Gabay M. The drug quality and security act. Hosp Pharm. 2014;49(7):615-676. doi:10.1310/hpj4907-615

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History's Impact on Modern Standards

Compounded products shift from behind the counter to manufacturing plants

FDAMA passed to establish standards for evolving practice, including section 503A

Further regulation like USP <797> overshadowed by a lack of adaption and compounding tragedies like at the NECC

Significant regulatory reform brought about to protect the public, starting with the DQSA

FDAMA: Food and Drug Administration Modernization Act; USP: United States Pharmacopeia; NECC: New England Compounding Center; DQSA: Drug Quality and Security Act

Assessment Question #1

Which option best describes how key historical events shaped modern sterile compounding standards in the United States?

A. The FDAMA of 1997 expanded FDA authority over traditional compounding pharmacies, USP <797> introduced manufacturing-level regulations for all sterile products, and the 2012 NECC outbreak led to repeal of USP compounding chapters.

B. The FDAMA of 1997 distinguished traditional pharmacy compounding from drug manufacturing, USP <797> established standardized minimum practice requirements for sterile compounding, and the 2012 NECC meningitis outbreak prompted increased federal oversight and creation of FDA-registered 503B outsourcing facilities.

C. The FDAMA of 1997 required all compounded sterile products to comply with FDA cGMPs, USP <797> focused primarily on non-sterile compounding, and the 2012 NECC outbreak resulted only in enhanced state board oversight.

D. The FDAMA of 1997 eliminated state authority over compounding, USP <797> addressed medication shortages through bulk compounding allowances, and the 2012 NECC outbreak led to voluntary accreditation standards without federal involvement.

503A vs 503B: Roles, Requirements, and Risk Profiles

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Outline

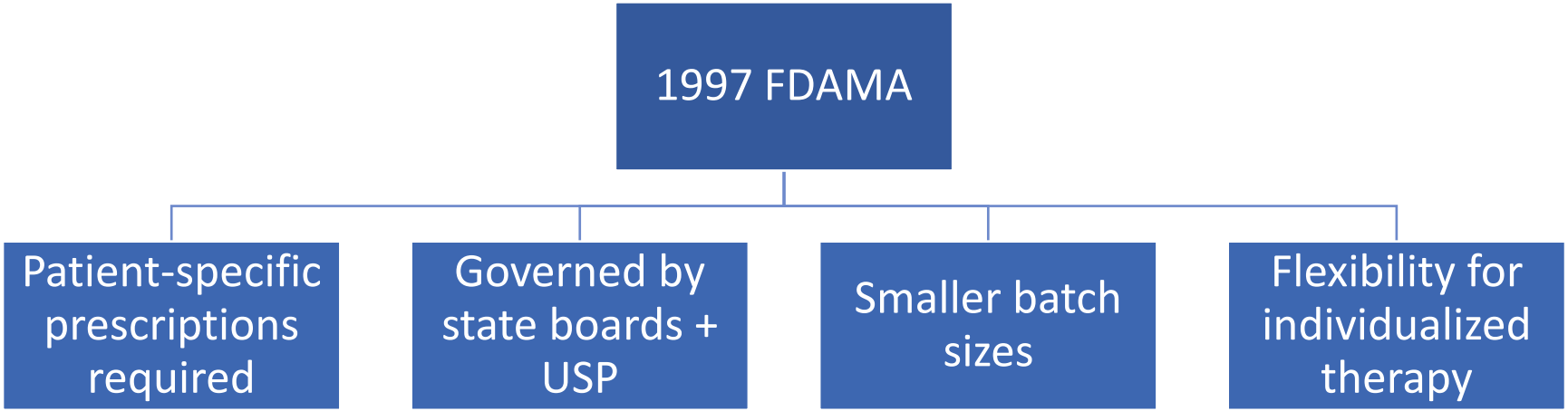
Overview of 503A Compounding Pharmacies

Overview of 503B Outsourcing Facilities

Regulatory Requirements Comparison

Risk Profile Comparison

Overview of 503A Traditional Compounding Pharmacies



FDAMA: Food and Drug Administration Modernization Act; USP: United States Pharmacopeia

