AB-48 Nursing Facility Resident Informed Consent Protection Act of 2023. (2023-2024)

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Assembly Bill No. 48

CHAPTER 794

An act to amend Section 1599.1 of, and to add Section 1599.15 to, the Health and Safety Code, relating to nursing facilities.

[Approved by Governor October 13, 2023. Filed with Secretary of State October 13, 2023.]

LEGISLATIVE COUNSEL'S DIGEST

AB 48, Aguiar-Curry. Nursing Facility Resident Informed Consent Protection Act of 2023.

Existing law provides for the licensure and regulation of health facilities, including skilled nursing facilities and intermediate care facilities, by the State Department of Public Health. Existing law requires skilled nursing facilities and intermediate care facilities to have written policies regarding the rights of patients.

This bill would add to these rights the right of every resident to receive the information that is material to an individual's informed consent decision concerning whether to accept or refuse the administration of psychotherapeutic drugs, as specified. This bill would also add the right to be free from psychotherapeutic drugs used for the purpose of resident discipline or convenience, or from psychotherapeutic drugs used as a chemical restraint except in an emergency, as specified. Under the bill, all residents of skilled nursing facilities, intermediate care facilities, and hospice facilities would have the right to appeal an involuntary transfer or discharge through the appeal process, as specified, regardless of a resident's payment source or the Medi-Cal or Medicare certification status of the facility in which the resident resides.

The bill would make the prescriber responsible for disclosing the material information relating to psychotherapeutic drugs to the resident and obtaining their informed consent, as defined. The bill would require facility staff to verify that a resident's health record contains a signed, written consent form before initiating treatment with psychotherapeutic drugs, except as specified. The bill would require the facility, within 6 months after the consent form is signed, and every 6 months thereafter, to provide a written notice to the resident and their representative of any recommended dosage adjustments and the resident's right to revoke consent, as specified. The bill would permit the use of remote technology, including telehealth, to allow a prescriber to examine and obtain informed written consent.

The bill would declare the willful or repeated violation of these provisions to be punishable as a misdemeanor. By creating a new crime, the bill would impose a state-mandated local program.

The bill would require the State Department of Public Health, in consultation with interested stakeholders, to develop a standardized informed consent form. The bill would require the informed consent form to be available to skilled nursing facilities and intermediate care facilities by December 31, 2025, and would exempt the facilities from including the written consent form in the resident's health record until the informed consent form is available. Under the bill, the above-described provisions would be inapplicable to an individual under the care of the State Department of State Hospitals.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known, and may be cited, as the Nursing Facility Resident Informed Consent Protection Act of 2023.

SEC. 2. The Legislature finds and declares all of the following:

(a) The protection of residents in California's nursing facilities is of paramount importance to the citizens of California.

(b) In 2022, the Office of Inspector General for the United States Department of Health and Human Services found that approximately 80 percent of long-stay nursing home residents are receiving psychotherapeutic drugs.

(c) Nursing facility residents and residents' representatives must be well-informed in advance about the risks of proposed psychotherapeutic drugs and their consent must be obtained before drugs are used.

(d) It is, therefore, the intent of the Legislature to enact legislation that would do all of the following:

(1) 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) Specify that residents and their representatives must be informed in writing about the content of black box warnings for proposed drugs and whether a proposed drug is being prescribed for a purpose that has or has not been approved by the United States Food and Drug Administration.

(3) Establish a process for the development of a model informed consent form, with input from physicians, nursing homes, and resident advocates.

SEC. 3. Section 1599.1 of the Health and Safety Code is amended to read:

1599.1. Written policies regarding the rights of residents shall be established and shall be made available to the resident, to any guardian, next of kin, sponsoring agency or representative payee, and to the public. Those policies and procedures shall ensure that each resident admitted to the facility has the following rights and is notified of the following facility obligations, in addition to those specified by regulation:

(a) The facility shall employ an adequate number of qualified personnel to carry out all of the functions of the facility.

(b) Each resident shall show evidence of good personal hygiene and be given care to prevent bedsores, and measures shall be used to prevent and reduce incontinence for each resident.

(c) The facility shall provide food of the quality and quantity to meet the residents' needs in accordance with physicians' orders.

(d) The facility shall provide an activity program staffed and equipped to meet the needs and interests of each resident and to encourage self-care and resumption of normal activities. Residents shall be encouraged to participate in activities suited to their individual needs.

(e) The facility shall be clean, sanitary, and in good repair at all times.

