SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

AB 48 (Aguiar-Curry)
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ID

SUBJECT

Nursing Facility Resident Informed Consent Protection Act of 2023

DIGEST

In order to protect the dignity of nursing home residents and decrease the misuse of psychotherapeutic drugs, this bill establishes new rights and processes for obtaining informed consent for psychotherapeutic drugs for nursing home patients. The bill also establishes mechanisms to enforce the new rights and processes.

EXECUTIVE SUMMARY

AB 48 attempts to address the issue of the overuse of psychotherapeutic drugs in California nursing homes. Psychotherapeutic drugs are meant to control behavior and thought disorder processes. Psychotherapeutic drugs, specifically antipsychotics, can increase the risk of death for elderly patients with dementia, yet are still widely used for residents with dementia in nursing homes. AB 48 aims to reduce the use of antipsychotics in nursing homes for elderly patients with dementia by requiring that nursing home facilities obtain the informed written consent of a resident or their representative before using or prescribing antipsychotics. It also requires that nursing home facilities provide residents with specific information about antipsychotics, their risks, and alternative options. The bill requires the Department of Public Health (DPH) to develop an informed written consent form for use by nursing homes under these provisions, and requires that nursing homes keep the signed form in the resident's medical file, provide certain notices every six months after obtaining the consent, and affirm that informed written consent has been obtained before administering any antipsychotics. Lastly, the bill requires that the DPH conduct regular inspections of nursing home facilities for compliance, and makes the willful or repeated violation of the bill's sections punishable as a misdemeanor. AB 48 is a reintroduction of a bill that passed the Legislature last year but was vetoed by the Governor, AB 1809 (Aguiar-Curry, 2022). This bill is sponsored by the California Advocates for Nursing Home

Reform, and supported by 21 other organizations and individuals. There is no known opposition.

PROPOSED CHANGES TO THE LAW

Existing law:

1) Sets forth the bill of rights for patients in a skilled nursing, intermediate care, or hospice facility. (Health & Saf. Code § 1599 et seq.)

2) Defines "skilled nursing facility" as a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis, including a small house skilled nursing facility. (Health & Saf. Code § 1250 (b).)

3) Defines "intermediate care facility" as a health facility that provides inpatient care to ambulatory or nonambulatory patients who have a recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care. (Health & Saf. Code § 1250 (d).)

4) Requires DPH to conduct periodic inspections of long-term health facilities to ensure compliance with statutory and regulatory requirements, and authorizes DPH to assess penalties, including citations which may result in monetary fines, against nursing facilities that have violated the law. (Health & Saf. Code § 1420 et seq.)

5) Requires an attending physician at a skilled nursing facility to obtain informed consent from a nursing facility resident when prescribing, ordering, or increasing an order for an antipsychotic medication. (Health & Saf. Code § 1418.9.)

6) Requires the attending physician to, with the nursing home resident's consent, notify the resident's family member, as designated within the resident's medical record, within 48 hours of the prescription, order, or increase of an order of an antipsychotic medication, as specified. (Ibid.)

7) Establishes a process whereby an attending physician and surgeon of a resident in a skilled nursing facility or intermediate care facility may prescribe or order a medical intervention requiring informed consent when they are unable to obtain informed consent because a resident lacks the capacity to provide informed consent. (Health & Saf. Code § 1418.8.)

8) Establishes that it is the responsibility of the attending licensed healthcare practitioner to determine what information a reasonable person in the patient's

condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. (22 Cal. Code of Regs. § 72528(a).)

9) Establishes that information material to a decision concerning the administration of a psychotherapeutic drug or other specified treatments must include the following:
    a) the reason for the treatment and the nature and seriousness of the patient's illness;
    b) the nature of the procedures to be used in the proposed treatment including their probable frequency and duration;
    c) the probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment;
    d) the nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions; and
    e) alternative treatments and risks, and why the health professional is recommending this particular treatment. (22 Cal. Code of Regs. § 72528(b).)

