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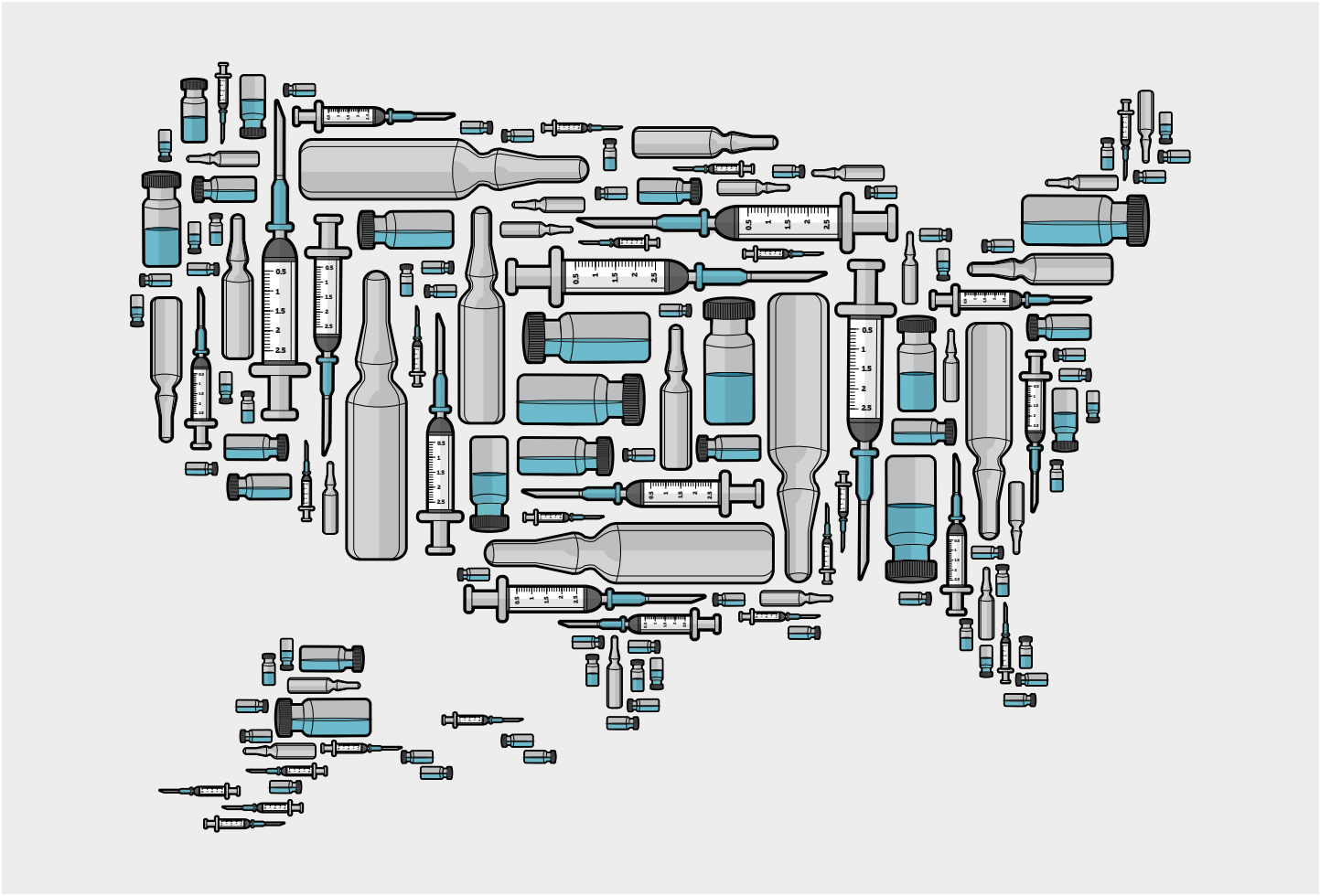

National Assessment of State Oversight of Sterile Drug Compounding

Contents

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Overview

Drug compounding is a long-standing practice wherein a pharmacist "combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[1] While the Food and Drug Administration (FDA) has the authority to enforce applicable federal laws over pharmacies, states remain the principal regulators of pharmacy practice, including pharmacy compounding activity. Relevant laws and regulations are updated at the discretion of each state and jurisdiction. This study, commissioned by The Pew Charitable Trusts and conducted by researchers from the University of Illinois at Chicago, assesses the national landscape of state policies on compounding sterile drugs—such as medicines that are injected or infused into the body.

Between 2012 and 2013,[2] an outbreak involving hundreds of patient illnesses and dozens of deaths linked to tainted compounded injections drove state and federal officials to re-examine oversight of sterile drug compounding, particularly when it exceeds traditional practice in scale and risk.[3] However, until now there has been no single central repository for information describing policy and practice across states.

This study collected data from publicly available websites and from a questionnaire on state oversight that was completed by representatives from 43 of the 51 state boards of pharmacy (50 states plus the District of Columbia) in spring and summer 2015.

The study found that states vary significantly in their policies for sterile compounding. While some policy areas showed greater alignment across states, such as the application of recognized quality standards, others differed notably, including disparate systems to oversee out-of-state compounding pharmacies. Some states have updated their standards in the wake of the 2012-13 outbreak and to conform to new federal law. The Drug Quality and Security Act of 2013, among other reforms, added a new category of compounders called outsourcing facilities that can compound supplies of drugs without obtaining prescriptions. However, the state policy landscape remains fluid: New policies are not uniform. Some states are still working to advance change, and others have yet to act. This remains a transitional time for compounding drug policy in many states, which should be weighed in the interpretation of the findings of this study.

Among the notable findings and themes of this research:

- About half of the respondents (representing 21 of 43 states, or 49 percent) reported that they required sterile compounding to fully conform to the widely recognized quality standards set by the U.S. Pharmacopeial Convention (USP) in its General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. Thirteen respondents (30 percent) reported that their states mandated at least some part of USP Chapter <797>. Just over half of respondents (representing 24 of 43 states, or 56 percent) reported that their states tracked the number of pharmacies that perform sterile compounding.
- The majority of respondents (representing 26 of 43 states, or 60 percent) said their states did not require pharmacies to report serious adverse events and reactions related to sterile compounding.
- Twenty-eight respondents (65 percent) said their states allowed pharmacies to compound without patient-specific prescriptions. Most of these states (21 of the 43 respondents, or 49 percent) had specific limits on this practice, but with varying degrees of restriction—such as a narrow allowance for emergency veterinary use only, compared with a broader allowance for any drug that is not commercially available. State policies permitting compounding without a prescription for human use conflict with recently clarified federal law.
- Nine respondents (21 percent) said their state required pharmacies to have a separate license or registration to perform sterile compounding.

- Twelve respondents (28 percent) reported that when inspecting sterile compounding pharmacies in the state, they prioritized inspections for pharmacies where high-risk sterile compounding occurs.
- Sterile compounding sometimes takes place in physician offices or clinics, which are normally regulated by a state board of medicine. When asked, only one state reported that their state had a mechanism to track nonpharmacy locations where sterile compounding occurs, and only seven respondents (17 percent) reported that physician offices were held to the same compounding quality standards as pharmacies.

The variations in sterile compounding policy across states suggest that an opportunity exists to review state oversight systems for potential weaknesses, and consequently to advance regulatory practices to better protect patients. This study is intended to provide helpful information to policymakers and stakeholders in pursuit of that goal.

Background

Traditional pharmacy compounding involves the specialized preparation of a drug tailored to the needs of an individual patient. Compounding is distinct from commercial drug manufacturing, in which standardized drug products are approved by FDA and produced on a large scale. Pharmacists may prepare customized drugs in a number of ways, such as by combining or diluting existing drugs, or creating a drug product from bulk active chemicals. Compounding is considered a fundamental skill for pharmacists,[4] and like other licensed health care professions, pharmacy practice is regulated by the state. State pharmacy law is typically enforced by a state board of pharmacy.[5]

Meaningful quality standards are important for all forms of compounded drugs, including pills, syrups, and topical creams. But rigorous standards are critical for drugs that are injected or infused into the body, and therefore must be sterile to minimize the risk of infection. The preparation of sterile injectables and IV infusion products by a pharmacist or other practitioner emerged as a practice in the early 20th century primarily in the hospital setting, where those products were used.[6] However, as the complexity of sterile preparations increased and demand grew, outsourced sterile compounding became a commercial enterprise.[7]

Pharmaceutical manufacturers were among the first companies to enter the outsourced compounding services market in the 1980s and 1990s, establishing pharmacies to prepare sterile medications for hospitals. Other compounding pharmacies also began to supply doctors' offices and clinics.[8] Some of these outsourcers were providing supplies of compounded drugs without patient prescriptions, which created an oversight and enforcement challenge for FDA.[9] There was no explicit federal regulatory framework for compounding pharmacies, and the agency became increasingly concerned about appropriate oversight of businesses that looked more like manufacturers than traditional compounders.[10]

In 1997, Congress introduced new federal policy on compounding as part of the Food and Drug Administration Modernization Act, adding Section 503A to the Federal Food, Drug, and Cosmetic Act (FDCA).[11] Under this section, compounders must obtain a prescription for an individually identified patient in order to receive exemptions from several FDA requirements, including new drug approval processes, labeling with adequate directions for use, and adherence to FDA Current Good Manufacturing Practices (CGMPs). Among other provisions to distinguish compounding from commercial manufacturing, Section 503A prohibited compounders from "advertising, promoting, or soliciting prescriptions."[12]

However, soon after the passage of Section 503A, several pharmacies challenged the restrictions on advertising in court, claiming a free-speech violation.[13] This led to a series of conflicting rulings resulting in invalidation of the

law in some parts of the country. In 2001, the U.S. Court of Appeals for the 9th Circuit upheld a lower court ruling that the advertising provision was unconstitutional and further said that the provision could not be separated from the rest of the section, rendering it inoperable.[14] In 2002, the Supreme Court affirmed this ruling and did not address whether the advertising provisions could be separated from the rest of the section, leaving the 9th Circuit's decision in place.[15]

In response to the invalidation of Section 503A, FDA reissued a Compliance Policy Guide.[16] The guide stated that FDA would generally defer to state boards of pharmacy to oversee traditional pharmacy compounding but would enforce federal drug law over entities that crossed the line into drug manufacturing based on certain criteria, such as offering compounded drugs for wholesale.[17] Later, in 2008, the U.S. Court of Appeals for the 5th Circuit ruled that the advertising restrictions were invalid but that the rest of Section 503A should remain in effect.[18] This created additional ambiguity about the enforceability of federal law in different jurisdictions.

Compounding practice across the U.S. became complex and diverse as states pursued varied regulatory approaches.[19] FDA continued to harbor concerns regarding the quality and safety of compounded products. In 2001, the agency tested sterile preparations sold online by 12 compounding pharmacies for quality, purity, and potency.[20] They found that 34 percent of the 29 samples failed quality and safety tests, most frequently for potency. In contrast, the failure rate cited by FDA among commercial manufacturers was less than 2 percent.[21] Between 1990 and 2005, the agency discovered more than 240 serious illnesses and deaths associated with compounded products.[22] It also stated that this estimate might be an underrepresentation because pharmacists and physicians were not required to report adverse events to FDA.[23]

Between 2012 and 2013, 753 patients were sickened—64 of whom died—during an outbreak of fungal meningitis and other infections attributed to tainted steroid injections made by a large compounding pharmacy center in Massachusetts.[24] A subsequent examination identified numerous other incidents involving over 300 adverse events, including 26 deaths since 2001.[25] In the aftermath of the 2012-13 outbreak policymakers, including the U.S. Congress, and other groups moved to examine underlying issues around drug compounding and identify solutions.[26] Since the outbreak, FDA has conducted over 200 inspections of compounding facilities and issued approximately 60 warning letters.[27]

Congressional investigations identified several urgent issues related to (1) the need to distinguish between traditional compounding activities and those that resemble manufacturing; (2) reconsideration of appropriate oversight and quality standards for nontraditional compounding; and (3) the need for sufficient enforcement of standards by state and federal officials. Over the course of 2013, Congress developed legislation intended to address these concerns. On Nov. 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law by President Barack Obama.[28] The law's first major component was the Compounding Quality Act (CQA).

The CQA clarified the distinction between traditional compounding pharmacies, which prepare drugs pursuant to individual prescriptions to meet specific patient needs and are regulated under Section 503A of the FDCA, and companies selling supplies of compounded drugs without patient-specific prescriptions. These latter are now regulated as part of a new "outsourcing facility" sector under Section 503B and are required to meet stricter quality controls. FDA implementation of the law is active and ongoing. Following passage of the DQSA, Pew commissioned a report, "Quality Standards for Large-Scale Sterile Compounding Facilities,"[29] to review the differences between traditional compounding pharmacies and operations that supply compounded drugs without prescriptions on a larger scale. The report describes the stringent standards that are critical to ensuring drug quality and patient safety in facilities that make standing supplies of drugs with the potential to reach many thousands of patients.

The Compounding Quality Act and New Outsourcing Facility Sector

The Compounding Quality Act (CQA) created a new type of compounder known as an "outsourcing facility" (OF) under Section 503B of the FDCA.[30] In exchange for submitting to more stringent FDA oversight and adherence to formal CGMPs, OFs are permitted to sell unlimited quantities of compounded drugs without a prescription anywhere in the U.S. and are exempt from the drug approvals process.[31] OFs are subject to several requirements and limitations: They may not sell drugs through wholesalers[32] and are not allowed to compound copies of drug products already on the market,[33] including a drug made using an active ingredient that is part of an approved medicine, unless the product is on the drug shortage list.[34] Further, while OFs may take an FDA-approved drug out of its packaging and alter it when required for patient care, they may not compound using a bulk chemical active ingredient unless it is on an FDA list identifying bulk drug substances for which there is a clinical need.[35] Compounding at an OF must be done under the supervision of a licensed pharmacist,[36] and OFs must also follow new labeling requirements (including the drug name, dosage form, and strength, and a statement that the drug is compounded),[37] report any adverse drug events to FDA,[38] be inspected by FDA based on a set of risk factors,[39] and pay FDA an annual fee.[40] As of Oct. 29, 2015, 55 compounding entities had registered as outsourcing facilities.[41]

The CQA also reaffirmed the applicability of Section 503A of the FDCA by removing the contested advertising provisions. Section 503A stipulates that traditional pharmacies—unlike OFs under 503B—must compound based on an individual patient prescription, or in limited quantities (not defined) before the receipt of a prescription, in order to receive exemptions from CGMP, drug approval, and labeling requirements.[42] Section 503A also directs FDA to develop a memorandum of understanding with state regulatory agencies to address the inordinate interstate distribution of compounded drugs.

The CQA helped clarify that FDA has primary oversight of all commercial pharmaceutical manufacturing as well as the new outsourcing facility compounding sector, while states are primarily responsible for regulating the practice of pharmacy, including compounding by traditional pharmacies. FDA also retains authority to enforce applicable federal law over pharmacies.

Each state has laws and regulations setting pharmacy standards and requirements, and addressing issues related to the authority pharmacies are granted to compound products for patients. But until now, there has been no single public repository for information describing state policies.

This report aims to describe state oversight of sterile compounding practices using publicly available data, and information solicited from state regulatory bodies. The authors worked with each state to characterize current efforts to oversee sterile compounding, as well as anticipated policy changes in certain areas in response to the 2013 federal law.

Methodology

The research team convened an expert advisory panel (EAP) to develop a questionnaire aimed at eliciting current state practices related to the oversight of sterile compounding practices; this panel was also consulted on how to best approach each state and implement data collection. The EAP consisted of eight individuals with extensive experience in pharmacy and compounding practice, jurisprudence, regulation, research methods and questionnaire design, and pharmaceutical policy in the U.S. health care system. The research protocol was reviewed and approved by the institutional review board at the University of Illinois at Chicago.

