Sterile Compounding: Where Do We Stand?
A Symposium Conducted at the 2014 ASHP Summer Meetings & Exhibition

Activity Description
In the wake of the 2012-13 fungal meningitis outbreak tied to contaminated compounded steroid injections, the Drug Quality and Security Act (DQSA) was enacted in November 2013. The DQSA allows for compounding pharmacies, or “outsourcing facilities,” to register with the FDA and be subject to FDA inspection requirements, quality standards, and adverse event reporting. The FDA Commissioner has strongly encouraged U.S. hospitals and other providers to work exclusively with FDA-registered facilities. Implementation of the new law poses challenges on several levels - federal, state, and local regulation; operations at compounding pharmacies; and operations within health systems and their pharmacy departments. This symposium will draw upon the expertise of those currently working through the implementation challenges of the DQSA at the regulatory and health-system pharmacy levels.

Location / Agenda
Mirage Las Vegas
3400 Las Vegas Blvd South
St. Croix Room
Las Vegas, Nevada
June 3, 2014
5:45 AM - 6:15 AM Registration & Breakfast
6:15 AM - 7:45 AM Educational Activity

Learning Objectives
The target audience for this activity includes pharmacists in health-system settings. At the completion of this activity, the participant will be able to:
- Differentiate Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act
- Define what FDA oversight entails for registered outsourcing facilities
- Describe the current status of federal and state implementation of the Drug Quality and Security Act and the anticipated impact on sterile drug compounding operations
- Discuss enhanced efforts by the NABP and state boards of pharmacy to oversee the compounding of sterile products
- Outline criteria and processes for ensuring that the safest and highest-quality sterile preparations are provided to patients

Faculty / Funding
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Accreditation
ProCE, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number 0221-0000-14-061-L05-P has been assigned to this live knowledge-based activity (initial release date 06-03-14). This activity is approved for 1.5 contact hours (0.15 CEUs) in states that recognize ACPE providers. The activity is provided at no cost to participants. Completion of an online self-assessment and evaluation at www.ProCE.com is required to receive CE credit. CE credit will be uploaded automatically to NABP/CPE Monitor within 3 to 4 weeks after completion of the self-assessment and evaluation. No partial credit will be given.

Faculty Disclosure
It is the policy of ProCE, Inc. to ensure balance, independence, objectivity and scientific rigor in all of its continuing education activities. Faculty must disclose to participants any significant financial interest or affiliation with companies that manufacture or market products discussed in this activity. Ms. Kienle is a stockholder and employee of Cardinal Health. Dr. Madigan has no relevant commercial or financial relationships to disclose. Dr. Paulsen has no relevant commercial or financial relationships to disclose. A portion of grant funds received by ProCE from PharMEDium will be used to compensate the faculty for this presentation.

Please note: The information and views presented in this activity are those of the faculty through clinical practice and knowledge of the professional literature. Portions of this activity may include the use of drugs and/or devices for unlabeled indications, which should be considered experimental. Participants are advised to consult manufacturer product information and the professional literature, and use professional judgment in applying the presented information in patient-care activities.
About the Faculty

Patricia C. Kienle, RPh, MPA, FASHP

Patricia Kienle is the Director of Accreditation and Medication Safety for Cardinal Health Innovative Delivery Solutions. She received her pharmacy degree from the Philadelphia College of Pharmacy and Science, and a Masters in Public Administration from Marywood University in Scranton, Pa. She completed an Executive Fellowship in Patient Safety from Virginia Commonwealth University and is an adjunct associate professor at Wilkes University in Wilkes-Barre, Pa.

