

Senate Bill 303 (Alquist)

PROHIBIT FORCED USE OF CHEMICAL RESTRAINTS IN NURSING HOMES

ISSUE

Existing state law establishes various rights for nursing home residents, including requirements for residents, or their representatives, to give informed consent before being administered psychotherapeutic medications, such as antipsychotic drugs, and sedatives. However, these informed consent requirements are rarely enforced, leaving residents unaware of the potential powerful, and dangerous side effects often associated with the psychotherapeutic drugs given to them, and undermining their rights to make informed decisions about their care and treatment.

SUMMARY

This bill would enact the Nursing Facility Resident Informed Consent Protection Act of 2009 which would strengthen current informed consent requirements by codifying existing regulations that establish a nursing home resident's right to informed consent concerning the use of psychotherapeutic drugs.

The bill would also:

- Specify the type of information about the psychotherapeutic drugs nursing home residents shall receive, including potential side effects and risks associated with the proposed psychotherapeutic drugs, as well as any black box warnings, or other precautionary information required by the federal Food and Drug Administration (FDA).
- Require nursing home staff to verify that a resident has given informed consent prior to the administration of a psychotherapeutic drug.
- Clarify that the Department of Public Health (DPH) shall inspect nursing homes for compliance with resident informed consent requirements during periodic inspections currently required by law.

- Update and clarify existing law pertaining to representatives of nursing home residents who lack the capacity to understand their rights, such as a conservator, or next-of-kin.

The regulations codified in this bill also establish residents' rights to informed consent concerning the use of physical restraint or devices that limit bodily function.

BACKGROUND

The use of antipsychotic drugs in nursing homes throughout California and the nation has significantly increased during recent years, as more and more physicians prescribe these drugs, for off-label use, to patients with Alzheimer's disease and other forms of dementia, in order to quiet their symptoms. But many of these drugs have major side effects and risks, including increased risk of heart attack, stroke, and death among elderly patients, thereby prompting the FDA to require black box warnings on their labels, informing patients of the severe health risks associated with their use. In fact, a recent study shows that antipsychotic drugs triple the risk of stroke among dementia patients.

According to data provided by the Centers for Medicare and Medicaid Services (CMS), approximately 60 percent of nursing home residents are prescribed psychotherapeutic drugs. Nursing home residents do not generally see the black box warnings, or other information about side effects and risks, when the medication is administered to them, making informed consent central to the protection of residents' rights and health.

The Department of Public Health (DPH) is responsible for the enforcement of existing informed consent requirements. However, existing regulations pertaining to informed consent are rarely enforced, resulting in little evaluation and oversight of nursing home compliance.

RECENT CALIFORNIA ACTION

On February 18, 2009, after investigations by the Department of Public Health and the Bureau of Medi-Cal Fraud and Elder Abuse, Attorney General Jerry Brown announced the arrests of a nurse, physician, and pharmacist of a nursing home in Bakersfield for “forcibly administering” antipsychotic drugs to several residents without informed consent, leading to three resident deaths, according to the criminal complaint.

RECENT FEDERAL ACTION

In response to the growing trend of off-label marketing and prescription of antipsychotic medications to nursing home residents, the federal government, and other states are taking action:

- This January, in a federal court settlement, drug manufacturer Eli Lilly agreed to pay \$1.4 billion in civil and criminal penalties for illegally marketing an antipsychotic drug for off-label use, end encouraging doctors to prescribe the drug to dementia patients. California’s Medi-Cal program will receive \$112 million from the settlement.
- In 2007, U.S. Senator Chuck Grassley (R-Iowa), asked the U.S. Inspector General to investigate the growing use of antipsychotic medications in nursing homes, and also launched an inquiry of three leading antipsychotic drug manufacturers to examine their practices of marketing the drugs for use by nursing home residents.
- In 2007, CMS asked states to step up enforcement of misuse of antipsychotic drugs in nursing homes, and issued guidelines regarding their use with nursing home residents.

ACTION IN OTHER STATES

- In 2007, the Minnesota Department of Health Services increased enforcement of the misuse of antipsychotic medications in nursing homes. Of the state’s 398 nursing homes, 38 percent were cited for misuse, an increase of 11 percent from the year before.

- In 2007, the Arkansas Attorney General filed suit against Johnson & Johnson, claiming, among other things, that it “engaged in a false and misleading campaign” to promote its antipsychotic drug Risperdal to geriatric patients.

SUPPORT

California Advocates for Nursing Home Reform
(sponsor)

FOR MORE INFORMATION

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