The Joint Commission

Medication Compounding Certification Review Process Guide

2022

Medication Compounding Certification

Review Process Guide

2022

What's New in 2022

New or revised content for 2022 is identified by underlined text in the activities noted below.

Changes effective January 1, 2022

No changes.

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Organization Review Preparation

The purpose of this activity guide is to inform organizations about how to prepare for the Medication Compounding Certification onsite certification review, including:

- Identifying ways in which the organization can facilitate the onsite review process
- Describing logistical needs for the onsite review

Important Reading

The Certification Review Process Guide describes each activity of a Joint Commission onsite certification review. Organizations should read through each of the following activity descriptions, which include:

- The purpose of the activity,
- Descriptions of what will happen during the activity
- Discussion topics, if applicable
- Recommended participants
- Any materials required for the session

These descriptions can be shared organization-wide as appropriate.

Pre-Review Phone Call

A Joint Commission account executive will contact your organization by phone shortly after receiving your application for certification. The purpose of this call is to:

- Confirm information reported in the application for certification, to verify travel planning information and directions to office(s) and facilities,
- Confirm your access to The *Joint Commission Connect* extranet site and the certification-related information available there (onsite visit agenda, Certification Review Process Guide, etc.), and
- Answer any organization questions and address any concerns.

Logistics

- While onsite, the reviewer(s) will need workspace for the duration of the visit. A desk or table, telephone, internet connection and access to an electrical outlet are desirable. The reviewer will also need a secure and accessible location to keep their belongings during the review.

- Some review activities will require a room or area that will accommodate a group of participants. Group activity participants should be limited, if possible, to key individuals that can provide insight on the topic of discussion. Participant selection is left to the organization's discretion; however, this guide does offer suggestions.

- The reviewer will want to move to the pharmacy, pharmacy satellites, if applicable, and in hospitals, a patient care unit during the Compounded Medication Tracer, talking with staff and observing the day-to-day medication compounding activities performed by pharmacy staff. The reviewer will rely on organization staff to find locations where discussions can

take place that allow confidentiality and privacy to be maintained and that will minimize disruption to the area being visited.

- Your onsite review agenda template similar to the one presented later in this guide, will be posted to your *Joint Commission Connect* extranet site. The review agenda presents a suggested order of activities and timeframes for each. Discuss with the reviewer any changes to the agenda that may be needed throughout the course of the onsite visit.

- **The reviewer must observe medication compounding during the visit. Please inform the reviewer, upon arrival, of any changes to the agenda that are required in order to observe scheduled/planned medication compounding.**

Information Evaluated Prior to the Onsite Certification Review

The Joint Commission certification reviewer assigned to perform your organization's onsite visit will receive information you supplied with your organization's Request for Certification. Please inform the reviewer of any changes in your medication compounding operations upon their arrival.

Information Needed During Onsite Review

Please note that it is not necessary to prepare documentation just for purposes of the certification review. The reviewer is interested in seeing the resources that staff reference in their day-to-day activity. These items need not be stand-alone documents; the items noted may represent sections contained within other documents. It is not necessary to print documents for the reviewer if the documentation is routinely maintained and accessed by staff electronically. The reviewer can look at this material on the computer with the assistance of a staff member.

Information needed for the Orientation to Program Activity includes:

- Pharmacy organization chart
- List of staff involved in compounding, including the pharmacist in charge

Information needed for the Reviewer Planning Session

- Job descriptions for each category of pharmacy staff involved in medication compounding
- 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
- Policy, procedures, and software supporting medication recall and compounded medication returns
- Submitted DEA Form 222 and associated powers of attorney
- Competency assessments and performance evaluations for staff involved in medication compounding
- Remedial follow-up on failed competency reviews
- 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
- All medication compounding related policies and procedures
- For Home Care: A list of current patients with start of care date and the type of compounded medication being provided. If there are a limited number of active patients receiving compounded medication, provide a list of discharged patients who received compounded medications representative of those provided by the organization.

Questions about Standards

If you have a question about a standard, element of performance or any advanced certification requirement, please consider reviewing the Standards Interpretation FAQs page: https://www.jointcommission.org/standards_information/jcfaq.aspx prior to submitting a question. To submit a question, Login to your organization's Joint Commission extranet site, *Connect*: https://customer.jointcommission.org/TJCPages/TJCHomeEmpty.aspx and click on Resources - Standards Interpretation, to submit your question. If you do not have access to *Connect*, please go to the Standards Interpretation Page: https://www.jointcommission.org/standards_information/jcfaq.aspx to submit a question.

Questions about onsite review process, agenda, scheduling, or other questions – Call your Joint Commission Account Executive.