She has served on the Board of Directors of the American Society of Health-System Pharmacists and as President of the Pennsylvania Society of Hospital Pharmacists. She is a Fellow of the American Society of Health-System Pharmacists, was named Pharmacist of the Year by the PSHP, and was the recipient of the Distinguished Achievement Award in Hospital and Institutional Practice from the American Pharmaceutical Association Academy of Pharmacy Practice and Management. She has served on the Pharmacotherapy Specialty Council of the Board of Pharmaceutical Specialties, as the pharmacist member of the Hospital Professional and Technical Advisory Committee of The Joint Commission, and on the Board of Governors of the National Patient Safety Foundation. She is a current member of the USP Expert Committee on Compounding, and Chair of the Subcommittee and Expert Panel on Hazardous Drugs.

Patti is the author of *Compounding Sterile Preparations: ASHP’s Visual Guide to Chapter <797> video and Companion Guide*, and co-author of *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide, 8th edition*. She also edited *Understanding JCAHO Requirements for Hospital Pharmacies*. She is a frequent presenter to professional groups, with special interests in promoting medication safety, compounding sterile preparations, accreditation, and regulatory issues.

Melissa Madigan, PharmD, JD

Melissa Madigan, PharmD, JD, is the Policy and Communications Director for the National Association of Boards of Pharmacy (NABP). After graduating from DePaul University College of Law, Melissa began her tenure with NABP in 1995 as Professional Affairs Manager. Prior to that time, she worked as a pharmacist in a variety of pharmacy practice settings, including the University of Illinois Hospital, Loyola University Hospital’s Cancer Center, and Osco Drug. Melissa is a graduate of the University of Illinois at Chicago College of Pharmacy. She also spent 5 years as a Pharmacy Law instructor for third-year pharmacy students at Midwestern University Chicago College of Pharmacy in Downers Grove, Ill. Melissa is a member and a Past President of the American Society for Pharmacy Law.

Lynn Mulcahy Paulsen, PharmD

Lynn Paulsen has spent her 40-year career leading acute-care hospital pharmacies within small, large, community, and academic institutions. During these years, she has seen sterile compounding evolve. For the last 3 years, she has pioneered a role as an internal consultant for the University of California to support its 5 medical centers and 10 hospitals in the management of issues that affect all facilities. An emphasis on practice standards is particularly germane in the decision to outsource sterile compounding and to address associated risk and quality issues.
Patricia C. Kienle, RPh, MPA, FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions

Sterile Compounding:
Highlights of the New Law

The Big Questions

• What does compliance with 503B mean?
• What do I need to monitor?
• How can I identify safety and quality issues?
• What’s likely to happen next?
Traditional Compounding

- Nonsterile compounding
- Sterile compounding
  - 1970s: TPN, antibiotics
  - Common infusions not available from manufacturers
  - Old drugs → no new dosage forms

Sterile Compounding Timeline

- FDA Alert Letter
- ASHP Urgent Attention Letter


- NCC LVP
- National Survey
- ASHP TAB
  - USP <1206>
  - National Survey
  - ASHP Guidelines
- USP <797>
- National Survey
The Regulatory Evolution

Compliance Policy Guide
Compounded drugs exempted from certain provisions of FD&C Act if specific criteria were met

FDAMA Challenge
Section 503 invalidated based on advertising issue
FDA focus: non-patient-specific + cross state lines

Drug Quality & Security Act
Section 503 A
Section 503 B

What Got Us Here?

• Market needs
• USP <797>
• Resources
  – Facilities
  – Competent personnel
  – Use of compounds not commercially available
Outsourcing Facilities

- Fill the void
- Control
- Labeling
- Bar code

While still common, outsourced compounding has yet to recover from last year’s decline.*


Sterile Products and Preparations

- Compounded preparation mixed in pharmacy
- Compounded preparation mixed in FDA-registered facility
- FDA-approved drug manufactured in FDA-registered facility
Drug Quality & Security Act

- Quality → compounding
- Security → track and trace
- Section 503
  - 503A: Traditional compounding
  - 503B: Outsourcing facilities

DQSA Applies to. . .

