

# GAO Survey of State Pharmacy Regulatory Bodies on Drug Compounding

## U.S. Government Accountability Office

### SECTION I. Your Information

1. Who may we contact if we have any questions or need to clarify a response?

Name
Title
Agency
Department/Office
Email Address
Telephone Number

2. Does your office have **primary** responsibility for the oversight of drug compounding for human use performed by pharmacies, pharmacists, physicians, [FDA-registered outsourcing facilities](#), and other nonpharmacist practitioners in your state?

Yes	No
Drug compounding by pharmacies and pharmacists	
Drug compounding by <a href="#">FDA-registered outsourcing facilities</a>	
Drug compounding by physicians	
Drug compounding by other nonpharmacist health care practitioners (e.g., nurse practitioners, physician assistants)	
Other	

a. If 'Yes' to 'Other' is selected, please specify.

3. Do any other state agencies, offices, or departments have oversight responsibility for drug compounding in your state?

State Entity	Oversight responsibility for drug compounding?	Please describe the oversight responsibilities for this state entity.
Board of Medicine, other health professional boards	Yes ➡ ----- No ⬇ Don't know ⬇	
State Attorney General's Office	Yes ➡ ----- No ⬇ Don't know ⬇	
Department of Health (office or agency other than the board of	Yes ➡	

pharmacy)

-----  
No ↓

Don't know ↓

Department of Public Health  
(i.e., state agency monitoring  
community health)

Yes →

-----  
No ↓

Don't know ↓

Other (please describe in  
comment box);

Yes →

-----  
No ↓

Don't know ↓

## SECTION II. Information on Pharmacists, Pharmacies, and Drug Compounding in Your State

To provide an overview of **drug compounding for human use** in the United States, we would like to obtain information from states on pharmacists, pharmacies, pharmacy inspectors, the types of entities that compound drugs, and the extent of drug compounding in your state. For purposes of our survey, drug compounding includes general compounding (e.g., nonsterile creams, capsules, and ointments) and sterile compounding (e.g., sterile injections, parenteral solutions, and ophthalmic solutions). The questions in this section ask you to provide this information, as available and applicable, for your state, as of January 1, 2016.

4. Our study is focused on drug compounding for human use and not animal (veterinary) use. Can your office differentiate data on pharmacists, pharmacies, and pharmacy inspectors on drug compounding for human use versus drug compounding for animal use?

Yes, for all of the data

Yes, for some of the data

No

If 'Yes, for all of the data', in completing the survey please only enter data related to drug compounding for human use.

If 'Yes, for some of the data', in completing the survey please only enter data related to drug compounding for human use when possible.

a. Please explain which data your office can differentiate (e.g., if your office can differentiate data on pharmacists who compound drugs for human use but cannot do so for pharmacy inspectors).

If 'No', in completing the survey please enter the data you have available that combines both human and animal use.

5. Please provide the number of active and inactive licensed or registered pharmacists and pharmacy technicians, as applicable, in your state, as of January 1, 2016, or latest available date. If your office does not distinguish active and inactive please put a 'total' in

the *Active* column and note this in the comment box. If your most recent data are prior to January 1, 2016, please indicate the cut-off date here:

(ENTER DATE USING YYYY-MM-DD FORMAT)

Licensed or registered pharmacist and pharmacy technician categories	Number of active	Number of inactive	Comments/explanations
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**Resident** (in-state) pharmacists

**Nonresident** (out-of-state) pharmacists

**Resident** (in-state) pharmacy technicians (include all types of pharmacy technicians, e.g., certified and in-training)

**Nonresident** (out-of-state) pharmacy technicians (include all types of pharmacy technicians, e.g., certified and in-training)

Other types of pharmacists (please specify in comment box)

6. Does your state issue the following pharmacy licenses, permits, or registrations? If yes, provide the number of licensees, permit holders, or registrants for each category, as of January 1, 2016, or latest available date; if data are prior to January 1, 2016, please indicate the cut-off date here:

(ENTER DATE USING YYYY-MM-DD FORMAT)

Category of pharmacy license, permit, or registration	Does your state have this category of pharmacy license, permit, or registration?	If yes, provide the number of licensees, permit holders, or registrants for this category.	Comments/explanations
---	--	--	-----------------------

Total <b>resident</b> (in-state) pharmacies	Yes ➡		
	-----		
	No ↓		

Total <b>nonresident</b> (out-of-state) pharmacies	Yes ➡		
	-----		
	No ↓		

a. For the total number of resident and nonresident pharmacies noted above, please provide a breakdown by specific categories below, as applicable, in your state:

Category of pharmacy license, permit, or registration	Does your state have this category of pharmacy license, permit, or registration?	If yes, provide the number of licensees, permit holders, or registrants for this category.	Comments/explanations
---	--	--	-----------------------

<b>Resident</b> (in-state) sterile compounding pharmacy	Yes ➡		
	-----		
	No ↓		

**Nonresident** (out-of-state) sterile compounding pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) nonsterile compounding pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) community pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) nuclear pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) long-term-care pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) hospital pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) home infusion pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) specialty pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) Internet pharmacy or mail-order pharmacy