10) States that the patient has the right to accept or refuse the proposed treatment, and has the right to revoke his or her consent for any reason at any time. *Id.*

11) Before initiating psychotherapeutic drugs or other specified procedures, facility staff must verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure. (22 Cal. Code of Regs. § 72528(c).)

12) Establishes certain procedures for how a nursing facility may initiate a proposed treatment without the resident's informed consent in certain circumstances, including when an emergency exists. (22 Cal. Code Regs., §§ 72528 (a)-(f).)

This bill:

1) Makes various legislative findings and declarations, including that as of 2021, 22% of California nursing facility residents are given powerful antipsychotic drugs, which are a subset of psychotherapeutic drugs; that the FDA has issued black box warnings stating that antipsychotic drugs greatly increase the risk of death for seniors with dementia; and, that it is the intent of the Legislature to codify and expand rules that establish a resident's right to provide or withhold written informed consent concerning the use of psychotherapeutic drugs and the right to be free from chemical restraint.

2) Requires a prescriber, prior to prescribing a psychotherapeutic drug to the resident of a Skilled Nursing Facility (SNF) or Intermediate Care Facility (ICF) to

personally examine and obtain the informed written consent of the resident or the resident's representative.

3) Defines the following terms for the purposes of this bill:
    a) "Informed consent" means the voluntary agreement of a resident or a resident's representative to accept a treatment or procedure after receiving specified information;
    b) "Psychotherapeutic drug" means a drug to control behavior or to treat thought disorder processes, excluding antidepressants; and,
    c) "Representative" means an individual who has authority to act on behalf of the resident, including, but not limited to, a conservator, guardian, person authorized as agent in the resident's advanced health care directive, the resident's spouse, registered domestic partner, or family member, a person designated by the resident, or other legally designated individual.

4) Requires the prescriber to communicate, and the written consent form to contain, in a language the resident understands, the information a reasonable person in the resident's condition and circumstances would consider material to a decision to accept or refuse the drug. Permits the written consent form to be provided in English if written translation services are not timely available. Requires the information and written consent form to be provided in an accessible format if the resident is hearing or vision impaired.

5) Requires the written consent form, for purposes of the requirement in 3) above, to be signed by the resident or the resident's representative, and to be signed by a health care professional who declares the resident or resident representative has been provided the material information. Requires copies of the signed consent form to be given to the resident and their representative.

6) Requires, if the signature of the resident or resident's representative cannot be obtained, a licensed nurse to sign the form and verify that they confirmed informed consent with the resident or resident's representative and to state the name of the person with whom they verified consent and the date.

7) Requires the nursing facility, within six months after the consent form is signed and every six months thereafter during which the resident receives a psychotherapeutic drug, to provide a written notice to the resident and the resident's representative of any recommended dosage adjustments and the resident's right to revoke consent and to receive gradual dose reductions and behavioral interventions in an effort to discontinue the psychotherapeutic drug.

8) Authorizes the use of remote technology, including, but not limited to, telehealth, to allow a prescriber to examine and obtain informed written consent.

9) Requires the prescriber to provide, in addition to the information required in specified regulations governing informed consent in SNFs and ICFs, the following additional information material to an informed consent decision concerning the administration of a psychotherapeutic drug:
    a) possible non-pharmacologic approaches that could address the resident's needs;
    b) any current boxed warning labels and accompanying detailed information regarding contraindications, warning, and precautions required by the United States Food and Drug Administration (FDA);
    c) whether a proposed drug is being prescribed for a purpose that has not been approved by the FDA;
    d) possible interactions with other drugs the resident is receiving; and,
    e) how the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects.

10) Requires facility staff, before initiating treatment with psychotherapeutic drugs, to verify that the resident's health record contains a written consent form with the required signatures. Requires facility staff, for a prescription written prior to the admission and encompassing the admission of the resident, to verify that the resident provided informed consent or refused treatment or a procedure pertaining to the administration of psychotherapeutic drugs.

11) Requires residents' rights policies and procedures established pursuant to this bill concerning informed consent to specify how the facility will verify that the resident provided informed consent or refused treatment or a procedure pertaining to the administration of psychotherapeutic drugs.