The questionnaire was developed through an iterative process in which questions and response options were generated, revised for clarity, and grouped into themes. Each theme related to an aspect of sterile compounding practices oversight: quality standards, monitoring and enforcement, compounding without patient-specific prescriptions (also called office stock compounding), licensure, inspection and inspector training, and compounding in physician offices or clinics.

Questionnaire items were reviewed and revised multiple times, with some items eliminated for reasons of redundancy and relevance. The final questionnaire consisted of 50 items. To minimize respondent burden, the research team pre-populated questionnaire responses from publicly available sources (i.e., state government websites on legislation and regulation) prior to contacting the state. These responses were then verified, or modified as needed, by the state contacts completing the questionnaire.

A list of potential respondents was compiled with input from the EAP; it included experts in pharmacy compounding regulation for each state, primarily executive directors of state boards of pharmacies. These individuals were contacted by the research team via telephone to explain the purpose of the questionnaire, and they were invited to participate. The questionnaire was administered through either a Web-based version developed in Qualtrics (Provo, Utah), which was sent by the research team to the respondent via an email link, or by telephone with an interviewer-administered questionnaire, depending upon respondent choice. The questionnaire was shared with external reviewers for comment prior to deployment, and pilot tested with respondents from five state boards of pharmacy. Minimal modifications were made in response to feedback from external reviewers.

Those who agreed to complete the Web-based questionnaire were sent a personal email summarizing the voluntary nature of participation, some information about the questionnaire, and a link to it. Follow-up reminder emails with the questionnaire link, and/or telephone calls, were made to respondents every week until the questionnaire was completed, the respondent declined to participate, or the respondent did not complete the questionnaire before the final deadline had passed.

Once the primary data collection phase ended, all respondents were sent a summary of their questionnaire responses for verification. For states not participating in the primary data collection phase, a copy of the questionnaire pre-filled with publicly available information was sent to the state board of pharmacy director, or equivalent. In early August 2015, state contacts were again asked to verify the accuracy of the information collected for their state and given two weeks to provide comments.

Current landscape of sterile compounding state oversight

Characteristics of participating states

After the final outreach to all 51 individual state boards of pharmacy (which includes the District of Columbia), 43 of the states (84 percent) had completed the questionnaire. Eight states (Alaska, Delaware, Florida, Georgia, Maine, North Carolina, Ohio, and Wisconsin) did not complete the questionnaire. Some of these states simply declined to participate, while others were willing to complete it but were unable to respond in a timely manner. The results were generally representative of the main regions of the United States: Northeast (eight of nine states and the District of Columbia, or 89 percent), Midwest (10 of 12 states, or 83 percent), South (13 of 17 states, or 76 percent), and West (12 of 13 states, or 92 percent). According to 2014 U.S. census data, the states that responded to our questionnaire represented the majority of the population in each region: Northeast (97 percent), Midwest (74 percent), South (66 percent), and West (99 percent). Additional characteristics of the 50 states and the District of Columbia are provided in Table 1, which presents pharmacy counts in each state using information from the National Council for Prescription Drug Programs (NCPDP) Pharmacy Provider Database. This database contains over 75,000 pharmacies and is used by many prescription processors, pharmacy benefit managers, health plans, and government entities. Table 1 also presents the number of sterile compounding pharmacies in each state where this information was provided by respondents. Pharmacies performing sterile compounding as a percentage of all pharmacies in each state ranged from 3 to 24 percent.

Results from this group of 43 participating states are described and discussed below. Data from all states, including those not participating in the questionnaire, are available in Appendix B. Information for nonparticipant states was retrieved for tables in this appendix from public websites, to the extent possible.

Table 1

Number of Pharmacies, and Pharmacies That Perform Compounding, in All U.S. States and the District of Columbia

State	Total number of pharmacies (NCPDP* data)	Number of pharmacies that list compounding functions (NCPDP* data)	Number of pharmacies performing sterile compounding (state-provided data)	Percentage of all pharmacies that perform sterile compounding
AK	153	36		
AL	1,527	588	224	15%
AR	799	260	48	6%
AZ	1,288	472		
CA	7,278	2,751	934	13%
CO	996	319	167	17%

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State	Total number of pharmacies (NCPDP* data)	Number of pharmacies that list compounding functions (NCPDP* data)	Number of pharmacies performing sterile compounding (state-provided data)	Percentage of all pharmacies that perform sterile compounding
CT	761	332		
DC	160	48	15	9%
DE	218	91		
FL	5,966	2,322		
GA	2,768	1,102		
HI	316	65		
IA	862	466	90	10%
ID	380	149	90	24%
IL	2,699	1,303		
IN	1,393	467		
KS	722	335		
KY	1,299	598		
LA	1,323	435		
MA	1,277	616		
MD	1,411	678	190	13%
ME	321	198		
MI	2,663	1,581		
MN	1,290	650		
MO	1,465	706		
MS	915	263		
MT	312	123		
NC	2,546	880		
ND	220	113		
NE	548	275		

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State	Total number of pharmacies (NCPDP* data)	Number of pharmacies that list compounding functions (NCPDP* data)	Number of pharmacies performing sterile compounding (state-provided data)	Percentage of all pharmacies that perform sterile compounding
NH	299	157	43	14%
NJ	2,167	1,236	180	8%
NM	427	149		
NV	652	160	35	5%
NY	5,202	2,877		
OH	2,623	1,066		
OK	1,024	387	195	19%
OR	837	362		
PA	3,736	1,759		
RI	268	101	8	3%
SC	1,436	526	122	8%
SD	253	116		
TN	1,952	735	305	16%
TX	5,298	1,928	723	14%
UT	580	230		
VA	1,849	699	172	9%
VT	168	116		
WA	1,473	553	80	5%
WI	1,307	654		
WV	615	306		
WY	147	58		

Note:

* Data are from the National Council for Prescription Drug Programs (NCPDP) Pharmacy Provider Database. Counts of pharmacies listing compounding activity may be an overestimation because they include entities that perform any compounding, not just pharmacies specializing in this practice. It is also possible that they are an underestimation because providing this information was optional.

Quality standards

Conforming to scientifically sound standards, such as those established by the U.S. Pharmacopeial Convention (USP), is critical to preventing dangerous contaminations, especially for sterile compounding. Deficiencies in sterile compounding practices can, and have, led to patient harm and death. The USP has established widely recognized quality standards for pharmacy compounding: USP Chapters <797> (sterile preparations) and <795> (nonsterile preparations). (See sidebar.)

United States Pharmacopeia Chapter <797>

The USP has developed standards to help compounding practitioners adhere to widely accepted, scientifically sound procedures and practices. USP standards can be legally enforceable when incorporated into or referenced by state laws or regulations.

The USP Chapter <797> provides procedures and requirements for compounding sterile preparations. It describes conditions and practices to prevent patient harm resulting from microbial contamination, excessive bacterial endotoxins,[43] variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations. Chapter <797> describes appropriate sterile gowning, cleaning procedures, environmental controls such as airflow, and monitoring practices to detect and prevent unsafe levels of contaminants in the air and on equipment and surfaces. Adherence to quality standards is essential to the safe preparation of sterile drugs.

Of note, the USP is currently working to update its standards for sterile compounding and published a proposed revision to Chapter <797> in September of 2015.[44] The USP is also working to develop Chapter <800>, which will cover the compounding of hazardous drugs.[45]

Our study found that most regulatory bodies (34 of 43 states, or 79 percent) referenced or incorporated USP <797> standards for sterile compounding in their laws and regulations. However, 13 of these 34 respondents (or 38 percent) indicated that the state does not require USP <797> in its entirety. Seven of the eight states reporting that they do not require USP <797> indicated that they will require the standard under pending policy changes. (See Table 2.)

Table 2

State Requirement of USP Chapter <797> on Sterile Compounding, and State Definitions of Compounding for the Purposes of Meeting This Requirement

	Number	Percentage*
Does the state mandate USP Chapter <797> on sterile compounding or equivalent for pharmacies that perform sterile compounding? (n = 43)		
Yes	21	49%
Yes, but not in its entirety	13	30%
No, but will under pending policy change	7	16%
No	1	2%
Don't know	1	2%
How is compounding defined by the states for the purpose of meeting USP Chapter <797> standards? Select all that apply. (n = 43)		
Constrained to 2 or more ingredients	14	33%
Repackaging	7	16%
Reconstituting, diluting, or pooling	10	23%
Other	17	40%

Note:

* Because of rounding, percentages may not always add to 100 percent.

At the time of the study, there were notable differences in how respondents defined compounding for the purposes of meeting USP <797> standards. (See Table 2.) State definitions included varying criteria, such as the combination of two or more ingredients, repackaging, reconstitution, diluting, or pooling. As a consequence, drugs prepared in one state may not be held to the same standard as those prepared in another, depending on the definition of compounding. This has implications for the quality standards applied to products shipped across state lines. For example, a repackaged sterile product made in a state that does not consider this compounding, and thus not subject to USP <797> standards, could be sent to a state that does require USP compliance for sterile repackaging. This presents an additional challenge for state regulators, who are already confronted with the task of how to best ensure the safety of compounded drugs shipped from other states. Minimum quality standards that are consistent across both drug preparation activities and states would help ensure that compounders within and outside of the state prepare safe drug products and protect the public from potential harms.

Table 3

Examples of State Requirements for Specific Minimum Training on Sterile Compounding Beyond Training Expectations Set Forth in USP Chapter <797>

Must receive five hours of continuing education, live, with written test, and must be monitored compounding in a hood [enclosed workspace with air controls] with written evaluation. Must receive passing grade on written monitoring evaluation.
To engage in the practice of sterile compounding, a minimum of one CPE hour must be ACPE accredited and related to the practice of sterile compounding.
Rule requires all individuals to obtain practical and/or academic training in the compounding and dispensing of sterile preparations, and further complete a minimum of one hour of accredited CE on an annual basis.
Have appropriate practical and didactic training in sterile compounding, clean room technology, laminar flow technology, quality assurance technique, and clinical applications of IV drug therapy.
Shall have didactic and practical training in sterile preparation compounding prior to compounding and annually thereafter.
All personnel, including pharmacists, pharmacists who supervise compounding personnel, pharmacy interns, and pharmacy technicians, shall have completed didactic and experiential training with competency evaluation through demonstration and testing (written or practical) as required by USP/NF (USP General Chapters: Pharmaceutical Compounding—Sterile Preparations). Pharmacy technicians shall complete 100 hours.
All sterile compounding personnel (pharmacy technicians and pharmacists) must have proof of personal competency in the art of sterile compounding completed annually.
To renew their license/registration, all pharmacists and pharmacy technicians must complete two hours of ACPE-accredited continuing education relating to one or more listed areas in sterile preparation if the pharmacy technician is engaged in compounding low- and medium-risk sterile preparations; or four hours if the pharmacy technician is engaged in compounding high-risk sterile preparations.

In response to questions regarding training requirements for pharmacists conducting sterile compounding, a majority of respondents (28 of 43 states, or 65 percent) reported that they did not mandate specific expectations for specialized training in sterile compounding, beyond what is currently required in USP <797>, as a condition of competency for pharmacists engaging in such activity. Ten states (23 percent of respondents) reported specific training requirements: Alabama, California, Idaho, Louisiana, Maryland, Missouri, New Jersey, New Mexico, South Carolina, and Texas. For example, as of September 2015, Texas indicated that it will require all pharmacists and pharmacy technicians who conduct sterile compounding to complete annual training in this practice (see Table 3 for additional examples). The number of hours required will depend on whether the practitioner is engaged in low- and medium-risk sterile preparations (two hours) or high-risk sterile preparations (four hours).[46] Both Texas and New Jersey clarified in their questionnaire responses that they assess compliance with specific sterile compounding training requirements during facility inspections.

Research suggests that many pharmacy schools and educational programs for pharmacists and technicians lack appropriate hands-on training in aseptic technique and sterile compounding. In 2005, 82 accredited U.S. pharmacy schools were surveyed regarding the extent to which they provided didactic and laboratory instruction related to compounded sterile preparations. Among the 53 schools that responded, 88 percent taught students about USP <797>; however, only 13 percent felt that their students had been adequately trained in sterile compounding prior to graduation.[47] Given this potential gap in education, it is possible that some pharmacists may not recognize deficiencies in their own sterile compounding practices.

Monitoring and enforcement

To effectively oversee compounding activity, state regulators need reliable information about facilities that compound and their ability to meaningfully respond to any safety deficiencies. In this regard, the monitoring and enforcement tools available to state regulatory bodies were uneven. Twenty-four of 43 respondents (56 percent) reported tracking the number of pharmacies performing sterile compounding in their state, and 17 of them provided a count. Slightly fewer respondents (19 of 43, or 44 percent) said their state tracked the number of out-of-state pharmacies shipping or dispensing compounded drugs into the state. Sixteen respondents (37 percent) reported that they did not track compounding pharmacies. (See Table 4.) Reliable data on total number of sterile compounding pharmacies in the U.S. remain elusive. There is no central repository of information tracking pharmacies that perform sterile compounding; NCPDP, the source this study used for counts of pharmacies performing compounding in each state, started collecting data in May 2011 on the specific type of compounding activity pharmacies performed, but these data have limitations. Compounding data is self-reported by pharmacies and questions about specific compounding services are currently optional.[48]

Few states (five, or 12 percent) responding to the questionnaire reported that they separately tracked sterile compounding violations. They are Alabama, Arizona, California, Maryland, and New Jersey. While most states indicated that they report pharmacy violations on a public website (36 states, or 84 percent), only three states—California, Massachusetts, and New Mexico—said they list compounding-related violations separately. (See Table 4.)

Most states did not require pharmacies performing sterile compounding to report voluntary recalls, either to the state only (7 percent do), FDA (7 percent), or both (9 percent). Reporting requirements were slightly more common for adverse events: 30 percent of states required sterile compounding pharmacies to report serious adverse events to the state, to FDA, or to both. (See Table 4.) Adverse event reporting is required by federal law for pharmaceutical companies and outsourcing facilities.[49] It can be used to identify problems that may affect other patients who received drugs from the same batch. While traditional compounding produces one-

Table 4

State Tracking and Reporting Requirements for Sterile Compounding Activity, Violations, Recalls, and Adverse Events

	Number	Percentage*
Does your state ... Select all that apply. (n = 43)		
Track the number of pharmacies in the state that perform compounding?	18	42%
Track the number of pharmacies in the state that perform sterile compounding?	24	56%
Track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients into the state?	19	44%
None of the above	16	37%
Don't know	3	7%
Does your state track sterile compounding-related violations separately from other pharmacy violations? (n = 43)		
Yes	5	12%
No	34	79%
Don't know	4	9%
Does your state list disciplinary actions related to pharmacy and/or compounding-related violations on a public website? (n = 43)		
Pharmacy violations listed	36	84%
Compounding violations separately listed	3	7%
Does your state require pharmacies that perform sterile compounding to report voluntary recalls to the state or FDA? (n = 43)		
To the state and FDA	4	9%
To the state only	3	7%
To FDA only	3	7%
Neither	25	58%
Don't know	8	19%
Does your state require pharmacies that perform sterile compounding to report serious adverse events to the state or FDA's MedWatch program? (n = 43)		
State and MedWatch	3	7%
State only	7	16%
MedWatch only	3	7%
Neither	26	60%
Don't know	4	9%

Note:

* Because of rounding, percentages may not always add to 100 percent.

