

Oversight of Outsourcing Facilities

**Inter-governmental Working Meeting
on Drug Compounding
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Overview

Gail Bormel:

- Overview of the panel
- Outsourcing facility oversight: reviewing the issues
- Overview of breakout sessions

Gabrielle Cosel:

- Observed challenges related to FDA and state oversight of outsourcing facilities
- Preliminary FDA recommendations to states

Overview of the Panel

- **Gail Bormel and Gabrielle Cosel, FDA:** issues related to FDA and state oversight of outsourcing facilities, FDA recommendations on state oversight of outsourcing facilities
- **Carmen Catizone, NABP:** FDA and state oversight of outsourcing facilities, related updates to NABP Model Act
- **Virginia Herold, CA Board of Pharmacy:** state perspective on oversight of outsourcing facilities and related issues
- **Caroline Juran, VA Board of Pharmacy:** state perspective on oversight of outsourcing facilities and related issues

Outsourcing facility oversight: reviewing the issues

- Clear and consistent regulation of outsourcing facilities is important to their success, and by extension, successful implementation of the Drug Quality and Security Act (DQSA).
- FDA recognizes that both its own regulation and state regulation have a significant impact on the success of outsourcing facilities.
- FDA believes there are opportunities to advance a more harmonized regulatory approach that will enhance oversight, clarity, and consistency, and support the compliance and success of outsourcing facilities.

Outsourcing facility oversight: reviewing the issues

- Licensing/registration of outsourcing facilities
 - How should states license or register outsourcing facilities?
 - How do we address challenges presented when state licensure requirements differ, and create compliance hurdles for outsourcing facilities?
- Allowing outsourcing facilities to fill patient-specific prescriptions
 - How can state law differentiate between outsourcing facilities and non-outsourcing facility compounders, while allowing outsourcing facilities to respond to patient-specific orders?

Outsourcing facility oversight: reviewing the issues

- Distribution
 - How do we regulate outsourcing facility distribution, as distinct from traditional wholesale distribution?
- Inspections and Compliance with CGMP requirements
 - How do we ensure outsourcing facilities are held to CGMP standards, and not to other standards such as USP <797>?
 - Would more frequent FDA inspections help address state challenges in the licensure and regulation of these facilities?
 - What type of FDA support or training is most useful to states?

Breakout Sessions

- Several of these topics will be covered next in our presentation of **FDA recommendations**.
- FDA is interested in your feedback on these recommendations during our subsequent breakout sessions as well as on other topics not covered.
- **Breakout sessions will begin after lunch.** You will break into the same groups as for our breakout sessions on oversight of pharmacies: prescription requirements.
- All groups will travel to all four breakout sessions over the course of the next two hours or so. Each breakout will last 30 minutes.

Breakout Sessions

- **Session 1: Licensure** - State laws and policies for licensure and outsourcing facility filling of patient-specific prescriptions
- **Session 2: Regulation** - distribution and wholesaling, pharmacist supervision of compounding at outsourcing facilities
- **Session 3: Inspections** - frequency of FDA inspections, State desire to conduct inspections and for related training
- **Session 4: Open Discussion** – achieving a functional outsourcing facility sector, other issues not yet raised

Breakout Sessions

	1:00 PM	1:35 PM	2:10 PM	2:45 PM
Group A	Session 1: Licensure 1406	Session 2: Regulation 1408	Session 3: Inspections 1504	Session 4: Open Disc. 1506
Group B	Session 2: Regulation 1408	Session 3: Inspections 1504	Session 4: Open Disc. 1506	Session 1: Licensure 1406
Group C	Session 3: Inspections 1504	Session 4: Open Disc. 1506	Session 1: Licensure 1406	Session 2: Regulation 1408
Group D	Session 4: Open Disc. 1506	Session 1: Licensure 1406	Session 2: Regulation 1408	Session 3: Inspections 1504

Observed Oversight Challenges

FDA Recommendations to States

Observed Oversight Challenges

- State requirements that apply to federally registered outsourcing facilities may differ from state to state.
- Because most outsourcing facilities ship interstate, heterogeneity in state requirements can cause challenges. Differences from federal requirements create additional challenges and confusion.
- Such challenges have the potential to undermine the development of outsourcing facilities as a source of compounded drugs prepared subject to higher quality standards.
- FDA developed a document outlining some challenges that we hear about frequently, and describing recommendations to states on regulatory approaches to help address them.