- All pharmacies
- Some types of medications are carved out
  - Radiopharmaceuticals
  - Investigational agents
  - Veterinary compounds
Oversight of Medications

<table>
<thead>
<tr>
<th>Pedigree</th>
<th>Oversight</th>
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<tbody>
<tr>
<td>Manufacturer</td>
<td>FDA</td>
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<tr>
<td>Outsourcing facility</td>
<td>FDA and SBOP</td>
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<tr>
<td>Compounding pharmacy</td>
<td>SBOP</td>
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<tr>
<td>Patient-specific</td>
<td></td>
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<tr>
<td>Non–patient-specific</td>
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<tr>
<td>Nuclear pharmacy</td>
<td>SBOP</td>
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<td></td>
<td>May include carve in or carve out in state regulations</td>
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Voluntary Registration

- Quality and safety issue
- Will be a market-driven selection
- FDA letter to each US hospital
FDA Letter – January 8, 2014

• To colleagues
• To hospital purchasers
• Encourages use of FDA-registered outsourcing facilities

Contracted Services

• CMS Hospital Conditions of Participation
• Accreditation organizations
  – The Joint Commission
  – DNV Healthcare
  – Healthcare Facilities Accreditation Program
  – Center for Improvement in Healthcare Quality
• Health-system leadership needs to be aware of and approve any contracted service
## Outsourcing Facility Requirements

- Registration fee
- Provide FDA with information about compounded products
- FDA inspection on risk-based schedule
- Comply with Good Manufacturing Practices
- Other conditions
  - Regulation
  - Report adverse drug reactions
  - Labeling information

## FDA Compounding Web Site

[www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm)
Market Issues

• Meet market needs
• Provide compounded sterile preparations
  – Appropriate
  – Consistent
  – Cost effective
  – Safely labeled
  – Available

What Needs to Be on Our Radar?

• Identify what you are using
  – Patient-specific
  – Not patient-specific
• Provide information to health-system administration
• Monitor FDA web site
• Stay informed about state issues (e.g., Ohio & NY)
• Be a savvy consumer
• Evaluate outsourcing facilities (e.g., nonsterile-to-sterile compounding)
Melissa Madigan, PharmD, JD
Policy and Communications Director
National Association of Boards of Pharmacy

State Boards of Pharmacy and NABP Efforts Related to the New Law

National Association of Boards of Pharmacy

- 501(c)(3) charitable and educational organization
  - Founded in 1904
- Members are state boards of pharmacy for the 50 states, District of Columbia, and United States territories
  - Boards regulate the practice of pharmacy laws/regulations
  - Boards license pharmacists, pharmacy technicians, pharmacies, and other facilities that handle prescription drugs (varies from state to state)
  - Disciplinary actions for violations of laws/regulations
- NABP’s mission is to assist member boards in public protection
  - License transfer program, examinations, and accreditations
  - Various support for day-to-day activities
  - Interactive meetings
Fungal Meningitis Outbreak: Lessons Learned

• States need to be able to better identify sterile compounding pharmacies
• States have differing (or no) standards for compounding
• States need adequate resources
  – More robust and timely inspection programs
  – Appropriate educational background and training for inspectors on sterile compounding

Fungal Meningitis Outbreak: More Lessons Learned

• Some states only require inspection on initial licensure, giving no assurance for subsequent renewals
• Legislation/regulation changes are needed to address needs
• A need exists for communication protocols
  – Between states
  – Between states and FDA
• The current nonresident pharmacy system is not working
Post-Outbreak NABP Action Plan

• Collaborate/communicate with FDA/Congress on behalf of the boards
• State-specific inspection programs
  – Iowa
    ▪ 2013: NABP inspected all nonresident pharmacies (about 600)
  – New Jersey
    ▪ 2013-2014: NABP inspected all in-state compounding pharmacies, sterile and non-sterile (about 170)
• Offer training and education
• Create an information-sharing network