12) Prohibits this bill from being construed to require a facility to obtain informed consent each time a drug is administered unless material circumstances or risks change.

13) Requires the DPH to inspect nursing facilities for compliance with this bill during required periodic inspections and, as appropriate, during complaint investigations. Prohibits this inspection requirement from limiting DPH's authority in other circumstances to cite for violations or to inspect for compliance with this bill.

14) Deems a violation of the requirement above for facility staff to verify that a resident has a signed written consent form prior to the administration of psychotherapeutic drugs to have caused the affected residents harm and to constitute a class "B," "A," or "AA" violation pursuant to the standards under existing law for these violations.

15) Specifies that in addition to any other penalties, the willful or repeated violation of this bill is punishable as a misdemeanor unless there is an emergency as described in specified regulations.

16) Specifies that nothing in this bill impairs or otherwise alters other non-conflicting statutory or regulatory requirements, including but not limited to, requirements contained in specified regulations pertaining to initiating treatment without informed consent if an emergency exists in which immediate action is necessary for the prevention of serious bodily harm or to alleviate severe physical pain.

17) Requires DPH to develop a standardized informed consent form in consultation with specified stakeholders.

18) Specifies that nursing facilities are not required to comply with this bill until the informed consent form is available as developed by DPH, and requires DPH to have a final informed consent form available by December 31, 2024.

19) Authorizes DPH to implement the provisions of this bill by means of an All Facilities Letter, or similar instruction, and specifies that nothing in this bill negates existing informed consent requirements in law or regulations.

20) Adds the following two requirements to the Skilled Nursing and Intermediate Care Facility Patient's Bill of Rights:
    a) requires a resident of a nursing home facility to have the right to receive the information that is material to an individual's decision concerning whether to accept or refuse a proposed treatment or procedure, pursuant to specified regulations governing informed consent. Requires the disclosure of material information for administration of psychotherapeutic drugs to also include the disclosures required by this bill in 9) above; and,
    b) requires a resident of a nursing home facility to have the right to be free from psychotherapeutic drugs used for the purpose of resident discipline or convenience, and to have the right to be free from psychotherapeutic drugs used as a chemical restraint, except in an emergency that threatens to cause immediate injury to the resident or others. Requires, if a chemical restraint is administered during an emergency, the chemical restraint to only be a drug that is required to treat the emergency condition, after being deemed the least intrusive treatment alternative for the resident, and used only for a specified and limited period of time. Defines "chemical restraint," for purposes of this provision, as a drug used to control behavior and used in a manner not required to treat the resident's medical symptoms.

COMMENTS

1. The Purpose of AB 48 according to the author

According to the author, AB 48 is necessary because:

> Nursing facilities have increasingly turned to psychotherapeutic drugs to sedate and control residents, especially those who display confused or agitated behaviors caused by dementia. While these drugs are sometimes appropriately prescribed to treat mental health conditions, many psychotherapeutic drugs are being misused in nursing facilities. For example, antipsychotic drugs are designed to treat serious psychiatric disorders like schizophrenia, but are instead prescribed to residents with dementia, which can increase the risks of dangerous side effects and death without medical justification. This bill gives nursing home residents and their families tools to decide if a medication is right for them. This bill codifies existing regulations that establish a nursing home resident's right to informed consent concerning the use of psychoactive drugs, strengthening requirements for informed consent verification, and clarifying that DPH must inspect for compliance with informed consent requirements.

2. Dementia and the Best Practices for Managing the Disease

Dementia is a general term referring to for a variety of diseases that are caused by abnormal changes in the brain. Dementia impairs a person's memory, cognition, attention, ability to communicate, reasoning and judgement, ability to complete daily tasks, and sometimes personality and behavior. Some types of dementia may cause difficulty with sleeping at night and hallucinations, while others can cause difficulty with walking or eating and irritability and personality changes. It is sometimes associated with particularly challenging behaviors like agitation, anger, disrobing, eating abnormalities, inappropriate sexual behavior, paranoia, and physical and verbal aggression.[1] Dementia occurs due to changes in the brain that result in the death of brain cells and prevents brain cells from communicating with each other. Certain factors also increase the risk of dementia, such as age, family history, poor cardiovascular health, and past or repeated traumatic brain injuries.[2] Additionally, race and ethnicity affect the likelihood of dementia – African Americans are twice as likely, and Latinos 1.5 times as likely, as Caucasians to have dementia. Behavioral and environmental interventions, such as increased structured activities, multisensory stimulation, music therapy, and reminiscence and problem-solving therapies, are the most effective interventions to manage dementia, but such therapies require investments in human resources and customization to each patient.[3] On the other hand, evidence shows that