U.S. Food and Drug Administration. *Section 503A of the Federal Food, Drug, and Cosmetic Act: Pharmacy Compounding*. FDA website. https://www.fda.gov/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act

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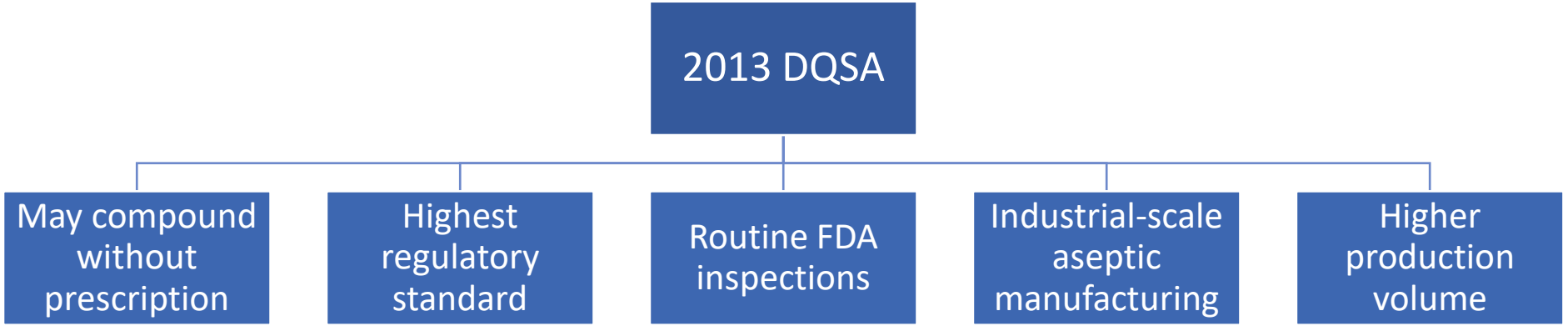
Overview of 503B Outsourcing Pharmacies



FDA: Food and Drug Administration; DQSA: Drug Quality and Security Act

FDA. *Facility definition under section 503B of the FD&C Act*. May 2018. https://www.fda.gov/media/97359/download

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Regulatory Requirements Comparison

503A	503B
Must comply with USP <795>, <797>, state board of pharmacy regulations	Must comply with state board of pharmacy regulations and good manufacturing practice (cGMP)
Required to obtain state board of pharmacy licensure	Required to register with each state board of pharmacy, Drug Enforcement Administration (DEA), FDA, and report their product list to FDA biannually
Beyond Use Dating (BUD) may be assigned based on internal or external scientific literature showing stability	Organizations required to maintain their own quality department
Environmental Monitoring must be performed every six months	Environmental monitoring must be performed, at minimum, per production shift

USP: United States Pharmacopeia; FDA: Food and Drug Administration; DQSA: Drug Quality and Security Act

The FDA Group. 503A vs. 503B: a quick guide to compounding pharmacy designations and regulations. *The FDA Group Blog*. Published November 16, 2021. Accessed March 19, 2026. https://www.thefdagroup.com/blog/503a-vs-503b-compounding-pharmacies

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Risk Profile Comparison

503A Benefits	503A Considerations
Patient-specificity	Limited supply
No cost markup for vendor usage	Staffing and training
Closer integration with patient-specific care	Cost for compliance

Pamphile G, Yaniv A, Burton S, Boreen C, Eggers G. Considerations for developing a health-system 503B outsourcing strategy. *Am J Health Syst Pharm*. 2025;82(6):350-358. doi:10.1093/ajhp/zxae271

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Risk Profile Comparison

503B Benefits	503B Considerations
Accessibility	Limited specificity
Less reliance on in-house staff	Variance across vendors
Reduced special storage conditions and Beyond Use Dating (BUD) limitations	Cost

Pamphile G, Yaniv A, Burton S, Boreen C, Eggers G. Considerations for developing a health-system 503B outsourcing strategy. *Am J Health Syst Pharm*. 2025;82(6):350-358. doi:10.1093/ajhp/zxae271

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Assessment Question #2

Which statement best distinguishes the roles, regulatory requirements, and relative risk profiles of 503A traditional compounding pharmacies versus 503B outsourcing facilities?