Certification Review Notification and Postponement Policies

Notice of Initial Certification On-site Review
If this is your program's first time through the certification process you will receive a thirty (30) day advance notice of your on-site review date(s). Notice will be provided via e-mail to the individuals identified on your account as the Primary Certification Contact and CEO. Also thirty (30) days prior to your review, the Notification of Scheduled Events section on your organization's extranet site, The *Joint Commission Connect*, is populated with the event along with a link to the reviewer(s) name, biographical sketch and photograph.

Notice of Re-Certification On-site Review
Your organization will receive notice from The Joint Commission seven (7) business days prior to the first day of the scheduled review date(s) for Medication Compounding re-certification. The notice will be emailed to the individuals identified on your account as the Primary Certification Contact and CEO and will include the specific review date(s) and the program(s) being reviewed. Additionally, at 7:30 a.m. in your local time zone on the morning of the review, the Notification of Scheduled Events section on your organization's extranet site, The *Joint Commission Connect*, is populated with the review event including a link to the reviewer(s) name, biographical sketch and photograph.

Review Postponement Policy
The Joint Commission may not certify a program if the Organization does not allow The Joint Commission to conduct a review. In rare circumstances, it may be appropriate to request a review postponement. An organization should direct a request for postponement to its Account Executive. A request to postpone a review may be granted if a major, unforeseen event has occurred that has totally or substantially disrupted operations, such as the following:

- A natural disaster or major disruption of service due to a facility failure
- The organization's involvement in an employment strike
- The organization's cessation of admitting or treating patients
- The organization's inability to treat and care for patients and its transference of patients to other facilities

The Joint Commission may, at its discretion, approve a request to postpone a review for an organization not meeting any of the criteria listed above.

Your organization's Certification Account Executive can answer questions about these policies, or put you in contact with other Joint Commission staff that can assist you.

Opening Conference and Orientation to Medication Compounding Services

This session combines two activities into one 60-90 minute block of time depending on the length of review, either one-day or multi-day. The breakdown of activities and suggested length for each follows.

Organization Participants

- Opening Conference – Administrative and Pharmacy leadership and others at the discretion of the organization

- Orientation to the Program – Pharmacy administrative and clinical leadership, and others at the discretion of the organization (for example, environmental services, laboratory, infection control, and nursing representatives)

Materials Needed for Activities

- Roster or sign-in sheet
- Pharmacy organization chart

Opening Conference

Approximately 10-15 minutes in duration and includes:

- Reviewer introduction
- Introduction of organization review coordinator, Pharmacist in Charge, other organization leaders (Please note: Other staff can be introduced as the reviewer encounters them throughout the onsite visit.)
- Overview of The Joint Commission Medication Compounding Certification
- Agenda review with discussion of any needed changes
- Brief introduction of the SAFER™ portion of the Summary of Certification Review Findings Report
- Questions and answers about the onsite review process.

Orientation to Medication Compounding Services

This 45-70 minute activity is an exchange between the organization and reviewer about the scope of Medication Compounding services. The reviewer will facilitate the discussion and use the information that is shared as a base to build on while continuing the review in other activities.

The activity will begin with introductions of the participants and their role in the organization and related to medication compounding services.

Program representatives participating in this session should be able to discuss topics such as:

- Mission, goals and objectives, especially those related to medication compounding services
- Medication compounding services leadership and management
- Leadership oversight process for pharmacy medication compounding
- How leaders establish priorities and decide which items/issues they will monitor

- Roles and responsibilities
- Job descriptions
    - Medication compounding staff and pharmacist in charge
- Scope of sterile compounding services that are carried on throughout the organization
- Types of medication compounding performed (sterile, nonsterile, hazardous, immediate use)
- Medication compounding services structure, workflows, and technology in use
- Routine cleaning requirements and procedures (including who is responsible)
- Beyond Use Dating assignment
- Managing medication shortages
- Managing compounded medication returns
- Assessing compounding staff competencies using both documentation and observation; organizational support of staff, and staff education and specialized training necessary to maintain compliance with the medication compounding requirements
- Medication compounding educational offerings for organization compounding staff
- Identification of areas outside the main pharmacy where medication compounding is being performed, and by whom. Sterile compounding will only be observed in the main pharmacy and pharmacy satellites.
- Access to medication compounding services
- Hours of operation
- Accessing medication compounding services after hours or in case of an emergency
- Any unique communication regarding patient rights and responsibilities regarding medication compounding services
- Evaluating the medication compounding services provided through the organization
- Improving the medication compounding services provided in the organization.

Based upon this discussion, the reviewer may identify additional documentation they would like to see, if available.

Reviewer Planning and Document Review Session

During this activity, the reviewer(s), in conjunction with pharmacy representatives, will identify the medications they would like to trace, with a particular focus on those where observation of compounding will be possible, and when. If there is no compounding activity occurring at this time, the reviewer will proceed with the document review activity.

