The Joint Commission
Medication Compounding Certification Webinar for Providers: Compounding Pharmacies

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Business Development
Control Panel

- Minimize
- Audio pane
- Question pane
Presentation Goals

Participants will have an understanding of:

- Standards development process
- Overview of Joint Commission Certification Standards
- On-site Certification Process
- Value of MDC Certification
- The pharmacy’s responsibilities post-review to submit Evidence of Standard Compliance
Medication Compounding Certification Standards and Review Process Overview
Standard Development Process

- Technical Advisory Panel (TAP) developed
  - Members non TJC and support staff TJC
  - Utilized to provide advice and comment
  - Represented multiple organization sizes and settings
Standard Development Process

Department Standards and Survey Methods
Standards Development Process

- Standard Research
  - TAP
  - USP/FDA
  - Learning Visits

- Standard Application
  - Voice of Customer
  - Pilots

- Standard Publication
  - MDC Standards and Survey Process
Medication Compounding Standards
Standards

Medication Compounding Standards
- Adapted from USP 795, 797, 800*
- Five Chapters
  - General Responsibilities
  - Education, Training, and Evaluation
  - Compounding Sterile Preparations
  - Compounding Sterile and Nonsterile Preparations
  - Compounding Nonsterile Preparations
General Responsibilities
General Responsibilities

- Leadership responsibilities
- Staff responsibilities
- Patient or patient caregiver’s education (Home Care only)
Education, Training and Evaluation
Education, Training, and Evaluation

- Implementation and Training of Policies and Procedures
- Initial and ongoing education and training for compounding personnel
  - Observation and demonstration of competency
- Knowledge and competency concerning compounding equipment and environment
Compounding Sterile Products
Compounding Sterile Preparations

- Work practices and environment based on USP 797 risk level:
  - Low, Medium and High Risk
  - Immediate use
  - Single-dose and multiple-dose
  - Radiopharmaceuticals
  - Allergen extracts
Compounding Sterile Preparations

- Verification of accuracy and sterility of compounded sterile preparations
- Environmental quality control
- Verification of automated compounding devices (ACDs)
- Maintaining the sterility, purity, and stability of compounded sterile preparations (CSPs)
Compounding Sterile Preparations

- Transporting of compounded products
  - Communicating Storage requirements when shipping items
  - Education and training for patients/caregivers for proper storage, handling, and administration (Home Care Only)
Compounding Sterile and Non-Sterile Products
Compounding Sterile and Nonsterile Preparations

- Assigning beyond-use dates (BUD)
  - Including extended BUD
- Hazardous medication compounding
- Requirements for Non-sterile compounding
Medication Compounding
On-Site Review Process
Review Process Overview

- Certification reviews performed by trained pharmacist
- Number of review days based on complexity and number of compounding sites
- Reviews are “announced”
- Reviews are on a 2 year cycle
- Tracer methodology utilized during review process
## MDC Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>8:00 – 8:10 a.m.</td>
<td>Opening Conference</td>
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<td>(10 minutes)</td>
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<tr>
<td>8:10 – 9:00 a.m.</td>
<td>Orientation to Program</td>
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<td>(50 minutes)</td>
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<tr>
<td>9:00 – 10:00 a.m.</td>
<td>Reviewer Planning Session &amp; Document Review</td>
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<td>(60 minutes)</td>
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<tr>
<td>10:00 – 12:30 p.m.</td>
<td>Compounded Medication Tracers, Pharmacy Visits and Satellite Pharmacy Visits</td>
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<td>(2 hours 30 minutes)</td>
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<tr>
<td>12:30 – 1:00 p.m.</td>
<td>Reviewer Lunch</td>
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<tr>
<td>(30 minutes)</td>
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<td>1:00 – 1:30 p.m.</td>
<td>System Tracer – Data Use</td>
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<td>(30 minutes)</td>
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<tr>
<td>1:30 – 2:30 p.m.</td>
<td>Competence Assessment Session</td>
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<td>(60 minutes)</td>
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<tr>
<td>2:30 – 4:00 p.m.</td>
<td>Issue Resolution and Reviewer Report Preparation</td>
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<tr>
<td>(1 hour, 30 minutes)</td>
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<tr>
<td>4:00 – 4:30 p.m.</td>
<td>Program Exit Conference</td>
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<tr>
<td>(30 minutes)</td>
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Required Documents

