

**Pharmacy Rules/Regulations by State for Compliance with USP 797  
Medication Compounding  
2/28/2017**

<b>State</b>	<b>Agency</b>	<b>Specifically Requires USP 797</b>	<b>State Specific Language</b>	<b>Citation</b>	<b>Notes</b>
Alabama	State Board of Pharmacy	No	Yes	<a href="#">Alabama Pharmacy Rules</a>	No direct mention of USP or 797.
Alaska	State Board of Pharmacy	No	Yes	<a href="#">AK Pharmacy Rules - 2016</a>	Extensive listing of rules & requirements for compounding areas, but no direct mention of federal laws/regulations.
Arizona	State Board of Pharmacy	No	No	<a href="#">Arizona Pharmacy Rules</a>	No mention of Federal laws/regulations
Arkansas	State Board of Pharmacy	No	Yes	<a href="#">Arkansas Pharmacy Regulations</a>	
California	State Board of Pharmacy	No	Yes	<a href="#">CA Sterile Compounding</a>	
Colorado	State Board of Pharmacy	Yes	Yes	<a href="#">Colorado Pharmacy Regulations</a>	USP/NF is cited
Connecticut	State Board of Pharmacy	Yes	Yes	<a href="#">Connecticut pharmacy rules</a>	A sterile compounding pharmacy must comply with State Regulations & USP797
Delaware	State Board of Pharmacy	No	Yes	<a href="#">Delaware Pharmacy Laws</a>	USP referred to in specific instances
District of Columbia	State Board of Pharmacy	Yes	No	<a href="#">DC Pharmacy Rules</a>	Requires areas for compounding to follow USP/NF

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Florida	State Board of Pharmacy	Yes	Yes	<a href="#">Florida Compounding Rules</a>	Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.
Georgia	State Board of Pharmacy	Yes	Yes	<a href="#">Georgian Pharmacy Rules</a>	The board shall establish rules and regulations governing the compounding and distribution of drug products by pharmacists, practitioners, and pharmacies licensed or registered by this state. Such rules and regulations shall include provisions ensuring compliance with USP-NF standards.
Hawaii	State Board of Pharmacy	No	No	<a href="#">Pharmacy Regulations</a>	All compounding must be in compliance with FFDCA Section 503A and any regulations promulgated by FDA concerning compounding

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Idaho	State Board of Pharmacy	No	Yes	<a href="#">Idaho Pharmacy Regulations</a>	In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product
Illinois	State Board of Pharmacy	No	Yes	<a href="#">Illinois Sterile Compounding Preparation Standards</a>	Certification of LAF.
Indiana	State Board of Pharmacy	Yes	Yes	<a href="#">Indiana Pharmacy Rules</a>	Pharmacy adheres to good compounding practices & the current USP/NF chapter on sterile preparation.
Iowa	State Board of Pharmacy	Yes	Yes	<a href="#">Iowa Pharmacy Sterile Compounding</a>	Requires USP 797
Kansas	State Board of Pharmacy	No	Yes	<a href="#">Kansas Pharmacy Regulations - 2015</a>	Updated regs.
Kentucky	State Board of Pharmacy	Yes	Yes	<a href="#">Kentucky Compounding FAQ's</a>	Lists what an inspector will be looking at.

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Louisiana	State Board of Pharmacy	Yes	Yes	<a href="#">LA Title 46, Part LIII, Chapter 25, Subchapter C</a>	Pharmacies must comply with federal regulations regarding compounding but do not cite USP 797 though requirements closely mirror the chapter.
Maine	State Board of Pharmacy	Yes	No	<a href="#">Maine Pharmacy Rules</a>	Codified - Violation of Federal Laws or regulations constitutes unprofessional conduct.
Maryland	State Board of Pharmacy	Yes	Yes	<a href="#">Maryland Compounding Pharmacy inspection</a>	(COMAR 10.34.19.17): Pharmacies will be inspected by the Board at least annually. During the inspection, the pharmacy shall provide quality assurance testing reports, documentation of reporting adverse events, microbial testing of a sampling of the sterile compounded products of the pharmacy, if applicable under USP 797, and any other information requested to ensure compliance with USP 797 standards.
Massachusetts	State Board of Pharmacy	Yes	Yes	<a href="#">Massachusetts Pharmacy rules</a>	
Michigan	State Board of Pharmacy	Yes	Yes	<a href="#">Michigan Pharmacy Rules</a>	Accreditation/Certification Required. TJC recognized
Minnesota	State Board of Pharmacy	Yes	No	<a href="#">Minnesota Compounding Rules</a>	Must follow USP 795, 797

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Mississippi	State Board of Pharmacy	Yes	Yes	<a href="#">Mississippi Compounding Regulations</a>	Every compounding facility under the jurisdiction of the Mississippi Board of Pharmacy shall comply with USP 797 and applicable portions of USP 795.
Missouri	State Board of Pharmacy	No	Yes	<a href="#">Missouri Compounding</a>	Compliance with USP rules
Montana	State Board of Pharmacy	Yes	Yes	<a href="#">Montana 24.174.841 Sterile Products</a>	The board expects pharmacies/pharmacists engaged in compounding to have policies and procedures to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of United States Pharmacopeia (USP) Chapter 795 "Compounding Nonsterile Preparations" and USP Chapter 797 "Pharmaceutical Compounding-Sterile Preparations."
Nebraska	State Board of Pharmacy	Yes	No	<a href="#">Nebraska Pharmacy Regulations 2015</a>	Any person authorized to compound shall compound in compliance with the standards of chapters 795 and 797 of The United States Pharmacopeia and The National Formulary, as such chapters existed on January 1, 2015
Nevada	State Board of Pharmacy	No	Yes	<a href="#">Nevada NAC 639.661 Sterile &amp; Compounding</a>	Refers to USP 797 in definitions.
New Hampshire	State Board of Pharmacy	Yes	Yes	<a href="#">NH Administrative rules</a>	Board requires all copounders to comply with current USP 795 & 797