Organization Participants

- Pharmacy representative(s) that can orient the reviewer to available documentation or retrieve additional documents as needed
- Pharmacy representative that can assist with identifying compounded medications for tracer activty
  Note: The reviewer may not need staff to remain available for the entire time that they are reviewing documentation.

Materials Needed for this Activity

- Job descriptions for each category of pharmacy staff involved in medication compounding
- 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
- Policy, procedures, and software supporting medication recall and compounded medication returns
- Submitted DEA Form 222 and associated powers of attorney
- Competency assessments and performance evaluations for staff involved in medication compounding
- Remedial follow-up on failed competency reviews
- 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
- All medication compounding related policies and procedures
- For Home Care: A list of current patients with start of care date and the type of compounded medication being provided. If there are a limited number of active patients receiving compounded medication, provide a list of discharged patients who received compounded medications representative of those provided by the organization.

Planning Guidelines – Selecting Compounded Medications to Trace

1. Reviewers will describe the types of medications they want to trace and request assistance in identifying these medications among current orders for active patients.
2. The reviewer will select a minimum of three compounding activities per risk level (low, medium, and high). These must:
    - Be representative of the therapies compounded in the organization
    - Include hazardous medications and radiopharmaceuticals, if they are being compounded in the organization
        - Note: If the organization receives compounded radiopharmaceuticals from an outside source, the reviewer will visit the area and speak to the staff that receive delivery of these medications.
3. The reviewer will prioritize tracing of medium and high risk medications, for example, compounding of TPN, chemotherapy, and compounding of product from non-sterile powder such as narcotic infusions.
    - If the organization does not do any high risk compounding, then the reviewer will select three (3) medium and three (3) low risk medications to review.
4. If there are a limited number of active infusion patients at the time of the onsite review, or the active patients do not cover all the therapies compounded by your organization, the reviewer will want to walk through the compounding processes for these therapies, including the clean room activity, with compounding staff.

Planning Guidelines – Contact with Home Care Patients

Reviewers will want to have some contact with the home care organization's patients and/or family members of patients, if they are available, who are receiving compounded medications.

Organization representatives will be asked to assist the reviewer in identifying a minimum of five patients from the current list of active infusion patients receiving high, medium, or low risk compounds. See the *Compounded Medication Tracer, Pharmacy Visits and Pharmacy Satellite Visits* activity for further details about this contact.

Pharmacy Visit and Pharmacy Satellite Visit (if applicable) and Compounded Medication Tracer Activity

During the activity the reviewer will want to follow a specific selection of medications through the sterile compounding process. This tracing will include observing from receipt of the order through the compounding process, including packaging and delivery to the location where the patient will receive the medication.

Organization Participants
Program staff and other organization staff who have been involved in the patient's care, treatment or services

Materials Needed for this Activity
Access to the pharmacy computer system to identify medication orders

Medication Tracer and Pharmacy/Satellite Visit Description

The majority of the review agenda is designated for the pharmacy visit and compounded medication tracer activity.

For the compounded medications selected during the Planning Session, the reviewer will want to see:

- An order on the pharmacy computer system or the patient's record
- A product mixing record
- Activity leading up to compounding (for example, gathering of information, components and supplies needed for compounding, and preparing these items for the sterile environment)
- Staff preparations for entering the sterile environment (for example, hand washing, garbing, gloving)
- Staff cleaning of hoods, isolators in preparation to compound
- Staff performing compounding of the medication
- Labeling of the compounded medication
- Packaging of the product
- Storage of the compounded medication until dispensing from the pharmacy to the unit or the patient
- Delivery process from the pharmacy to the unit or patient
- Storage of the product on the unit or instructions to the patient for storing in the home until administration

NOTE: If the types of medications selected for tracing are not being compounded on the day(s) of the review, the organization will be required to demonstrate how they perform sterile compounding of at least one medication, something inexpensive, and that will allow the reviewer to observe as many steps as possible in the process.

