CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Hazardous Sterile Compounding High-Level Assessment Tool

The California Board of Pharmacy's newly revised sterile compounding regulations apply to both sterile hazardous and non-hazardous compounding of pharmaceuticals. Because the hazardous sterile compounding requirements include potential physical plant changes, as well as new engineering controls, CHA has developed this high-level assessment tool to help hospitals determine what — if any — changes they will need to make related to hazardous sterile compounding regulations that take effect January 1, 2017.

Because many of the necessary changes will include physical construction or alteration to a facility or physical environment, the Board of Pharmacy has included in the regulations a compliance waiver process for hospitals that may need time to complete necessary physical changes.

The tool can be used by the hospital pharmacist in charge (PIC) to determine if there are sufficient engineering controls and space, and whether changes are necessary for the facility to perform hazardous sterile compounding.

To use this assessment tool, answer the questions below and follow the instructions after each step:

Step 1: Do you perform hazardous sterile compounding in your hospital pharmacy?

- ☐ Yes – Proceed to Step 2.
- ☐ No – Stop here. You don't need to perform an assessment regarding *hazardous* sterile compounding. However, you will need to assess and compare changes that may be required for *non-hazardous* sterile compounding. Those changes can be found in the "CHA Sterile Compounding Matrices," included with this packet.

Step 2: What engineering controls and hazardous sterile compounding space do you have now? Check all that apply.

- ☐ A separate negative pressure room
- ☐ International Standard Classification Organization (ISO) class 7 or cleaner air
- ☐ A negative pressure, unidirectional airflow hood vented to the outside, **and** at least 30 air exchanges per hour

If you have checked the previous three boxes above, you will meet the January 1, 2017 requirements for the full beyond use date (BUDs) requirements. ***Stop here****. You have completed the assessment and will meet the regulatory requirements for hazardous compounding for full BUD requirements.*

Step 3: If you don't have all three of the above, do you have any of the following?

- ☐ A separate, negative pressure room
- ☐ Unclassified International Organization for Standardization (ISO) and air
- ☐ A negative pressure, unidirectional non-turbulent airflow hood, vented to the outside and at least 10 air exchanges per hour

If all three are checked, you will meet the January 1, 2017 requirements for the short BUDs (12 hours) hazardous sterile compounding, without the need for a waiver. ***Stop here****. You have completed the assessment, unless you plan to extend your BUD capabilities, in which case you will need to skip to* ***"Next Steps"*** *(see below).*

Step 4: If you don't have the engineering controls and space described in Steps 2 or 3, do you have any of the following scenarios for hazardous sterile compounding listed below? Check all that apply.

- ☐ A separate, negative pressure room
- ☐ With or without ISO Class 7 air
- ☐ A negative pressure, unidirectional airflow hood, not vented to the outside

If all three are checked, this will not meet the requirements. Proceed to ***Next Steps*** *(see below).*

Step 5: **If you do not have any of the scenarios described in Step 4, do you have following?**

- ☐ A negative pressure, unidirectional hood vented to the outside but not in a negative pressure room

If the box above is checked, this will not meet the requirements and will need to be reconfigured. If the hood is already vented, consider any space that could become a room and meet the air exchange and still use the same vent for the 12-hour BUD requirement. Proceed to ***Next Steps*** *(see below).*

Step 6: If you do not have the scenario described in Step 5, do you have following?

- ☐ A negative pressure hood not vented to the outside

If you checked the box above, this will not meet the requirements. Proceed to ***Next Steps*** *(below).*

Next Steps

If you are planning to continue sterile hazardous compounding in your facility and you currently have the engineering controls and space described in Steps 4, 5 or 6 — or if the scenarios in Step 3 apply to your facility and you want to upgrade your BUD requirements — you may want to consider the following next steps:

- ☐ Inform your senior management team of your initial assessment and potential changes needed to perform hazardous sterile compounding relative to BUD requirements. Also, inform them that the Board of Pharmacy will require a waiver for planned changes if the proposed facility changes will not meet the January 1, 2017, regulatory deadline.
- ☐ Meet with appropriate staff and your facilities manager to determine a suitable location that can become a negative pressure room with venting to the outside (one vent per hood).
- ☐ If you have a recirculating hood, add a new hood to the budget and or contact the manufacturer for a possible change.
- ☐ Engage an architect, if applicable, for construction plans/modifications.
- ☐ Confer with your facilities manager to determine a tentative budget and timeline.
- ☐ Prepare for OSHPD approval process, if applicable.
- ☐ Begin the process for capital budget and seek Capital budget approval.
- ☐ ***Submit a waiver to the Board of Pharmacy that includes:***
    - The assessment
    - The plan
    - The timeline

This tool is intended for hospital and health care PIC and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption" Sterile Compounding Regulations found at www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf, page 231, and designed by CHA's Medication Safety senior pharmacy leaders.

This tool is not a fixed compliance assessment that must be followed and should not be construed as entirely inclusive or exclusive of all methods that can achieve the same results. Information contained in this document should not be construed as legal advice or used to resolve legal problems.