(f) A nurses' call system shall be maintained in operating order in all nursing units and provide visible and audible signal communication between nursing personnel and residents. Extension cords to each resident's bed shall be readily accessible to residents at all times.

(g) (1) If a facility has a significant beneficial interest in an ancillary health service provider or if a facility knows that an ancillary health service provider has a significant beneficial interest in the facility, as provided by subdivision (a) of Section 1323, or if the facility has a significant beneficial interest in another facility, as provided by subdivision (c) of Section 1323, the facility shall disclose that interest in writing to the resident, or the resident's representative, and advise the resident, or the resident's representative, that the resident may choose to have another ancillary health service provider, or facility, as the case may be, provide any supplies or services ordered by a member of the medical staff of the facility.

(2) A facility is not required to make any disclosures required by this subdivision to a resident, or the resident's representative, if the resident is enrolled in an organization or entity that provides or arranges for the provision of health care services in exchange for a prepaid capitation payment or premium.

(h) (1) If a resident of a long-term health care facility has been hospitalized in an acute care hospital and asserts their rights to readmission pursuant to bed hold provisions, or readmission rights of either state or federal law, and the facility refuses to readmit them, the resident may appeal the facility's refusal.

(2) The refusal of the facility, as described in this subdivision, shall be treated as if it were an involuntary transfer under federal law, and the rights and procedures that apply to appeals of transfers and discharges of nursing facility residents shall apply to the resident's appeal under this subdivision.

(3) If the resident appeals pursuant to this subdivision, and the resident is eligible under the Medi-Cal program, the resident shall remain in the hospital and the hospital may be reimbursed at the administrative day rate, pending the final determination of the hearing officer, unless the resident agrees to placement in another facility.

(4) If the resident appeals pursuant to this subdivision, and the resident is not eligible under the Medi-Cal program, the resident shall remain in the hospital if other payment is available, pending the final determination of the hearing officer, unless the resident agrees to placement in another facility.

(5) If the resident is not eligible for participation in the Medi-Cal program and has no other source of payment, the hearing and final determination shall be made within 48 hours.

(i) (1) Sections 483.10, 483.12, 483.15, and 483.24 of Title 42 of the Code of Federal Regulations in effect on July 13, 2017, shall apply to each skilled nursing facility and intermediate care facility, regardless of a resident's payment source or the Medi-Cal or Medicare certification status of the skilled nursing facility or intermediate care facility in which the resident resides, except that a noncertified facility is not obligated to provide notice of Medicaid or Medicare benefits, covered services, or eligibility procedures.

(2) Sections 483.10, 483.12, 483.15, and 483.24 of Title 42 of the Code of Federal Regulations in effect on July 13, 2017, shall apply to each hospice facility, regardless of a resident's payment source or the Medi-Cal or Medicare certification status of the hospice facility in which the resident resides, except that a noncertified facility is not obligated to provide notice of Medicaid or Medicare benefits, covered services, or eligibility procedures and a hospice facility is not obligated to comply with the provisions of subdivision (f) of Section 483.15 of Title 42 of the Code of Federal Regulations.

(3) All residents of skilled nursing facilities, intermediate care facilities, and hospice facilities have the right to appeal an involuntary transfer or discharge through the appeal process provided under Section 483.204 of Title 42 of the Code of Federal Regulations, regardless of a resident's payment source or the Medi-Cal or Medicare certification status of the skilled nursing facility, intermediate care facility, or hospice facility in which the resident resides.

(j) In addition to other rights to provide or withhold informed consent to a proposed treatment or procedure, a resident shall have the right to receive the information that is material to an individual's informed consent decision concerning whether to accept or refuse the administration of psychotherapeutic drugs pursuant to Sections 72528 and 73524 of Title 22 of the California Code of Regulations. The disclosure of material information for administration of psychotherapeutic drugs shall also include the disclosures required by Section 1599.15.

(k) A resident shall have the right to be free from psychotherapeutic drugs used for the purpose of resident discipline or convenience. The resident shall have the right to be free from psychotherapeutic drugs used as a chemical restraint, except in an emergency as described in subdivision (e) of Section 72528 of, or subdivision (e) of Section 73524 of, Title 22 of the California Code of Regulations. If a chemical restraint is administered during that emergency, that drug shall be only a drug that is required to treat the unanticipated condition, after being deemed the least intrusive treatment alternative for the resident, and used only for a specified and limited period of time. As used in this section, "chemical restraint" means a drug used to control behavior and used in a manner not required to treat the resident's medical symptoms.