Nonresident Pharmacy Licensure Process Prior to Outbreak

• Submit application and fee to state board
• Provide proof of licensure from state of domicile
• Submit copy of inspection or proof of inspection
  – In some, not all, states
    ▪ Some states require an inspection on initial application, but not for renewals
    ▪ Nonresident states were relying on resident states to provide adequate oversight, inspections, and investigations/complaint resolution
Solution: Verified Pharmacy Program

- VPP system was developed to fill gaps in the nonresident system and to provide states complete information needed to make licensing decisions
- NABP extrapolated successes of the Electronic Licensure Transfer Program for pharmacists and applied it to facilities that want to operate in multiple states
- NABP e-Profile ID is created for each pharmacy and linked to e-Profiles for key pharmacy personnel
- An inspection clearinghouse was created to facilitate sharing of inspection reports/results

VPP: Unified Resource for States

- Verify pharmacy licenses (resident/nonresident)
- Verify pharmacist-in-charge licenses, both resident and nonresident
- Verify that a qualified inspection has occurred
  - By resident state in accordance with established uniform standards
  - By NABP
- Report any disciplinary action by another state
- All information packaged through VPP within the Board e-Profile Connect interface
Benefits for State Boards

- Agreement on uniform, minimum standards that would be acceptable to all boards
  - Ability to customize, if necessary, to ensure that nonresident pharmacies are practicing at the standard required by resident state
- Boards will be able to make informed licensing decisions on nonresident pharmacies
- Information will be seamlessly integrated into the Board e-Profile Connect system
- No cost to the boards

Benefits to Nonresident Pharmacies

- One inspection meets needs of multiple states
  - Resident state inspection is reviewed to determine if it meets VPP criteria
    - Timeliness and inspection content are considered
    - If inspection is not approved, NABP will perform the inspection
- Uniform standards accepted by the states creates level playing field for all pharmacies operating in multiple states
- Costs are lower than would be if every state sent its own inspectors and required the pharmacy to cover costs
Future Enhancements

• Assist nonresident pharmacies with pushing information to boards, e.g., change in pharmacist-in-charge
• Criminal background checks based on state requirements
• Other customizations that could provide value for NABP member boards or pharmacies will be evaluated

DQSA and NABP

• NABP is recognized in the new federal law as having a consulting role with FDA in the law’s implementation
• System established for boards of pharmacy to report:
  – Suspensions, revocations, disciplinary actions, sanctions, and warning letters for pharmacy compounding violations
  – Pharmacy recall activities related to purity or quality of compounded products
  – Concerns that a pharmacy may be exceeding the scope of 503A of the Federal Food, Drug, and Cosmetic Act
• U.S. Department of Health and Human Services is also required to report such activities to boards
Current 503A and NABP: Memorandum of Understanding

- Section 503A(b)(3) of the FD&C Act directs the FDA to develop a Memorandum of Understanding (MOU), in consultation with NABP, for use between FDA and the states
- MOU will address:
  - Interstate distribution of inordinate amounts of compounded drug products
  - Appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside the state

Current 503A and NABP: Limitations Without an MOU

- Under 503A(b)(3)(B)(ii), an individual or firm in a state that does not enter into an MOU with the FDA can compound only 5% of total prescription orders for distribution outside the state
  - FDA does not intend to enforce this limitation until 90 days after FDA finalizes an MOU and makes it available to states for their consideration and sign-off
From Action Plan to Now

- Continue to provide training opportunities to the boards and their compliance officers as needed
- Develop a system to continue providing inspection assistance within NABP staffing resources
- Improve communication systems between states and federal agencies
- Development of MOU

What Actions Are States Taking?