Table 5

State Authorities Regarding Pharmacies That Perform Sterile Compounding

For pharmacies that perform sterile compounding, does your state have the authority to ...	Number	Percentage
Mandate a recall (n = 43)		
Yes	13	30%
No	19	44%
Don't know	11	26%
Issue a cease-and-desist order (n = 42*)		
Yes	37	88%
No	4	10%
Don't know	1	2%
Request reports from pharmacies that perform sterile compounding on the number of sterile products prepared (n = 43)		
Yes	38	88%
No	3	7%
Don't know	2	5%

Note:

* One state chose not to answer this question.

off medications for individual patients, mandatory reporting could still signal quality concerns associated with a specific facility.

With respect to enforcement authority, most respondents (88 percent) reported that the state had the power to request reports of sterile products prepared by pharmacies. An ability to know the amount of sterile compounded products that pharmacies ship out of state may be relevant to state participation in an anticipated FDA-state memorandum of understanding system to address the inordinate interstate distribution of compounded drugs. As required under Section 503A of the FDCA, FDA is working to develop a standard memorandum of understanding for this purpose.

Most respondents had the authority to issue cease-and-desist orders (88 percent), but approximately two-thirds (70 percent) were unable to mandate a recall of compounded drugs or were unsure of their explicit authority to do so. (See Table 5.) This may reflect a technical lack of recall authority rather than an inability to advance a recall, given that state regulators ultimately control licensure and may use this to request pharmacy actions when there is a real or perceived emergent threat to public health. In addition, other state officials, such as state governors, have the ability to take action when public health is threatened.[50] Understanding recall authority is important as it is a powerful tool to ensure that drug compounders are compliant with state regulations having

implications for protecting public health. Similar to adverse event reporting, the need for an effective recall system is greater for facilities making standardized or batched medicines, which can affect more patients.

Compounding without prescriptions and the new outsourcing facility sector

Section 503A of the FDCA does not allow the compounding of drugs for human use without a prescription, also known as office stock or office use compounding. This is only allowed if a facility registers with FDA as an outsourcing facility under Section 503B of the FDCA and meets CGMP standards. However, there was some legal uncertainty about the enforceability of Section 503A until the passage of the DQSA in 2013, and states may still be working to adapt their regulations. Our study found that nearly two-thirds of respondents allowed traditional compounding pharmacies to produce drugs without prescriptions to at least some extent. (See Table 6.) Ten respondents reported that their policies did not allow compounding without prescriptions: the District of Columbia, Hawaii, Illinois, Maryland, Missouri, Montana, New York, Rhode Island, Washington, and West Virginia. Based on public websites, Maine (a nonrespondent state) also prohibits compounding without a prescription.[51] An additional three states—Minnesota, Louisiana, and New Mexico—reported that compounding without prescriptions was allowed only for veterinary use, and based on public information North Carolina took the same position.[52] Finally, Nebraska indicated in its response that pharmacies engaging in this practice should be FDA-registered outsourcing facilities to comply with federal regulations. Other limits placed on compounding without prescriptions were less restrictive, such as allowing any quantity justified by a doctor's prescribing habits. (See Table 6.)

Although states may have written policies prohibiting compounding without a patient-specific prescription, this study did not assess whether or how such policies were enforced. In addition, in some cases states appeared to conflate anticipatory compounding—compounding before the receipt of an anticipated valid prescription—with compounding a supply of a drug without a prescription to be stocked by a doctor's office or clinic. While federal law allows for anticipatory compounding, it still requires the compounder to receive a prescription prior to dispensing the compounded drug to the patient.

Notably, few respondents (7 percent) reported pending policy changes on compounding by pharmacies without a patient-specific prescription. The few states that did report changes were evenly split between prohibiting the practice, limiting it, or allowing it. Regulatory disparity both between states and with federal law may make attempts to harmonize the oversight of compounding without prescriptions (office stock compounding) challenging. Under the DQSA, in exchange for submitting to more stringent oversight, the new outsourcing facility category is now the only group allowed to legally compound without prescriptions. If states allow compounding by traditional pharmacies without patient-specific prescriptions, it could remove incentives for companies to participate in the new outsourcing facility system.

State approaches to recognizing outsourcing facilities (OFs) varied, and only seven states had developed a specific OF licensure or registration category at the time of data collection. Five of these states reported this through our questionnaire: California (bill pending in Legislature), Idaho, Mississippi, New York, and Tennessee. Based on the review of public websites, Delaware and Florida also have an OF category, although this was not confirmed by a state contact. Additionally, 12 respondents reported that they were currently developing an OF licensure or registration category. Other states were mixed: Some required OFs to license as manufacturers, some as wholesalers, and some as pharmacies, while some permitted multiple licensure categories. (See Tables 7 and 8.) Federal law neither prohibits nor requires pharmacy licensure for OFs. If OFs maintain a traditional pharmacy practice as well as an outsourcing facility, continued licensure as a pharmacy is likely to be appropriate. In some cases, state licensure requirements may be mutually exclusive, for example, if one state

Table 6

State Policies on Compounding Without Patient-Specific Prescriptions

	Number	Percentage
Does your state allow pharmacies to compound without patient-specific prescriptions? (n = 43)		
Yes	7	16%
Yes, with specific limits	21	49%
Depends on pending policy change	3	7%
No	10	23%
Don't know	2	5%

Selected examples of specific limits placed on compounding without patient-specific prescriptions by states
Potentially more restrictive
Veterinary emergency only
Nonsterile compounding that is not dispensed to patient
For emergency only
Potentially less restrictive
For noncommercially available drugs
For in-office use only
Under direct supervision of physician only
Only 5 or 10% of total pharmacy's monthly sales
Based on prescriber habits
Only for anticipatory prescription orders

does not permit OF licensure as a pharmacy whereas another state requires it. This puts OFs that wish to be licensed by both states in an unworkable compliance situation.

There also appeared to be some uncertainty among states regarding how to address facilities performing sterile compounding without patient-specific prescriptions that are not registered as an OF with FDA, as federal law requires. While approximately half of respondents reported that they would take some action, this was fairly evenly split between requiring these facilities to register with FDA, informing the agency of their existence, or disciplining the facility. Four states, Maryland, Minnesota, Tennessee, and West Virginia, reported that they would take all three actions. Nine states (21 percent) said they would take none of these actions. (See Table 8.)

Table 7

State Licensure or Registration Policy for Facilities That Register With FDA Under the Outsourcing Facility Category of Drug Compounders

	Number	Percentage*
How does your state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders? (n = 43)		
State law or regulation has a specific outsourcing facility licensure or registration category	5	12%
State is currently developing a specific outsourcing facility licensure or registration category	12	28%
State licenses or registers outsourcing facilities as manufacturers	4	9%
State licenses or registers outsourcing facilities as wholesalers	4	9%
State does not license or register outsourcing facilities	5	12%
State licenses or registers outsourcing facilities as pharmacies	2	5%
State licenses or registers outsourcing facilities as manufacturers and wholesalers	2	5%
Other	5	12%
Don't know	4	9%

Note:

* Because of rounding, percentages may not always add to 100 percent.

Table 8

State Actions to Address Facilities Not Registered With FDA That Perform Sterile Compounding Without Patient-Specific Prescriptions

	Number	Percentage
How does your state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA? Select all that apply. (n = 42*)		
State requires these facilities to register as outsourcing facilities	13	31%
State informs FDA of such facilities	10	24%
State takes disciplinary action	13	31%
None of the above	9	21%
Don't know	9	21%

Note:

* One state chose not to answer this question.

This mixed response was true even for the subset of states that allow some degree of compounding without a prescription. However, of the seven states that allowed this practice without limitation, none reported that they would take disciplinary action; one reported that it would require registration with FDA, and one indicated that it would inform the agency of such facilities.

Licensure

Pharmacy licensure is an important method for states to set both the general and activity-specific requirements that drug compounders must meet, as well as monitor the activity of compounders. Separate licensure for sterile compounding pharmacies is one approach to more closely targeting oversight and enforcement activities—for example, it could allow a regulator to address sterile compounding violations at a pharmacy without shutting down other activities. However, separate licensure systems are yet to be widely adopted. One in five respondents required pharmacies to have a separate licensure to perform sterile compounding. (See Table 9.) Some of these policies were recently enacted: In December 2014, the Massachusetts Legislature passed a law that established separate licensure for sterile compounding pharmacies both in and out of state.[53] Regulations to implement the law also stipulate that out-of-state pharmacies cannot dispense any sterile compounded drug into Massachusetts unless they hold a "Nonresident Sterile Compounding Pharmacy" license. Whether or not they perform compounding, licensure or registration of out-of-state pharmacies is the norm across states. (See Table 9.)

Table 9

State Licensure of Pharmacies That Perform Sterile Compounding and Nonresident Pharmacies

	Number	Percentage
Does your state have a separate license or other requirement (e.g., permit) for pharmacies that perform sterile compounding? (n = 43)		
Yes	9	21%
No	32	74%
Don't know	2	5%
Does your state independently license out-of-state pharmacies that ship or dispense products to providers or patients inside of the state? (n = 43)		
Yes	43	100%

Inspections and inspector training

Facility inspection is a key instrument that regulatory bodies can use to assess pharmacy compliance with laws and regulations on compounding—it protects the public by ensuring that appropriate quality standards are met. This study explores state policies on important aspects of inspections of pharmacies that perform sterile compounding. The most commonly reported circumstances that triggered inspections of such pharmacies in the state were initial licensure, when a pharmacy remodels or moves locations, occurrences of complaints or incidents, and licensure renewal. (See Table 10.) Respondents generally required that inspections occur at least every 12 months, though 10 states reported an inspection frequency of every two years or longer, and several states reported no specific frequency.

Table 10

Criteria Driving State Inspections of In-State Pharmacies That Perform Sterile Compounding

	Number	Percentage*
What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? Select all that apply. (n = 43)		
Initial licensure	34	79%
Licensure renewal	11	26%
When pharmacy remodels or moves location	29	67%
When a complaint or incident occurs	30	70%
Other	3	7%
None of the above	4	9%
Unsure	2	5%
How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding? (n = 43)		
At least every 6 months	0	0%
At least every 1 year	23	53%
At least every 2 years	7	16%
At least every 3 years	2	5%
At least every 5 years	1	2%
No specific frequency	7	16%
Don't know	3	7%

Note:

* Because of rounding, percentages may not always add to 100 percent.

The number of reported pharmacy inspector FTEs (full-time equivalents—a unit representing a full-time employee) in each of the states responding ranged from one to 50. To better understand these differences in the context of the number of pharmacies within the state, the researchers divided the number of pharmacies in each state in the NCPDP database by the number of pharmacy inspectors reported by the state. The number of pharmacies per inspector ranged from 40 to 900, with a mean of 230 (standard deviation = 159) and a median of 183. It is worthwhile to note that differences in state policy and inspector workload allocation also affect how oversight is conducted. In addition, in some cases states may outsource inspections to third parties to improve their oversight reach.

Inspections require resources, and insufficient funding can affect inspection frequency, as well as staff hiring and training. In any situation, but particularly when resources are limited, states may seek to prioritize oversight of compounding pharmacies based on risk. Approximately one-quarter of respondents (12 states, or 28 percent) reported prioritizing inspections for in-state pharmacies where high-risk sterile compounding occurs. However, respondents generally did not report higher than annual inspection frequencies for these high-risk facilities. One state, Colorado, reported inspecting these facilities every six months.

The questionnaire also asked regulators how drug compounders shipping into their state from other locations were assessed for compliance, which may or may not include an in-person inspection (Table 11), and respondents varied in their approaches. While some states such as California[54] conduct their own inspections of out-of-state pharmacies, many states reported relying on inspections by the state where the pharmacy is located (49 percent), and/or inspections by a third party (53 percent), and states may also combine approaches. States

Table 11

Methods Used by States to Examine Out-of-State Pharmacy Compliance With Applicable Standards

	Number	Percentage
How does the state verify that out-of-state pharmacies performing sterile compounding comply with their applicable regulations? Select all that apply. (n = 43)		
Compliance is not verified	5	12%
Inspection performed by National Association of Boards of Pharmacy's Verified Pharmacy Program	22	51%
Inspection performed by a third party, approved in advance by the state	10	23%
Inspection performed by a third party, not approved in advance by the state	3	7%
Review of inspection report by another state, conducted in the past ____ years	21	49%
The pharmacy must provide self-evaluation or attestation of compliance	3	7%
Other	6	14%

that relied on inspection reports from another state had different requirements for how recent the inspection must be, ranging from 90 days to four years. Most respondents relying on a third party reported working with the National Association of Boards of Pharmacy's Verified Pharmacy Program. Five respondents (12 percent) reported that they did not verify the compliance of out-of-state sterile compounders. The frequency for assessing the compliance of out-of-state pharmacies varied considerably, with 40 percent of respondents indicating that there was no specific time frame. (See Table 12.) However, it is possible that some states may have interpreted this question as "frequency of inspection," which is one of several possible strategies of assessing compliance.

Table 12

Criteria Driving State Compliance Assessment of Out-of-State Pharmacies Performing Sterile Compounding

	Number	Percentage
What specific circumstances trigger the state to assess compliance with state requirements for out-of-state pharmacies that perform sterile compounding? Select all that apply. (n = 43)		
Initial licensure	31	72%
Licensure renewal	20	47%
When pharmacy remodels or moves location	14	33%
When a complaint or incident occurs	29	67%
None of the above	1	2%
Don't know	5	12%
How frequently does the state assess compliance with state standards for out-of-state pharmacies that perform sterile compounding?* (n = 43)		
At least every 6 months	0	0%
At least every 1 year	10	23%
At least every 2 years	7	16%
At least every 3 years	1	2%
At least every 5 years	0	0%
No specific frequency	17	40%
Don't know	8	19%

Note:

* Some states may have interpreted this question as "frequency of in-person inspection," not including regular, required review of inspections by other states or third parties.

Table 13

Characteristics of State Inspections of Pharmacies Performing Sterile Compounding

	Number	Percentage*
How long do inspections of pharmacies that perform sterile compounding usually last? (n = 43)		
Less than 4 hours	9	19%
4-8 hours	20	47%
1-3 days	3	7%
Other	6	14%
Don't know	5	12%
Are inspections of pharmacies that perform sterile compounding announced? (n = 43)		
Yes	0	0%
No	37	86%
Sometimes	3	7%
Don't know	3	7%
Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated? (n = 43)		
Yes	10	23%
No	27	63%
Don't know	6	14%
Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations? (n = 43)		
Yes	18	42%
No	15	35%
Don't know	10	23%

Note:

* Because of rounding, percentages may not always add to 100 percent.

Table 14

Factors Evaluated During Inspections of Pharmacies Performing Sterile Compounding

	Number	Percentage
What factors are evaluated during a sterile compounding inspection? Select all that apply. (n=43)		
Equipment certification and calibration	39	91%
Environmental monitoring	38	88%
Cleaning	38	88%
Standard operating procedures	37	86%
Training	37	86%
Documentation	37	86%
Facility design and construction	36	84%
Aseptic technique	36	84%
Hand hygiene	34	79%
Garbing	34	79%
Sterilization procedures and verification	33	77%
Control of components and materials	32	74%
All major inspection areas	24	56%
Other	5	12%
Don't know	4	9%

Tables 13 and 14 summarize additional characteristics of inspections for sterile compounding pharmacies. Inspections of sterile compounding pharmacies typically lasted for less than eight hours. (See Table 13.) Only the District of Columbia, Minnesota, and Washington reported that inspections of sterile compounding pharmacies usually lasted from one to three days. Virginia reported that hospital pharmacy inspections usually take two days. Most states held inspections that were unannounced but did not require direct observation of sterile compounding activity, even if by simulation. Ten jurisdictions reported that they required direct observation of sterile compounding activity during inspections: California, the District of Columbia, Indiana, Maryland, Montana, New Jersey, Oklahoma, Rhode Island, Tennessee, and Washington. Given the additional

quality standards required to safely compound sterile drug products, observation of compounding activity, whether actual or simulated, is relevant to an inspector's ability to meaningfully assess compounder compliance with state regulations.

