CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Important Information About Hospital Pharmacy Sterile Compounding – New or Remodeled Pharmacy Clean Room Projects

July 31, 2019

Following is important information about hospital pharmacy sterile compounding related to new or remodeled pharmacy clean room projects. **Help us educate lawmakers and regulators on compliance challenges by having your pharmacist-in-charge complete this survey by August 14.**

Background

On June 3, 2019, the United States Pharmacopeia (USP) updated the federal standards for new or remodeled pharmacy clean room projects, instituting a December 1, 2019, deadline for compliance. The updated federal guidelines will conform with the California State Board of Pharmacy (BoP) regulations. Hospitals were granted state sterile compounding compliance waivers during the construction process (Title 16, CCR, section 1735. 6(F)) to sterile compound under the existing state regulations. The waivers will expire on December 1, 2019, when the federal standards take effect.

While USP is not the regulatory enforcement agency, the standards have been adopted by both state and federal regulators, as well as accrediting organizations. You will be surveyed as to your compliance with the new sterile compounding regulations as of December 1, 2019. If your construction projects are not finalized, you are at risk for survey citation and may lose your ability to perform sterile compounding.

Where things stand

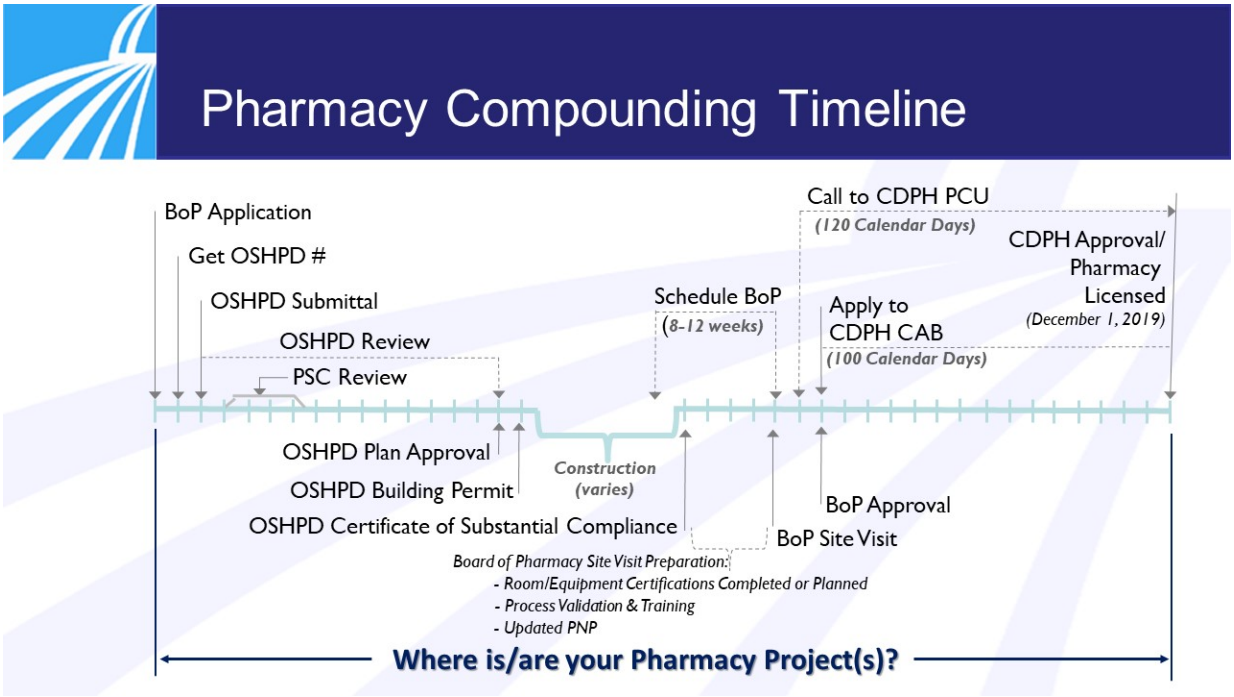
As many California hospitals are actively involved in the construction process for new or remodeled pharmacy clean rooms, there is an analysis underway to determine how many hospitals will meet the December 1, 2019, deadline, and how many will not. In addition to this baseline analysis, CHA, the Office of Statewide Health Planning and Development (OSHPD), the California Department of Public Health (CDPH), and the BoP are working to identify specific barriers for hospitals in meeting the upcoming deadline. While some are well positioned to meet the deadline, many, for myriad reasons, may fall short. Given the deadline, we encourage all hospitals to make every effort to comply by December 1, 2019.

How you can help broader advocacy efforts

CHA, together with the American Hospital Association, is telling accreditors and CMS of these new federal standard challenges and the current deadline. Providers will have had only six months from the finalization of the USP standards to make significant and complex upgrades. The information gathered in this survey will inform our collective efforts to seek a delay in enforcing the new standards with regard to the federal Medicare Conditions of Participation. This delay could also influence a state decision to

extend the timeline for implementation. We need your help to explain why these delays are needed to federal and state regulators.

The timeline below depicts the construction and approval process that was generated to assist hospitals and regulatory agencies. To support hospitals in meeting these deadlines, CHA secured a commitment from CDPH that hospitals can contact the department's Pharmacy Consultant Unit 120 days in advance for application assistance (AFL 19-19).



What you need to know

- CHA's Medication Safety Committee has produced a library of educational tools, such as gap analyses and specific sterile compounding resources, to support ongoing work. These can be found on the CHA website.
- CHA's Medication Safety Committee and state pharmacy leaders, along with CDPH, BoP, and OSHPD, are identifying gaps, barriers, and issues that could prevent compliance by December 1, 2019.
- When these analyses are completed, CHA will develop additional tools to respond to identified problems, including mitigation measures if your facility is non-compliant as of December 1, 2019.

What you need to do now

- Have your PIC complete this survey for each affected hospital. If you have more than one pharmacy clean room project in this hospital, the survey will prompt you to complete for each clean room.

- Meet with your Pharmacist in Charge (PIC), plant facilities staff, and other leadership regarding present clean room construction status.
- Conduct an analysis to identify barriers to meeting the compliance deadline.
- Document progress and barriers to implementation.
- If non-compliance with the December 1, 2019, deadline is projected, strategize with your PIC on contingency plans for sterile compounding.
- Formalize a plan of action on how and when you will meet compliance.