Yes ➡

-----

No ⬇

**Nonresident** (out-of-state) Internet pharmacy or mail-order pharmacy

Yes ➡

-----

No ⬇

**Resident** (in-state) wholesale distributor

Yes ➡

-----

No ⬇

**Nonresident** (out-of-state) wholesale distributor

Yes ➡

-----

No ⬇

**Resident** (in-state) [outsourcing facility](#)

Yes ➡

-----

No ⬇

**Nonresident** (out-of-state) [outsourcing facility](#)

Yes ➡

-----

No ⬇

Other (Please specify in the comment box)

Yes ➡

-----

No ⬇

b. Please elaborate on any of the above responses you feel need explanation:

7. Please provide the number of full time equivalents (FTE), as applicable, of pharmacy inspectors who are authorized by your state to inspect pharmacies, as of January 1, 2016 or latest available date; if data are prior to January 1, 2016, please indicate the cut-off date here:  
(ENTER DATE USING YYYY-MM-DD FORMAT)

Pharmacy inspectors	Number of FTEs	Comments/explanations
All pharmacy inspectors employed by your office or other state entity who are authorized to inspect <b>both</b> licensed <b>resident</b> (in-state) pharmacies and licensed or registered <b>nonresident</b> (out-of-state) pharmacies		
Pharmacy inspectors employed by your office or other state entity who are authorized to inspect <b>only</b> licensed <b>resident</b> (in-state) pharmacies		
Pharmacy inspectors employed by your office or other state entity who are authorized to inspect <b>only</b> licensed or registered <b>nonresident</b> (out-of-state) pharmacies		
Contracted or third party pharmacy inspectors who are authorized to inspect <b>both</b> licensed <b>resident</b> (in-state) pharmacies and licensed or registered <b>nonresident</b> (out-of-state) pharmacies		
Contracted or third party pharmacy inspectors who are authorized to inspect <b>only</b> licensed <b>resident</b> (in-state) pharmacies		
Contracted or third party pharmacy inspectors who are authorized to inspect <b>only</b> licensed or registered <b>nonresident</b> (out-of-state) pharmacies		
Other types of pharmacy inspectors (please specify in the comment box)		

8. What qualifications are required for pharmacy inspectors in your state?

(Check all that apply.)

- Current pharmacist's license
- Current pharmacy technician's license
- Law enforcement (e.g., sworn peace officers)
- Practiced pharmacy for a minimum number of years
- Prior experience in investigations and/or auditing
- Prior experience in compounding
- Completed investigator training program
- Completed a specialized training program in nonsterile compounding
- Completed a specialized training program in sterile compounding
- Other

If you checked 'Other', please specify.

a. Please elaborate on any of the above responses you feel need explanation:

9. Do your state pharmacy inspectors conduct [joint pharmacy inspections](#) with FDA inspectors?

Yes  
No

a. If yes, please describe the situations in which joint inspections have occurred.

b. How many joint inspections with FDA have your pharmacy inspectors conducted since January 1, 2014?

c. If no, please explain why your state has not conducted any [joint pharmacy inspections](#) with FDA inspectors.

10. Please indicate which of the following types of entities are authorized to prepare **sterile** compounded drugs in your state.

	Yes, authorized	No, not authorized	Don't know
Corporate chain pharmacies (e.g., Walgreens, CVS)			
Retail pharmacies (e.g., independently owned pharmacies, community pharmacies, compounding pharmacies that fill walk-in patient prescriptions)			
Compounding pharmacies (e.g., large-scale pharmacies that do not fill walk-in patient prescriptions, licensed in multiple states)			
<a href="#">FDA-registered outsourcing facilities</a>			
<a href="#">Outsourcing facility</a> (licensed or registered by state)			
Hospital pharmacies			
Outpatient clinics			
Home infusion pharmacies			
General practitioner's offices			
Medical specialty offices (e.g., dermatologists, pediatricians)			
Home health care agencies			
Hospice and palliative care agencies			

Other (please describe)

If 'Yes' is selected for 'Other', please describe.

11. Does your state collect information related to drug compounding on any of the following? If you do not have actual data but can estimate it, please input the estimates.

Information related to drug compounding	Does your state collect this information?	How frequently do you compile data?	Yearly total 2014	Yearly total 2015	Comments/explanations
The number of <b>all</b> licensed or registered pharmacies that compound <b>sterile</b> drugs	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in comment box)			
The number of licensed <b>resident</b> (in-state) pharmacies that compound <b>sterile</b> drugs	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in comment box)			
The number of licensed or registered <b>nonresident</b> (out-of-state) pharmacies that compound <b>sterile</b> drugs	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in comment box)			
The number of <b>all</b> licensed or registered pharmacies that compound <b>nonsterile</b> drugs	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in comment box)			
The number of licensed <b>resident</b> (in-state) pharmacies that compound <b>nonsterile</b> drugs	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in comment box)			
The number of licensed or registered <b>nonresident</b> (out-of-state) pharmacies that compound	Yes, actual data ➡ Yes, estimated counts ➡ ----- No ⬇	Weekly Monthly Quarterly Yearly Other (please specify in			