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[1] Zwijsen, et al., *Coming to grips with challenging behavior: a cluster randomized controlled trial on the effects of a multidisciplinary care program for challenging behaviors in dementia*, Journal of the American Medical Directors Association (May 28, 2014), available at https://pubmed.ncbi.nlm.nih.gov/24878214/.
[2] Cal. Center for Disease Control, "About Dementia" (Apr. 5, 2019), available at https://www.cdc.gov/aging/dementia/index.html.
[3] Art Walaszek, "Best Practices In the Care of Patients with Behavioral and Psychological Symptoms of Dementia," Alzheimer's Disease Research Center, University of Wisconsin-Madison (Sept. 6, 2019),

pharmacological interventions, particularly antipsychotic drugs, have only mixed results at best and pose significant risks to patients.[4]

3. The state of nursing facilities that care for patients with dementia and other illnesses

Nationally, it has been estimated that about 49% of all nursing home residents and 45.5% of all long-term care hospital patients have been diagnosed with some form of dementia.[5] About 400,000 Californians are cared for in long-term care facilities every year.[6]

Despite the extensive scholarship on best practices for managing dementia and the risks and limited efficacy of pharmacological treatments, a 2022 report from the United States Office of Inspector General (OIG) found that 80% of residents of nursing homes who resided at the home for at least 100 days were routinely given psychotropic drugs.[7] Other reports, such as by Human Rights Watch and the Long Term Care Community Coalition, support these findings as well.[8] Proponents of this bill also assert that nursing homes underreport psychotropic drug use by using psychotropic drugs not counted by the federal government or by misdiagnosing schizophrenia to hide the utilization of psychotropic drugs. A report by the New York Times supports this assertion as well.[9] These reports suggest that many nursing homes are turning to antipsychotic drugs for their residents with dementia despite the risks due to staffing shortages and insufficient training to adequately provide the care and treatment experts say is most effective. A number of reports have shown a correlation between lower ratios of registered nurse staff to residents and between higher percentages of residents with low-income subsidies with a high use of psychotropic drugs.[10] Reports indicate that nursing homes are using antipsychotics as a way of sedating residents with dementia instead, and they may even be hiding the true numbers through misdiagnosing schizophrenia or other illnesses to avoid having to report antipsychotic use to the federal government.

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available at https://www.adrc.wisc.edu/news/best-practices-care-patients-behavioral-and-psychological-symptoms-dementia.

[4] *Id.*

[5] Christine Caffrey et al, "Post-acute and Long-term Care Providers and Services Users in the United States, 2017-2018," U.S. Dept. of Human Services (May 2022), available at https://www.cdc.gov/nchs/fastats/alzheimers.htm.

[6] "Facts and Statistics: Long-Term Care Providers," California Association of Health Facilities (Mar. 2021), available at https://www.cahf.org/About/Consumer-Help/Facts-and-Statistics.

[7] Office of the Inspector General, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes*, U.S. Dept. of Health & Human Svcs. OEI-07-20-00500 (Nov. 2022).

[8] *See,* Human Rights Watch, "'They Want Docile': How Nursing Homes in the United States Overmedicate People with Dementia," (February 2018); Long Term Care Community Coalition, "A Decade of Drugging: Sedation of Nursing Home Residents with Dangerous Antipsychotic Drugs Persists Despite Federal Partnership," (2022).

[9] Katie Thomas, et al, "Phony Diagnoses Hide High Rates of Drugging at Nursing Homes," The New York Times (Sept. 11, 2021), available at https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html.