Respondents generally indicated that inspection factors included important sterile compounding topics covered by USP <797> (Table 14), which is interesting given that only about half of respondents reported mandating USP <797> in its entirety. However, these questions did not assess the specific requirement for each inspection factor assessed by the state, so they cannot be used to evaluate alignment with USP <797>. Finally, when issues are discovered during inspection, most respondents (79 percent) required a written response from the pharmacy describing how the issues were addressed, and a majority (67 percent) also needed an additional on-site inspection to verify compliance. (See Table 15.) The ability of states to take samples of compounded products for testing also varied. This may be due, in part, to the high costs of sample testing, which can be prohibitive depending on state resource constraints.

Majorities of respondents reported that their states required that inspectors who assess sterile compounding be licensed pharmacists (70 percent), have prior experience within a pharmacy (60 percent), and have training on applicable USP standards (58 percent). (See Figure 1.) Interestingly, among states that mandated full or partial compliance with USP <797> (21 and 13 respondents, respectively) for sterile compounding, only 14 of 21 (67 percent) and 6 of 13 (46 percent) required that their inspectors to be trained in applicable USP standards. Lack of a requirement does not mean that states never secure such training for inspectors, but insufficient training can undermine the state's ability to recognize a violation through inspection.

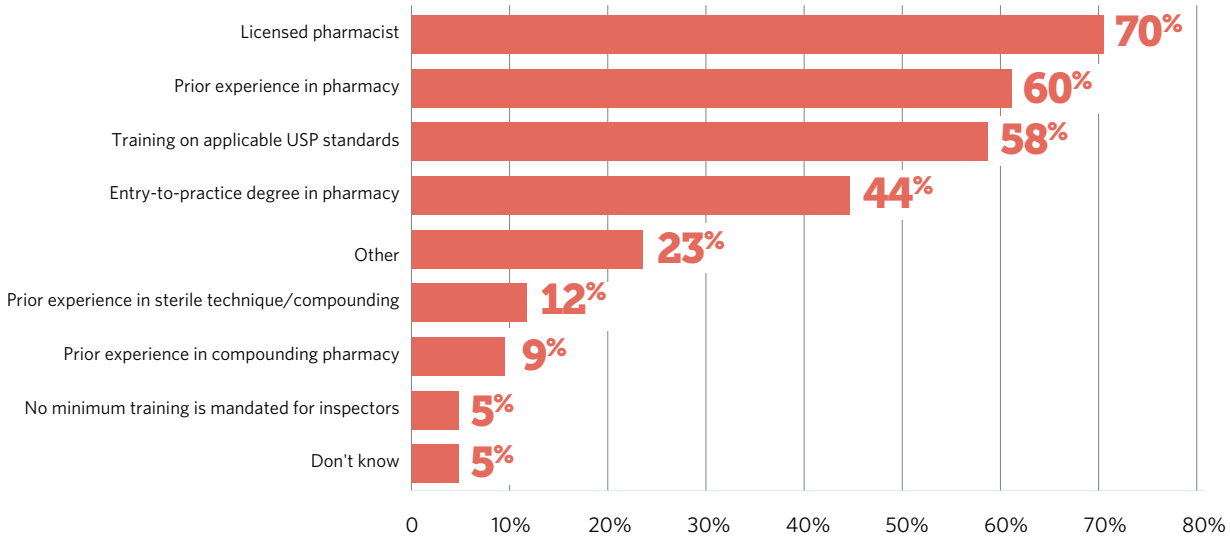
Table 15

State Follow-Up With Pharmacies Performing Sterile Compounding in Violation of State Regulations

	Number	Percentage
How does the state follow up with pharmacies to ensure that violations are addressed? Select all that apply. (n = 43)		
State conducts on-site inspection to verify that issues are addressed	29	67%
State requires written response from pharmacy describing how issues are addressed	34	79%
Other	8	19%
Don't know	2	5%

Figure 1

State-Required Training for Inspectors of Pharmacies That Perform Sterile Compounding (n=43)



Finally, given states' reliance on one another's inspections, they arguably would benefit from better harmonization of inspection protocols, minimum inspector training, and the ability to share information related to oversight and investigations. Our study found variability in the authority of states to share information about inspections, investigations, and enforcement concerns related to drug compounding with in-state, out-of-state, and federal officials. Twenty-six, 28, and 30 respondents reported that they could share information with in-state, federal, and other state officials, respectively (corresponding to 60 percent, 65 percent, and 70 percent of the 43 respondents). One respondent reported no authority to share information. (See Table 16.) Third parties, such as the National Association of Boards of Pharmacy, are engaged in efforts to establish clearinghouses of inspection information for states to access, and to facilitate state recognition of one another's inspections through harmonized inspection checklists.

Physician office or clinic compounding

Drug compounding generally occurs in pharmacies but may also take place in doctors' offices or clinics. Regardless of where sterile compounding is practiced, quality assurance is critical. Some research suggests that the frequency of contamination of parenteral (injected or infused) drug preparations is higher in clinical environments (e.g., hospital unit or operating room) than in controlled pharmacy environments.[55] Only one respondent state, Idaho, reported that its state board of pharmacy oversaw compounding that occurs within doctors' offices; most states were not certain that any meaningful oversight system exists, even by state medical boards. (See Table 17.) There is little to no clarity on which quality standards apply to sterile compounding in physician offices, and often no mechanisms exist to track adverse events in these settings. (See Figure 2.)

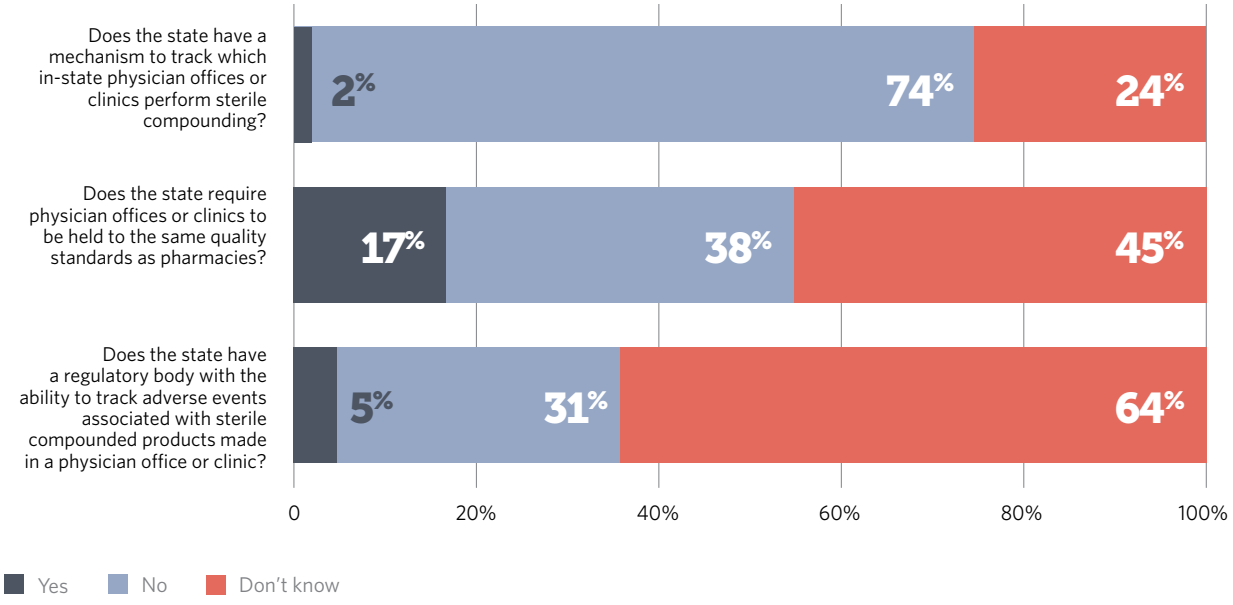
Table 16

State Authority to Share Inspection Information Related to Drug Compounding

	Number	Percentage*
Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials at the state or federal level? Select all that apply. (n = 43)		
State has no authority to share	1	2%
Can share on a public website	10	23%
Can share with in-state officials	26	60%
Can share with federal officials	28	65%
Can share with officials from other states	30	70%

Figure 2

State Oversight Systems for Sterile Compounding That Occurs in Physician Offices (n=42*)†



Note:

* One state chose not to answer this question.

† Because of rounding, percentages may not always add to 100 percent.

Table 17

State Body Responsible for Oversight of Sterile Compounding Occurring in Physician Offices

	Number	Percentage*
How do states provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards? (n=43)		
Oversight provided by the state board of medicine	7	16%
Oversight provided by the state board of pharmacy	1	2%
There is no oversight system to ensure compliance	24	56%
Other	7	16%
Don't know	4	9%

Note:

* Because of rounding, percentages may not always add to 100 percent.

Conclusions

Although the national outbreak of meningitis linked to contaminated compounded injections has driven a number of individual states to revisit the regulation of sterile compounding, this study revealed substantial variability in state regulation and oversight. Although many states had adopted widely recognized USP quality standards, some applied them only in part, and some did not require them at all. Inspection practices varied in frequency and length, and the ratio of pharmacy inspectors to pharmacies ranged widely, revealing potentially uneven oversight practices across the nation. States also applied notably different policies on compounding without a prescription; some were permissive, and others were restrictive. While federal law passed in 2013 clarified that pharmacies may not compound without prescriptions unless they are registered with FDA, it appears that states have not moved quickly to synchronize their regulations to federal policy.

States bear the primary responsibility for oversight of pharmacy compounding in their jurisdictions. Significant variability in state oversight systems, particularly given the interstate movement of some compounded drugs, suggests that quality assurance practices to protect patients may be inconsistent.

Many states are currently considering policy changes, and this study was designed to provide a useful landscape assessment of oversight systems that states can use when considering both their own policies and those governing out-of-state pharmacies that ship to the state. The results suggest that states may benefit from additional tools that describe policy best practices, lessons learned from states successfully advancing change and effectively allocating resources, and up-to-date model legislation and regulation in conformance with changes to federal law. These tools could be a resource to individual states reviewing practices, and also

support greater harmonization across states, particularly regarding appropriate rigor in the oversight of sterile compounding practice. Ideally, best practices should inform broader research pursuits to assess the landscape of state oversight systems today and analyze their strengths and weaknesses. This study may be useful in providing a baseline that facilitates the evaluation of policy transitions with respect to state oversight of sterile compounding practices.

Study limitations

This study had several limitations. First, although the study achieved a response rate of more than 80 percent from the 50 states and the District of Columbia, eight states did not complete our questionnaire. Second, the study could not definitively ascertain the accuracy of some responses where information was not available on public websites. However, the research team was careful to select potential respondents based on the experiences of our expert advisory panel.

Furthermore, state boards of pharmacy are responsible for defining state oversight of pharmacy compounding practice, and therefore respondents from these regulatory bodies should be authorities on the most current status of their jurisdiction. The authors are therefore confident that respondents participating in this study were among the most appropriate and knowledgeable sources of information available on current state oversight practices. Owing to rigorous follow-up and diligence, there were no missing responses to individual questions; however, two respondents reported as being "unsure" on several questions. This may have reflected an inability to answer questions before the questionnaire deadline, rather than uncertainty among regulators about their state's policy or authority. In addition, one question regarding state oversight of out-of-state facilities was not understood uniformly by respondents, potentially limiting our ability to interpret responses to that particular question, as noted in Table 12. Finally, responses to questions on whether compounding without prescriptions was permitted in states may reflect differing interpretations of what constitutes a full prohibition on compounding without prescriptions.

Appendix A: Glossary of terms

503B facility. See *outsourcing facility*.

Adverse event. Any undesirable experience associated with the use of a medical product in a patient.

Anticipatory compounding. Creation of a drug product prior to receipt of a prescription, based on a history of receiving such prescriptions. A prescription is received before the compounder dispenses or distributes the product. (This is distinct from office stock compounding, in which the compounder dispenses or distributes products to a provider without ever receiving prescriptions.)

Current Good Manufacturing Practice (CGMP). Minimum requirements for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug product. They are enforced in the United States by FDA, under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USCS § 351).

Drug Quality and Security Act (DQSA). On Nov. 27, 2013, President Obama signed the Drug Quality and Security Act, legislation with two titles: Title I contains important provisions relating to the oversight of compounding of human drugs, and Title II creates a drug serialization and tracking system.

Food and Drug Administration (FDA). The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services responsible for, among other things, protecting the public health by ensuring that human and veterinary drugs, vaccines and other biological products, and medical devices intended for human use are safe and effective.[56]

Good Manufacturing Practice. See *Current Good Manufacturing Practice.*

High-risk sterile compounding. Includes compounding activities that present potentially higher risk of compromised sterility in the end product, such as the preparation of sterile drugs from nonsterile components.

In-state pharmacy. Licensed pharmacy physically located within the state. May be referred to as a resident pharmacy.

Nonresident pharmacy. See *out-of-state pharmacy*.

Office stock compounding. Creating standardized drug products to be kept as stock in a doctor's office or hospital. By definition, these products are not compounded, dispensed, or distributed by a compounder pursuant to an individual patient prescription. Normally this is differentiated from anticipatory compounding, in which the product is prepared in advance of receiving a prescription but is not dispensed or distributed by a compounder until the prescription is received. FDA's current position is that office stock compounding is not permitted under federal law—Section 503A of the Federal Food, Drug, and Cosmetic Act specifies that traditional compounders may only receive exemptions from federal drug approval requirements if they compound pursuant to an individual patient prescription.

Out-of-state pharmacy. Licensed pharmacy not physically located within the state. Also referred to as nonresident pharmacy.

Outsourcing facility. Under Section 503B of the Drug Quality and Security Act, a compounder can become an "outsourcing facility," defined as a facility at one geographic location or address that (1) is engaged in the compounding of sterile drugs, (2) has elected to register as an outsourcing facility, and (3) complies with all of the requirements of Section 503B. Major requirements include registration with FDA, reporting of adverse

events and products compounded to FDA, and payment of fees to FDA. Outsourcing facilities are permitted to compound and distribute drugs without receiving individual patient prescriptions, but they are not exempt from current Good Manufacturing Practices. They may hold a pharmacy license but are not required to do so under federal law.

Physician office compounding. Compounding that occurs in a physician's office, either by a physician or by another practitioner for that physician.

Recalls. Actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative or by regulator request. FDA does not currently have the statutory authority to mandate a drug recall. State authorities here may differ.

Resident pharmacy. Licensed pharmacy physically located within the state. May be referred to as in-state pharmacy.

Serious adverse event. As defined by FDA, an adverse event that results in death, hospitalization (initial or prolonged), disability or permanent damage, or congenital anomaly or birth defect; is life-threatening; or requires an intervention to prevent permanent impairment or damage.[57]

State board of pharmacy. A state licensing board that develops, implements, and enforces standards relating to pharmacy practice.

United States Pharmacopeial Convention (USP). Scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. The USP's drug standards are enforceable in the United States by FDA and are used in more than 140 countries.

USP <795>. Chapter of the USP that provides compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals.

USP <797>. Chapter of the USP that describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations.

USP <800>. Proposed chapter of the USP that provides compounders with standards to protect personnel and the environment when handling hazardous drugs.