Throughout the observation activity above, the reviewer will be talking with the pharmacy compounding staff about topics such as:

- Length of service in the pharmacy
- Orientation to compounding responsilities
- Types of compounded medications being prepared
- Supervisor and performance reviews of compounding technique
- Gloved fingertip test and performance of a media fill; last time occurred; results
- Access to Safety Data Sheets
- If pharmacy prepares hazardous medications, discuss staff safety and protection;
- Types of monitoring; any documentation
- Cleaning hoods or isolators—when, how, with what, and documentation of cleaning
- Process for checking compounding work
- Beyond Use Dating (BUD) and product expiration dates
- Delivery of products to patient units
- Retrieval and handling of compounded medications returned to the pharmacy
- Discuss compounded medication storage on patient units and maintaining stability and integrity of products
- For Home Care: Packaging and delivery of compounded medications to patients; instructions to delivery staff; instructions to patients about storage of the medications upon receipt

Pharmacy and Pharmacy Satellite Visits

During the pharmacy visit and any satellite visits, the reviewer will be observing the environment in which medication compounding is occurring. The reviewer will be concerned with:

- Environmental monitoring – type, frequency, who performs, who is responsible for acting on results
- Orientation to the compounding location and any training that is specific to compounding in the location
- Environmental impact on safety and quality of medication compounding

If there are pharmacy satellite locations, during these visits reviewers will ask about:

- Rotation of pharmacy staff between main pharmacy and satellites
- Satellite hours of operation
- Types of medications compounded in the satellite
- Compounding policies and procedures specific to the satellite
- Satellite supervisor, satellite-specific performance review of compounding technique
- Environmental samples taken in the location

Home Care Patient Calls

Reviewers will want to have some contact with the home care organization's patients and/or family members of patients that are receiving compounded medications.

During the Reviewer Planning activity, organization representatives assisted the reviewer in identifying a minimum of five patients from the current list of active infusion patients receiving high, medium, or low risk compounds.

An organization representative is asked to contact the selected patients to explain that the organization is undergoing a certification review, and determine if the patient or a family member is available and would be willing to speak with the reviewer.

The reviewer will be asking the patient or patient's family member about:

- Length of time the patient has been receiving the infusion
- The type of infusion being received and frequency of delivery
- Condition of the medication when it is delivered (if it requires refrigeration, does it arrive cold; other product conditions they have been advised to report to the organization before use)
- Any instances where they have run out of the medication
- Instructions they have received about storing the medication
- Instructions for disposal of the medication if no longer needed
- The medication label and clarity of instructions for administering the medication; and does it show an expiration date
- Any occasion when they needed to contact the organization about the medication

Upon concluding patient calls the reviewer will share feedback with the organization.

Team Meeting & Planning Session

This activity only takes place on multi-day, certification onsite visits. Reviewers use this session to debrief on the day's observations and plan for upcoming review activities.

Before leaving the organization, reviewers will return organization documents to the program's review coordinator or liaison. If reviewers have not returned documentation, your organization is encouraged to ask reviewers for the documents prior to their leaving for the day.

Organization Participants
None

Logistical Needs
The suggested duration for this session is 30 minutes.

Daily Briefing

This activity only takes place on multi-day certification reviews. Reviewers will use this time to provide organization representatives with a brief summary of review activities of the previous day and relay observations and note examples of strengths and possible vulnerabilities in performance.

Duration
15-30 minutes

Participants
- Pharmacist in Charge
- Organization administrative and clinical leaders
- Others at the discretion of the program

Overview
Reviewers will:
- Briefly summarize review activities completed on the previous day. Discuss at a high-level some of the patterns and trends they are seeing.
- Ask the organization representatives to clarify or help them understand what they have been hearing and observing.
- Answer questions and clarify comments when requested.
- Review the agenda for the day.
- Make necessary adjustments to plans based on organization needs or the need for more intensive assessment
- Confirm logistics for the day, sites that will be visited, transportation arrangements, and meeting times and locations for any group activities, as applicable

Reviewers may ask to extend the Daily Briefing if necessary. However, they will be considerate of staff time. They will **not** make all program representatives stay for a discussion that is specific to a small group of individuals.

Competence Assessment

The purpose of this activity is to discuss how the program meets the need for qualified and competent medication compounding staff.

Organization Participants
- Pharmacist in Charge
- Pharmacy supervisors or managers
- Organization representatives responsible for human resources processes (license verification, education, competence assessment of compounding staff)
- Others at the discretion of the organization

Materials Needed for this Activity
The reviewer will want to see the following records:
- 20% of compounding staff records (a minimum of 10)
- 20% of pharmacy services staff members who oly compound on an occasional or part-time basis (such as staff that may compound, but it is not the primary duty in their job description)
- Minimum of two (2) staff members who are involved in the clean-up and disposal activities associated with medication compounding
- Minimum of two (2) staff members that are involved in storing, packing, and delivering compounded medications

Note: The reviewer will select these files based on the individuals encountered during compounded medication tracer activity, pharmacy, and pharmacy satellite visits.