[10] Office of Inspector General, *supra* note 7.

4. The risks of psychotherapeutic drugs to nursing facilities residents

The proponents of AB 48 assert nursing homes use of antipsychotic drugs have dire consequences, and the research supports the claim. Antipsychotics are not recommended as treatment options for dementia; rather, they are meant to treat schizophrenia or mania. Clinical studies have shown that using antipsychotics for dementia, an off-label use (a use other than their intended or described use), leads to a mortality rate 1.6 to 1.7 times higher for older patients with dementia given antipsychotics than those not given antipsychotics.[11] Death from antipsychotics most often occurs from cardiovascular illnesses or from infection. Because of these serious risks, the FDA requires pharmaceutical companies to "black-label" antipsychotics, the highest safety-related warning that medications can be assigned by the FDA. Their labels must state on the label must state atypical use of antipsychotics are dangerous to older patients with dementia.

5. The History of nursing home reform and campaigns to reduce the use of antipsychotics:

One of the earliest reports on the over-use of antipsychotics in nursing homes was published by the United States Senate Special Committee on Aging in 1975. The report stated that "the flow of drugs through most of America's 23,000 nursing homes is almost totally without controls; it is haphazard, inefficient, costly, and, most of all, dangerous to the patients who must trust others for their protection."[12] That report also noted that the elderly are particularly susceptible to the side effects of antipsychotic drugs, such that good medical practice requires that their use be strictly time-limited, episodic, and only supplementary to addressing the cause of a dementia patient's agitation. Another report of the Institute of Medicine again highlighted the issue of the misuse of antipsychotics in 1986.[13] In response, the United States Congress passed the Nursing Home Reform Law of 1987, which created a Resident's Bill of Rights and banned the use of drugs that serve the interest of the nursing home or staff rather than the patient. The Bill of Rights at that time included the right to participate in the review of one's own patient care plan and be informed of changes to the plan, including the risks and benefits of any medication, the right to refuse a medication, and included the right to be free from chemical restraints.

In 2005, the FDA published a public health advisory on the dangers of antipsychotics for elderly nursing home residents with dementia.[14] That report resulted in the FDA

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[11] Karen Dagerman, "Risk of Death With Atypical Antipsychotic Drug Treatment for Dementia," JAMA 294(15):1934-1943 (2005), available at https://jamanetwork.com/journals/jama/article-abstract/201714.
[12] Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks, Sen.Doc. No. 41-557, 94th Cong., 1st Sess. (1975).
[13] Institute of Medicine, *Improving the Quality of Care in Nursing Homes*, (1986).
[14] Food & Drug Adm., *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances*, U.S. Dept. Health & Hum. Svcs. (Apr. 11, 2005).

announcing that manufacturers of certain antipsychotics must include the "black-label" warnings for atypical antipsychotics warning of these increased dangers of death. Three years later, this black-label warning requirement was extended to all antipsychotics. Research later suggested that the FDA's black-label warnings, while decreasing the usage of antipsychotics, resulted in nursing homes simply shifting drugs, from antipsychotics to antiepileptics and opioids.[15] Another report from the Office of Inspector General in 2011 highlighted the continued rampant use of antipsychotics in nursing homes.[16] That report found that elderly patients with dementia accounted for 88 percent of antipsychotic prescriptions in nursing homes.

Following the 2011 OIG report, resident advocates and the United States Center for Medicare and Medicaid Services (CMS) created the National Partnership to Improve Dementia Care. That partnership aimed to reduce the use of antipsychotics in nursing homes through training for nursing home staff, emphasizing non-pharmacological alternatives to manage dementia patients, and through the collecting and publishing of data on each nursing home's antipsychotic drug use. As part of this last strategy, CMS began requiring that nursing homes disclose how many of their residents are taking antipsychotics; however, there is an exception for instances in which the resident is taking the antipsychotics because of a schizophrenia, Huntington's Disease, or a Tourette's Syndrome diagnosis. Reporting, such as that by the New York Times previously mentioned, suggest that nursing homes may be undercounting the number of their residents taking antipsychotics by simply over diagnosing or misdiagnosing residents with schizophrenia.[17] Therefore, the reporting and studies have suggested that the modest decrease in overall antipsychotic usage is misleading, and overuse of antipsychotics continues to pose serious risks to elderly residents in nursing homes. All of this evidence suggests that the nursing home patients can benefit from additional protections under the law.