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New Jersey	State Board of Pharmacy	Yes	Yes	<a href="#">New Jersey Board of Pharmacy rules</a>	
New Mexico	State Board of Pharmacy	Yes	No	<a href="#">New Mexico Compounding Regulations</a>	Establish standards to ensure that the citizens of New Mexico receive properly compounded contaminant-free sterile preparations properly compounded in accordance with all applicable USP/NF General Chapters numbered below 1000.
New York	State Board of Pharmacy	No	Yes	<a href="#">New York Pharmacy</a>	Definition of outsourcing facility includes compliance with all applicable federal, state laws, including Federal Food Drug & Cosmetic Act.

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North Carolina	State Board of Pharmacy	Yes	Yes	<a href="#">North Carolina Compounding</a>	The preparation, labeling, and dispensing of sterile compounded preparations shall comply with standards established by United States Pharmacopeia chapter <797>, including all United States Pharmacopeia chapters and standards incorporated into chapter <797> by reference and including all subsequent amendments and editions of the same, governing both the sterile compounded products and the physical and environmental conditions under which sterile compounded products are prepared, labeled, and dispensed.
North Dakota	State Board of Pharmacy	No	Yes	<a href="#">North Dakota Regulations</a>	Updated Regulations - 2015 - names USP 795, 797 in packaging, etc.
Ohio	State Board of Pharmacy	Yes	Yes	<a href="#">Ohio Pharmacy rules for Compounding</a>	Requires compliance with USP 795, 797
Oklahoma	State Board of Pharmacy	Yes	Yes	<a href="#">Oklahoma Pharmacy Rules - 2016</a>	Pharmacies that engage in Non-sterile and sterile compounding are responsible for complying with all aspects of USP compounding Standards and these rules

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Oregon	State Board of Pharmacy	No	Yes	<a href="#">Division 45 Sterile &amp; Non-Sterile Compoundin</a>	(3) Whilst the Board does not insist on rigid application of, or adherence to, all the guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP 795) and 797 (USP 797), it expects pharmacists engaging in compounding to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of USP 795 and USP 797.
Pennsylvania	State Board of Pharmacy	No	No	<a href="#">Pennsylvania Pharmacy Regulations</a>	The pharmacist is responsible for compounding and dispensing nonproprietary drugs consistent with the Federal Controlled Substances Act (21 U.S.C.A. § § 801—904), The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-101—780-144) and the regulations promulgated under these acts.
Rhode Island	State Board of Pharmacy	No	Yes	<a href="#">Rhode Island Pharmacy Regulations</a>	pharmacies must comply with federal regulations concerning commounding but do not cite USP 797, though regulations closely mirror the chapter.
South Carolina	State Board of Pharmacy	No	Yes	<a href="#">South Carolina Pharmacy Regulations</a>	USP referred to in specific instances



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South Dakota	State Board of Pharmacy	Yes	Yes	<a href="#">South Dakota Pharmacy Regulations</a>	The pharmacist shall select the sterilization method that complies with the standards identified in United States Pharmacopoeia, Chapter 797
Tennessee	State Board of Pharmacy	Yes	No	<a href="#">Tennessee Sterile Product Preparation</a>	Hospitals do not have to submit lists of high risk sterile products to the Board of Pharmacy.
Texas	State Board of Pharmacy	Yes	Yes	<a href="#">Texas Sterile Compounding Regulations</a>	Policies established by the pharmacy should consider provisions of USP 797.
Utah	State Board of Pharmacy	Yes	No	<a href="#">Utah R156.17b - Pharmacy Practice Rule</a>	Lists monetary penalties for failure to comply with USP 795, 797, etc.
Vermont	State Board of Pharmacy	Yes	No	<a href="#">Vermont Pharmacy Rules</a>	Pharmacies shall file with the Board proof of USP 797 compliance or an affidavit
Virginia	State Board of Pharmacy	Yes	Yes	<a href="#">Virginia Pharmacy Rules</a>	The compounding of both sterile and non-sterile drug products shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.
Washington	State Board of Pharmacy	Yes	Yes	<a href="#">Washington State Pharmacy Regulations</a>	USP is cited, but specific regulations by state are the main focus

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West Virginia	State Board of Pharmacy	Yes	No	<a href="#">West Virginia Pharmacy Rules - 2016</a>	16.1.2 - The compounding and preparation of sterile prescription orders shall be accomplished in a pharmacy environment subject to West Virginia Code and the Rules of this Board and all Federal Laws and Regulations.
Wisconsin	State Board of Pharmacy	No	Yes	<a href="#">Wisconsin Sterile Pharmaceuticals</a>	Currently a bill pending on changes.
Wyoming	State Board of Pharmacy	Yes	Yes	<a href="#">Wyoming Pharmacy Regulations</a>	USP & 797 cited.