Appendix B: Complete tables on state oversight of sterile compounding

Table B.1

Quality Standards Responses by State

B.1	Quality standards for pharmacies that perform sterile compounding		Pharmacist training requirements
	Does the state mandate USP Chapter <797> on sterile compounding or equivalent?	Legislation or regulation that mandates USP Chapter <797> on sterile compounding or equivalent	For pharmacists who perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)? And if so, what are these standards?
AK*	Yes, but not in its entirety	12 AAC 52.430 and 12 AAC 52.440 and sterile pharmaceuticals guidelines	Unsure
AL	Yes, but not in its entirety	The state has a clause which says pharmacies must follow all USP standards and we have been functioning under that requirement to enforce USP <797>. We are presently rewriting our legislation and debating whether or not we will state simply to follow USP <797> or write specific requirements which mimic USP <797>.	Yes—must receive 5 hours continuing education, live, with written test and must be monitored compounding in a hood with written evaluation. Must receive passing grade on written monitoring evaluation.
AR	Yes, but not in its entirety	07-02-0002 http://pharmacyboard.arkansas.gov/licenseeInfo/Documents/lawBook/mergedLawbook.pdf	No
AZ	Unsure	NA	Unsure
CA	Yes, but not in its entirety	Chapter 9 Division 2 Article 7.5, Portions of 16 CA Code of Regulations 1735 et seq. and 1751 et seq.; Also regulations currently undergoing substantial revision	Yes—annual assessment; See 16 CA Code of Regulations Section 1751.6
CO	Yes, but not in its entirety	3 CCR 719-1, chapter 21	No
CT	Yes	Public Act No 14-224 Sc (4)c Sec 20-576-66	Unsure
DC	No, but will under pending policy change	NA	No
DE*	Yes, but not in its entirety	Only under hospital inspection form http://regulations.delaware.gov/AdminCode/title24/2500.shtml	No
FL*	Yes	64B16-27.797	Unsure
GA*	Yes	Rules and Regulations of State of Georgia: Chapter 480-11-.02 Compounded Drug Preparations	Yes—pharmacists who engage in drug compounding, and any other pharmacy personnel, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding procedures and shall maintain that proficiency through current awareness and training and documentation of that training

B.1	Quality standards for pharmacies that perform sterile compounding		Pharmacist training requirements
	Does the state mandate USP Chapter <797> on sterile compounding or equivalent?	Legislation or regulation that mandates USP Chapter <797> on sterile compounding or equivalent	For pharmacists who perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)? And if so, what are these standards?
HI	Yes	Hawaii Administrative Rules § 16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (17) Failure to comply with the pharmaceutical compounding requirements found in Chapter 795 (nonsterile preparations) and 797 (sterile preparations) of the United States Pharmacopeia National Formulary, as amended.	No
IA	No, but will under pending policy change	NA	No
ID	No	NA	Yes—to engage in the practice of sterile compounding, a minimum of one (1) of the CPE hours must be ACPE-accredited and related to the practice of sterile compounding
IL	No, but will under pending policy change	NA	No
IN	Yes	IAC-1-Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing	No
KS	No, but will under pending policy change	NA	No
KY	Yes	KRS 217	No
LA	Yes	LAC 46:L III.2535	Yes—rule requires all individuals obtain practical and/or academic training in compounding and dispensing of sterile preparations and further complete minimum of 1 hour of accredited CE on annual basis
MA	Yes	247 CMR 6.01.(5)c	No
MD	Yes	COMAR 10.34.19	Yes—have appropriate practical and didactic training in sterile compounding, clean room technology, laminar flow technology, quality assurance technique, and clinical applications of IV drug therapy. COMAR 10.34.19.05A
ME*	Yes	Chapter 37: Licensure of Sterile Compounding Pharmacies. 10. Operational Requirements	No
MI	Yes	Act 280 of 2014	No
MN	Yes	6800.3300 Compounding Standards Subpart 2	No

B.1	Quality standards for pharmacies that perform sterile compounding		Pharmacist training requirements
	Does the state mandate USP Chapter <797> on sterile compounding or equivalent?	Legislation or regulation that mandates USP Chapter <797> on sterile compounding or equivalent	For pharmacists who perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)? And if so, what are these standards?
MO	Yes, but not in its entirety	20 CSR 2220-2.200	Yes—personnel trained for risk level of sterile compounding (Risk level 1, 2, and 3)
MS	No, but will under pending policy change	NA	No
MT	Yes	24.174.841 (not legislation—a rule that went into effect March 2015 in definition)	Unsure
NC*	Yes	NCBOP-Pharmacy Rules. 21 NCAC 46 .2801, Section.2800 Compounding	No
ND	Yes, but not in its entirety	61-02-01-03. Pharmaceutical compounding standards	No
NE	Yes, but not in its entirety	Legislative Bill 37 (LB 37), effective Aug. 30, 2015	No
NH	Yes	NH RSA 318:14-a Compounding and NH Pharmacy Rules Chapter 400 part Ph 404	No
NJ	Yes, but not in its entirety	NJAC 13:39 Subchapter 11	Yes—shall have didactic and practical training in sterile preparation compounding prior to compounding and annually thereafter, 13:39-11:16(a)
NM	Yes	26-1-2.L.NMSA	Yes—all personnel, including pharmacists, pharmacists who supervise compounding personnel, pharmacist interns, and pharmacy technicians, shall have completed didactic and experiential trainings with competency evaluation through demonstration and testing (written or practical) as required by USP/NF (USP General Chapters: Pharmaceutical Compounding-Sterile Preparations). Pharmacy technicians shall complete 100 hours.
NV	Yes, but not in its entirety	Chapter 639—Pharmacists and Pharmacy NAC 639.67015 Establishment of policies and procedures	No
NY	Yes	Our NYS guidelines inform whether a product was prepared competently	No
OH*	Yes	Ohio Administrative Code (OAC) Drug Compounding 4729-16-07	Yes—there shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities

B.1	Quality standards for pharmacies that perform sterile compounding		Pharmacist training requirements
	Does the state mandate USP Chapter <797> on sterile compounding or equivalent?	Legislation or regulation that mandates USP Chapter <797> on sterile compounding or equivalent	For pharmacists who perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)? And if so, what are these standards?
OK	Yes	535:15-10-54. CSP microbial contamination risk levels, 535:15-10-61. Beyond use dating.	No
OR	Yes, but not in its entirety	Oregon Administrative Rules Chapter 855 855-045-0200 (3) pharmacists engaging in compounding should adhere to those guidelines that apply to their practice setting and in all situations comply with the spirit of USP <795> and USP <797>	No
PA	No, but will under pending policy change	NA	No
RI	Yes, but not in its entirety	R5-19.1-PHAR	No
SC	No, but will under pending policy change	H3349	Yes—all sterile compounding personnel (pharmacy technicians and pharmacists) must have proof of personal competency in the art of sterile compounding completed on an annual basis
SD	Yes, but not in its entirety	ARSD 20:51:31	No
TN	Yes	Public Chapter 266	No
TX	Yes	22 TAC §291.133	Yes—all pharmacists must complete through a single course a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE-accredited provider as well as OJT. Technicians must complete a 40-hour ACPE or ASHP course and OJT. In addition, to renew their license/registration, all pharmacists and pharmacy technicians must complete two hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding low- and medium-risk sterile preparations; or four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in compounding high-risk sterile preparations.

B.1	Quality standards for pharmacies that perform sterile compounding		Pharmacist training requirements
	Does the state mandate USP Chapter <797> on sterile compounding or equivalent?	Legislation or regulation that mandates USP Chapter <797> on sterile compounding or equivalent	For pharmacists who perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)? And if so, what are these standards?
UT	Yes	R156. Commerce, Occupational and Professional Licensing. R156-17b. Pharmacy Practice Act Rule. R156-17b-614a. Operating Standards—General Operating Standards, Class A and B Pharmacy (3)	No
VA	Yes	Regulations Governing Practice of Pharmacy Title 18. VAC110-20-321: Compounding—performed in accordance with USP-NF compounding for sterile and nonsterile drug products and §54.1-3410.2 of the Code of Virginia	No
VT	Yes	Administrative Rules of the Board of Pharmacy 13.22 USP <797> Compliance for Compounded Sterile Products	Unsure
WA	Yes	2013 HB 1800	No
WI*	No	NA	No
WV	Yes	Title 15 Series 1 Section 16	No
WY	Yes, but not in its entirety	WY Pharmacy Act Rules Chapter 17	Unsure

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

Table B.2

Monitoring and Enforcement Responses by State

B.2		AK*	AL	AR	AZ	CA	CO	CT	DC	DE*	FL*
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Yes	Yes	No	Yes	No	Yes	No	Yes	No	Yes
	Does your state track the number of in-state pharmacies that perform sterile compounding?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	Yes	Yes	No	Yes	Yes	No	Unsure	No	Unsure	Unsure
	Does the state list disciplinary actions related to pharmacy violations on a public website?	No	Yes	Yes	Yes	Yes	Yes	Unsure	No	Yes	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	NA	No	No	No	Yes	No	NA	NA	Yes	Yes
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Cannot share information with any regulators or officials, either federal or state	Can share with in-state regulators and officials, and federal regulators and officials	Can share with other state regulators and officials	Can share with other state regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Unsure	Unsure	Unsure	Unsure	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Yes, to the state and to MedWatch	No	No	No	Yes, to the state and to MedWatch	Yes, to the state only	Unsure	Yes, to the state and to MedWatch	Yes, to the state only	Yes, to MedWatch only
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Unsure	Yes, to FDA only	No, to either	Unsure	Yes, to both	Unsure	Unsure	No, to either	Unsure	Unsure
State authorities	Does the state have the authority to mandate a recall?	Unsure	Yes	No	No	No	Unsure	Yes	Yes	Yes	Unsure
	Does the state have the authority to issue cease-and-desist orders?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Unsure
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Yes	Yes	Yes	Yes	Yes	Yes	Unsure	Yes	No	Unsure

B.2		GA*	HI	IA	ID	IL	IN	KS	KY	LA
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Yes	No	Yes	No	No	No	Yes	No	No
	Does your state track the number of in-state pharmacies that perform sterile compounding?	No	No	Yes	Yes	No	No	Yes	No	No
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Yes	No	Yes	No	No	No	No	No	No
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	Unsure	Unsure	No	No	No	No	No	No	No
	Does the state list disciplinary actions related to pharmacy violations on a public website?	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	NA	No	No	No	No	NA	No	No	No
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Unsure	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Unsure	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Yes, to the state only	No	No	No	No	No	No	No	No
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Yes, to the state only	Unsure	No, to either	No, to either	No, to either	No, to either	Yes, to both	No, to either	No, to either
State authorities	Does the state have the authority to mandate a recall?	Yes	Unsure	Yes	No	No	Yes	No	Yes	No
	Does the state have the authority to issue cease-and-desist orders?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes

B.2		MA	MD	ME*	MI	MN	MO	MS	MT
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Unsure	No	No	Yes	Yes	Yes	No	No
	Does your state track the number of in-state pharmacies that perform sterile compounding?	Unsure	Yes	Yes	Yes	Yes	Yes	No	No
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Unsure	Yes	No	Yes	Yes	Yes	No	No
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	Unsure	Yes	Unsure	No	No	No	No	No
	Does the state list disciplinary actions related to pharmacy violations on a public website?	Yes	Yes	Yes	Yes	Yes	No	No	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	Yes	No	Yes	No	No	NA	NA	No
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Unsure	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Unsure	Cannot share information with any regulators or officials, either federal or state
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Yes, to the state only	Yes, to the state only	Yes, to the state only	Yes, to the state only	No	No	No	No
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Yes, to the state only	Yes, to FDA only	Yes, to the state only	Yes, to both	No, to either	Yes, to the state only	No, to either	No, to either
State authorities	Does the state have the authority to mandate a recall?	Unsure	Yes	Yes	Yes	No	No	Unsure	Unsure
	Does the state have the authority to issue cease-and-desist orders?	Yes	Yes	Unsure	Yes	Yes	NA†	Yes	Yes
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

B.2		NC*	ND	NE	NH	NJ	NM	NV	NY
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Unsure	Yes	No	Yes	No	No	Yes	Unsure
	Does your state track the number of in-state pharmacies that perform sterile compounding?	Unsure	Yes	No	Yes	Yes	No	Yes	Unsure
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Unsure	Yes	No	Yes	Yes	No	Yes	Unsure
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	Unsure	No	No	No	Yes	No	No	No
	Does the state list disciplinary actions related to pharmacy violations on a public website?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	No	No	No	No	No	Yes	NA	No
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Unsure	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with other state regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with other state regulators and officials, and with federal regulators and officials
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Unsure	No	No	Yes, to MedWatch only	Yes, to the state only	Yes, to the state only	No	No
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Unsure	No, to either	No, to either	Unsure	No, to either	No, to either	Unsure	No, to either
State authorities	Does the state have the authority to mandate a recall?	Yes	Yes	Unsure	Unsure	No	No	Yes	Unsure
	Does the state have the authority to issue cease-and-desist orders?	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Unsure	Yes	Yes	Yes	Yes	Yes	Yes	Yes

B.2		OH*	OK	OR	PA	RI	SC	SD	TN
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Unsure	Yes	No	No	Yes	Yes	Yes	No
	Does your state track the number of in-state pharmacies that perform sterile compounding?	Unsure	Yes	No	No	Yes	Yes	Yes	Yes
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Unsure	Yes	No	No	Yes	Yes	Yes	Yes
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	Unsure	No	No	No	No	No	No	No
	Does the state list disciplinary actions related to pharmacy violations on a public website?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	NA	No	No	No	No	No	No	No
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Unsure	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with other state regulators and officials	Unsure	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with federal regulators and officials
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Yes, to the state only	No	No	No	Yes, to MedWatch only	No	Yes, to MedWatch only	No
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Unsure	No, to either	No, to either	No, to either	Yes, to both	No, to either	Unsure	No, to either
State authorities	Does the state have the authority to mandate a recall?	Unsure	No	No	No	Yes	No	Unsure	No
	Does the state have the authority to issue cease-and-desist orders?	Unsure	Yes	No	Yes	Yes	Yes	Yes	Yes
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

B.2		TX	UT	VA	VT	WA	WI*	WV	WY
Tracking facilities	Does your state track the number of in-state pharmacies that perform compounding?	Yes	No	Yes	Unsure	No	Unsure	No	No
	Does your state track the number of in-state pharmacies that perform sterile compounding?	Yes	No	Yes	Unsure	No	Unsure	No	No
	Does your state track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients in the state?	Yes	No	Yes	Unsure	No	Unsure	No	No
Tracking violations	Are sterile compounding-related violations tracked separately by the state?	No	No	No	No	Unsure	No	No	No
	Does the state list disciplinary actions related to pharmacy violations on a public website?	Yes	Yes	Yes	Yes	No	Unsure	Yes	Yes
	Does the state separately list disciplinary actions for compounding-related violations?	No	No	No	No	No	NA	No	No
	Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state?	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Can share with in-state regulators and officials, other state regulators and officials, federal regulators and officials, and on public websites	Unsure	Unsure	Unsure	Can share with in-state regulators and officials, other state regulators and officials, and federal regulators and officials	Unsure
Pharmacy reporting	Does the state require pharmacies that perform sterile compounding to report serious adverse events to the state and/or MedWatch?	Yes, to the state only	Yes, to the state and to MedWatch	No	Unsure	Unsure	No	Unsure	No
	Are pharmacies that perform sterile compounding required to report voluntary recalls to the state and/or FDA?	Yes, to the state only	Yes, to FDA only	No, to either	Unsure	No, to either	No, to either	No, to either	No, to either
State authorities	Does the state have the authority to mandate a recall?	Yes	No	No	Unsure	No	Unsure	Unsure	Yes
	Does the state have the authority to issue cease-and-desist orders?	Yes	Yes	No	Unsure	Yes	Unsure	No	Yes
	Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?	Yes	Yes	Yes	Unsure	Yes	Unsure	No	Yes

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

† Indicates that the state opted to abstain from answering that specific question.