A. 503A pharmacies compound sterile medications in bulk under FDA cGMP standards for nationwide distribution, whereas 503B facilities compound only patient-specific prescriptions under state board oversight.

B. 503A pharmacies compound patient-specific medications under state board of pharmacy oversight and USP standards, while 503B outsourcing facilities compound sterile drugs in bulk without patient-specific prescriptions under FDA registration and cGMP requirements, reflecting distinct risk considerations managed though federal oversight.

C. 503A pharmacies and 503B outsourcing facilities are regulated identically under USP <797> and state boards of pharmacy, with no difference in FDA involvement or clinical risk.

D. 503B outsourcing facilities are exempt from USP standards but subject only to voluntary FDA inspections, whereas 503A pharmacies are required to meet cGMP standards due to higher contamination risk.

Regulatory Framework

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Regulatory Ecosystem

FDA: Food and Drug Administration; USP: United States Pharmacopeia

FDA Role

Inspections of state-licensed pharmacies that are not registered as outsourcing facilities

- May intervene in 503A pharmacies if unsafe practices occur

Inspections of registered outsourcing facilities under 503B

Enforcement of Current Good Manufacturing Practice (cGMP)

Authority to issue warning letters and demand drug product recall

FDA: Food and Drug Administration

Sheikh HZ. *Drug Compounding: FDA Authority and Possible Issues for Congress*. Congressional Research Service; January 5, 2018. Report No. R45069. https://www.congress.gov/crs-product/R45069. Accessed March 20, 2026.

State Board Role

- Enforcement of licensure requirements for 503A
- Adoption and enforcement of USP chapters
- Inspections and complaint investigations

USP: United States Pharmacopeia

NC Board of Pharmacy. 21 NCAC 46 .2801: Sterile Compounding. Accessed Apr 25, 2026.

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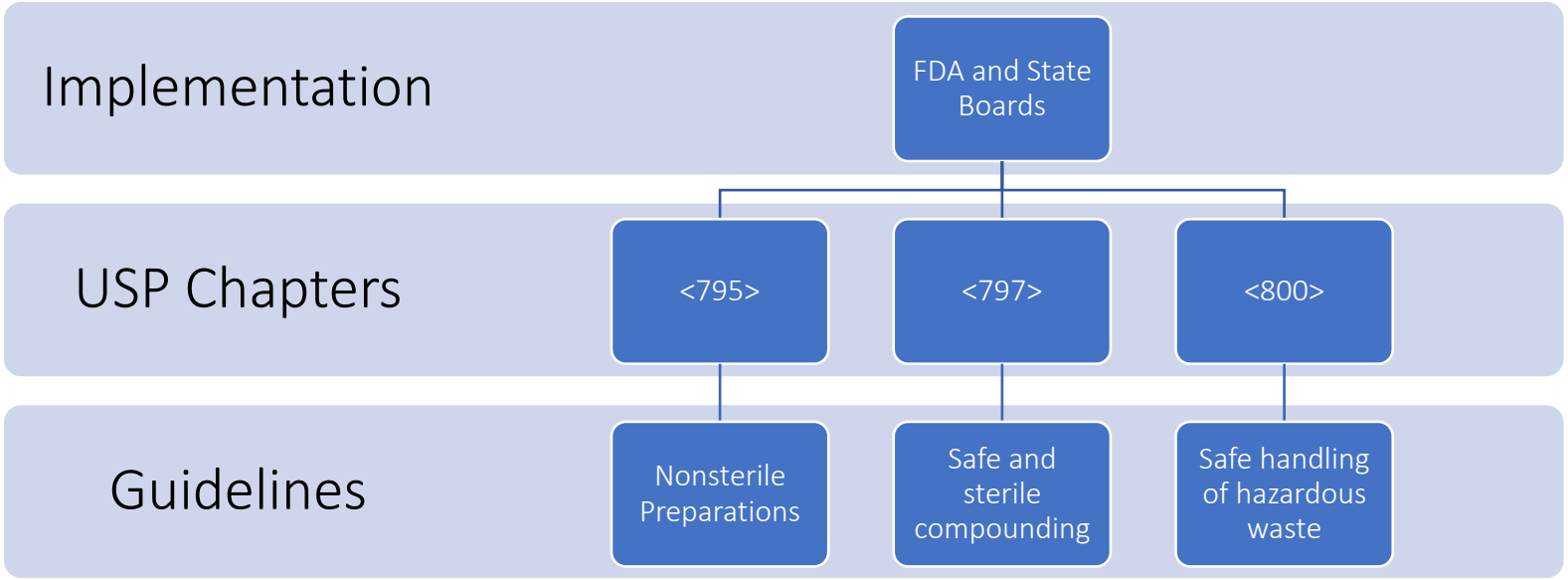
USP Role