- NABP surveyed states earlier this year
- About 1/3 of states replied that they:
  - Will/might license outsourcing facilities as pharmacies
  - Have or will/might create a sterile compounding facility category of licensure
- About 1/4 of states replied that they:
  - Will/might license outsourcing facilities as wholesalers
- Creation of a new outsourcing facility category of licensure
  - About 10% replied they will
  - 60% said they are considering it
Outsourcing Facility Outlook for New York

• Emergency legislation passed as part of NY State budget bill in April
• State Board of Pharmacy is amending Section 6802 of the education law
• Best approach of the SBOP was creation of new “outsourcing facility category”
• Draft regulation was reviewed on May 7 at public session in Albany
• Regulation expected to pass official vote June 22-23
• With adherence to specifics of the new regulation, outsourcing facilities as early as July 1

Outsourcing Facility Outlook for Ohio

• Similar to New York, creation of new category expected at state level
• Special rules committee expected to recommend approach to outsourcing facility licensure at state level
• Potential Ohio Board of Pharmacy vote on this rule in early June
• With passage, no more than 60 days to allow outsourcing facilities registered as 503B to provide services in Ohio
Lynn Paulsen, PharmD  
Director, Pharmacy Practice Standards  
University of California  

Outsourcing of Sterile Compounding:  
The Experience at UC Health  

What We Did at UC Health  

- Site visits for all compounding pharmacies (patient-specific and batches) used by any of our 10 hospitals on 5 campuses  
- 503A and 503B pharmacies  
- Utilization of Risk Management Advisor (RMA)  
  - 1 member of the RMA group  
  - 1 pharmacist-attorney specializing in compounding litigation  
  - 1 pharmacist from one of our hospitals  
  - 1 pharmacy manager from Central Operations
What RMA Group Did

- Prepared standard review process and documentation tool
- Identified external expert for the review:
  - Pharmacist-attorney specializing in compounding litigation; knew exactly what questions to ask
- Made all formal arrangements for site visits
- Comprehensive report at conclusion
- Paid by central System Risk Oversight group

The Review Process

- One full day per facility (4-6 hours)
  - First 2 hours: hear about process and review P&P
  - Direct observation of sterile compounding
    - Through window; if none, full garbing required
  - Interview compounding staff
  - Review QA data for past year
    - Request any 483s not posted on FDA website
    - Board of Pharmacy inspections
- Post-visit review of data
  - Report to Directors of Pharmacy on the 5 campuses
Data Collection

- Whatever tool you use to look at your facility
- Requires a line-item (yes/no) tool to preclude inter-operator variability
- Examples:

<table>
<thead>
<tr>
<th>Policies &amp; Procedures in place</th>
<th>NOT OK – too vague</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hood inspection reports on file every 6 months</td>
<td>OK – every reviewer can see the files</td>
</tr>
</tbody>
</table>

Our Tool

- 45 pages of line-item detail
- Divided responsibilities among the team
- Tool was validated by using several of our own compounding centers before the survey
Example

<table>
<thead>
<tr>
<th>USP Requirement</th>
<th>Compliance</th>
<th>On site reviewer</th>
<th>Comments</th>
<th>Post visit review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal written quality assurance program for sterile compounding.</td>
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</table>
| Adequate training and instruction of personnel who perform compounding activities. | • Training materials reflect current practice requirements
• Training included didactic and audio-visual demonstrations
• Training is both test and observation
• Training is documented in personnel records and meets the requirements for frequency (q 6 and q 12 mo) | | | |
| Competence assessment of personnel who perform compounding activities. | • Process includes validation of low and medium risk preparation activities.
• Check that documentation is every 6 months for high risk prep
• Identify who is responsible for this activity and check qualifications | | | |
| Environment design of drug preparation rooms. | | | | |
| Air-quality testing and environmental monitoring of the compounding environment. | • Conduct twice annual testing of Laminar Airflow Workbenches (LAFWs) and clean rooms twice annually.
• Complete bioburden tests monthly, including identification of CFUs to the genus level. (Caution: zero cfu’s in ISO-7 or greater is unlikely- check process) | | | |