nonsterile drugs		comment box)
The number of prescriptions in the state for <b>sterile</b> compounded drugs	Yes, actual data ➡	Weekly
	Yes, estimated counts ➡	Monthly
	-----	Quarterly
	No ⬇	Yearly
		Other (please specify in comment box)
The number of prescriptions in the state for <b>all</b> compounded drugs	Yes, actual data ➡	Weekly
	Yes, estimated counts ➡	Monthly
	-----	Quarterly
	No ⬇	Yearly
		Other (please specify in comment box)
The volume (e.g., number of units) of drugs that are compounded in your state	Yes, actual data ➡	Weekly
	Yes, estimated counts ➡	Monthly
	-----	Quarterly
	No ⬇	Yearly
		Other (please specify in comment box)

### SECTION III. Types of State Laws, Regulations, and Policies Related to Drug Compounding

To obtain information on states' [laws, regulations, and policies](#) regarding **drug compounding for human use**, the following questions ask about specific state laws, regulations, and policies related to drug compounding. In addition to licensed pharmacists and pharmacies in your state, we are asking for information on your state's laws, regulations, and policies relating to [FDA-registered outsourcing facilities](#) and **drug compounding for human use** performed by physicians or other health care practitioners in your state. The questions in this section ask you to provide this information, as available and applicable, for your state, as of January 1, 2016.

12. Does your state have laws, regulations, or policies specific to any of the following?

State law, regulation, or policy	Does your state have this law, regulation, or policy?	Please identify the state statute(s), regulation(s), and/or policy(ies) that contain them.	Briefly describe these laws, regulations, or policies.
Does your state have laws, regulations, or policies specific to the practice of drug compounding?	Yes ➡ ----- No ⬇		
Has your state enacted laws or adopted regulations or policies related to drug compounding in response to the federal Drug Quality and Security Act (Pub. L. No. 113-54) enacted in November 2013?	Yes ➡ ----- No ⬇		



Are any additional legislation, regulations, or policies related to drug compounding under consideration in your state?

Yes ➡  
-----  
No ↓  
Don't know ↓

Does your state have laws, regulations, or policies specific to drug compounding by physicians or other nonpharmacist health care practitioners?

Yes ➡  
-----  
No ↓  
Don't know ↓

Are there any pending or proposed laws, regulations, or policies specific to drug compounding by physicians or other nonpharmacist health care practitioners?

Yes ➡  
-----  
No ↓  
Don't know ↓

Does your state have laws, regulations, or policies specific to [FDA-registered outsourcing facilities](#)?

Yes ➡  
-----  
No ↓  
Don't know ↓

Does your state have any pending or proposed legislation specific to [FDA-registered outsourcing facilities](#)?

Yes ➡  
-----  
No ↓  
Don't know ↓

Any other state laws, regulations, or policies specific to drug compounding (please list and describe all 'others' that apply).

Yes ➡  
-----  
No ↓  
Don't know ↓

13. **Drug compounding for office use** is the compounding of a drug product, without an individual patient prescription, to be kept as stock in a doctor's office, hospital, or other health care facility. Is drug compounding for office use authorized or allowed in your state?

Yes  
No

a. If yes, what limitations or requirements, if any, apply to this practice?

b. Please provide the citations to the statutes, regulations, and/or policies regarding drug compounding for office use.

14. **Anticipatory compounding** is the creation of a drug product prior to receipt of a prescription. Is anticipatory drug compounding authorized or allowed in your state?

Yes, for both sterile and nonsterile compounding  
Yes, for sterile compounding only  
Yes, for nonsterile compounding only  
No

a. If yes, what limitations or requirements, if any, apply to this practice?

b. Please provide the citations to the statutes, regulations, and/or policies regarding anticipatory compounding.

15. Please indicate whether your state's laws, regulations, or policies include the following types of provisions/rules related to drug compounding, as of January 1, 2016.

a. Provisions related to requiring a separate license or registration for sterile compounding

Type of provision related to drug compounding	Does this provision appear in your state's laws, regulations, or policies related to drug compounding?	Provide citation to the related state statute, regulation, and/or policy.	Comments: Please provide any qualifications or clarification for your response.
License or registration for <b>sterile</b> compounding facilities	Yes ➡ ----- No ↓ Don't know ↓		
License or registration for pharmacists who <b>prepare</b> sterile compounded drugs	Yes ➡ ----- No ↓ Don't know ↓		
License or registration for physicians or other nonpharmacist health care practitioners who <b>prepare</b> sterile compounded drugs	Yes ➡ ----- No ↓ Don't know ↓		
License or registration for physicians or other nonpharmacist health care practitioners who <b>administer or dispense</b> sterile compounded drugs	Yes ➡ ----- No ↓ Don't know ↓		
Other provisions related to licensing for <b>sterile</b> drug compounding (please list and describe all 'others' that apply)	Yes ➡ ----- No ↓ Don't know ↓		

b. Provisions related to labeling and testing

Type of provision related to drug compounding	Does this provision appear in your state's laws, regulations, or policies related to drug compounding?	Provide citation to the related state statute, regulation, and/or policy.	Comments: Please provide any qualifications or clarification for your response.
Compounded drug products are required to have labeling that	Yes ➡ -----		

