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AFL 14-18

**TO:** Skilled Nursing Facilities and Nursing Facilities

**SUBJECT:** Centers for Medicare and Medicaid Services / California Department of Public Health Joint Letter Related to Antipsychotic Drug Use

The Centers for Medicare and Medicaid Services (CMS) and the California Department of Public Health (CDPH) are committed to ending inappropriate use of antipsychotic drugs in skilled nursing facilities (SNFs). This letter identifies actions that CMS and CDPH are taking to enforce laws and regulations governing use of antipsychotics in SNFs.

In May 2011, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services issued a report on antipsychotic drug use in elderly nursing home residents. In its report, the OIG found that when nursing home residents received these drugs, approximately half of the time they were not given for medically accepted indications as required by Medicare, and one-fifth were not given in accordance with federal standards to protect residents from unnecessary antipsychotic drug use.

In response to this report, nursing home advocates expressed their concern urging CMS "to do more to address this ongoing threat to quality care and patient safety." In early 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes. CDPH previously issued All Facility Letter (AFL) 12-56 and AFL 13-25.1 regarding California's goal to lead the nation in stopping the unnecessary use of antipsychotic drugs and actions and resources related to this objective.

Federal regulations impose extra protections for nursing home residents receiving antipsychotic drugs; in part due to concerns regarding potential serious adverse effects and an increased risk of death associated with their use (see Food and Drug Administration Boxed Warnings for typical and atypical antipsychotics).

California regulations establish additional informed consent requirements for nursing home residents before antipsychotic drugs or other psychoactive drugs can be used. These requirements are discussed in AFLs 11-08 and 14-11.

CMS is increasing its focus on reviewing the use of antipsychotic drugs in SNFs. For example, CMS Region IX (which includes California) uses, as one element for selecting which facilities are surveyed for a Federal Monitoring Survey (FMS) – also known as a Federal Oversight/Support Survey (FOSS) – facilities with an antipsychotic drug use rate of 20 percent of residents or greater. A CDPH pharmaceutical consultant will participate in these surveys whenever possible.

Similarly, CDPH surveyors (including pharmaceutical consultants) are intensifying their focus on antipsychotic drug use with emphasis on potential care issues as identified in 42 Code of Federal Regulations (CFR) at F222 Section 483.13 (a) Chemical Restraints; F309 Section 483.25 Quality of Care; F329 Section 483.25(l) Unnecessary Drugs, and Title 22 California Code of Regulations Sections 72527 and 72528, Patients' Rights and Informed Consent Requirements.

A facility's interdisciplinary team, including the attending physician and consultant pharmacist, should carefully evaluate each SNF resident receiving antipsychotic medication to ensure that the drug is necessary and that all requirements related to its use are met. The medical director, the administrator, director of nursing, consultant pharmacist, prescribers (including nurse practitioners and physician assistants), and other clinical staff should discuss antipsychotic prescribing patterns and use in the facility.

CMS and CDPH are committed to protecting the health and safety of SNF residents and enforcing the regulations that provide that protection.

If you have any questions, please contact Debra Brown, PharmD, FASCP, Pharmaceutical Consultant II, at [Debra.Brown@cdph.ca.gov](mailto:Debra.Brown@cdph.ca.gov) or at (916) 319-9239.

Sincerely,

**Original signed by Jean Iacino**

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