Table B.3

Office Use Compounding and Outsourcing Facilities Responses by State

B.3		AK*	AL	AR	AZ	CA	CO
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes	Yes, but with specific limits	Yes	Yes	Yes	Yes, but with specific limits
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	NA	Until we sign MOU with FDA, we allow small amount of compound for in-office use. May not supply large quantities or multiple units.	NA	NA	NA	10% of total sales, in-state only
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	Sec.08.80.045	Code of Alabama Title 34 Chapter 23, Section 160	07-02-0002—Good Compounding Practices. (I) Compounding for a prescriber's office use.	Not verified†	Business and Professions Code Section 4050-4068 4052. (a) Notwithstanding any other law, a pharmacist may: (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber. Also Title 16, California Code of Regulations Section 1735.2 (b) and (c), also Title 16 CA Code of Regulations 1735.2(c)—compounding for office use and for future furnishing	3 CCR 719-1 Rule 21.00.20
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State does not license or register outsourcing facilities	State is currently developing a specific outsourcing facility licensure or registration category	By other means: They are working on future regulations to have potential for single outsourcing permit but currently licensed under our wholesaler and pharmacy permits. Statute for the wholesaler permits has already been updated to include language for outsourcing.	State does not license or register outsourcing facilities	State law or regulation has a specific outsourcing facility licensure or registration category	State licenses or registers outsourcing facilities as wholesalers
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA	NA	Senate Bill 619 (Morrell) still pending in Legislature	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Unsure	Take disciplinary action	None of the above	Unsure	None of the above	Unsure

B.3		CT	DC	DE*	FL*	GA*	HI
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Unsure	No	Unsure	Yes, but with specific limits	Yes, but with specific limits	No
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	NA	NA	NA	Can compound if it will be used in a treatment setting, is in a reasonable quantity and doesn't exceed the practitioner's anticipatory amount, and the pharmacy and practitioner enter into a written agreement	If there is a valid prescription or for anticipatory prescription drug based on routine	NA
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	NA	Definition of Compounding in DC Pharmacy Laws	NA	64B16-27.700 Definition of Compounding (3)	Georgia State Board of Pharmacy: Pharmaceutical Compounding 480-1.02	Nothing specific, interpretation of various pharmacy laws/rules that a valid prescription that is patient-specific is required for any pharmacy to "dispense" a prescription drug
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	Unsure	State is currently developing a specific outsourcing facility licensure or registration category	State law or regulation has a specific outsourcing facility licensure or registration category	State law or regulation has a specific outsourcing facility licensure or registration category	Unsure	State does not license or register outsourcing facilities at this time
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	Section 5 outsourcing facility permit application: Section 503B	64B16-27.700 Definition (3)(g)	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Unsure	Require those facilities to register with FDA as outsourcing facilities	None of the above	Require those facilities to register with FDA as outsourcing facilities and take disciplinary action	Unsure	None of the above

B.3		IA	ID	IL	IN	KS
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Pending policy change: State will prohibit compounding without patient-specific prescriptions	Yes, but with specific limits	No	Yes, but with specific limits	Yes
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	NA	If the compounded drug product is not sterile and not intended to be sterile; compounded drug product is not further dispensed or distributed by the practitioner; and quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the pharmacy, which may include a drug compounded for the purpose of, or incident to, research, teaching, or chemical analysis	NA	Referred to federal law	NA
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	NA	Section 230 05	Title 68: Professions and Occupations Chapter VII: Department of Financial and Professional Regulation Subchapter B: Professions and Occupations Part 1330 Pharmacy Practice Act Section 1330.640 Pharmaceutical Compounding Standards. These rules will be amended within the next year.	None	It is not addressed, so it isn't prohibited
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	By other means: State licenses outsourcing facilities as pharmacies or wholesalers; the choice is left to the outsourcing facility	State law or regulation has a specific outsourcing facility licensure or registration category	State licenses or registers outsourcing facilities as manufacturers and wholesalers	State does not license or register outsourcing facilities	State licenses or registers outsourcing facilities as pharmacies
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	740 Outsourcing facility and 615 Drug distribution 01.b and 070	NA	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Unsure	Take disciplinary action	Take disciplinary action	Require those facilities to register with FDA as outsourcing facilities	None of the above

B.3		KY	LA	MA	MD	ME*	MI
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes, but with specific limits	Yes, but with specific limits	Unsure	No	No	Yes, but with specific limits
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	Only within Kentucky	For veterinarian use only; pharmacy may not distribute such products in excess of 5% of its total sales per month	NA	NA	NA	Limited quantities only
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	201 KAR 2:310	LAC 46:L III.2535	NA	Health Occupations Article, 12-101, Annotated Code of MD	Chapter 117: Maine Pharmacy Act Heading: PL 1987 c.710	Act 280 of 2014
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State licenses or registers outsourcing facilities as wholesalers	By other means: Another state agency licenses outsourcers as distributors; we only license as pharmacies if they dispense patient-specific preparations	Unsure	State licenses or registers outsourcing facilities as wholesalers	Unsure	State licenses or registers outsourcing facilities as manufacturers
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA	NA	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Require those facilities to register with FDA as outsourcing facilities and inform FDA of such facilities	Take disciplinary action	Unsure	Require those facilities to register with FDA as outsourcing facilities, inform FDA of such facilities, and take disciplinary action	Unsure	None of the above

B.3		MN	MO	MS	MT
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes, but with specific limits	No	Yes	No
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	Only for drugs that are needed for emergency veterinarian use. Such drugs may be administered in the veterinary offices or dispensed in limited quantities. No other compounding for office use is permitted. Technically, all compounding for office use is illegal except as authorized by the rules of the Board. The Board will promulgate rules allowing for emergency veterinary compounding for "office use" but, for now, is exercising enforcement discretion and allowing such compounding pending promulgation of the rules.	NA	NA	NA
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	Minnesota Statutes Section 151.253 addresses compounding and specifically prohibits compounding without receipt of patient-specific prescriptions	NA	Mississippi Pharmacy Practice Regulations Article XXXI Compounding Guidelines 1. General Provisions C	NA‡
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State licenses or registers outsourcing facilities as manufacturers	By other means: Must be registered as a drug distributor	State law or regulation has a specific outsourcing facility licensure or registration category	State does not license or register outsourcing facilities
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	Mississippi Pharmacy Practice Regulations Article VI Practice of Pharmacy Permits 1. F. Sterile Product Outsourcing	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Require those facilities to register with FDA as outsourcing facilities, inform FDA of such facilities, and take disciplinary action	NA‡	Require those facilities to register with FDA as outsourcing facilities	Unsure

B.3		NC*	ND	NE	NH	NJ
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes, but with specific limits	Yes, but with specific limits	Yes, but with specific limits	Yes, but with specific limits	Yes, but with specific limits
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	For veterinary use only	Only used in the office and can't be dispensed to patients	Pharmacies should be FDA-registered outsourcing facilities to comply with federal regulations	Limited Quantities is defined in NH Pharmacy Rule Ph 404.02(u), "Limited quantities" means a batch with 50 or fewer dosage units provided to a hospital or practitioner to administer to their own patient.	Pending review, as federal law prohibits this practice
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	NCBOP-Pharmacy Rules. 21 NCAC 46 .2801, Section.2800 Compounding. North Carolina Board of Pharmacy FAQ clarifies office use compounding for human use is not permitted because it is not allowed under federal law.	61-02-01-03. Pharmaceutical compounding standards	LB 37; Section 45 1(c)—effective Aug. 30, 2015	NH RSA 318:14-a I: Products that are not commercially available may be compounded for hospital or office use but shall not be resold or dispensed; NH RSA 318:14-a(III) and NH Pharmacy Rule Ph 404.04(c)	Title 13:39 Subchapter 11.18 (sterile) and Subchapter 11A.6 (nonsterile)—Compounded Sterile Preparations for Prescriber practice use: May compound for licensed prescriber
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	By other means: Every person doing business in NC and operating as a wholesaler, manufacturer, or repackager of prescription drugs and devices must register with the NC Department of Agriculture's Food and Drug Safety Division ("Outsourcing only" facility must be properly permitted by that office and FDA but need not obtain a pharmacy permit from the NCBOP)	State is currently developing a specific outsourcing facility licensure or registration category	State licenses or registers outsourcing facilities as manufacturers and wholesalers	State is currently developing a specific outsourcing facility licensure or registration category	By other means: Outsourcing facilities fall under the regulation of the New Jersey Department of Health, Wholesaler Division. Exact registration type determined by this agency.
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Unsure	Require those facilities to register with FDA as outsourcing facilities	Inform FDA of such facilities	None of the above	None of the above

B.3		NM	NV	NY	OH*	OK
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes, but with specific limits	Yes, but with specific limits	No	Yes, but with specific limits	Pending policy change: State will limit compounding without patient-specific prescriptions
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	Only for veterinarians. Nonsterile. For office use only	For in-office administration only	NA	For direct administration to patients as long as it is not greater than 5% of the pharmacy's total dollar amount of sales	NA
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	16.19.30.9.A.4 NMAC	Chapter 639—Pharmacists and Pharmacy Standards for Compounding and Dispensing Generally NAC 639.6702	Our law only authorizes patient-specific; Education Law Section 6810	4729-16-02 of the Administrative Code	NA
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State is currently developing a specific outsourcing facility licensure or registration category	State is currently developing a specific outsourcing facility licensure or registration category	State law or regulation has a specific outsourcing facility licensure or registration category	State licenses or registers outsourcing facilities as wholesalers	State is currently developing a specific outsourcing facility licensure or registration category
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	§63.8 Registration of nonresident establishments. Education Law §6831. Special provisions relating to outsourcing facilities	Yes	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Take disciplinary action	Require those facilities to register with FDA as outsourcing facilities	Require those facilities to register with FDA as outsourcing facilities and take disciplinary action	Require those facilities to register with FDA as outsourcing facilities	Require those facilities to register with FDA as outsourcing facilities

B.3		OR	PA	RI	SC	SD	TN
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes, but with specific limits	Pending policy change: State will allow compounding without patient-specific prescriptions	No	Yes	Yes, but with specific limits	Yes, but with specific limits
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	Need Board-approved Shared Service Agreement	NA	NA	NA	Based on the prescribers' habits	Only for non-commercially available products
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	Oregon Administrative Rules Chapter 855 855-045-0230 General Requirements (b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0220(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship	NA	Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors, Section 19.5	40-43-81c (CC)(2)(e)	SDCL 36-11-2	Public Chapter 266
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State licenses or registers outsourcing facilities as manufacturers	State licenses or registers outsourcing facilities as wholesalers	State does not license or register outsourcing facilities	Unsure	State is currently developing a specific outsourcing facility licensure or registration category	State law or regulation has a specific outsourcing facility licensure or registration category
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA	NA	NA	Not verified[†]
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Require those facilities to register with FDA as outsourcing facilities and take disciplinary action	Inform FDA of such facilities	Inform FDA of such facilities and take disciplinary action	None of the above	Unsure	Require those facilities to register with FDA as outsourcing facilities, inform FDA of such facilities, and take disciplinary action

B.3		TX	UT	VA	VT	WA
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Yes	Yes, but with specific limits	Yes, but with specific limits	Yes, but with specific limits	No
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	NA	But only for anticipatory prescription orders	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under direct and immediate supervision, if there is critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.	Only for anticipatory stock	NA
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	Texas Pharmacy Act, Occupations Code, Chapter 562, Subchapter D	R156. Commerce, Occupational and Professional Licensing. R156-17b. Pharmacy Practice Act Rule. R156-17b-614a. Operating Standards—General Operating Standards, Class A and B Pharmacy (3).	§54.1-3410.2	Administrative Rules of the Board of Pharmacy 10.23 Drugs Compounded in a Pharmacy (C)	Legislation HB 1800 in 2013
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	State is currently developing a specific outsourcing facility licensure or registration category	State licenses or registers outsourcing facilities as pharmacies	State is currently developing a specific outsourcing facility licensure or registration category	Unsure	State is currently developing a specific outsourcing facility licensure or registration category
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Inform FDA of such facilities	Take disciplinary action	Unsure	Unsure	Inform FDA of such facilities

B.3		WI*	WV	WY
Compounding without prescriptions (also known as office stock)	Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?	Unsure	No	Yes, but with specific limits
	If the state applies specific limits to pharmacy compounding without patient-specific prescriptions, what are these limits?	NA	NA	Must be administered in the office
	What is the name of legislation or regulation that addresses compounding without patient-specific prescriptions?	NA	Violation of 30-5-4 sub 12 (definition of compounding)	WY Pharmacy Act Rules Chapter 13 Section 3 (d)
Outsourcing facilities	How does the state license or register facilities that register with FDA under the new federal outsourcing facility (OF) category of drug compounders?	Unsure	State licenses or registers outsourcing facilities as manufacturers	State is currently developing a specific outsourcing facility licensure or registration category
	What is the name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category?	NA	NA	NA
Enforcement	How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA?	Unsure	Require those facilities to register with FDA as outsourcing facilities, inform FDA of such facilities, and take disciplinary action	None of the above

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

† Indicates that the state did not respond to an email regarding further clarification that was needed to adequately address what the question was intended for. On those questions, the answer was defaulted to "Not verified."

‡ Indicates that the state opted to abstain from answering that specific question.

