**Approved: Medication Compounding Certification Program**

*Effective January 1, 2017,* The Joint Commission launched its new Medication Compounding Certification program for all *compounding pharmacies.* The initial rollout for this program is applicable only to pharmacies operating in or shipping to states with regulations requiring compliance with United States Pharmacopeial Convention (USP*) General Chapter(s) *<797>* and/or *<795>* (demand and resource capacity will determine future rollouts to other states). Unlike other Joint Commission certification programs, organizations do not need to be accredited by The Joint Commission in order to obtain this certification.

Across the United States, events related to medication compounding have led many state legislatures and pharmacy boards to enhance laws and regulations pertaining to the practice of compounding pharmaceuticals. Several states have enacted legislation—and many more are in the process of revising their regulations—to require that pharmacies achieve compliance with USP General Chapter *<795>* Pharmaceutical Compounding—Nonsterile Preparations and General Chapter *<797>* Pharmaceutical Compounding—Sterile Preparations. The Joint Commission received considerable feedback from its accredited organizations indicating the need for a more focused and specialized evaluation of facilities’ compounding practices to meet the expectations of state regulatory bodies.

The Medication Compounding Certification program is designed to help qualifying organizations reduce risk and harm, ensure USP compliance, discover and remedy hidden gaps in policies and procedures, and demonstrate excellence through compliance with The Joint Commission standards for medication compounding and the USP standards. These standards were adapted from current USP requirements to keep pace with the latest technology and support field compliance with USP General Chapter *<795>* and USP General Chapter *<797>.* Standards will be modified to remain consistent with

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the latest USP changes—including changes proposed for USP General Chapter <797> and changes that will be implemented once USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings becomes effective (scheduled for July 1, 2018).*

Because microbial contamination of compounded sterile preparations occurs through direct contact or exposure to moisture or particles in the air generated by personnel, objects, or other mechanisms, the certification requirements focus on the following areas:

- **People**—Training, competency, proper use of personal protective equipment, aseptic technique
- **Product**—Sterility of base products, beyond-use dates, labeling
- **Environment**—Airflow, buffer areas, guidelines for cleaning and documentation, storage

This certification was developed in part to address concerns about the nationwide outbreak of fungal meningitis and other infections among patients who received contaminated compounded medications, as these occurrences increased the importance of updated national compounding standards. Since these occurrences, The Joint Commission has conducted extensive research and in-depth literature reviews related to medication compounding as well as strategic leadership meetings with internal and external stakeholders. The new Medication Compounding certification standards are a result of these activities and extensive Joint Commission–USP collaboration.

Eligibility and free 90-day access to the standards for Medication Compounding Certification are available on The Joint Commission website at https://www.jointcommission.org/certification/medication_compounding.aspx and in the Medication Compounding Certification Manual, available only online through the E-dition*. The website also will be updated soon to include a list of states that require compliance with USP General Chapter <795> and USP General Chapter <797>.

Questions about this certification may be directed as follows:

- **Hospital-based pharmacies:** Contact Brian R. Johnson, Associate Director, Hospital Business Development, The Joint Commission at 630-792-5144 or bjohnson@jointcommission.org.
- **Home care pharmacies:** Contact Cynthia Cook, Associate Director, Home Care Business Development, The Joint Commission at 630-792-5121 or ccook@jointcommission.org.

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