- Job descriptions for each category of pharmacy staff involved in medication compounding
- Medication Compounding and Beyond Use Dating assignment policy
- List of all Primary Engineering Controls (PECs) and Secondary Engineering Controls (SECs)
- Clean room monitoring and certification records for all PECs and SECs (certification records for the last year will be needed)
- All pharmacy facility licenses
- Most recent State Board of Pharmacy reports
Required Documents

- Competency assessments and performance evaluations for staff involved in medication compounding
- Pharmacy quality control checks and performance improvement data
- Performance improvement action plans that demonstrate how data have been used to improve care and services, when available
- For Home Care: A list of current patients with start of care date and the type of compounded medication they are receiving.
Document Review

- Orientation to facility and confirm identified compounding locations in application
- Review Primary Engineering Control Certification documentation
- Review Secondary Engineering Control Certification documentation
- Review cleaning logs for daily and monthly cleaning
Pharmacy and Satellite Pharmacy Visits

- Validate environmental requirements
- Observe
  - PEC cleaning/disinfection
  - Staff preparation for medication compounding
  - Compounding activity
  - In process and final product Verification

*Every effort will be made to observe every risk classification compounded for hazardous and non-hazardous*
Discussion will include:

- Performance improvement approach and plan
- Performance improvement priorities identified for medication compounding processes
- Collection of data to monitor performance
- Activities to improve processes and outcomes
Competency Assessment Session

- Staff competency file selection process
- Minimally
  - Media fills
  - Glove fingertip testing
  - Most recent observation of compounding technique (including hazardous, if applicable)
  - Didactic training (including hazardous, if applicable)
  - Equipment training
Top 5 Scored Elements of Performance

Data reflective of MDC Certification Reviews finalized
January 1, 2017 to April 7, 2017
MDCS.01 EP 1

- Cleaning and disinfecting process for SEC not followed
- Cleaning and disinfecting process for PEC not followed
- Improper aseptic technique (does not include blocking first air)
MDCS.08 EP 6

Improper hand and supply placement blocking first air
MDCS.13 EP 1

- Lack of cleaning PEC per USP 797
  - After spills
  - At beginning of shift

- Lack of using Sterile Alcohol in cleaning process
MDCGR.02 EP 2

- Lack of efficient process for evaluating competencies
- No defined remediation process when environmental monitoring is out of defined parameters
MDCS.01 EP 2

- Not wiping items entering the PEC with sterile alcohol
- Not including inspection for particulate matter as part of final verification of the compounded product
Value Added by MDC Certification
External Risk Analysis

- Provides validation for process taken in reduction of previously identified risk
- Assist in identifying unknown risk
Incorporation into Quality Development Program

- Provides organizational awareness
  - Incorporation into organizations QAPI

- Provides sets standards to develop internal auditing to monitor ongoing quality
Post Review Follow-up
Survey Analysis for Evaluating Risk (SAFER)

- A transformative approach for identifying and communicating risk levels associated with deficiencies cited during surveys
- Helps organizations prioritize and focus on corrective actions
- Provides one, comprehensive visual representation of survey findings
# The SAFER Model

<table>
<thead>
<tr>
<th>Likelihood to Harm a Patient/Staff/Visitor</th>
<th>Immediate Threat to Life (a threat that represents immediate risk of potential to have serious adverse effects on the health of the patient, resident, or individual served)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH (harm could happen at any time)</td>
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<tr>
<td>MODERATE (harm could happen occasionally)</td>
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<tr>
<td>LOW (harm could happen, but would be rare)</td>
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<tr>
<td>LIMITED (unique occurrence that is not representative of routine/regular practice)</td>
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<tr>
<td>PATTERN (multiple occurrences with potential to impact few/some patients, visitors, staff and/or settings)</td>
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<tr>
<td>WIDESPREAD (multiple occurrences with potential to impact most/all patients, visitors, staff and/or settings)</td>
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**Post On-site Review Process**