Table B.4

Licensure Responses by State

	Sterile compounding	Out-of-state pharmacies
	Is there a separate license or other requirement (e.g. permit) for pharmacies that perform sterile compounding?	Does the state independently license or register out-of-state pharmacies that ship or dispense products to providers or patients in the state?
AK*	No	Yes
AL	Yes	Yes
AR	No	Yes
AZ	Unsure	Yes
CA	Yes	Yes
CO	No	Yes
CT	No	Yes
DC	No	Yes
DE*	No	Yes
FL*	Yes	Yes
GA*	No	Yes
HI	No	Yes
IA	No	Yes
ID	No	Yes
IL	No	Yes
IN	No	Yes
KS	No	Yes
KY	No	Yes
LA	No	Yes
MA	Unsure	Yes
MD	No	Yes
ME*	Yes	Yes
MI	Yes	Yes
MN	Yes	Yes
MO	Yes	Yes
MS	No	Yes
MT	No	Yes
NC*	No	Yes
ND	No	Yes
NE	No	Yes
NH	No	Yes
NJ	No	Yes
NM	No	Yes
NV	No	Yes
NY	No	Yes
OH*	No	Yes
OK	Yes	Yes
OR	No	Yes
PA	No	Yes
RI	No	Yes
SC	No	Yes
SD	No	Yes
TN	Yes	Yes
TX	Yes	Yes
UT	No	Yes
VA	No	Yes
VT	No	Yes
WA	No	Yes
WI*	No	Yes
WV	Yes	Yes
WY	No	Yes

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

Table B.5

Inspectorate and Inspector Training Responses by State

B.5	Number of pharmacy inspectors and number of pharmacies					Minimum training requirements for inspectors who assess pharmacies that perform sterile compounding							
	How many inspectors (full-time equivalents, FTEs) does the state employ who conduct pharmacy inspections?	Based on NCPDP data†			Number of pharmacies that perform sterile compounding	Entry-to-practice degree in pharmacy (e.g., B.Sc. Pharm., Pharm.D.)	Licensed pharmacist	Training on applicable USP standards	Prior experience in pharmacy	Prior experience in compounding pharmacy	Prior experience in sterile technique/compounding	No minimum training is mandated	Other
		Number of pharmacies	Number of pharmacies per pharmacy inspector (FTE)	Number of pharmacies that list compounding functions									
AK*	Unsure	153		36		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
AL	9	1,527	170	588	224	No	No	Yes	No	No	No	No	No
AR	3	799	266	260	48	Yes	Yes	Yes	Yes	No	No	No	No
AZ	5	1,288	258	472		No	Yes	No	Yes	No	No	No	No
CA	48	7,278	152	2,751	934	Yes	Yes	Yes	No	No	Yes	No	Yes, additional training in sterile compounding
CO	3	996	332	319	167	Yes	Yes	No	Yes	No	No	No	Yes, critical point boot camp and online training
CT	12	761	63	332		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
DC	4	160	40	48	15	No	Yes	Yes	Yes	Yes	Yes	No	No
DE*	Unsure	218		91		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
FL*	Unsure	5,966		2,322		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
GA*	Unsure	2,768		1,102		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure

B.5	Number of pharmacy inspectors and number of pharmacies					Minimum training requirements for inspectors who assess pharmacies that perform sterile compounding							
	How many inspectors (full-time equivalents, FTEs) does the state employ who conduct pharmacy inspections?	Based on NCPDP data†			Number of pharmacies that perform sterile compounding	Entry-to-practice degree in pharmacy (e.g., B.Sc. Pharm., Pharm.D.)	Licensed pharmacist	Training on applicable USP standards	Prior experience in pharmacy	Prior experience in compounding pharmacy	Prior experience in sterile technique/compounding	No minimum training is mandated	Other
		Number of pharmacies	Number of pharmacies per pharmacy inspector (FTE)	Number of pharmacies that list compounding functions									
HI	1	316	316	65		No	No	No	No	No	No	Yes	No
IA	8	862	108	466	90	No	Yes	No	No	No	No	No	No
ID	3	380	127	149	90	No	No	No	No	No	No	No	Yes, NABP training
IL	3	2,699	900	1,303		Yes	Yes	No	Yes	No	No	No	No
IN	5	1,393	279	467		No	No	Yes	No	No	No	No	No
KS	2	722	361	335		Yes	Yes	Yes	Yes	Yes	Yes	No	No
KY	5	1,299	260	598		Yes	Yes	Yes	No	No	Yes	No	Yes, sterile compounding boot camp
LA	5	1,323	265	435		Yes	Yes	Yes	Yes	Yes	Yes	No	No
MA	Unsure	1,277		616		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
MD	5	1,411	282	678	190	No	Yes	Yes	Yes	No	No	No	Yes, pharmacy technician license

B.5	Number of pharmacy inspectors and number of pharmacies					Minimum training requirements for inspectors who assess pharmacies that perform sterile compounding							
	How many inspectors (full-time equivalents, FTEs) does the state employ who conduct pharmacy inspections?	Based on NCPDP data†			Number of pharmacies that perform sterile compounding	Entry-to-practice degree in pharmacy (e.g., B.Sc. Pharm., Pharm.D.)	Licensed pharmacist	Training on applicable USP standards	Prior experience in pharmacy	Prior experience in compounding pharmacy	Prior experience in sterile technique/compounding	No minimum training is mandated	Other
		Number of pharmacies	Number of pharmacies per pharmacy inspector (FTE)	Number of pharmacies that list compounding functions									
ME*	Unsure	321		198		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
MI	4	2,663	666	1,581		Yes	Yes	Yes	Yes	No	No	No	No
MN	7	1,290	184	650		Yes	Yes	Yes	Yes	No	Yes	No	Yes, sterile compounding inspection training
MO	8	1,465	183	706		Yes	Yes	Yes	Yes	No	No	No	Yes, annual training
MS	4	915	229	263		Yes	Yes	Yes	Yes	No	No	No	No
MT	2	312	156	123		Yes	Yes	Yes	Yes	No	No	No	No
NC*	12	2,546	212	880		No	No	Yes	No	No	Yes	No	No
ND	3	220	73	113		No	No	No	No	No	No	No	Yes, there is no set standard
NE	3	548	183	275		No	Yes	Yes	Yes	No	No	No	No
NH	3	299	100	157	43	No	Yes	Yes	Yes	No	No	No	No
NJ	6	2,167	361	1,236	180	No	No	No	Yes	No	No	No	Yes, NABP training
NM	6	427	71	149		No	Yes	No	Yes	No	No	No	No

B.5	Number of pharmacy inspectors and number of pharmacies					Minimum training requirements for inspectors who assess pharmacies that perform sterile compounding							
	How many inspectors (full-time equivalents, FTEs) does the state employ who conduct pharmacy inspections?	Based on NCPDP data†			Number of pharmacies that perform sterile compounding	Entry-to-practice degree in pharmacy (e.g., B.Sc. Pharm., Pharm.D.)	Licensed pharmacist	Training on applicable USP standards	Prior experience in pharmacy	Prior experience in compounding pharmacy	Prior experience in sterile technique/compounding	No minimum training is mandated	Other
		Number of pharmacies	Number of pharmacies per pharmacy inspector (FTE)	Number of pharmacies that list compounding functions									
NV	4	652	163	160	35	Yes	Yes	Yes	Yes	No	No	No	No
NY	50	5,202	104	2,877		No	No	Yes	No	No	No	No	Yes, individualized training, pharmacy board members may assist
OH*	Unsure	2,623		1,066		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
OK	6	1,024	171	387	195	Yes	Yes	Yes	Yes	No	No	No	No
OR	5	837	167	362		Yes	Yes	No	Yes	No	No	No	Yes, 5 years' experience to qualify for an inspector position
PA	Unsure	3,736		1,759		No	Yes	No	No	No	No	No	No
RI	Unsure	268		101	8	No	No	No	No	No	No	No	Yes, no training is mandated, however, inspectors are sent to training
SC	5.5	1,436	261	526	122	Yes	Yes	Yes	Yes	No	No	No	No
SD	2	253	127	116		No	Yes	No	No	No	No	No	No
TN	8	1,952	244	735	305	Yes	No	Yes	Yes	No	No	No	No
TX	12	5,298	442	1,928	723	Yes	Yes	Yes	Yes	No	No	No	Yes, pharmacy technician license
UT	3	580	193	230		No	No	No	Yes	Yes	Yes	No	No

B.5	Number of pharmacy inspectors and number of pharmacies					Minimum training requirements for inspectors who assess pharmacies that perform sterile compounding							
	How many inspectors (full-time equivalents, FTEs) does the state employ who conduct pharmacy inspections?	Based on NCPDP data†			Number of pharmacies that perform sterile compounding	Entry-to-practice degree in pharmacy (e.g., B.Sc. Pharm., Pharm.D.)	Licensed pharmacist	Training on applicable USP standards	Prior experience in pharmacy	Prior experience in compounding pharmacy	Prior experience in sterile technique/compounding	No minimum training is mandated	Other
		Number of pharmacies	Number of pharmacies per pharmacy inspector (FTE)	Number of pharmacies that list compounding functions									
VA	5	1,849	370	699	172	No	Yes	Yes	Yes	No	No	No	No
VT	1	168	168	116		No	No	No	No	No	No	Yes	No
WA	10	1,473	147	553	80	No	Yes	No	No	No	Yes	No	No
WI*	Unsure	1,307		654		Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
WV	3.5	615	176	306		No	Yes	Yes	No	No	No	No	Yes, 5 years' experience is preferred
WY	1.5	147	98	58		Yes	Yes	Yes	Yes	No	No	No	Yes, NABP training

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

† Data from NCPDP Pharmacy Provider Database. Counts of pharmacies listing compounding activity may be an overestimation, as they include entities that perform any compounding, not just pharmacies specializing in this practice. It is also possible they are an underestimation, as this information was optional to provide.

Table B.6

Inspection Policy and Procedure Responses by State

B.6		AK*	AL	AR	AZ
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	Unsure	At least every 2 years	At least every year	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	No	Unsure	Yes; At least every year
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Unsure	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure	Initial licensure
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	Unsure	No	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	Unsure	4-8 hours	Other duration: Most last less than 4 hours, but some run over that time	Unsure
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	No	No	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	No	Yes	Unsure	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	Unsure	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Unsure	Yes	Yes	Unsure
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	No	Yes	Sometimes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	No	Yes	Unsure	NA
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	No	Unsure	NA

B.6		CA	CO	CT	DC
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	At least every year	Unsure	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	Yes; At least every 6 months	Unsure	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure	Unsure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, when a complaint or incident occurs, and other circumstances: Damaged premises shall be inspected by the mayor to determine their continued suitability for pharmacy operations
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	Unsure	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	4-8 hours	Less than 4 hours	Unsure	1-3 days
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	Yes	No	Unsure	Yes
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Unsure	Unsure	Yes
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	Other mechanisms: Could include submitting proof of correction, additional training of staff, additional inspections, citations and fines, license restriction	State requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed	State requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Unsure	No
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Yes	No	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	NA	Unsure	Yes	Yes
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	NA	Unsure	Yes	Unsure

B.6		DE*	FL*	GA*	HI	IA
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	At least every year	Unsure	No specific frequency	No specific frequency
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	Unsure	Unsure	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure and licensure renewal	Initial licensure, licensure renewal, and when a pharmacy remodels or moves location	Unsure	When a complaint or incident occurs and random inspections	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	Unsure	Unsure	Unsure	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	Unsure	Unsure	Unsure	Less than 4 hours	Other duration: It varies, depending on all services provided by the pharmacy; inspection not limited to sterile compounding practices
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	Unsure	Unsure	Unsure	Unsure	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Yes	Unsure	Unsure	Yes
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	Unsure	Unsure	Unsure	Unsure	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Unsure	Unsure	Unsure	Unsure	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Yes	Yes	Sometimes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	No	Yes	Yes	Yes	No
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	Unsure	Unsure	NA	Unsure

B.6		ID	IL	IN	KS	KY
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	No specific frequency	At least every 3 years	At least every year	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	Yes; No specific frequency	No	Yes; At least every year	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	When a pharmacy remodels or moves location and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	No	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	Less than 4 hours	4-8 hours	4-8 hours	4-8 hours	4-8 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	No	Yes	No	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Yes	No	No	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed	State conducts on-site inspection to ensure that issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Yes	Yes	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Yes	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	No	No	Yes	No	No
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	NA	Yes	Unsure	NA

B.6		LA	MA	MD	ME*	MI
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	Unsure	At least every year	At least every year	No specific frequency
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	Yes; At least every year	Unsure	No	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Unsure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, and when a complaint or incident occurs	Initial licensure and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	Unsure	No	Unsure	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	4-8 hours	Unsure	Less than 4 hours	Unsure	4-8 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	Unsure	Yes	Unsure	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Unsure	No	Yes	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed. Other mechanisms: Depends on level of disciplinary action. Follow-up is made part of monitoring team if issue rises to disciplinary action; if not, state conducts education and ensures compliance.	State requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Unsure	No	Unsure	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Unsure	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	Unsure	Yes	Unsure	Yes
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	Unsure	Unsure	Unsure	Unsure

B.6		MN	MO	MS	MT	NC*
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every 2 years	No specific frequency	At least every year	Unsure	At least every 5 years
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	Yes; At least every 2 years	Yes; At least every year	No	No	Yes; At least every year
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	No specific circumstances (other than annual inspections)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and other circumstances: change in ownership	Initial licensure and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	No	No	Unsure
	How long do inspections of pharmacies that perform sterile compounding usually last?	1-3 days	Other duration: It depends on the nature/scope of activities	Unsure	Less than 4 hours	Unsure
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	Unsure	Unsure	Yes	Unsure
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Yes	Unsure	Unsure	Unsure
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed. Other mechanisms: Responses depend on the nature of the violation.	State conducts on-site inspection to ensure that issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	Unsure
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Yes	No	Unsure
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Sometimes	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	NA	NA	NA	NA
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	NA†	Yes	Unsure	Unsure

B.6		ND	NE	NH	NJ	NM
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	At least every 5 years	At least every year	At least every year	At least every 2 years
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	No	No	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	No specific circumstances (other than annual inspections)	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	No specific circumstances (other than annual inspections)	Initial licensure, when a complaint or incident occurs, and when a pharmacy remodels or moves location	Initial licensure and when a pharmacy remodels or moves location
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	Sometimes	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	Less than 4 hours	Other duration: It depends on the individual pharmacy	4-8 hours	4-8 hours	Less than 4 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	No	No	Yes	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Unsure	Yes	No	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State requires written response describing how issues were addressed. Other mechanisms: Follow-up inspections may be conducted.	State requires written response describing how issues were addressed. Other mechanisms: Unannounced reinspections may occur depending on the nature of the violation.	State requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	No	Yes	Yes	Yes	No
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Sometimes	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	Unsure	Yes	Yes	No
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Yes	Unsure	No	Yes	Yes

B.6		NV	NY	OH*	OK	OR
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	At least every 3 years	Unsure	At least every year	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	Yes; At least every 2 years	Unsure	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, when a complaint or incident occurs, and other circumstances: Whenever board requests	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Unsure	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	No specific circumstances (other than annual inspections)
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	Unsure	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	4-8 hours	Other duration: It is variable	Unsure	4-8 hours	Less than 4 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	No	Unsure	Yes	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Yes	Unsure	Yes	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed. Other mechanisms: annual inspections; review of self-assessment form; notes regarding discrepancies or deficiencies; correction of discrepancies or deficiencies.	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	Unsure	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Unsure	Yes	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Yes	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	NA	Unsure	Yes	Unsure
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	NA	NA	Yes	Yes	No

B.6		PA	RI	SC	SD	TN
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every year	No specific frequency	At least every 2 years	At least every year	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	No	Yes; No specific frequency	No	No	Yes; At least every year
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, when a pharmacy remodels or moves location, when a complaint or incident occurs, and random inspections	Initial licensure, when a complaint or incident occurs, and random inspections	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	Unsure	No	No	Sometimes	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	Unsure	4-8 hours	Not verified‡	4-8 hours	4-8 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	Unsure	Yes	No	No	Yes
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Unsure	No	Yes	No	Yes
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	Unsure	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Yes	Yes	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Yes	Yes	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	NA	Yes	No	Unsure	Yes
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	NA	Yes	Unsure	NA	Yes

B.6		TX	UT	VA
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every 2 years	No specific frequency	At least every 2 years
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	Yes; At least every 2 years	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, when a complaint or incident occurs, and random inspections	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	No	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	4-8 hours	4-8 hours	4-8 hours; hospitals usually take 2 days
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	No	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	Yes	Yes	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed. Other mechanisms: For less serious violations, a warning notice is issued that requires a response from the pharmacy to indicate the correction. For more serious violations, the Board notifies the licensee of the Board's intent to institute disciplinary action, provides the licensee with the opportunity to show compliance. If the licensee is unable, they may consent to, and agree to the terms of, an Agreed Board Order. If the licensee does not wish to have an informal conference, a disciplinary hearing is scheduled.	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed	State requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Yes
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Yes	Sometimes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	Unsure	Yes
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Yes	Unsure	Yes

B.6		VT	WA	WI*	WV	WY
Inspection frequency	How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?	At least every 2 years	At least every year	At least every year	At least every year	At least every year
	Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding? If so, how frequently are these prioritized inspections conducted?	Unsure	Yes; At least every year	Unsure	No	No
	What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure and when a pharmacy remodels or moves location	When a complaint or incident occurs	Unsure	Initial licensure and when a pharmacy remodels or moves location	Initial licensure and when a complaint or incident occurs
Inspection protocols	Are inspections of pharmacies that perform sterile compounding announced?	Sometimes	No	Unsure	No	No
	How long do inspections of pharmacies that perform sterile compounding usually last?	4-8 hours	Less than 4 hours	Unsure	Other duration: 12 hours; FDA-led inspections may vary	4-8 hours
	Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?	No	Yes	Unsure	No	No
	Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?	No	Unsure	Unsure	No	No
	How does the state follow up with pharmacies to make sure that violations are addressed? (Includes other mechanisms reported by states in addition to response options provided.)	State requires written response describing how issues were addressed	State conducts on-site inspection to ensure that issues were addressed	Unsure	State requires written response describing how issues were addressed. Other mechanisms: Under certain circumstances, state goes back to conduct on-site inspections.	State conducts on-site inspection to ensure that issues were addressed and requires written response describing how issues were addressed
	Do state inspectors conduct or coordinate inspections with FDA?	Yes	Yes	Unsure	Yes	No
	Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?	Unsure	Yes	Unsure	Yes	Yes
Inspections by third parties	Must inspection reports by third parties or other states demonstrate compliance with USP standards?	Yes	No	No	No	Yes
	Do third-party inspectors provide all information on compliance and any compliance failures that are observed?	Unsure	Unsure	Unsure	No	Unsure

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

† Indicates that the state opted to abstain from answering that specific question.

