ITL CONSULTING

CALIFORNIA PHARMACY LAW

CONSIDERATIONS FOR DETERMINING PHARMACY - SPECIFIC HAZARDOUS DRUGS

As of January 1, 2017, California law requires pharmacies compounding with anti-neoplastic agents as classified by National Institute for Occupational Safety and Health (NIOSH) do so within the proper facilities and engineering controls as defined in CCR §1735.6(e) and 1751.4. The law also requires any other drugs, compounds or materials to require these same conditions if determined hazardous by the PIC. Each pharmacy must review their operations to ensure they are meeting this new mandate to protect their employees and the public. The following are considerations in determining if any other drugs outside of the NIOSH anti-neoplastic agents require the same compounding conditions.

NIOSH GROUP 1 DRUGS: ANTI-NEOPLASTIC AGENTS

All Group 1 (anti-neoplastic) drugs can be found on the 2016 NIOSH list in Table 1. Compounding with any of these agents requires the proper environmental conditions and engineering controls. See CCR §1735.6(e) and 1751.4 for detailed requirements.

PHARMACY REVIEW OF HAZARDOUS DRUGS

Pharmacist should review the NIOSH list and create pharmacy's list of hazardous drugs used for compounding. This list should include name of drug, classification, the presented risk, and the type of compounding it is used for (e.g. powder capsules). Any other agents that may be considered hazardous to health should be included.

RISK ASSESSMENT

The compiled list should be reviewed to assess the risk presented to employees and public. Determine who your employees are (e.g. primarily young female compounding staff). Review MSDS and manufacturer-provided information on health risks. Consider the type of compounding each agent is used for (e.g. more aerosolized powder for compounding powder capsules). Consider the volume of hazardous agent preparations relative to overall compounded prescription volume (e.g. 75% hormone compounds overall)

FACILITIES AND ENGINEERING CONTROLS

Further considerations for determining risk are pharmacy facilities and controls. Is the compounding area segregated or is it open air flow? Do other pharmacy members freely pass through the area? Does the compounding use a powder hood or other equipment to contain active ingredients during compounding? Is the compounding area located near patient areas? Is the compounding area easily cleanable in the event of of a spill?

STANDARD OPERATING PROCEDURES & PERSONNEL

Lastly, observe how well SOPs for receipt, storage, transport, compounding and disposal of hazardous drugs are followed by compounding personnel. Are SOPs well written? Are they being followed? Is training for all personnel documented? Are there areas that need require retraining? Do SOPs need updating?

These considerations are not meant to be an comprehensive review. Each institution will need to consider the factors that most influence the potential for adverse health effects that may result from compounding with hazardous agents. Please keep in mind this may include drugs that are not currently on the NIOSH list. It is up to each institution's PIC to understand his or her responsibilities for conducting this review in the interest of employees and the public.

ITL CONSULTING, INC. - 625 THE CITY DRIVE SUITE 475 - ORANGE, CA - 92868