6. Current informed consent obligations

Currently, attending physicians are required to obtain informed consent from nursing home residents when prescribing, ordering, or increasing an order for antipsychotics. (Health & Saf. Code § 1418.9(a)(1).) They also are required to seek the resident's consent to notify the resident's interested family member that is designated in the resident's medical record, and to attempt to notify that family member within 48 hours of a prescription, order, or increase of any antipsychotic medication if the resident consents.

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[15] Michael Ganz et al., "Association of the US Food and Drug Administration Antipsychotic Drug Boxed Warning with Medication Use and Health Outcomes in Elderly Patients with Dementia," JAMA Network Open (Apr. 28, 2020), available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765053#:~:text=Meaning%20The%202005%20FDA%20boxed,patients%20to%20new%20health%20risks.

[16] Office of the Inspector General, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, U.S. Dept. of Health & Hum. Svcs., OEI-07-08-00150 (May 2011).

[17] Thomas, *supra* note 9; Long Term Care Community Coalition, *supra* note 8 at 8.

(Health & Saf. Code § 1418.9(a)(2).) The attending physician is not required to attempt to notify a family member if no interested family members have been designated in the resident's medical record, if the resident has been diagnosed with a terminal illness and is in hospice care, or if the resident does not consent to the notification. (Health & Saf. Code § 1418.9(b).) Before administering antipsychotics or physical restraints, nursing home staff is required to verify that the resident's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure.

However, the law allows for some medical intervention without the resident's informed consent. If medical staff determine that consent cannot be obtained, the medical staff may initiate treatment without the resident's informed consent if it is determined that the resident lacks the capacity to make a decision regarding their healthcare, is unable to understand the nature and consequences of the proposed intervention, or is unable to express a preference, and the nursing home follows additional procedures for documenting the lack of capacity, attempting to locate a suitable legal decision-maker, or conducting an interdisciplinary team review. (Health & Saf. Code § 1418.8.) In the case of an emergency where immediate action is needed for the preservation of life, for the prevention of serious bodily harm to the patient or others, or to alleviate severe physical pain, medical staff may initiate a medical invention without the resident's informed consent even if that informed consent would otherwise be required.

Existing regulations further define what constitutes informed consent. California Code of Regulations mandates that the attending licensed healthcare practitioner at the skilled nursing facility "determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure." (22 Cal. Code Regs. § 72528(a).) For the administration of a psychotherapeutic drug or a physical restraint, or the prolonged use of a device that could prevent the resident from regaining normal bodily function, the information considered material and required for disclosure includes:

a) the reason for the treatment and the nature and seriousness of the patient's illness;
b) the nature of the procedures to be used in the proposed treatment, including their probable frequency and duration;
c) the probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment;
d) the nature, degree, duration and probability of the side effects and significant risks, commonly known by health professions;
e) the reasonable alternative treatment and risks, and why the health professional is recommending this particular treatment; and
f) that the patient has the right to accept or refuse the proposed treatment, and if they consent, has the right to revoke their consent for any reason at any time. (22 Cal. Code of Regs. § 72528(b).)

7. What AB 48 does to address the issue of overprescribing of psychotherapeutics:

Proponents of this bill assert that strong informed consent requirements are essential to ameliorating the problem of the overuse of antipsychotics in nursing homes. They propose codifying the regulations in section 72528 of the California Code of Regulations, and strengthening the existing rules and procedures on informed consent.

First, AB 48 establishes a new right that residents receive all "information that is material to an individual's informed consent decision concerning whether to accept or refuse the administration of psychotherapeutic drugs." The bill specifically states that the information required under this rule should be pursuant to the material information listed in section 722528 of the California Code of Regulations, and adds the following to the list of material information:

a) possible nonpharmacologic approaches that could address the resident's needs;
b) whether the drug has a current boxed warning label along with a summary of, and information about how to find, the contraindications, warnings, and precautions required by the FDA;
c) whether a proposed drug is being prescribed for a purpose that has not been approved by the FDA;
d) possible interactions with other drugs the resident is receiving; and
e) how the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects.