‡ Indicates that the state did not respond to an email regarding further clarification that was needed to adequately address what the question was intended for. On those questions, the answer was defaulted to "Not verified."

Table B.7

Sterile Compounding Inspection Evaluation Responses by State

B.7	Factors evaluated during a sterile compounding inspection												
	Hand hygiene	Garbing	Aseptic technique	Training	Facility design and construc-tion	Cleaning	Environ-mental monitoring	Equipment certifica-tion and calibration	Steril-ization procedures and verification	Control of compo-nents and materials	Standard operating procedures	Documen-tation	Other
AK*	No	No	No	Yes	No	No	No	Yes	No	Yes	No	Yes	No
AL	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Hazardous product compounding, hazardous training, signed consent form, waste management, lists of which products are compounded and whether they are FDA-approved for compounding, invoices for bulk ingredients for source and certificate of analysis, shipping records and billing records to see who receives products and who pays for products; documentation for beyond use dating
AR	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No
AZ	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No
CA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
CO	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
CT	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
DC	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No
DE*	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
FL*	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No
GA*	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure

B.7	Factors evaluated during a sterile compounding inspection												
	Hand hygiene	Garbing	Aseptic technique	Training	Facility design and construc-tion	Cleaning	Environ-mental monitoring	Equipment certification and calibration	Sterilization procedures and verification	Control of compo-nents and materials	Standard operating procedures	Documen-tation	Other
HI	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
IA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
ID	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
IL	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No
IN	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
KS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
KY	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
LA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
MA	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
MD	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No
ME*	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
MI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No
MN	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
MO	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Other standards/issues that may affect the public health
MS	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
MT	No	No	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No
NC*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
ND	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

B.7	Factors evaluated during a sterile compounding inspection												
	Hand hygiene	Garbing	Aseptic technique	Training	Facility design and construction	Cleaning	Environ-mental monitoring	Equipment certification and calibration	Sterilization procedures and verification	Control of components and materials	Standard operating procedures	Docu-mentation	Other
NE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
NH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
NJ	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Records of required ongoing training for personnel involved in CSP preparation
NM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
NV	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
NY	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
OH*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
OK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
OR	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
PA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No
RI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
SC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
SD	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
TN	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

B.7	Factors evaluated during a sterile compounding inspection												
	Hand hygiene	Garbing	Aseptic technique	Training	Facility design and construction	Cleaning	Environ-mental monitoring	Equipment certification and calibration	Sterilization procedures and verification	Control of components and materials	Standard operating procedures	Docu-mentation	Other
TX	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Specific initial training for both pharmacist and pharmacy technicians who compound sterile products; and all pharmacy personnel preparing sterile preparations shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially followed by: every 12 months for low- and medium-risk level compounding; and every six months for high-risk level compounding
UT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
VA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
VT	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No
WA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
WI*	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
WV	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
WY	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Risk level

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

Table B.8

Oversight of Nonresident (Out-of-State) Compounding Pharmacies Responses by State

B.8		AK*	AL	AR	AZ
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	No	Yes; Within the past 2 years	Yes; Time period not specified
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes	Yes	Yes	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes—planning to require copy of other inspections; research FDA documentation, NABP report, disciplinary action from other states	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	Unsure	No specific frequency	No specific frequency	Unsure
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	License renewal, when a facility remodels or moves location, and when a complaint or incident occurs	Initial licensure and when a complaint or incident occurs	Initial licensure and other circumstances: Working on this for renewal	When a complaint or incident occurs

B.8		CA	CO	CT	DC	DE*
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	No	Unsure	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Unsure	Yes	No
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Unsure	No	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Unsure	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	No	Unsure	No	No
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Unsure	No	Yes
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Unsure	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	At least every year	Unsure	Unsure	At least every 2 years	At least every year
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Unsure	Unsure	Licensure renewal	Unsure

B.8		FL*	GA*	HI	IA	ID
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	No	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	Yes	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Yes
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	Yes; Within the past 6 months for initial licensure, within the past year for renewal	Yes; Within the past 6 months for initial licensure, within the past 2 years for renewal	No	No	Yes; Within the past 3 years
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	At least every year	At least every 2 years	No specific frequency	At least every year	No specific frequency
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure and licensure renewal	Initial licensure and licensure renewal	When a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, when a complaint or incident occurs, and other circumstances: failure to provide acceptable inspection report	Initial licensure

B.8		IL	IN	KS	KY	LA
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes	Yes	No	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	No	Yes; Within the past year	Yes; Time period not specified	No
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes—must be licensed in home state	No	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	No specific frequency	Unsure	At least every year	No specific frequency	At least every year
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	When a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure and licensure renewal

B.8		MA	MD	ME*	MI	MN
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Unsure	Yes	Yes	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	Yes	Yes	Yes	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	Yes	No	Yes	Yes
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	Yes	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	Unsure	Yes; Within the past 90 days	No	Yes; Time period not specified	Yes; Within the past 2 years
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	Unsure	At least every 2 years	At least every year	No specific frequency	At least every year
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Unsure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, and when a complaint or incident occurs	Initial licensure, licensure renewal, and when a complaint or incident occurs	Initial licensure and licensure renewal

B.8		MO	MS	MT	NC*	ND
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Unsure	No	Yes	Unsure	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	Unsure	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	Unsure	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	Unsure	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	Unsure	No	No	Unsure	Yes; Within the past year
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Unsure	No	No	Unsure	Yes
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	The Board is unaware of any way to verify compliance with regulations in other states	No	No	Unsure	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	No specific frequency	No specific frequency	No specific frequency	Unsure	At least every year
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, when a complaint or incident occurs, and other circumstances: Multiple factors may result in a compliance assessment, including news reports, disciplinary actions, investigations, inquiries, anonymous tips, FDA recall notices, etc.	Unsure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, when a complaint or incident occurs, and other circumstances: change in ownership	Unsure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs

B.8		NE	NH	NJ	NM	NV
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes	Yes	No	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Yes
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Yes
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	Yes; Within the past 18 months	Yes; Within the past 2 years	Yes; Time period not specified	Yes; Within the past year
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes—Mail Service Pharmacy License application requests the last 2 inspections conducted by the regulatory agency of the home state in which the pharmacy is located	Yes—pharmacy must provide GAP analysis	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	Unsure	At least every year	At least every year	No specific frequency	At least every 2 years
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure and when a complaint or incident occurs	Initial licensure and licensure renewal	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure and when a complaint or incident occurs	Initial licensure and when a complaint or incident occurs

B.8		NY	OH*	OK	OR	PA
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	Yes	No
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes	No	Yes	No	No
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	Yes	No	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	Yes; Within the past 2 years	Yes; Within the past 2 years	Yes; Within the past 3 years	No
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	At least every 3 years	At least every 2 years	No specific frequency	No specific frequency	No specific frequency
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	When a complaint or incident occurs	Unsure	Initial licensure, licensure renewal, and when a complaint or incident occurs	Initial licensure and when a complaint or incident occurs	No specific circumstances trigger an inspection

B.8		RI	SC	SD	TN	TX
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes	Yes	Yes	Yes	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes	Yes	No	No	Yes
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	Yes; Within the past 2 years	Yes; Within the past 4 years	Yes; Within the past year	No
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	No
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	No specific frequency	At least every 2 years	At least every year	At least every 2 years	At least every 2 years
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure, licensure renewal, when a pharmacy remodels or moves location, and when a complaint or incident occurs

B.8		UT	VA	VT	WA	WI*
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes	Yes	No	Unsure
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes	No	No	Unsure
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes	No	No	Unsure
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Unsure
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	Yes; Within the past year	Yes; Within the past 6 months for initial licensure, within the past 2 years for renewal	Yes; Within the past 3 years	No	Unsure
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Unsure
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No	No	No	Unsure
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	No specific frequency	At least every 2 years	Unsure	No specific frequency	Unsure
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	Initial licensure, when a pharmacy remodels or moves location, and when a complaint or incident occurs	Initial licensure and licensure renewal	Unsure	Initial licensure and when a complaint or incident occurs	Unsure

B.8		WV	WY
Methods used to assess out-of-state pharmacy compliance	For out-of-state pharmacies performing sterile compounding, does the state verify compliance with their applicable regulations?	Yes	Yes
	Are inspections performed by the National Association of Boards of Pharmacy (NABP) used by the state to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	Yes
	Are inspections performed by a third party approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No
	Are inspections performed by a third party not approved in advance by the state done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No
	Are reviews of inspection reports by another state, conducted in the past ____ years, done to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? If so, specify the number of years.	No	No
	Must the pharmacy provide self-evaluation or attestation of compliance to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	No	No
	Are there other means used to verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations?	Yes—FDA oversight as well	Yes—disciplinary actions must be provided
Frequency	How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?	Unsure	At least every year
	What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding? (Includes other circumstances reported by states in addition to response options provided.)	When a complaint or incident occurs	Initial licensure, licensure renewal, and when a complaint or incident occurs

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

Table B.9

Physician Office/Clinic Compounding Responses by State

B.9		AK*	AL	AR	AZ	CA	CO	CT	DC	DE*	FL*	GA*	HI
Physician office or clinic compounding	How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?	Unsure	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	Unsure	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	Unsure	There is no oversight system to ensure compliance	Unsure	Unsure	Other: Oversight provided by the state board of medicine, oversight provided by the state board of pharmacy	Unsure
	Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding?	Unsure	No	Unsure	Unsure	No	Unsure	Unsure	No	Unsure	Unsure	Unsure	No
	Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?	Unsure	No	Unsure	Unsure	No	Unsure	Unsure	Unsure	Unsure	Unsure	Yes	Unsure
	Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?	Unsure	No	Unsure	Unsure	Unsure	Unsure	Unsure	No	Unsure	Unsure	Unsure	Unsure

B.9		IA	ID	IL	IN	KS	KY	LA	MA	MD	ME*	MI	MN
Physician office or clinic compounding	How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?	There is no oversight system to ensure compli-ance	Oversight provided by the state board of pharmacy	There is no oversight system to ensure compli-ance	There is no oversight system to ensure compli-ance	There is no oversight system to ensure compli-ance	There is no oversight system to ensure compli-ance	Oversight provided by the state board of medicine	Unsure	Oversight provided by the state board of medicine	Unsure	Other: Oversight informed by allega-tions and complaints	Other: The Board of Pharmacy may have the authority to pro-vide oversight, but that authority is not clear. Consequently, the Board is not currently conducting inspections of sterile compounding done in offices and clinics.
	Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding?	No	No	No	No	No	No	No	Unsure	Unsure	Unsure	No	No
	Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?	Unsure	Yes	No	No	No	Unsure	Unsure	Unsure	Unsure	Unsure	No	No
	Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?	Unsure	Yes	No	Unsure	Unsure	No	Unsure	Unsure	Unsure	Unsure	Yes	Unsure

B.9		MO	MS	MT	NC*	ND	NE	NH	NJ	NM	NV	NY	OH*
Physician office or clinic compounding	How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?	Other: Missouri Board of Pharmacy does not have jurisdiction over physician offices	Oversight provided by the state board of medicine	Oversight provided by the state board of medicine	Unsure	There is no oversight system to ensure compliance	Other: Currently, only offices/clinics that possess a dispensing practitioner's pharmacy license will be inspected on drugs that are dispensed and charged to patients	Other: The Board of Pharmacy conducts inspections and reports findings to appropriate licensing board	Other: Clinics are under the regulation of the New Jersey Department of Health. Physician offices are under the regulation of the Board of Medical Examiners.	Other: Private physician offices are not inspected. But clinics are registered with NMBOP.	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	Oversight provided by the state board of pharmacy
	Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding?	NA†	No	No	Unsure	No	No	No	Unsure	No	No	No	Yes
	Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?	NA†	No	No	Unsure	Yes	Yes	Yes	Unsure	Yes	Unsure	Unsure	Unsure
	Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?	NA†	Unsure	No	Unsure	Unsure	Unsure	Unsure	Unsure	No	Unsure	No	Yes

B.9		OK	OR	PA	RI	SC	SD	TN	TX	UT	VA	VT
Physician office or clinic compounding	How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance	Oversight provided by the state board of medicine	Oversight provided by the state board of medicine	There is no oversight system to ensure compliance	Oversight provided by the state board of medicine	There is no oversight system to ensure compliance
	Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding?	No	No	No	No	No	No	No	Unsure	No	Yes	Unsure
	Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?	No	No	Unsure	Yes	Unsure	Unsure	No	Unsure	Yes	No	Unsure
	Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?	Unsure	No	Unsure	No	Unsure	Unsure	Unsure	Unsure	No	No	Unsure

B.9		WA	WI*	WV	WY
Physician office or clinic compounding	How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?	There is no oversight system to ensure compliance	Unsure	There is no oversight system to ensure compliance	There is no oversight system to ensure compliance
	Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding?	No	Unsure	Unsure	No
	Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?	No	Unsure	No	No
	Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?	Unsure	Unsure	No	No

Note:

* Indicates that a state either declined to participate in the survey or did not complete the survey. The answers for these states' responses have been found on publicly available websites.

† Indicates that the state opted to abstain from answering that specific question.

Endnotes

1 U.S. Food and Drug Administration, "Compounding and the FDA: Questions and Answers: What Is Compounding?" last updated Oct. 6, 2015, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#what.

2 Catherine Staes et al., "Description of Outbreaks of Health-Care-Associated Infections Related to Compounding Pharmacies, 2000-12," *American Journal of Health-System Pharmacy* 70, no. 15 (2013): 1301–12, doi: 10.2146/ajhp130049; and Centers for Disease Control and Prevention, "Multistate Outbreak of Fungal Meningitis and Other Infections" (Oct. 30, 2015), http://www.cdc.gov/hai/outbreaks/meningitis.html.

3 Kevin Outterson, "The Drug Quality and Security Act—Mind the Gaps," *New England Journal of Medicine* 370, no. 2 (2014): 97–9, doi:10.1056/NEJMp1314691; and Eric S. Kastango and Katherine H. Douglass, "Quality Standards for Large-Scale Sterile Compounding Facilities" (2014), http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/05/21/ensuring-the-safety-of-compounded-drugs.

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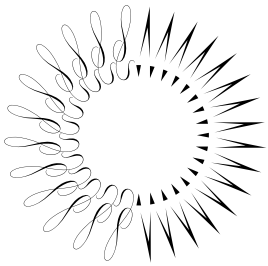

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