(l) "Resident" shall have the same meaning as provided in Section 1599.15.

SEC. 4. Section 1599.15 is added to the Health and Safety Code, to read:

1599.15. (a) As used in this section, the following definitions shall apply:

(1) "Informed consent" means the voluntary agreement of a resident or a resident's representative to accept a treatment or procedure after receiving information in accordance with subdivisions (b) to (e), inclusive, of this section, subdivision (j) of Section 1599.1, and in accordance with Section 1418.8, if applicable.

(2) “Psychotherapeutic drug” means a drug to control behavior or to treat thought disorder processes, excluding antidepressants.

(3) “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 valid advance 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) “Resident” means a person who is receiving care at a skilled nursing facility or an intermediate care facility, as those facilities are defined in Section 1250.

(b) (1) Prior to prescribing a psychotherapeutic drug for a resident, the prescriber shall personally examine and obtain the informed written consent of the resident or the resident’s representative.

(2) The prescriber shall communicate, and the written consent form shall 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. However, if written translation services are not timely available, the written consent form may be provided in English with oral interpretation in a language that the resident understands. If the resident is hearing impaired or vision impaired, the material information and written consent form shall be provided in an accessible format.

(3) The form shall be signed by the resident or the resident’s representative. The form shall also be signed by a health care professional who declares the resident or resident representative has been provided the material information. If the signature of the resident or resident’s representative cannot be obtained, a licensed nurse shall sign the form and verify that they confirmed informed consent with the resident or resident’s representative and state the name of the person with whom they verified informed consent and the date. Copies of the signed consent form shall be given to the resident and their representative.

(4) Within six months after the consent form is signed, and every six months thereafter during which the resident receives a psychotherapeutic drug, the facility shall provide a written notice to the resident and, if applicable, 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.

(5) For purposes of obtaining informed written consent pursuant to this subdivision, the use of remote technology, including, but not limited to, telehealth, to allow a prescriber to examine and obtain informed written consent, and for the prescriber, the resident or the resident’s representative to use electronic signatures, shall be permitted.

(c) In addition to the information required by subdivision (j) of Section 1599.1, the prescriber shall provide the following information material to an informed consent decision concerning the administration of a psychotherapeutic drug:

(1) Possible nonpharmacologic approaches that could address the resident’s needs.

(2) 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 United States Food and Drug Administration.

(3) Whether a proposed drug is being prescribed for a purpose that has or has not been approved by the United States Food and Drug Administration.

(4) Possible interactions with other drugs the resident is receiving.

(5) How the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects.

(d) Before initiating treatment with psychotherapeutic drugs, facility staff shall verify that the resident’s health record contains a written consent form with the signatures required under subdivision (b), except as specified in subdivision (j). For a prescription written prior to the admission and encompassing the admission of the resident, the facility staff shall verify that the resident or the resident’s representative gave informed consent and make a notation in the resident’s records.

(e) Residents’ rights policies and procedures established pursuant to this section and Section 1599.1 concerning informed consent shall 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.

(f) This section shall not be construed to require a facility to obtain informed consent each time a drug is administered unless material circumstances or risks change.

(g) A violation of subdivision (c) shall be presumed to have caused the affected residents harm, which may be rebutted, and shall be classified as a class “B,” “A,” or “AA” violation, according to the nature of the violation pursuant to the standards established in Section 1424, and cited accordingly by the State Department of Public Health.

(h) In addition to any other penalties set forth in this section, the willful or repeated violation of this section is punishable as a misdemeanor unless there is an emergency as described in subdivision (e) of Section 72528 of, or subdivision (e) of Section 73524 of, Title 22 of the California Code of Regulations.

(i) The State Department of Public Health shall, in consultation with interested stakeholders, develop a standardized informed consent form.

(j) Skilled nursing facilities and intermediate care facilities shall not be required to include the written consent form in the resident's health record until the informed consent form is available as developed by the department. The department shall have a final informed consent form available to skilled nursing facilities and intermediate care facilities by December 31, 2025. Nothing in this section negates existing informed consent requirements in law or regulations.

(k) This section shall not apply to an individual under the care of the State Department of State Hospitals.

(l) Notwithstanding any other law, the department may, without taking any regulatory actions pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement, interpret, or make specific this section by means of an All Facilities Letter (AFL) or similar instruction.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.