Competence Assessment and Credentialing Process Activity Description
During the session, the reviewer and organization representatives will discuss the following competence assessment topics while reviewing the selected records:

- Job descriptions for medication compounding staff, supervisors/managers, pharmacist in charge
- Experience, education, and competence assessment for medication compounding staff
- Orientation of medication compounding staff
- Frequency of competence assessment, both written and observation, this will include looking for documentation of:
  - Media fills
  - Glove fingertip testing, and
  - Most recent observation of compounding technique
- Remedial actions when competence is not demonstrated
- Ongoing education and training for medication compounding staff

System Tracer- Data Use

This session is focused on the program's use of data in improving safety and quality of care for their patients. The reviewer and the organization will:

- Identify strengths and weaknesses in the organization's use of data, areas for improvement, and any actions taken or planned to improve performance.
- Identify specific data use issues requiring further exploration as part of subsequent review activities.

Organization Participants

- Pharmacist in Charge
- Medication compounding supervisors or managers
- Administrative and clinical leaders
- Others at the discretion of the organization

Materials Needed for this Activity

- Performance measure data reports
- Action plans demonstrating the use of and response to data

Data Use System Tracer Description

During this activity, the reviewer(s) and organization will discuss:

- The basics of data gathering and preparation, including:
  - Selection of performance measures to study medication compounding
    - Who is involved,
    - Prioritizing what to measure
    - Source of measures
  - Data collection, including validity and reliability
    - Quality control data being collected (such as, completeness of clean room monitoring activities or clean room staff competencies completed per organizational policy and USP guidelines)
    - Staff assigned to collect data, education and training provided
    - Data collection process – manual or on computer
    - Frequency of data collection
  - Data analysis and interpretation
    - Types of analyses being performed; who is involved
    - Data trending and comparison to expected level of performance
    - Any potential cause and effect relationships being explored
  - Dissemination /transmission
    - Are staff made aware of performance monitoring results
    - Who receives the data within the organization
  - Data use and actions taken on opportunities for improvement
    - What information would prompt the organization to make improvements
    - Describe any performance improvement projects underway

- Monitoring performance and evaluating improvements
  - What aspects of performance are being monitored
  - Describe any goals or targets for performance

The reviewer(s) will want to know about the priorities for medication compounding related performance improvement activities and how these fit into the organization's overall performance improvement processes. This discussion may include a review of:

- Selection and prioritization of performance improvement activities
- Data reporting – when it occurs and who receives the information
- Type of analyses being conducted – approach to trending data over time, comparing data to an expected level of performance, and looking at data in combination for potential cause and effect relationships.

Issue Resolution

Issue resolution time is an opportunity for the reviewer to follow-up on potential findings that could not be resolved in other onsite activities. If no issues need to be resolved, this session will be cancelled or used for another purpose.

Organization Participants
Will vary depending upon the issue

Materials Needed for this Activity
Will vary depending upon the issue

Preparation for Issue Resolution
None required

Issue Resolution Description
The reviewer may have identified issues during compounded medication tracer activity or other sessions that require further exploration or follow-up with staff. This follow-up may include a variety of activities such as:

- Review of policies and procedures
- Review of human resources files
- Review of performance improvement data
- Discussions with selected staff

The reviewer will work with the certification review coordinator to organize and conduct all issue resolution activity.

Reviewer Report Preparation

The reviewer uses this time to compile, analyze and organize the data he or she has collected throughout the review into a preliminary report reflecting the program's compliance with standards.

Organization Participants
None required, unless specifically requested by the reviewer

Materials Needed for this Activity
Private work space with access to an electrical outlet and an internet connection

Reviewer Report Preparation Description
The reviewer uses this time to analyze their observations and determine if there are any findings that reflect standards compliance issues. If organization interruptions can be kept to a minimum during this time, it will help the reviewer remain on schedule and deliver a report at the appointed time. The reviewer will be using their laptop computer to prepare the preliminary report and plan for the Exit Conference.

Exit Conference

The Program Exit Conference is the final onsite activity when the organization receives a preliminary report of findings from the reviewer. In addition, reviewers will

- Review the the Summary of Certification Review Findings report, including the new SAFER™ matrix feature
- Discuss any standards compliance issues that resulted in Requirements for Improvement (RFIs)
- Allow the organization a final onsite opportunity to question the review findings and provide additional material regarding standards' compliance
- Mention revisions to the post-review Clarification process
- Review required follow-up actions as applicable

Organization Participants

- Pharmacist in Charge
- Administrative or clinical leaders
- Other staff at the discretion of the organization

Materials Needed for this Activity

Copies of the certification report—if it is being distributed to staff

Preparation for the Program Exit Conference

None required

Program Exit Conference Description

This is a 30-minute activity that takes place at the completion of a certification review. The Pharmacist in Charge and other participants, as invited, will hear a verbal report of observations, review findings, requirements for improvement, and where these are appearing on the SAFER™ matrix. The Summary of Certification Review Findings Report is shared with participants in the Exit Conference ONLY with the permission of the CEO. All reports left onsite are preliminary and subject to change upon review by Joint Commission central office staff.