A health care professional at the nursing home facility must sign a form attesting to the fact that the resident received this material information, and keep this record in the resident's file. AB 48 states that a violation of these provisions for the providing of material information shall be deemed to have caused the affected resident's harm.

AB 48 also adds to the code the right for a resident to be free from the use of psychotherapeutic drugs for the "purposes of resident discipline or convenience." It adds to the emergency exception for the use of a psychotherapeutic drug as a "chemical restraint" the requirements that the psychotherapeutic only be a drug that is required to treat the emergency condition, after being deemed the least intrusive treatment alternative, and that the drug only be used for a specified and limited period of time.

Lastly, AB 48 establishes a written informed consent procedure and requires that the California Department of Public Health create an informed consent form that must be signed by a resident before a nursing home can prescribe and administer a psychotherapeutic drug to a resident. The written consent must be in language the resident understands, and must be kept in the resident's medical file. It must be provided in an accessible format if the resident is hearing or vision impaired. Copies of this form must be given to the resident or their representative, and must be kept in the resident's medical file. AB 48 requires that every six months after such written informed consent is provided, the facility provide a written notice to the resident or their

representative of any recommended dosage adjustments and the resident's right to revoke consent and to receive gradual dose reductions and behavioral interventions in an effort to discontinue the psychotherapeutic drug.

To enforce these provisions requiring obtaining written informed consent, this bill requires the California Department of Public Health to inspect nursing facilities for compliance during periodic inspections and complaint investigations. The willful or repeated violation of the requirements created by AB 48 will be punishable as a misdemeanor.

8. How AB 48 addresses concerns with AB 1807 that was vetoed in 2022

AB 48 is very similar to AB 1809 that was passed by the Legislature in 2022 but vetoed by Governor Newsom. The Governor's veto message stated:

> This bill would establish new rights and procedures for obtaining informed consent from nursing home residents before administering treatments or procedures and provides residents with the right to refuse psychotherapeutic drugs used as a chemical restraint, except in an emergency. The bill would also require the California Department of Public Health (CDPH) to develop an informed consent form for long-term care residents that includes a model disclosure statement for providing material information on the use of psychotherapeutic medications and the resident's right to withdraw informed consent.
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> I support the author's goal of improving informed consent requirements and protecting long-term care residents from inappropriate uses of psychotherapeutic medications. However, this bill creates ambiguity as to whether long-standing informed consent requirements will continue to be required until a new standardized form is developed, which could put the health of long-term care residents in jeopardy. Furthermore, the State Health Facilities Citation Penalties Account is not an appropriate funding source for the development of this form because the funds in the account are by law reserved for the protection of health or property of residents of long-term health care facilities. I encourage the author to work with CDPH to resolve these concerns in the next legislative session.

To address the Governor's concerns regarding AB 1809's ambiguity regarding the informed consent requirements while the Department of Public Health develops the informed consent form, AB 48 makes clear that nursing facilities are not required to comply with the provisions of AB 48 until the informed consent form is available. It also sets a deadline for the department to have the informed consent form available at December 31, 2024. AB 48 also includes a provision stating that nothing in the bill negates existing informed consent requirements.

To address the Governor's other concern with AB 1809, that the fund designated for funding the development of the informed consent form was not an appropriate funding source, AB 48 does not specify a funding source for the development of the form by the Department of Public Health.