indicates that the drug is a compounded drug	No <input type="checkbox"/> Don't know <input type="checkbox"/>
<b>Nonsterile</b> compounded drugs are subject to random or routine sampling for potency and purity	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>
<b>Sterile</b> compounded drugs are subject to random or routine sampling for potency, purity, and/or sterility	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>
Other provisions related to labeling and testing (please list and describe all 'others' that apply).	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>

c. Provisions related to compounding qualifications and standards

Type of provision related to drug compounding	Does this provision appear in your state's laws, regulations, or policies related to drug compounding?	Provide citation to the related state statute, regulation, and/or policy.	Comments: Please provide any qualifications or clarification for your response.
Pharmacy staff are required to demonstrate competence in compounding	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
Pharmacy staff are required to demonstrate competence in <b>sterile</b> compounding	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
Compliance with the U.S. Pharmacopeia (USP) Chapter 795 Pharmaceutical Compounding- <b>Nonsterile</b> Preparations (in part or whole)	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
Compliance with USP Chapter 797 Pharmaceutical Compounding- <b>Sterile</b> Preparations (in part or whole)	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
Compounding continuing education for licensed pharmacists and/or pharmacy technicians	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
<b>Sterile</b> compounding continuing education for licensed pharmacists and/or pharmacy technicians	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
State inspectors must have competence in <b>sterile</b> compounding	Yes <input type="checkbox"/> ----- No <input type="checkbox"/> Don't know <input type="checkbox"/>		
	Yes <input type="checkbox"/>		

Clean room alteration plan must be submitted for approval to the state pharmacy board	<div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>
Compounding facilities must be accredited or inspected by a board-approved third party	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>
Pharmacists must perform final check on a prescription compounded by a pharmacy technician	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>
Specific requirements for compounding of hazardous products, including biohazards, blood-borne pathogens, and other hazardous products	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>
Other provisions related to compounding qualifications and standards (please list and describe all 'others' that apply)	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>

#### d. Provisions related to reporting

Type of provision related to drug compounding	Does this provision appear in your state's laws, regulations, or policies related to drug compounding?	Provide citation to the related state statute, regulation, and/or policy.	Comments: Please provide any qualifications or clarification for your response.
Pharmacists report adverse drug events to the state pharmacy board or other entity	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		
Adverse drug events are reported to the state pharmacy board or other state entity, or FDA's MedWatch program	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		
Compounded drug recalls are made public by the state pharmacy board or other state entity	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		
Specific corrective actions for quality control deviations by pharmacists or pharmacies are made public by the state pharmacy board or other state entity	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		
Complaints filed by another state are reported to the state pharmacy board or other state entity	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		
Nonresident states report to resident state board of pharmacy on any actions taken against resident entities	<div> <div>Yes </div> <div>-----</div> <div>No </div> <div>Don't know </div> </div>		

Other provisions related to reporting (please list and describe all 'others' that apply)

Yes ➡

-----

No ↓

Don't know ↓

16. Does your state require [FDA-registered outsourcing facilities](#) that conduct business within your state to be licensed or registered in the state?

Yes

No

a. If yes, in which categories are [FDA-registered outsourcing facilities](#) required to be licensed or registered in your state? (Check all that apply.)

Pharmacy

Wholesale distributor

Manufacturer

Outsourcing facility (licensed or registered by the state)

Other (please describe)

If 'Other', please describe.

#### SECTION IV. Inspections and Enforcement Actions

As part of our study, we would like to obtain information on inspections of states' licensed pharmacies and other licensed or registered entities (e.g., wholesale distributors); the types of enforcement actions that states may take against pharmacists or pharmacies for violations of state laws, regulations, or policies regarding pharmacy practice; and the number of pharmacies that were subject to specific enforcement actions related to **drug compounding for human use**. The questions in this section ask you to provide this information, as available and applicable, for your state, as of January 1, 2016.

17. Please provide information on the frequency and types of inspections for licensed pharmacies and other licensed or registered entities required by your state as of January 1, 2016, or latest available date; if data are prior to January 1, 2016, please indicate the cut-off date here:  
(ENTER DATE USING YYYY-MM-DD FORMAT)

Licensed or registered entity	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Resident</b> (in-state) pharmacy	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No, none ↓	Recurring
		Other

If you checked 'recurring' for '**Resident** (in-state) pharmacy', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Resident** (in-state) pharmacy', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Nonresident</b> (out-of-state) pharmacy	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No, none ↓	Recurring
	No, rely on home state inspection ↓	Other

If you checked 'recurring' for '**Nonresident** (out-of-state) pharmacy', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Nonresident** (out-of-state) pharmacy', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Resident</b> (in-state) <b>sterile</b> compounding pharmacy	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No ↓	Recurring
	N/A, our state does not have this type of entity ↓	Other

If you checked 'recurring' for '**Resident** (in-state) **sterile** compounding pharmacy', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Resident** (in-state) **sterile** compounding pharmacy', please describe.