Medication Compounding Certification -- Competency Checklist

Required Competencies/Training	Employees							
Training on procedures related to job functions (facilities, compounding, use of equipment, packaging, storing & dispensing (MDCED.02 EP 1)								
Training re: hazardous medication storing, safe handling, disposal for staff that work with hazardous medications (MDCED.02, EPs 2-3)								
Training re: cleaning and removing of waste from hazardous medication areas for staff assigned to these areas (MDCED.02, EP 4)								
Training for staff conducting sterile compounding: use of all equipment, apparatuses, and devices; ability to identify malfunctions (MDCED.04, EP 1)								
Training and competency assessment: avoidance of touching critical sites (MDCED.04, EP 2)								
Sampling of compounding staff glove fingertips for all CSP risk levels per USP 797 (MDCED.04, EP 3)								
Visual observation and documentation of garbing and gloving (MDCED.04, EP 4)								
For ancillary support services that clean and disinfect the clean room: training in hand hygiene, garbing, cleaning, and disinfection procedure (MDCED.04, EP 5)								
Annual competency for sterile compounders: Aseptic technique through written, media-fill and fingertip sample testing (Media Fill and Fingertip sampling every 6 months for High Risk Compounding) (MDCED.05, EP 2)								
Prior to beginning to compound, completion of initial 3 fingertip samples (documentation for employees that started compounding in the last 12 months (MDCED.05, EP 4)								
Staff who fail assessment of aseptic technique are retrained and re-evaluated (may be NA) MDCED.05, EP 5)								
Competency assessment and documentation of procedural breaches; administrative errors; complications associated with medication dose or administration (MDCED.07, EP 1)								

Sample Two-Day Certification Review Agenda

The Joint Commission
Medication Compounding Certification
Two-Day Review Agenda

Compounding areas to be observed in Michigan organizations: Reviewers will only observe sterile compounding activity performed in the central pharmacy and all satellite pharmacies. Compounding on patient care units, ED, ICU, etc. is not included in the scope of review. Patient care unit visits are to observe how medications from the pharmacy are delivered and stored prior to administration.

Information needed for the Orientation to Program Activity includes:

- Pharmacy organization chart
- List of staff involved in compounding, including the pharmacist in charge

Information needed for the Reviewer Planning Session

- Job descriptions for each category of pharmacy staff involved in medication compounding
- 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
- Policy, procedures, and software supporting medication recall and compounded medication returns
- Submitted DEA Form 222 and associated powers of attorney
- Competency assessments and performance evaluations for staff involved in medication compounding
- Remedial follow-up on failed competency reviews
- 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
- All medication compounding related policies and procedures
- For Home Care: A list of current patients with start of care date and the type of compounded medication being provided. If there are a limited number of active patients receiving compounded medication, provide a list of discharged patients who received compounded medications representative of those provided by the organization.

DAY 1

Time	Activity	Organization Participants
8:00 – 8:10 a.m. (10 minutes)	**Opening Conference** • Greetings and introductions • Introductions of key program and organization staff	Leaders who oversee medication compounding Pharmacist in Charge Compounding Supervisor
8:10 – 9:00 a.m. (50 minutes)	**Orientation to Program** Discussion topics: • Compounding risk level for sterile with specifications for each (low, medium, high) • Compounding complexity level for non-sterile with specifications for each (simple, moderate, complex) • Compounding related policies and procedures, including: o BUD assignment o Compounding staff gowning and gloving o Clean room monitoring requirements	Individual(s) responsible for performance improvement processes within the program and, as applicable, the organization Others at the discretion of the organization

Time	Activity	Organization Participants
	○ Medication recall and return ○ Others as requested • List of Primary and Secondary Engineering Controls (PECs and SECs) • Controlled substance compounding requirements with security and ordering processes • Compounding staff requirements ○ Job descriptions for staff involved in sterile compounding ○ Remedial follow-up on failed competency reviews, staff assessments • Regulatory Information ○ Pharmacy facility licenses ○ Recent BOP reports ○ Controlled substance policies and procedures, including a review of submitted DEA 222 ordering documents for the last 3 months • Performance Improvement efforts related to medication compounding	
9:00 – 10:00 a.m. (60 minutes)	**Reviewer Planning Session & Document Review** (60 minutes) See above for the list of documents needed for this activity **Note:** The organization and reviewer should adjust agenda activities to allow for the observation of batching, hazardous, and, when applicable, low-, medium-, and high-level risk, and non-sterile medication compounding processes.	Pharmacy representative as requested by reviewer
10:00 – 12:30 p.m. (2 hours 30 minutes)	**Compounded Medication Tracers, Pharmacy Visits and Satellite Pharmacy Visits** • This activity will evaluate the medication compounding process from order receipt, all steps involved in preparing the product, maintaining the integrity of the product until and during delivery to patient care location, and handling and storage in the patient care location until administered to the patient. • Visit the main pharmacy, and as applicable, all satellite pharmacies where sterile medication compounding is taking place • Assess environment of care: Primary Engineering Control (PEC) and Secondary Engineering Control (SEC) including review of ongoing monitoring and hood certification etc. *Observe the following:* • Staff preparations for medication compounding (e.g., gathering products, supplies, preparing them for sterile environment, garbing for sterile environment, any cleaning activity in preparation for compounding within the sterile environment	Pharmacy leaders Pharmacy managers/supervisors Pharmacy staff members