9. Arguments in support

According to the California Advocates for Nursing Home Reform, who sponsored this bill:

> There are many routes to reducing the misuse of psychotropic drugs in nursing homes: prescribers, pharmacists, frontline nursing staff, and regulators. Perhaps the best assurance against misuse, though, is to provide each resident and, if applicable, their representative, with robust information about the proposed drug's risks, benefits, and alternatives. An informed resident or their representative is best situated to decide whether a proposed drug is truly in their best interests: no prescriber, pharmacist, or nurse cares more about the well-being of the resident than the resident or their representative.
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> Informed consent is built on a rich tradition of centuries' old common law and constitutional precepts. Courts throughout the country have fiercely guarded patient autonomy and self-determination, finding that, despite the expertise of prescribers, patients have the ultimate say regarding the treatment they receive. Physicians must provide information that would be material to the patient, including the nature and purpose of the proposed treatment, risks and benefits, and alternative treatments (including doing nothing). The decision, however, is left to the patient.
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> Despite the deep foundation of informed consent laws and protections that are specific in nursing homes, the process of obtaining informed consent is often meaningless. In 2011, the Department of Public Health (DPH) conducted an Antipsychotic Drugs Collaborative to evaluate the use of antipsychotics in nursing homes.10 The results were stunning. DPH found 147 violations involving 41 different regulations in just 24 facilities, an average of 6.1 deficiencies per facility. …
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> AB 48 enhances the current nursing home informed consent requirements in two critical ways. First, it requires doctors to provide pertinent information, like Black Box warnings and notifications of off-label use. Black Box warnings are the FDA's sternest warning label, telling consumers when a prescribed drug will increase their risk of death. Nursing home residents never see Black Box warnings. Their drugs are received by nursing home staff who discard the packaging, leaving residents ignorant of the important message it conveys. Sharing Black Box information, off label use, and other important information about risks, benefits, and alternatives

with residents or their representatives assures that consent for antipsychotic drugs is truly informed.

Second, AB 48 requires the prescriber to use a written consent form, documenting that material information is delivered and consent is obtained. In addition, the bill requires nursing home staff to verify when a consent form is signed and make it part of the resident's medical record. This simple process for written informed consent is already routine at many nursing homes in California.

SUPPORT

California Advocates for Nursing Home Reform (CANHR) (Sponsor)
California Long-Term Care Ombudsman Association (CLTCOA)
National Association of Social Workers – California (NASW)
California Health Coalition Advocacy
Office of the State Long-Term Care Ombudsman
AARP California
A Voice for Choice Advocacy
Alzheimer's Los Angeles
Alzheimer's Orange County
Alzheimer's San Diego
California Alliance for Retired Americans (CARA)
California Commission on Aging
California Retired Teachers Association (CalRTA)
Consumer Attorneys of California
Educate. Advocate.
Elder Law & Advocacy
Essential Caregivers Coalition California
California Geriatric Circle
Gray Panthers of San Francisco
Justice in Aging
Office of Vice Mayor Kate Harrison, Berkeley City Council District 4
Long Term Care Services of Ventura County, Inc.
Oakland Privacy
Retired Public Employees Association (RPEA)
California Continuing Care Residents Association (CALCRA)

OPPOSITION

None known

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

AB 1809 (Aguiar-Curry, 2022) would have enacted the Nursing Facility Resident Informed Consent Protection Act of 2022 which establishes the rights of skilled nursing facility (SNF) and intermediate care facility (ICF) residents to receive information that is material to the individual's decision whether to accept or refuse a proposed treatment or procedure and provides residents with the right to be free from psychotherapeutic drugs used as a chemical restraint, except in the case of an emergency, as specified. This bill was vetoed by the Governor. *See* Comment 8 for a description of the Governor's veto.

SB 303 (Alquist, 2009) would have enacted the Nursing Facility Resident Informed Consent Protection Act of 2009, which establishes the right of a resident of a skilled nursing or intermediate care facility (nursing facility) to receive information material to the decision to accept or refuse any treatment or procedure, including the administration of psychotherapeutic drugs, and codifies existing regulations requiring attending physicians to obtain informed consent after providing specified material information.

PRIOR VOTES:

Senate Health Committee (Ayes 12, Noes 0)
Assembly Floor (Ayes 77, Noes 0)
Assembly Appropriations Committee (Ayes 15, Noes 0)
Assembly Judiciary Committee (Ayes 9, Noes 0)
Assembly Health Committee (Ayes 13, Noes 0)
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