Does the state conduct inspections of this	Type of inspection
--	--------------------

	type of entity?	(Check all that apply)
<b>Nonresident</b> (out-of-state) <b>sterile</b> compounding pharmacy	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No, none ↓	Recurring
	No, rely on home state inspection ↓	Other
	N/A, our state does not have this type of entity ↓	

If you checked 'recurring' for '**Nonresident** (out-of-state) **sterile** compounding pharmacy', please indicate the frequency.

At least once a year

1 - up to 2 years

2 - up to 3 years

3 - up to 5 years

5 or more years

If you checked 'Other' for '**Nonresident** (out-of-state) **sterile** compounding pharmacy', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Resident</b> (in-state) wholesale distributor	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No ↓	Recurring
	N/A, our state does not have this type of entity ↓	Other

If you checked 'recurring' for '**Resident** (in-state) wholesale distributor', please indicate the frequency.

At least once a year

1 - up to 2 years

2 - up to 3 years

3 - up to 5 years

5 or more years

If you checked 'Other' for '**Resident** (in-state) wholesale distributor', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Nonresident</b> (out-of-state) wholesale distributor	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No, none ↓	Recurring
	No, rely on home state inspection ↓	Other
	N/A, our state does not have this type of entity ↓	

If you checked 'recurring' for '**Nonresident** (out-of-state) wholesale distributor', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Nonresident** (out-of-state) wholesale distributor', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Resident</b> (in-state) <a href="#">outsourcing facility</a>	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No ↓	Recurring
	N/A, our state does not have this type of entity ↓	Other

If you checked 'recurring' for '**Resident** (in-state) outsourcing facility', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Resident** (in-state) outsourcing facility', please describe.

	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
<b>Nonresident</b> (out-of-state) <a href="#">outsourcing facility</a>	Yes, all ➡	Pre-licensure
	Yes, some ➡	One time only (post-licensure)
	-----	For cause (e.g., in response to complaint)
	No, none ↓	Recurring
	No, rely on home state inspection ↓	Other
	N/A, our state does not have this type of entity ↓	

If you checked 'recurring' for '**Nonresident** (out-of-state) outsourcing facility', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for '**Nonresident** (out-of-state) outsourcing facility', please describe.



	Does the state conduct inspections of this type of entity?	Type of inspection (Check all that apply)
Other licensed or registered entity (please list and describe all 'others' that apply)	Yes ➡	Pre-licensure
	-----	One time only (post-licensure)
	No ↓	For cause (e.g., in response to complaint)
	Don't know ↓	Recurring
		Other

If you checked 'recurring' for 'Other licensed or registered entity', please indicate the frequency.

- At least once a year
- 1 - up to 2 years
- 2 - up to 3 years
- 3 - up to 5 years
- 5 or more years

If you checked 'Other' for 'Other licensed or registered entity', please describe.

18. Has your state experienced any challenges in maintaining or meeting the required inspection time frames as defined in your state's laws, regulations, or policies?

- Yes
- No
- Don't know

a. If yes, please explain the challenges you have encountered.

19. How does your state manage inspections of licensed or registered **nonresident** (out-of-state) pharmacies?  
(Check all that apply.)

- We conduct inspections using our own staff
- We recognize or accept inspections conducted by an outside entity (e.g., the National Association of Boards of Pharmacy)
- We accept records of inspections conducted by the resident state's pharmacy regulatory body
- We obtain a list of all compounded drugs shipped into the state
- We do not keep records of nonresident (out-of-state) pharmacy inspections. ([Click here to go to Question 20](#))
- Other

If 'Other', please describe.

a. Please explain the inspection schedule and any arrangements with an outside entity that conducts the inspections.

b. Please explain how these inspections are funded.

20. Please select the following types of enforcement actions your office may take against any pharmacists or pharmacies that are licensed or registered in your state. If data are available, for each applicable action, please indicate the number of such actions taken in 2014 and 2015 for violations involving **compounded drug products**.

Action	Can your state take this action?	Number of pharmacies receiving this type of action involving compounded drugs in calendar year 2014	Number of pharmacies receiving this type of action involving compounded drugs in calendar year 2015	Provide any comments/explanations
Monetary fine	Yes ➡ ----- No ⬇			
Suspension of pharmacist/pharmacy license	Yes ➡ ----- No ⬇			
Voluntary relinquishment or surrender of pharmacist/pharmacy license	Yes ➡ ----- No ⬇			
Mandatory recall of compounded drugs	Yes ➡ ----- No ⬇			
Probation of licensed pharmacist/pharmacy	Yes ➡ ----- No ⬇			
Revocation of pharmacist/pharmacy license	Yes ➡ ----- No ⬇			
Prosecution under state or federal law	Yes ➡ ----- No ⬇			
Cease and desist order	Yes ➡ ----- No ⬇			
Other (please list and describe all 'others' that apply)	Yes ➡ ----- No ⬇			

## SECTION V. Assessing the Safety and Quality of Compounded Drugs

The questions in this section are to help us obtain information on tools that purchasers of **compounded drugs for human use** and patients who receive prescriptions for compounded drugs can use to determine the safety and quality of those drugs. (We define "purchasers" as hospitals, clinics, pharmacies, health care

practitioners, and other entities that purchase compounded drugs directly from the compounding pharmacy or [FDA-registered outsourcing facility](#) that prepare the products.) Please provide the information as available and applicable.

