

California Association of Health Facilities RAP Session San Bernardino/Riverside District Offices

■ Presenters:

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Welcome !

- Please keep in mind that this presentation will not be all inclusive regarding CDPH Regulations
- Relevant questions are encouraged after the presentation.
- It is very important for everyone to remember that survey regulations (State and Federal) are the minimum standards and the facility should always strive for levels above this minimum.

Goals and Objectives

- Identify Federal and State regulatory websites
- Summarize SNF pharmaceutical services
- Discuss statistical patterns of federal survey deficiencies related to SNF pharmaceutical services for 2010 and January – June 2011
- Discuss Health and Safety Code 1261.6 related to use of Automated Drug Cabinets in SNFs
- Discuss elements of SNF Informed Consent for psychotherapeutic medications

Helpful Federal SNF Regulatory Websites

Federal Government

- Code of Federal Regulations (50) & U.S.C.

<http://www.gpoaccess.gov/cfr/>

Use retrieve by CFR Title 42 §§483

www.cms.hhs.gov - General Consumer Info.

- Skilled Nursing Regulations with Interpretive Guidelines & Appendix P

http://www4.cms.hhs.gov/GuidanceforLawsAndRegulations/12_NHs.asp

Helpful California State Regulatory Websites

- California CDPH Licensing and Certification Homepage

<http://www.dhs.ca.gov/lnc/default.htm>

- California's 29 Statutes: Health and Safety Code

<http://www.leginfo.ca.gov/calaw.html>

- California's 28 Regulations: Title 22

<http://ccr.oal.ca.gov/>

Pharmaceutical Services

- Dispensing, labeling, storage, administration and disposition of medications
- Timeliness of medication services
- Stop orders
- Monitoring of the medication distribution system (ordering, dispensing, storage and administering)
- Medication ordering process and record keeping
- Controlled substances accountability
- Provision of pharmaceutical consultant services

Pharmaceutical Consultant Services

- Assist in the development, coordination, supervision and review of pharmaceutical services
- Devote sufficient hours during visit for the purpose of coordinating, supervising and reviewing pharmaceutical services
- Provide consultation on all aspects of pharmaceutical services
- Serve on the following committees: Pharmaceutical Services, Patient Care Policy and Infection Control
 - Committee minutes must be maintained in the facility and indicate members present, date, length of meeting, subjects discussed and action taken

Pharmaceutical Consultant Services

DRR Requirement

- At least monthly
- Review of all drugs currently ordered
- Information concerning the resident's condition as related to drug therapy
- Medication administration records
- Physician progress notes
- Nurses notes
- Laboratory test results
- Report, in writing, to Administrator and DON

Deficiency Patterns For California Skilled Nursing Facilities 2010

- **F329** Drug regimen is free from unnecessary drugs (69/283 Rx deficiencies = 24.3%)
- **F332** Medication error rates of 5% or more (23/283 Rx deficiencies = 8.1 %)
- **F333** Residents free from significant medication errors (31/283 Rx deficiencies = 11%)
- **F425** Facility provides drugs and biologicals (65/283 Rx deficiencies = 23%)
- **F428** Resident's drug regimen reviewed monthly by the pharmacist (31/283 Rx deficiencies = 11%)
- **F431** Proper labeling of drugs and biologicals (64/283 Rx deficiencies = 22.6%)

Deficiency Patterns for California Skilled Nursing Facilities January – June 2011

- **F329** Drug regimen is free from unnecessary drugs (38/140 Rx deficiencies = 27.1%)
- **F332** Medication error rates of 5% or more (3/140 Rx deficiencies = 2.1 %)
- **F333** Residents free from significant medication errors (8/140 Rx deficiencies = 5.7%)
- **F425** Facility provides drugs and biologicals (35/140 Rx deficiencies = 25%)
- **F428** Resident's drug regimen reviewed monthly by the pharmacist (25/140 Rx deficiencies = 17.9%)
- **F431** Proper labeling of drugs and biologicals (31/140 Rx deficiencies = 22.1%)

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities

- Health and Safety Code Section 1261.5
 - Allows for 48 medications/16 doses of each in emergency supplies (amended 1/2010)
 - Does not apply to an automated drug delivery system **when the pharmacist controls access to the medications**
- Health and Safety Code Section 1261.6
 - ADC = mechanical system that stores/dispenses/distributes medication
 - ADC also collects, controls and maintains transaction information (for security/accuracy/accountability)
 - Written transaction information must be readily available for review/inspection
 - ADC access limited to facility/contracted personnel authorized to administer medications

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities (cont'd)

- Health and Safety Code Section 1261.6
 - Written P/P must be developed/implemented by the pharmacy and facility
 - Ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of quality/potency/purity of stored medications
 - P/P must be maintained at the pharmacy **and** the facility where ADC in use
 - ADC also collects, controls and maintains transaction information (for security/accuracy/accountability)

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities (cont'd)

- Health and Safety Code Section 1261.6
 - When used as an emergency medication supply container, drugs removed shall be limited to:
 - A new drug order prescribed to a facility patient prior to the next delivery, or 72 hours, whichever is less
 - Medications will be retrieved after authorization of the pharmacist (pursuant to review of the order)
 - Medications ordered on “as needed” basis, if utilization and retrieval subject to ongoing pharmacist review
 - Medications that patient care policy/pharmaceutical service committee agrees are emergency/acute onset drugs
 - Pharmacist must review the order within 48 hours of retrieval

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities (cont'd)

- Health and Safety Code Section 1261.6
 - When used to provide routine pharmacy services:
 - ADC medications must be in labeled units of packaging
 - Medications will be retrieved after review and approval of the pharmacist (pursuant to review of the order)
 - Pharmacy providing services controls ADC access
 - Access controlled using identification/password system/biosensor
 - ADC shall make complete/accurate record of transactions that includes all users and medications added/removed
 - After pharmacist reviews order, licensed staff only has access to patient-specific medications ordered by MD

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities (cont'd)

- Health and Safety Code Section 1261.6
 - ADC systems that allow licensed staff to have access to multiple medications/not patient specific in their design are allowed if:
 - ADC has electronic/mechanical safeguards to ensure retrieved medications are specific to that patient
 - Facility notifies the department in writing prior to utilizing the system
 - Notification shall include (not limited to) info re: ADC design, personnel access, P/P covering staff training, storage/security and administration issues
 - Department will review above and ensure adequate safeguards in place to ensure medications delivered appropriate to patient
 - If facility not in compliance, department may revoke authorization

Automated Drug Cabinets (ADCs) in Skilled Nursing Facilities (cont'd)

- Health and Safety Code Section 1261.6
 - Stocking of ADC shall be done by a pharmacist
 - If ADC utilizes removable pockets, cards, drawers, etc., the stocking system may be done outside the facility and delivered if:
 - The task of placing removable pockets, cards, etc. is performed by pharmacist/pharmacy intern/tech working under pharmacist
 - Removable pockets, cards, etc. are transported between the pharmacy and facility in a secure tamper-evident container
 - Facility/pharmacy have developed P/P to ensure that pockets, cards, etc. are properly placed into ADC