Observed Oversight Challenges

- **State licensure and registration requirements**
 - Variations in state licensure or registration categories and related regulatory requirements for outsourcing facilities can effectively prevent the outsourcing facility from doing business in multiple states.
 - For example, one state may require an outsourcing facility that sends compounded drugs into the state to be licensed as a pharmacy in its state of residence, but the state in which the outsourcing facility is located may prohibit the outsourcing facility from being licensed as a pharmacy.
 - Under federal law, outsourcing facilities are not required to, but may, hold a pharmacy license (Section 503B(d)(4)).

Observed Oversight Challenges

- **Filling patient-specific prescriptions**
 - Certain state laws may not provide for outsourcing facilities to fill patient-specific prescriptions.
 - Under federal law, an outsourcing facility may or may not obtain prescriptions for identified individual patients (Section 503B(d)(4)(C)).
 - If a state law were to prohibit an outsourcing facility from being licensed as a pharmacy, and if pharmacy licensure were required in the state in order for a facility to fill patient-specific prescriptions, an outsourcing facility could be prevented from engaging in this practice in that state.

Observed Oversight Challenges

- **CGMP requirements**

- Under federal law, an outsourcing facility, whether or not it is licensed as a pharmacy, must meet CGMP requirements for all compounding of human drugs in that facility, even when compounding drugs to fill patient-specific prescriptions.
- State regulations that require compliance with quality standards other than CGMP requirements could cause confusion about what standard applies or suggest a need to comply with more than one standard.

Preliminary Recommendations for States

- **State licensure and registration requirements**
 - We recommend that states create a licensure or registration category specific to outsourcing facilities.
 - Requiring these facilities to be primarily licensed as manufacturers, wholesale distributors, or pharmacies can result in conflicts with other states' laws.
 - Compliance with federal law applicable to outsourcing facilities should be a condition of state licensure or registration under this category.
 - State licensure or registration of outsourcing facilities allows the state to define the set of tools it may use to address an outsourcing facility's noncompliance, which may supplement or be more agile than those available to FDA.

Preliminary Recommendations for States

- **Filling patient-specific prescriptions**
 - We recommend that states allow entities that are licensed or registered with states as outsourcing facilities to fill patient-specific prescriptions.
 - We understand that the most practical way for many states to allow this may be to license the outsourcing facility as a pharmacy in addition to primary licensure as an outsourcing facility.
 - However, states should take care to address any state pharmacy requirements that, if applied to outsourcing facilities, could conflict with federal law
 - As state policies shift, we recommend that states consider differences between their requirements and other states' requirements that may prevent an outsourcing facility from doing business in both states, and make efforts, where reasonable, to address such barriers.

Preliminary Recommendations for States

- **CGMP requirements**

- We recommend that states make clear that as a condition of licensure or registration as an outsourcing facility, regardless of additional licensure as a pharmacy, all compounding activity that occurs at an outsourcing facility, including patient-specific compounding, are subject to CGMP requirements.
- Drugs compounded at an outsourcing facility registered with FDA under section 503B are subject to CGMP requirements, and while the outsourcing facility remains registered, such drugs cannot qualify for exemptions from CGMP requirements under section 503A.

For Further Discussion in Breakouts:

- **Inspections and training**
 - FDA consideration of CGMP training for states was an action item following the 2015 Intergovernmental Meeting.
 - FDA recognizes that states may wish to independently inspect outsourcing facilities for quality, particularly when a state requires more frequent inspections to maintain state licensure than FDA currently conducts.
 - State desire to inspect outsourcing facilities has also resulted in a desire for training on conducting a CGMP inspection.

For Further Discussion in Breakouts:

- **Inspections and training**

- FDA remains committed to supporting states by providing needed training, but would like to understand from states whether an increase in the frequency of FDA outsourcing facility inspections – which is FDA's goal – would alter states' desire to conduct independent inspections.
- Given the complexity of full CGMP inspections, we would also like to understand whether states would see utility in training on an abbreviated inspection for outsourcing facilities focusing on insanitary conditions as well as significant potency problems.

Conclusion

- Collaboration and alignment between FDA and the states are fundamental to instituting complementary compounding oversight programs.
- Alignment of oversight systems will help support the success of the outsourcing facilities by reducing regulatory confusion or potential conflict for compounded drug products in interstate commerce.
- FDA will continue to perform inspections of outsourcing facilities as required under section 503B(b)(4) of the FD&C Act, communicate as closely as possible with states regarding inspections in their jurisdictions, and provide states with the opportunity to accompany FDA on these inspections.