21. How would your office notify **purchasers** of compounded drugs in your state that a compounded drug was found to be of questionable safety or quality?
22. Aside from the actions noted above, what other resources would your office direct **purchasers** of compounded drugs in your state to use in order to determine the safety and quality of compounded drugs?
23. Are you aware of ways for **patients** who receive prescriptions for compounded drugs in your state to know that their prescription is a compounded drug?
- Yes
- No
- a. If yes, please explain how in the box below.
24. How would your office notify **patients** using compounded drugs in your state that a compounded drug was found to be of questionable safety or quality?
25. Please describe any other ways in which **patients** who receive prescriptions for compounded drugs in your state can determine the safety and quality of these drugs.
26. Please describe any new tools or resources that you think FDA **should** provide to help purchasers of compounded drugs and patients who receive prescriptions for compounded drugs determine the safety and quality of these compounded drugs.

We would like to get an understanding of your communication and interactions with FDA related to **drug compounding for human use**. The questions in this section ask about specific interactions with FDA, any additional types of communication with FDA you may have had, any additional communication and interactions you would like to have, and any challenges and suggestions for improvement with your communication and interactions with FDA related to drug compounding.

27. Have you or anyone in your office participated in the following FDA-sponsored activities related to drug compounding since the federal Drug Quality and Security Act (Pub. L. No. 113-54) was enacted on November 27, 2013? If yes, please rate how helpful each activity was for your office to better understand issues related to drug compounding.

FDA activity	Have you or anyone in your office participated in this activity?	If yes, how helpful was this activity?
One or more of <a href="#">FDA's Listening Sessions</a> on pharmacy compounding in <b>2014</b>	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
One or more of <a href="#">FDA's Listening Sessions</a> on pharmacy compounding in <b>2015</b>	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
FDA's <b>March 2014</b> Intergovernmental Working Meeting on Pharmacy Compounding	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
FDA's <b>March 2015</b> Intergovernmental Working Meeting on Pharmacy Compounding	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
FDA's <b>November 2015</b> Intergovernmental Working Meeting on Pharmacy Compounding	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
FDA's Pharmacy Compounding Advisory Committee meeting, <b>February 2015</b>	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know
FDA's Pharmacy Compounding Advisory Committee meeting, <b>June 2015</b>	Yes ➡ ----- No ⬇ Don't know ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know

Other (please describe all 'others' that apply ) -----

Yes ➡

No ↓

Don't know ↓

Very helpful

Moderately helpful

Slightly helpful

Not at all helpful

Don't know

If you said 'Yes' to 'Other' above, please describe the FDA activity.

28. Have you had any other types of communication with FDA outside of FDA-sponsored events or activities related to drug compounding?

Yes

No

a. If yes, please describe your additional communication with FDA.

29. Have you or anyone in your office used FDA's website to obtain any of the following information on [FDA-registered outsourcing facilities](#) or on FDA inspections of or actions taken against compounding pharmacies or [FDA-registered outsourcing facilities](#) since the federal Drug Quality and Security Act (Pub. L. No. 113-54) was enacted on November 27, 2013?

**Information on FDA's website regarding inspections of and actions taken against compounding pharmacies and FDA-registered outsourcing facilities**

**Have you obtained this information?**

**If yes, how helpful was the information you obtained on FDA's website?**

**Please explain your response**

List of [FDA-registered outsourcing facilities](#)

Yes ➡

No ↓

Very helpful

Moderately helpful

Slightly helpful

Not at all helpful

Don't know

Names of compounding pharmacies that were inspected by FDA

Yes ➡

No ↓

Very helpful

Moderately helpful

Slightly helpful

Not at all helpful

Don't know

FDA Form 483 observation reports to determine violations found during inspections of **compounding pharmacies**

Yes ➡

No ↓

Very helpful

Moderately helpful

Slightly helpful

Not at all helpful

Don't know

FDA Form 483 observation reports to determine violations

Yes ➡

Very helpful

Moderately helpful

Slightly helpful

found during inspections of [FDA-registered outsourcing facilities](#)

No ☐

Not at all helpful  
Don't know

FDA Warning Letters issued to  
**compounding pharmacies**

Yes ☐

-----  
No ☐

Very helpful  
Moderately helpful  
Slightly helpful  
Not at all helpful  
Don't know

FDA Warning Letters issued to  
[FDA-registered outsourcing facilities](#)

Yes ☐

-----  
No ☐

Very helpful  
Moderately helpful  
Slightly helpful  
Not at all helpful  
Don't know

Information on recalls of  
compounded drugs

Yes ☐

-----  
No ☐

Very helpful  
Moderately helpful  
Slightly helpful  
Not at all helpful  
Don't know

Other (please describe all  
'others' that apply in the  
comment box)

Yes ☐

-----  
No ☐

Very helpful  
Moderately helpful  
Slightly helpful  
Not at all helpful  
Don't know

30. Do you have any suggestions for making the information on FDA's website regarding FDA inspections of or actions taken against compounding pharmacies or [FDA-registered outsourcing facilities](#) more helpful?