NOT an enforcement body
Sets standards that may be enforced by state boards and recognized by the FDA

FDA: Food and Drug Administration, USP: United States Pharmacopeia

United States Pharmacopeia. *USP Compounding Standards: General Chapters <795>, <797>, and <800>*. USP website. https://www.usp.org/compounding

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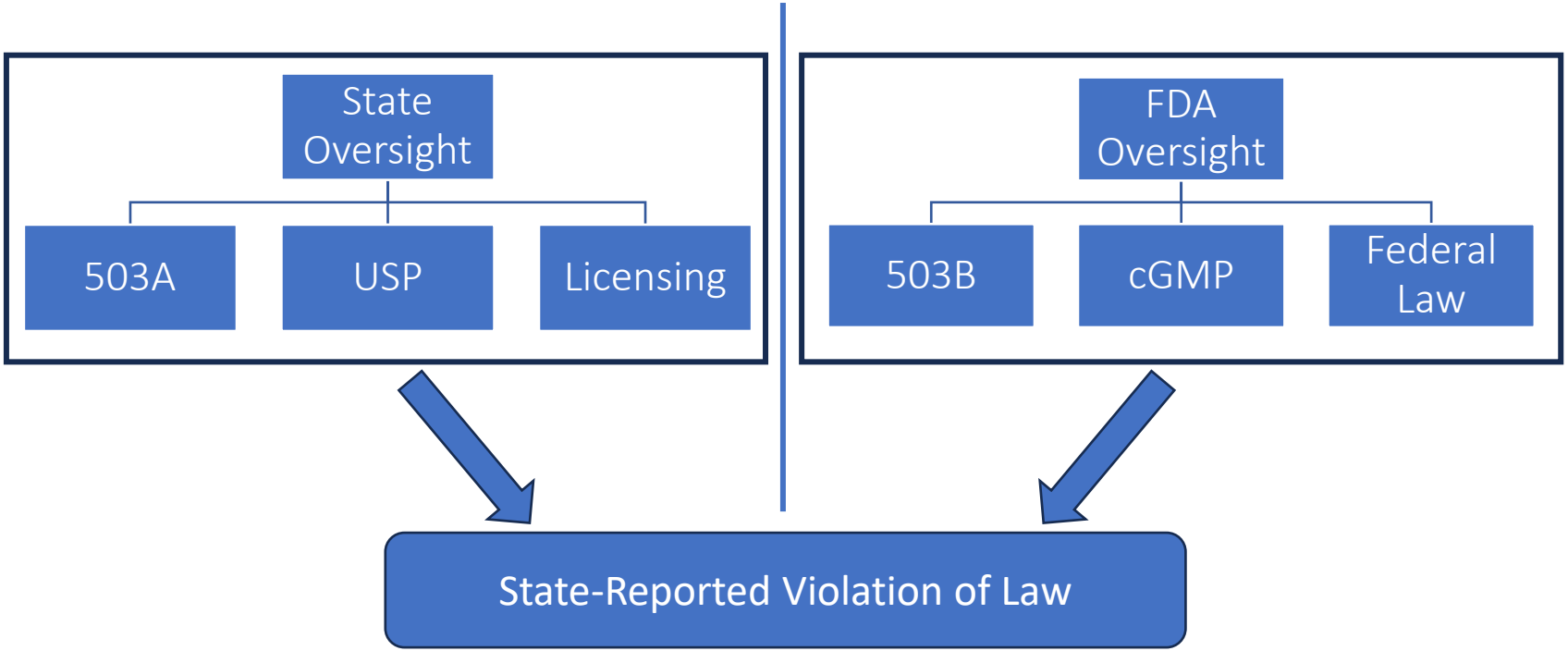
Collaboration



