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 leader-


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**Changes Announced for the Survey/Review Notification Policy**

Based on feedback received from accredited and certified organizations, The Joint Commission recently approved changes regarding how organizations are notified of upcoming Joint Commission survey/review events. **Beginning March 6, 2017**, The Joint Commission will incorporate e-mail notifications into its current process, notifying its accredited and certified organizations of survey/review activity as follows:

### Announced Events

- Thirty days prior to the scheduled announced event, The Joint Commission will post on the organization’s secure Joint Commission Connect™ extranet site the letter of introduction, the survey/review agenda, and the biography and picture of each surveyor/reviewer assigned to conduct the event. Once this notification—which serves as the official notice of the upcoming event—has been posted, an e-mail notification will be sent to the individuals listed as chief executive officer and primary accreditation/certification contact on the organization’s extranet. This e-mail will advise that an event has been scheduled and instruct the contact(s) to log in to the Joint Commission Connect site to view the event details. The organization will also receive a separate e-mail by 7:30 a.m. in the organization’s local time zone (for organizations within the United States and its territories) on the morning of the event with the same information listed above.

### Short-Notice Events

- Seven business days prior to the scheduled event, The Joint Commission will post on the organization’s secure Joint Commission Connect site the letter of introduction, the survey/review agenda, and the biography and picture of each surveyor/reviewer assigned

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* 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.**
to conduct the event. Certification and Laboratory events will continue to have this information posted on the Joint Commission Connect site the day of survey. Once the notification—which serves as the official notice of the upcoming event—has been posted, an e-mail notification will be sent to the individuals listed as chief executive officer and primary accreditation/certification contact on the organization’s extranet. This e-mail will advise that an event has been scheduled and instruct the contact(s) to log in to their Joint Commission Connect site to view the event details. The organization will also receive a separate e-mail by 7:30 a.m. in the organization’s local time zone (for organizations within the United States and its territories) on the morning of the event with the same information listed above. Organizations that are eligible for short notice will no longer receive a phone call from a Joint Commission representative notifying them that the event has been scheduled.

- Unannounced Events*—On the day of the unannounced

* This includes all events conducted for Medicare certification purposes through The Joint Commission’s available deemed status or Medicare recognition options.

FDA Bans Use of Powdered Gloves
Noncompliance Cited at Joint Commission Standard
LD 04.01.01, EP 2

The US Food and Drug Administration (FDA) recently published a final rule banning the use of powdered gloves.* As stated in the citation summary, “The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon’s Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon’s Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is banning these devices. This rule is effective on January 18, 2017.”

Further clarification in the final rule indicates that “the ban applies to all powdered surgeon’s gloves and powdered patient examination gloves without reference to the type of material from which they are made. Additionally, the identification of non-powdered surgeon’s gloves and non-powdered patient examination gloves is also being revised to remove reference to material.”


As a result of this FDA ban, The Joint Commission now evaluates organizations to assure that required implementation of non-powdered glove use occurs as part of the routine survey evaluation. Effective January 18, 2017, for all accreditation programs, instances of noncompliance are being cited at Leadership (LD) Standard LD 04.01.01, Element of Performance (EP) 2: The [organization] provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.”

The final rule also provides guidance on the proper disposal of remaining stock of powdered gloves, recommending that “unused supplies at hospitals, outpatient centers, clinics, medical and dental offices, other service delivery points (nursing homes, etc.), and in the possession of end users, will need to be disposed of according to established procedures of the local community’s waste management system.” While it is important for organizations to address and manage the disposal process, The Joint Commission will not evaluate the organization’s disposal process of any remaining stock because this is outside the scope of the Joint Commission survey.

Questions may be submitted via the form at https://web.jointcommission.org/sigsubmission/sigquestionform.aspx.