Yes  
No

a. If yes, please describe your suggestions in the box below.

31. FDA can share certain nonpublic information, including confidential commercial information, with state and local officials under a written confidentiality agreement entered into under its regulations at 21 C.F.R. § 20.88 (referred to as a 20.88 agreement). Has your office, or has any other agency, office, or department in your state, entered into a 20.88 Long-Term Drug Compounding Information Sharing Agreement with FDA?

Yes, our office has entered into a 20.88 agreement with FDA  
(Skip to a)  
Yes, another state agency, office, or department has entered into a 20.88 agreement with FDA (Skip to c)  
No (Skip to d)  
Don't know

a. From your perspective, how effective is the 20.88 agreement for sharing information regarding drug compounding?

Very effective

Somewhat effective  
Neither effective nor ineffective  
Somewhat ineffective  
Very ineffective  
Don't know

b. Please provide an explanation for your response.

[Click here to skip to Question 32](#)

c. Please provide the name of the state agency, office, or department.

[Click here to skip to Question 32](#)

d. If no, please explain why your state does not have a 20.88 agreement with FDA.

32. Commissioning is a process that permits state and local officials to conduct examinations, inspections, investigations, as well as collect and obtain samples, and copy and verify records under the Federal Food, Drug and Cosmetic Act even when their own state and municipal laws do not give them this authority. Does your office, or does any other agency, office, or department in your state, employ any individuals who are commissioned as an officer of the FDA for the purpose of engaging in designated federal functions related to drug compounding (e.g., conducting examinations, inspections and investigations; collecting and obtaining samples; or receiving and reviewing official FDA documents)?

Yes, our office has commissioned officers with FDA (*Skip to b*)

Yes, another state agency, office, or department has commissioned officers with FDA (*Skip to a*)

No (*Skip to e*)

Don't know

a. Please provide the name of the state agency, office, or department that has commissioned officers with FDA.

b. Please provide the number of FDA commissioned officers in your state as of January 1, 2016.

c. Please describe the types of interactions these employees have with FDA regarding engaging in designated federal functions related to drug compounding.

d. From your perspective, how effective is having commissioned officers in your state regarding sharing information and conducting activities with FDA related to drug compounding?

- Very effective
- Somewhat effective
- Neither effective nor ineffective
- Somewhat ineffective
- Very ineffective
- Don't know

Please provide an explanation for your response.

[Click here to skip to Question 33](#)

e. If no, please explain why your state does not have commissioned officers with FDA.

33. Have you or anyone in your office experienced any challenges regarding your communication or interactions with FDA related to drug compounding issues?

Yes

No - We have not experienced any challenges in our communication or interactions with FDA related to drug compounding issues.

N/A - We have not had any communication or interactions with FDA related to drug compounding issues. (*Skip to Q38*)

a. If yes, please indicate which of the following types of communication or interactions posed a challenge.

	Very challenging	Moderately challenging	Slightly challenging	Not at all challenging	Not applicable
Getting FDA to respond to our requests for information					
Scheduling an individual meeting with FDA					
Getting FDA to provide responses to our questions related to oversight of drug compounding					
Getting notification of pharmacy inspections conducted by FDA in our state					
Getting complete information from FDA in Form 483 observation reports on pharmacy inspections conducted by FDA in our state					
Getting FDA approval of our requests for joint inspections of licensed or registered pharmacies in our state					
Getting notification from FDA when FDA determines a licensed or registered pharmacy in our state is acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act					
Getting notification from FDA of FDA enforcement actions taken against licensed or registered pharmacies in our state					
Other communication or interactions					



(please specify below)

Please elaborate on any of the above responses you feel need explanation.

34. From your perspective, what has worked well in your communication and interactions with FDA related to drug compounding issues?

35. Please provide any suggestions you may have on ways to improve communication and interactions related to drug compounding between your office and FDA.

36. Overall, how satisfied are you with your communication and interactions with FDA related to drug compounding issues?

Very satisfied

Somewhat satisfied

Neither satisfied nor dissatisfied

Somewhat dissatisfied

Very dissatisfied

Don't know

a. Please provide an explanation for your response.

37. What additional communication or interactions, if any, would you like to have with FDA related to drug compounding issues, and why?

38. What communication or interactions, if any, would you like to have with FDA related to drug compounding issues, and why?

## SECTION VII. Communication with Other States

We would like to get an understanding of your communication and interactions with pharmacy regulatory bodies in other states related to **drug compounding for human use**. The questions in this section ask you to describe any specific communication and interactions your office has had with other state pharmacy regulatory bodies related to drug compounding, including any challenges and suggestions for improvement with your communication and interactions, and any

additional communication and interactions you would like to have.

39. Have you or anyone in your office communicated or interacted with representatives of pharmacy regulatory bodies in other states related to drug compounding issues since the federal Drug Quality and Security Act (Pub. L. No. 113-54) was enacted on November 27, 2013?