USP: United States Pharmacopeia; FDA: Food and Drug Administration; DQSA: Drug Quality and Security Act; cGMP: Current Good Manufacturing Practice

US Food and Drug Administration. *Compounding Information for States*. Updated December 3, 2024. https://www.fda.gov/drugs/human-drug-compounding/compounding-information-states. Accessed March 20, 2026.

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Assessment Question #3

Which option best explains how federal, state, and United States Pharmacopeia (USP) regulatory frameworks work together to govern compounding practice and reduce the risk of patient harm?

A. Federal law exclusively regulates all compounding activities through FDA enforcement, while state boards and USP standards serve only advisory roles without enforcement authority.

B. State boards of pharmacy establish binding compounding standards, federal law governs only manufactured drugs, and USP chapters apply solely to FDA-registered outsourcing facilities.

C. Federal law defines the legal categories and oversight authority for compounding, state boards regulate licensing and daily practice enforcement, and USP standards establish minimum practice requirements enforced through state adoption and accreditation bodies.

D. USP chapters replace state and federal regulations by providing uniform national requirements that are independently enforced by the FDA for all compounded medications.

Group Purchasing Organization Influence

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What is a Group Purchasing Organization (GPO)?

An entity that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself

eCFR. 42 CFR §403.902. Definitions of applicable group purchasing organizations. Accessed March 23, 2026.
U.S. Government Accountability Office. *Group Purchasing Organizations: Federal Oversight and Self-Regulation.* GAO-12-399R; 2012.

GPOs and 503B Outsourcing Facilities

Facilitate contracting and pricing for 503B-compounded products

Perform quality assessments and background checks of 503B pharmacies for clients

Update 503B supplier quality reports from both GPO standards and FDA standards

GPO: Group Purchasing Organization; FDA: Food and Drug Administration

U.S. Government Accountability Office. *Group Purchasing Organizations: Federal Oversight and Self-Regulation.* GAO-12-399R; 2012.

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GPO Influence on Hospital Decision-Making

Transition toolkits and projected net savings aid product switches and encourage uptake of biosimilars as opposed to brand products

Select product use in hospitals associated with GPO contracting

GPO-negotiated price adjustments, migration to alternative products, and real time data tracking impact drug product availability during shortages

GPO: Group Purchasing Organization

Emma Boswell Dean, Reekarl Pierre, Samuel Carter, Amelia M Bond, Role of supply chain intermediaries in steering hospital product choice: Group Purchasing Organizations and biosimilars, Health Affairs Scholar, Volume 2, Issue 6, June2024,qxae067, https://doi.org/10.1093/haschl/qxae067

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Assessment Question #4

Which statement best describes how Group Purchasing Organizations (GPOs) influence health-system purchasing decisions and shape quality expectations for 503B outsourcing facilities?

A. GPOs serve solely as pricing intermediaries and have no role in evaluating outsourcing facility quality or influencing health-system expectations beyond contract pricing.

B. GPOs directly manufacture compounded products and assume regulatory responsibility for 503B outsourcing facilities used by member health systems.

C. GPOs negotiate purchasing contracts and preferred vendor relationships that can influence health-system product selection and establish quality expectations for 503B outsourcing facilities.

D. GPOs replace FDA oversight by certifying 503B outsourcing facilities, allowing member hospitals to rely exclusively on GPO approval without further evaluation.

Conclusion and Discussion

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Key Takeaways

USP, the FDAMA, and NECC significantly impacted the modern compounding landscape

503A and 503B pharmacies are distinct from each other and come with their own risks and benefits

The FDA, State Boards of Pharmacy, and USP are a regulatory ecosystem focused on safe compounding practice

USP: United States Pharmacopeia; FDAMA: Food and Drug Administration Modernization Act; NECC: New England Compounding Center; FDA: Food and Drug Administration; USP: United States Pharmacopeia

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Questions?

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