The Joint Commission
Medication Compounding Certification
Michigan Webinar

September 8, 2016
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Questions/Comments:
- Submit questions and comments via the Questions panel.
Today’s Topics

- **Background**
  - Jennifer Hoppe, MPH, Senior Associate Director, State Relations

- **Framework and Scope of the Standards**
  - Dima Awad, PharmD, MS, APD- Pharmacist Specialist, Department of Standards and Survey Methods

- **Overview of the Onsite Review Process**
  - Wayne Murphy, RRT, MPS, Field Director, Operations

- **Pricing**
  - Brian Johnson, Ph.D., Associate Director, Business Development

- **Application Process for Michigan**
  - Jennifer Hoppe
Background

- Michigan Compounding Pharmacy Law
  - Public Act 280 of 2014
  - A provision of the Act requires licensed pharmacies that perform compounding services for sterile pharmaceuticals to obtain accreditation

- Michigan Board of Pharmacy’s approval of the Joint Commission’s Medication Compounding Certification program

- Board of Pharmacy definition of “in the accreditation process”
Background (cont.)

- Fast Track program developed for Michigan organizations
- Application deadline: **September 30, 2016**
  - Online form created to allow submission
  - Joint Commission’s Electronic Application (E-App) available later this Fall
- Deadline for completing certification process: **June 30, 2017**
Medication Compounding Standards
Standards

Medication Compounding Standards

- Adapted from USP
- Five Chapters
  - General Responsibilities
  - Education, Training, and Evaluation
  - Compounding Sterile Preparations
  - Compounding Sterile and Nonsterile Preparations
  - Compounding Nonsterile Preparations
General Responsibilities

- **Standard MDCGR.01**
  - Leadership responsibilities

- **Standard MDCGR.02**
  - Staff responsibilities

- **Standard MDCGR.03**
  - Patient or patient caregiver’s education
Education, Training, and Evaluation

Standard MDCED.01- MDCED.07

- Policies and procedures
- Initial and ongoing education and training
- Observation and demonstration of competency
- Knowledge and competency concerning equipment and spaces
Education, Training, and Evaluation

- Aseptic manipulation skills
- Evaluation of compounding staff performance
- Quality improvement process

Standard MDCED.01- MDCED.07 (continued)
Compounding Sterile Preparations

Standard MDCS.01-MDCS.21

- Work practices and an environment based on risk level
- Immediate use
- Single-dose and multiple-dose
- Radiopharmaceuticals
- Allergen extracts
Compounding Sterile Preparations

Standard MDCS.01- MDCS.21

- 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 and Nonsterile Preparations

Standard MDCSN.01- MDCSN.04

- Storage of CSPs and assigning beyond-use dates (BUD)
- Hazardous medications
Compounding Nonsterile Preparations

- Policies and procedures
- Facilities for nonsterile compounding
- Equipment for nonsterile compounding
- Packaging and medication preparation
- Documentation
- Quality control
Overview of the Onsite Review Process
Review Process – Opening Conference

Opening conference – suggested attendees

- Leaders who oversee medication compounding
- Staff involved with medication compounding
- Nursing Leadership/representation
- Risk or quality management
Review Process - Orientation

Potential topics

- Types of medication compounding – sterile, non-sterile, hazardous
- Roles and responsibilities for medication compounding
- Job descriptions
- Leadership of oversight of medication compounding
- Routine cleaning requirements and procedures
- Beyond use dating
- Management of medication shortages
Document Review

Includes but is not limited to:

- Primary engineering controls documentation
- Secondary engineering controls documentation
- Facility licenses
- State pharmacy board reports
- Medication recall and medication return processes
- DEA form 222 with associated power of attorneys
- Any medication compounding policies
- Safety Data Sheets
- Master formula records
Pharmacy Visit

- Observation and review of medication compounding activity – focus on medication compounding technique
  - Review Aseptic technique based upon risk level
  - Review Procedural technique based upon complexity for nonsterile medication compounding
- Observation of medication compounding process
- Observation of hazardous medication compounding
- Observation of different categories of risk in compounding
- Assessment of the environment used for compounding
Pharmacy Visit (Cont.)

- Review and assessment of medication labeling and storage
- Review of competency assessment and follow up
- Assess staff access to current reference materials
- Review of medication compounding devices and calibration procedures
Tracer Activity

- Review of a patient receiving a compounded product

For Home Care based pharmacies:
  - Phone interview with a patient who has received product and appropriate medication
Data Use

- Performance improvement approach and plan
- Collection of data
- Performance improvement priorities
- Activities for improvement and monitoring
Competence Assessment and Credentialing

- Competence assessment
- Review of personnel files
- Review of files for support staff
Exit Conference

- Review of observations and requirements for improvement
- Questions and answers
- Potential follow up
Certification Pricing
Certification Pricing

- MDC is a 2-year certification
- Price based on length of review
- Actual review days/length may vary
- Number of locations
- Annual fees billed in January 2017
- Review fee billed after on-site visit.
Estimated Certification Pricing

- Estimated Total = $10,000

- Annual Fee = $3,600
  $3,600 x 2 years = $7,200

- On-Site Fee
  $2,000 (Day 1)
  $800 (Day 2) = $2,800
  $800 (additional day)
For Additional Pricing Questions

Pricing Unit

pricingunit@jointcommission.org

or

630-792-5115
Application Process
Application Process

- Outreach conducted
- Online application form
  - Must be submitted by September 30, 2016
- Resources available to Michigan organizations
  - Dedicated webpage
    - Standards, fact sheet, online application form, webinar posting
    - Contact information for additional information
- Link to webpage: https://www.jointcommission.org/med_compounding_cert.aspx
Resources for Michigan Pharmacies Seeking Compliance with Public Act 280 of 2014

Joint Commission’s new Medication Compounding Certification (MDC) has been approved by the Michigan Board of Pharmacy to help pharmacies demonstrate compliance with the accreditation requirement contained in Michigan Public Act 280 of 2014. The Michigan Board of Pharmacy has indicated that all sterile compounding pharmacies must submit an application prior to September 30, 2016, and complete the certification process by June 30, 2017.

To make the process of becoming MDC certified with the Joint Commission as convenient as possible, we’ve compiled the key items you need all in one location. Just click on any of the Helpful Links (to the right) to access additional information.

Please bookmark this page to refer back to items as this page is not openly accessible via normal website navigation or search.

To apply for the Joint Commission’s Medication Compounding Certification program please click on the links below:

- [Online Application for Medication Compounding Certification](#)
  - Information you need to apply

The Joint Commission will be hosting an informational webinar on Thursday, September 8, 2016 from 10:00 am – 11:00 am ET. To register for the webinar please use the link below:

- [Medication Compounding Certification Webinar Registration](#)

For additional questions about this certification, please contact one of our team members:

- **Hospital-based pharmacies**
  - Brian Johnson, Associate Director, 630-792-5144, bjohnson@jointcommission.org

- **Home care pharmacies**
  - Cynthia Cook, Associate Director, 630-792-5121, ccook@jointcommission.org

**Helpful Links**

- Michigan Legislation
  - Public Act 280 of 2014
- Joint Commission’s Quick Facts on Medication Compounding Certification (MDC)
  - (includes eligibility, pricing, survey process and more)
- Joint Commission’s Medication Compounding Certification Standards - DRAFT
Application Process

Required components of the application:

- Enter each location where compounding activities are performed
  - Type of setting (central pharmacy, satellite, or off-site locations)
  - Type of compounding performed (sterile/non-sterile, hazardous, nuclear)
  - Time of day compounding activities are performed

List of applicants will be provided to the Board of Pharmacy/LARA
Questions