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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

June 14, 2010

AFL 10-12

TO: Skilled Nursing Facilities

SUBJECT: Donating Unused Medications

Note: *Effective July 1, 2010, CDPH, L&C will transition from mail to web posting for distribution of AFLs & other guidance documents to licensed facilities (See AFL 10-06).*

This letter is being sent to provide clarification about the requirements for donation of unused prescription medications. Health and Safety (H&S) Code, beginning with Section 150200 allows a skilled nursing facility to donate unused prescription medication to an authorized county repository and distribution program. "Unused prescription medication" refers to patient's drugs, supplied by prescription, which have been discontinued and/or those which remain in the facility after patient discharge. Participation in this program is permissible by statute but subject to additional requirements as outlined below. For facilities opting to participate in this program, the requirements found in Title 22 of the California Code of Regulations Section 72371, pertaining to disposition of non-controlled drugs supplied by prescription which have been discontinued or those which remain in the facility after patient discharge, are superseded by the statutes referenced above.

A county must first establish, by ordinance, a repository and distribution program, and then, only pharmacies that are county-owned or who contract with the county may participate in the acceptance and dispensing of medications donated through the repository and distribution program.

Any prescription medication donated by a skilled nursing facility to this program shall meet all of the following criteria:

- Medications shall not be a controlled substance, as defined under the Federal Comprehensive Drug Abuse Prevention and Control Department of 1970.

- Medications shall not have been adulterated, misbranded or stored under conditions contrary to standards set by the United State Pharmacopeia (USP) or the product manufacturer.
- Medications shall not have been in the possession of a patient or any individual member of the public.
- Medications donated shall have been under the control of staff of the skilled nursing facility.
- Only medication that is donated in an unopened, tamper-evident package or modified unit dose container that meets USP standards, is eligible for donation, provided the lot number and expiration date is affixed. Medications in open containers are not to be donated to this program.

A skilled nursing facility shall not be subject to criminal or civil liability for injury caused when donating prescription drugs in compliance with the above stated requirements. The immunities provided shall not apply in cases of noncompliance, bad faith, or gross negligence.

The information in this All Facilities Letter is a brief summary of the requirements of H&S Code Sections 150200-150207, and facilities should refer to the full text to ensure compliance. CDPH's failure to expressly notify facilities of legislative changes does not relieve facilities of their responsibility for following all laws and for being aware of all legislative changes.

If you have any questions, please contact your local District Office.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Health Care Quality