Recommendations

• Contract and conduct site visit before any compound is accepted from a 503A pharmacy
• Contract and review most recent FDA site visit data (including 483s) for any 503B pharmacy
• Single data-collection tool for 503A pharmacies that mirrors your internal IV prep QA processes
• Annual presentation of data to hospital committee with a listing by product and quantity of all preps made by compounding pharmacies
Pharmacies that will remain 503A: Patient-specific preps

Experiences with 503A Pharmacies

• Stark realization that compounded products are not tested for potency, sterility, or stability
• Safety varies by site and often by operator
• None followed all USP<797> requirements
• No notice for changes from commercial to compounded sources of electrolytes
• Most use stock bottles, unpreserved, over multiple days
• Most have no data on efficacy
  – Exception: ophthalmics
Questions to Think About

• Can a compounded prep ever go from high risk to low risk?
• Can a sterile compounded prep for single patient be made from a stock bottle (unpreserved), used for multiple patients over multiple days?

Would you allow this prep to be used on your mother or child?

Mix 100 mL from powder; filter; test a 2-mL aliquot (sterility); hold for test results x 2 weeks

Use 40 mL on multiple patient prescriptions over multiple days/weeks

Test a 2-mL aliquot for sterility (middle of the bottle)

Use the next 40 mL from the bottle without waiting for test results

Test the last 5 mL for sterility

Pharmacies that will become 503B: Sterile outsourcing facilities
Experience: Pharmacies That Will Become 503B

- Incredibly clean facilities, both national and local pharmacies
- Not compliant with USP<797> in all areas when we visited
  - No identification of all CFUs to genus level; only when they exceeded “threshold”
  - Testing for potency and stability done in another location, if done at all
  - Stopping in the middle of a prep for lunch or break

Additional 503B Experience:
Some Interesting Processes

- Every order is a single lot; in case of recall, it is only the location identifying the problem
  - No notification for recalls at other facilities
- Sterility testing is only for process; i.e., a few preps from the last batches of the day
  - Your batch of epidurals has not been sampled for sterility testing
- Most are compounded from commercial products
  - Maintaining sterility, rather than achieving sterility (e.g., sterile-to-sterile compounding)
503B Pharmacies: Transition to CGMP

- Might be a challenge for some
  - Potency and sterility testing per batch
  - Holding samples for a period of years
  - Could move the 503B pharmacies to more product
    - Potency and sterility testing for a batch of 500 vs a batch of 10,000

In-System Compounding Pharmacies: More Questions Than Answers

- If you build a central-fill pharmacy for your own facilities (e.g., 5-10 hospitals), do you use USP<797> or cGMP?
- How will the pharmacy be licensed?
- For patient-specific prescriptions, how do we control the formulations?
  - Require potency testing for the formulation before any patient-specific preps
  - Do we require efficacy data before we make the formulations?
  - If there is nothing published, does it make this investigational and require IRB oversight?
Questions to Keep You Up at Night

- Current risk levels are determined by:
  - Source of the product (sterile or non-sterile)
  - Whether it is a single prep or for multiple patients
  - Complexity of the formulation
- Should site of administration be considered?
  - Ophthalmic, epidural/intrathecal, synovial
- Should we consider patient’s immune status?
  - BMT, neutropenic, premature neonates

Beyond meeting regulatory guidelines, what responsibility do we have as pharmacists?
Questions?

Faculty Discussion
CE Activity Evaluation and Credit Instructions

Sterile Compounding: Where Do We Stand?
June 3, 2014 - Las Vegas, Nevada

1. To receive CE credit for this activity, you must complete the evaluation online no later than Friday, July 4, 2014.
2. Read the CPE Monitor information below.
4. Click on the Evaluation button which is listed with the Sterile Compounding: Where Do We Stand? - June 3, 2014 CE activity.
5. Enter the Event Code for this CE activity: ________________ (note: the event code will be announced at the conclusion of the CE activity).
6. Follow the online instructions to complete the evaluation and to receive CE credit.
7. If you need assistance or have questions, please contact ProCE at 630.540.2848 or via email at info@proce.com.

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