- Pharmacy will be left with a preliminary report at close of survey.
- Reports are reviewed in central office and finalized within 10 days.
- All Requirements for Improvement (findings) will require Evidence of Standards Compliance (ESC) to be submitted within 60 days.
# Prioritized Follow-up Action

<table>
<thead>
<tr>
<th>SAFER Matrix Placement</th>
<th>Required Follow-Up Activity</th>
</tr>
</thead>
</table>
| **LOW / LIMITED**      | • 60 day Evidence of Standards Compliance (ESC)  
  - ESC will include Who, What, When, and How sections |

| MODERATE / LIMITED, LOW / PATTERN, LOW / WIDESPREAD | **60 day Evidence of Standards Compliance (ESC)**  
- ESC will include Who, What, When, and How sections |

| MODERATE/PATTERN, MODERATE/WIDESPREAD | • 60 day Evidence of Standards Compliance (ESC)  
- ESC will include Who, What, When, and How sections  
- ESC will also include two additional areas surrounding Leadership Involvement and Preventive Analysis  
- Finding will be highlighted for potential review by surveyors on subsequent onsite surveys up to and including the next full triennial survey |

| HIGH/LIMITED, HIGH/PATTERN, HIGH/WIDESPREAD | • 60 day Evidence of Standards Compliance (ESC)  
- ESC will include Who, What, When, and How sections  
- ESC will also include two additional areas surrounding Leadership Involvement and Preventive Analysis  
- Finding will be highlighted for potential review by surveyors on subsequent onsite surveys up to and including the next full triennial survey |

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**Note:** If an Immediate Threat to Life (ITL) is discovered during a survey, the organization immediately receives a preliminary denial of accreditation (PDA) and, within 72 hours, must either entirely eliminate the ITL or implement emergency interventions to abate the risk to patients (with a maximum of 23 days to totally eliminate the ITL). Please see the Accreditation Process Chapter within the Comprehensive Accreditation Manual for more information.
Application Process

Brian R. Johnson, Ph.D.
Health Systems Director
The Joint Commission
1. Obtain a Copy of the Standards

- Medication Compounding Certification Manual
  - General Responsibilities
  - Education, Training, and Evaluation
  - Compounding Sterile Preparations
  - Compounding Sterile and Nonsterile Preparations
  - Compounding Nonsterile Preparations

- Also available, Review Process Guide (Agendas, required documents etc.)
2. Conduct a Self-Assessment Gap Analysis

- Develop work plans for areas that are not in compliance with standards

- Work with your team to develop a goal for when you expect you will be ready for certification – and focus your efforts on that shared timetable.
3. Use Resources from The Joint Commission

**Standards Interpretation Group** answers questions about how individual standards are applied

- [https://www.jointcommission.org/standards_information/jcfaq.aspx](https://www.jointcommission.org/standards_information/jcfaq.aspx)
- “Submit Your Standards Question Online”

Contact Business Development for questions about eligibility, the preparation process, data requirements, etc. at 630-792-5291 or [certification@jointcommission.org](mailto:certification@jointcommission.org)
3. Additional Resources

Medication Compounding Providers

Helps you provide safe medication compounding

First customer certified in February 2017.

“Quality compounding of medicine is foundational to patient safety and may serve to reduce the incidence of adverse healthcare associated conditions such as infections and medication errors. USP Compounding Standards <797> and <795> aim to assist hospitals in improving the quality of the healthcare they deliver. As such, it is part of USP’s mission to support the advancement of healthcare quality and safety. USP is proud to work with The Joint Commission on this important endeavor and would also like to commend institutions that demonstrate their commitment to quality through such certification processes.”

Jaap Venema, Ph.D., USP Chief Science Officer

https://www.jointcommission.org/certification/mdccert.aspx
4. Start the Application

Contact Business Development to open the application for you about 4-6 months before the date you’d like the on-site review.

