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AFL 07-33

TO: GENERAL ACUTE CARE HOSPITALS

SUBJECT: **MEDICATION SAFETY: USE OF MEDICATIONS WITH “BOXED WARNINGS”**

BACKGROUND: The Department of Public Health’s Center for Healthcare Quality Licensing and Certification Program is issuing this letter to address concerns pertaining to the safe use of medications whose labeling contains boxed warnings, also sometimes called black box warnings. The concerns identified have been noted throughout the state and have resulted in both licensing and federal noncompliance determinations, including Immediate Jeopardy declarations.

This letter is intended to provide guidance on the safe use of medications. The guidance is based on California Code of Regulations (CCR), Title 22, Section 70263(c) (1), 42 Code of Federal Regulations (CFR), Part 482.25 and 21 Code of Federal Regulations (CFR), Part 201.57. Use of medications must be in a manner that promotes patient safety in full consideration of the medication’s inherent risks. We ask that you consider these guidelines to evaluate the safe use of medications with boxed warnings.

BOXED WARNING: The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The FDA is also responsible for helping the public get the accurate science-based information they need to use medicines to improve their health. “FDA carefully controls the content of prescription drug labeling because such labeling is FDA’s principal tool for educating health care practitioners about the risks and benefits of the approved product to help ensure safe and effective use.”¹

¹ Federal Register Vol. 71, No. 15: Tuesday, January 24, 2006 (codified at 21 § 201.57)

The FDA can require a pharmaceutical company to place a boxed warning on the labeling of a prescription medication. It is the strongest warning that the FDA requires. When a medication's labeling includes a boxed warning it means that medical studies indicate that the medication carries a significant risk of serious or even life-threatening adverse effects. FDA's authority to require boxed warnings is codified under 21 CFR 201.57 (c). A boxed warning provides a brief, concise summary of the information that is critical for a prescriber to be aware of, including any restriction on distribution or use.

SAFE USE OF MEDICATIONS:

CCR, Title 22, Section 70263(c) (1) Pharmaceutical Service General Requirements, Pharmacy and Therapeutics Committee:

“The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. “

42 CFR §482.25 Condition of Participation Pharmaceutical Services (b) Standard: Delivery of Services:

“In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.”

The interpretative guidelines state in part: “The pharmacist, in consultation with appropriate hospital staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices and biologicals. For high risk medications...there should be systems in place to minimize adverse drug events. Such systems could include, but not be limited to: checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. ‘High risk medications’ are those medications involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes.”

42 CFR §482.25 Condition of Participation Pharmaceutical Services

“The hospital must have pharmaceutical services that meet the needs of the patients. The medical staff is responsible for developing policies and procedures that

minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service."

The interpretative guidelines state in part: "Policies and procedures to minimize drug errors should include: High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage." The guidelines additionally state, "The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration... Governmental agencies may include: Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality. "

It is the Department's expectation that appropriate safeguards for all medications are in place that acknowledge and manage each the medication's inherent risks with its benefits. Medications that have a boxed warning pose an additional challenge to promote safe use in light of their potential for serious adverse consequences.

We acknowledge that there may be occasions when a facility has the need to use medications in a manner that is not consistent with manufacturer's specifications, including those with boxed warnings. In those occurrences, documented evidence should be present of a deliberative, evidence-based process by your medical and pharmacy staff and appropriate hospital committees that support such use while ensuring patient safety.

Diligent and ongoing efforts to identify and improve processes in which medications are stored, prescribed, prepared, dispensed, administered and monitored can substantially reduce patient morbidity and mortality. We urge you to carefully review your current policies and procedures, including pre-printed orders, to ensure their adequacy in meeting this goal.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

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