SAMPLE AGENDA
Medication Compounding Certification

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 medications, provide a list of discharged patients who received compounded medications representative of those provided by the organization.

Disclaimer: Recording or transcribing this review is strictly prohibited, including the recording and transcribing that can occur with video conference applications. Discovery of any recording activities will result in the immediate cessation of the review and denial of certification.

DAY 1

Time	Activity	Organization Participants
8:00 – 8:10 a.m. (10 minutes) 8:10 – 9:00 a.m. (50 minutes)	**Opening Conference** • Greetings and introductions • Introductions of key program and organization staff **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 o Medication recall and return o 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 o Job descriptions for staff involved in sterile compounding o Remedial follow-up on failed competency reviews, staff assessments • Regulatory Information o Pharmacy facility licenses o Recent BOP reports o 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	Leaders who oversee medication compounding Pharmacist in Charge Compounding Supervisor Individual(s) responsible for performance improvement processes within the program and, as applicable, the organization 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
10:00 – 12:30 p.m. (2 hours 30 minutes)	**Compounded Medication Tracers, Pharmacy Visits and Satellite Pharmacy Visits**	Pharmacy leaders Pharmacy

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	• 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
	• 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 and quality control
	  ○ Availability of information (SDSs, policies and procedures)
	
	Interview topics for compounding supervisor, and Pharmacist in Charge:
	• Pharmacy staff access to current reference
		managers/supervisors
		
		Pharmacy staff members

Time	Activity	Organization Participants
	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 – 1:30 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
1:30 – 2:30 p.m. (60 minutes)	**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 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,	Pharmacist in Charge Compounding Supervisor

Time	Activity	Organization Participants
	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.	
2:30 – 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