Yes

No (*Skip to Q45*)

Don't know (*Skip to Q45*)

a. If yes, please indicate the types of communication or interactions you or your office has had with other state pharmacy regulatory bodies related to drug compounding issues (not including FDA-sponsored activities).

Type of communication or interaction	Have you or your office had this communication or interaction?	How helpful was this communication or interaction?	Please provide any comments/explanations.
National associations (e.g., National Association of Boards of Pharmacy conferences, annual national association meetings)	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	
Regional associations (e.g., conferences or regional meetings)	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	
State-to-state direct communication (e.g., in-person meetings, phone calls and/or emails with other state boards of pharmacy)	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	
Conduct joint inspections with other state boards of pharmacy or other state pharmacy regulatory bodies	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	
Informal networking with other states that takes place at FDA- or industry-sponsored events	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	
Other types of interactions (please describe all 'others' that apply in the comment box)	Yes ➡ ----- No ⬇	Very helpful Moderately helpful Slightly helpful Not at all helpful Don't know	

40. Have you or anyone in your office experienced any challenges regarding your communication or interactions with other state pharmacy regulatory bodies related to drug compounding issues?

Yes

No

a. If yes, please describe the challenges in the box below.

41. From your perspective, what has worked well in your communication and interactions with other state pharmacy regulatory bodies related to drug compounding issues?

42. Please provide any suggestions you may have on ways to improve communication and interactions among state pharmacy regulatory bodies related to drug compounding.

43. Overall, how satisfied are you with your communication and interactions with other state pharmacy regulatory bodies related to drug compounding issues?

Very satisfied

Somewhat satisfied

Neither satisfied nor dissatisfied

Somewhat dissatisfied

Very dissatisfied

Don't know

a. Please provide an explanation for your response.

44. What additional communication or interactions, if any, would you like to have with other state pharmacy regulatory bodies related to drug compounding issues, and why?

45. What communication or interactions, if any, would you like to have with other state pharmacy regulatory bodies related to drug compounding issues, and why?

## **SECTION VIII. Implementation of Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA)**

FDA is the federal agency responsible for implementing sections [503A](#) and [503B](#) of the FDCA. In this section, we would like to get your

perspectives on information available from FDA regarding these provisions, any concerns your office is aware of regarding implementation of these provisions, and any suggestions you may have to improve federal and state coordination regarding the oversight of **drug compounding for human use**.

46. How useful would you say FDA's website is for each of the following?

	Very useful	Moderately useful	Slightly useful	Not useful at all	Have not used
General information on drug compounding					
Information related to section <a href="#">503A</a> of the FDCA					
Information related to section <a href="#">503B</a> of the FDCA					
Information on the federal Drug Quality and Security Act (Pub. L. No. 113-54)					
Information on and time frames for FDA's plans for implementing the federal Drug Quality and Security Act (Pub. L. No. 113-54)					
FDA proposed and final rules related to drug compounding					
FDA guidance documents related to drug compounding					
Other (please describe)					

If you responded to 'Other' above, please describe.

47. Has your office heard any concerns from pharmacies, pharmacists, practitioners, patients, or anyone else regarding FDA's implementation of section [503A](#) related to the following areas, as of January 1, 2016?

Area related to section 503A	Has your office heard concerns?	If yes, specify nature of concern.	Who expressed those concerns?
Availability of compounded drugs for office use	Yes ➡ ----- No ↓ Don't know ↓		
Access to certain compounded drugs for patients with a medical need for these drugs	Yes ➡ ----- No ↓ Don't know ↓		
Issues related to the practice of compounding performed by physicians or other nonpharmacist health care practitioners.	Yes ➡ ----- No ↓ Don't know ↓		
Other concerns related to section <a href="#">503A</a> (please describe in comment box)	Yes ➡ ----- No ↓ Don't know ↓		

48. Do you have any suggestions for steps that could be taken to improve federal and state coordination regarding the oversight of drug compounding?

Yes  
No  
Don't know

a. If yes, please describe in the box below.

49. Has your office submitted any comments regarding any of FDA's draft and final guidance documents, or proposed rules related to section [503A](#) or section [503B](#) of the FDCA that you would like to share with us? (Please note files over 2MB may not load properly. If you have a large file please email directly to [DrugCompoundingSurvey@gao.gov](mailto:DrugCompoundingSurvey@gao.gov))

Yes  
No

a. If yes, please attach comments using the link below.  
(SELECT A FILE TO UPLOAD)

no file selected

## SECTION IX. Comments

50. If you have any additional explanations of your answers or have any comments you would like to make, please share them below.

## SECTION X. Submitting Completed Survey

51. If you have completed this survey, please indicate below. (Please note: Your answers will not be included unless you have selected **'Completed'** here and clicked the **'Save & Exit Questionnaire'** button below.)

Completed  
Not completed

52. If you would like to view and print your responses before exiting the survey and saving your responses to GAO's secure server, click on the **'Summary: View and print a summary of your responses'** link in the menu on the left.

If you answered **'Completed'** above and do not want to view or print your responses, click on the **'Save & Exit Questionnaire'** button below to exit the survey and save your responses to GAO's secure server.