Time	Activity	Organization Participants

	• Compounding activity, with a focus on compounding technique
	  ○ Aseptic technique based on risk level for sterile compounding
	  ○ Procedural technique based on complexity for nonsterile compounding (N/A for Michigan)
	• Anticipatory medication compounding process (if batching is done, observe this as well)
	• "Hazardous" medication compounding process
	  ○ Chemotherapy
	  ○ Gene therapy
	• High-, medium-, and low-risk medication compounding
	• Complex, moderate, and simple non-sterile medication compounding processes, as applicable (N/A for Michigan)
	
	Interview topics for compounding staff:
	• During compounding observation, at appropriate times, reviewers will ask staff about process and technique.
	• After observation, reviewers will ask staff about:
	  ○ Medication recall and return processes
	  ○ Orientation, training and education
	  ○ Last competence evaluation
	  ○ Oversight processes
	  ○ Availability of information (SDSs, policies and procedures)
	
	Interview topics for compounding supervisor, and Pharmacist in Charge:
	• Pharmacy staff access to current reference material and compounding requirements
	• Oversight of calibration process of automated medication compounding devices
	• Medication recall and medication return processes
	
	Hospital Reviews: Include a visit to patient care units to observe compounded medication delivery and storage prior to administration
	
	Home Care Reviews:
	Include phone contact with five (5) patients (or an attempt to speak with all patients on service if less than five) to discuss integrity of the product upon receipt, with a particular emphasis on storage and labeling; education of patient/caregiver about the product, supplies, etc.	

12:30 – 1:00 p.m. (30 minutes)	**Reviewer Lunch**	
1:00 – 3:30 p.m. (2 hours, 30 minutes)	**Compounded Medication Tracers, Pharmacy Visits, and Pharmacy Satellite Visits**, continued See description of this activity above	See participant list above
3:30 – 4:30 p.m. (60 minutes)	**Reviewer Planning Session and Document Review**, continued	Pharmacy representative as requested by reviewer

DAY 2

Time	Activity	Organization Participants
8:00 – 8:30 a.m. (30 minutes)	**Daily Briefing**	Leaders who oversee medication compounding Pharmacist in Charge Compounding Supervisor Staff involved in medication compounding Individual(s) responsible for performance improvement processes Others at the discretion of the organization
8:30 – 12:00 p.m. (3 hours 30 minutes)	**Compounded Medication Tracers, Pharmacy Visits, and Satellite Pharmacy Visits,** continued See description on Day 1	See recommended participants on Day 1
12:00 – 12:30 p.m. (30 minutes)	**Reviewer Lunch**	
12:30 – 1:00 p.m. (30 minutes)	**System Tracer – Data Use** 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	Pharmacist in Charge Organization-wide performance improvement representative Others at the discretion of the organization
1:00 – 2:00 p.m. (1 hour)	**Competence Assessment Session** Discussion topics will include: • Competence assessment process • Remedial follow-up process At a minimum, documentation of competency for each compounding employee must include: • Media fills, • Glove fingertip testing • Most recent observation of compounding technique Competency process will be evaluated in file reviews for the following organization staff: • The compounding supervisor (which may also be same person as Pharmacist in Charge) • 20% (a minimum of 10) of compounding staff members. Review the documented competencies of those who perform Low-Risk and Moderate-Risk. This review should	Pharmacist in Charge Compounding Supervisor

	include each of the compounding staff members that the reviewer observes during the visits to the pharmacies. • 100% of staff completing High Risk Compounding. This review includes media fills, glove fingertip testing, and the most recent competency observation. • A minimum of 2 service staff members who are involved in the cleanup and disposal associated with medication compounding (if done by staff members outside of pharmacy department) • A minimum of 2 staff members that are involved in storing, packing, and delivering compounded medications, including staff who deliver compounded medications to home care patients.	
2:00 – 3:30 p.m. (1 hour, 30 minutes)	**Issue Resolution and Reviewer Report Preparation**	Pharmacy representative as requested by reviewer
3:30 – 4:00 p.m. (30 minutes)	**Program Exit Conference** • Review observations and any requirements for improvement by standard, EP, and advanced requirement identifiers • Allow time for questions regarding review findings and provide additional material regarding compliance with requirements • Review required follow-up actions as applicable	Leaders who oversee medication compounding Pharmacist in Charge Others at the discretion of the organization

Note: This agenda is a guide and may be modified based on organizational need and reviewer discretion.