– Actual date of review is negotiated with you.
– Application stays valid for 12 months.
Application Process
Site Information

LD new hospital clinic site, NEW STREET ADDRESS

Medication Compounding

LD new hospital clinic site
NEW STREET ADDRESS
Beverly Hills, CA 90210 USA

Program Setting

Select the setting that best describes this site. Select all that apply:

- [ ] Ambulatory
- [ ] Behavioral Health Care
- [ ] Critical Access Hospital
- [ ] Home Care
- [x] Hospital

Volume

Non-Sterile Compounding Categories

Simple: Making a preparation that has a United States Pharmacopeia (USP) compounding monograph or appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include captopril oral solution and indomethacin topical gel.

Moderate: Making a preparation that requires special calculations or procedures (such as calibration of dosage-unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include morphine sulfate suppositories, diphenhydramine...
### Application Process

**Volume**

Enter the number of pharmacy compounding locations at this site (include Satellite, Nuclear, Central etc).

2

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**Compounding Services**

Please select all compounding services at this site:

- **Sterile Medication Compounding**
  - Low Risk
  - Medium Risk
  - High Risk
- **Hazardous Medication Compounding**
- **Nuclear Pharmacy/Radiopharmaceuticals Compounding**
- **Allergen Extract**
- **Non-Sterile Medication Compounding**
  - Simple
  - Moderate
  - Complex

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**Sterile Compounding Risk Levels**

**Low-risk:** Compounding that starts with sterile ingredients and devices using aseptic technique in an ISO Class 5 or higher quality of air. It must be a simple transfer of not more than three commercially manufactured sterile nonhazardous products from the original containers and not more than two entries into any one sterile container or package (such as a bag or vial). If sterility testing is lacking, low-risk compounded sterile preparations are stored for a maximum of 48 hours at a controlled room temperature between 20 and 25 degrees Celsius, 14 days at a cold temperature between 2 and 8 degrees Celsius, and for a maximum of 45 days at a freezing temperature between...
Satellite area(s) for Medication Compounding

<table>
<thead>
<tr>
<th>Location</th>
<th>Type of Compounding</th>
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<tbody>
<tr>
<td></td>
<td>Sterile Medication Compounding</td>
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<tr>
<td></td>
<td>Low Risk</td>
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<tr>
<td></td>
<td>Medium Risk</td>
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<tr>
<td></td>
<td>High Risk</td>
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<td></td>
<td>Moderate</td>
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<td></td>
<td>Complex</td>
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Yes ☐ No ☐

Application Process

Medium-risk: Compounding that starts with sterile ingredients in an ISO Class 5 or higher environment for multiple doses of sterile preparations for administration to either multiple patients or to a single patient. The compounding process uses aseptic technique and more than one transfer. If sterility testing is lacking, medium-risk compounded sterile preparations are stored for a maximum of 30 hours at a controlled room temperature between 20 and 25 degrees Celsius, 9 days at a cold temperature between 2 and 8 degrees Celsius, or 45 days at a freezing temperature between -10 and -25 degrees Celsius. Example include compounding total parenteral nutrition (TPN) and filling infusion devices with multiple sterile products.

High-risk: Compounding that starts with nonsterile ingredients or nonsterile devices, or exposes sterile ingredients and devices to air quality below ISO Class 5 for more than one hour; or uses opened containers that are preservative-free and stored in an environment of less than ISO Class 5. If sterility testing is lacking, high-risk compounded sterile preparations are stored for a maximum of 24 hours at a controlled room temperature between 20 and 25 degrees Celsius, 3 days at a cold temperature between 2 and 8 degrees Celsius. Example includes transferring sterile liquids from manufacturer-sealed packages to sterile containers using sterile devices manipulating up to three manufactured products to create a sterile preparation.
5. Advertise Your Achievement

https://www.jointcommission.org/certification/certification_publicity_kit.aspx
Certification Pricing
Certification Pricing

- MDC is a 2-year certification
- Annual fees billed in January
- Review fee billed after on-site visit
- Price based on length of review
- Actual review days/length may vary
- Number of locations
For Additional Pricing Questions

Pricing Unit

pricingunit@jointcommission.org

or

630-792-5115
Contact Information

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