Sample One-Day Review Agenda

The Joint Commission
Medication Compounding Certification
One-Day Review Agenda

Compounding areas to be observed in Michigan organizations: Reviewers will only observe sterile compounding activity performed in the central pharmacy and all satellite pharmacies. Compounding on patient care units, ED, ICU, etc. is not included in the scope of review. Patient care unit visits are to observe how medications from the pharmacy are delivered and stored prior to administration.

Information needed for the Orientation to Program Activity includes:

- Pharmacy organization chart
- List of staff involved in compounding, including the pharmacist in charge

Information needed for the Reviewer Planning Session

- Job descriptions for each category of pharmacy staff involved in medication compounding
- 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
- Policy, procedures, and software supporting medication recall and compounded medication returns
- Submitted DEA Form 222 and associated powers of attorney
- Competency assessments and performance evaluations for staff involved in medication compounding
- Remedial follow-up on failed competency reviews
- 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
- All medication compounding related policies and procedures
- For Home Care: A list of current patients with start of care date and the type of compounded medication being provided. If there are a limited number of active patients receiving compounded medication, provide a list of discharged patients who received compounded medications representative of those provided by the organization.

DAY 1

Time	Activity	Organization Participants
8:00 – 8:10 a.m. (10 minutes)	**Opening Conference** • Greetings and introductions • Introductions of key program and organization staff	Leaders who oversee medication compounding Pharmacist in Charge
8:10 – 9:00 a.m. (50 minutes)	**Orientation to Program** Discussion topics: • Compounding risk level for sterile with specifications for each (low, medium, high) • Compounding complexity level for non-sterile with specifications for each (simple, moderate, complex) • Compounding related policies and procedures, including:	Compounding Supervisor Individual(s) responsible for performance improvement processes within the program and, as applicable, the organization

Time	Activity	Organization Participants
	○ BUD assignment ○ Compounding staff gowning and gloving ○ Clean room monitoring requirements ○ Medication recall and return ○ Others as requested • List of Primary and Secondary Engineering Controls (PECs and SECs) • Controlled substance compounding requirements with security and ordering processes • Compounding staff requirements ○ Job descriptions for staff involved in sterile compounding ○ Remedial follow-up on failed competency reviews, staff assessments • Regulatory Information ○ Pharmacy facility licenses ○ Recent BOP reports ○ Controlled substance policies and procedures, including a review of submitted DEA 222 ordering documents for the last 3 months • Performance Improvement efforts related to medication compounding	Others at the discretion of the organization
9:00 – 10:00 a.m. (60 minutes)	**Reviewer Planning Session & Document Review** (60 minutes) See above for the list of documents needed for this activity **Note:** The organization and reviewer should adjust agenda activities to allow for the observation of batching, hazardous, and, when applicable, low-, medium-, and high-level risk, and non-sterile medication compounding processes.	Pharmacy representative as requested by reviewer
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Time	Activity	Organization Participants

	them for sterile environment, garbing for sterile environment, any cleaning activity in preparation for compounding within the sterile environment
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	  o Aseptic technique based on risk level for sterile compounding
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	  o Medication recall and return processes
	  o Orientation, training and education
	  o Last competence evaluation
	  o Oversight and quality control
	  o Availability of information (SDSs, policies and procedures)
	
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	• Pharmacy staff access to current reference material and compounding requirements
	• Oversight of calibration process of automated medication compounding devices
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12:30 – 1:00 p.m. (30 minutes)	**Reviewer Lunch**	
1:00 – 1:30 p.m. (30 minutes)	**System Tracer – Data Use** Discussion will include:	Pharmacist in Charge

Time	Activity	Organization Participants
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2:30 – 4:00 p.m. (1 hour, 30 minutes)	**Issue Resolution and Reviewer Report Preparation**	Pharmacy representative as requested by reviewer
4:00 – 4:30 p.m. (30 minutes)	**Program Exit Conference** • Review observations and any requirements for improvement by standard, EP, and advanced requirement identifiers • Allow time for questions regarding review findings and provide additional material regarding compliance with requirements • Review required follow-up actions as applicable	Leaders who oversee medication compounding Pharmacist in Charge Others at the discretion of the organization

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