

AMENDED IN ASSEMBLY JULY 7, 2009

AMENDED IN SENATE APRIL 27, 2009

AMENDED IN SENATE APRIL 16, 2009

AMENDED IN SENATE APRIL 14, 2009

SENATE BILL

No. 303

**Introduced by Senator Alquist
(Coauthor: Senator Florez)**

February 25, 2009

An act to amend Sections 1418.9 and 1599.1 of, and to add Section 1599.15 to, the Health and Safety Code, relating to nursing facility residents.

LEGISLATIVE COUNSEL'S DIGEST

SB 303, as amended, Alquist. Nursing facility residents: informed consent.

Existing law provides that patients of skilled nursing facilities and intermediate care facilities have prescribed rights.

This bill would add to these rights the right of every resident to receive all information that is material to an individual's decision concerning whether to accept or refuse any proposed treatment or procedure. This bill would make the physician responsible for disclosing the material information to the resident and obtaining his or her informed consent.

This bill would require that informed consent, as defined, be obtained in accordance with the above requirements of the bill, with respect to a resident's decision to accept or reject the administration of a psychotherapeutic drug.

This bill would also require the State Department of Public Health to inspect for compliance with this requirement during prescribed inspections.

Under existing law, the Long-Term Care, Health, Safety, and Security Act of 1973, an attending physician and surgeon that seeks to prescribe, order, or increase an order for an antipsychotic medication for a resident of a skilled nursing facility is required to obtain the informed consent of that resident. A violation of this provision is a misdemeanor.

This bill would apply the definition of “informed consent” contained in the bill to this provision. Because this bill would change the definition of a crime, this bill would impose a state-mandated local program.

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.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. This act shall be known, and may be cited, as the
- 2 Nursing Facility Resident Informed Consent Protection Act of
- 3 2009.
- 4 SEC. 2. The Legislature finds and declares all of the following:
- 5 (a) The protection of residents in California’s nursing facilities
- 6 is of paramount importance to the citizens of California.
- 7 (b) Almost 60 percent of California nursing facility residents
- 8 are prescribed ~~psychoactive~~ *psychotherapeutic* drugs, many of
- 9 which have dangerous side effects.
- 10 (c) Nearly 20 percent of California nursing facility residents are
- 11 receiving powerful antipsychotic drugs that are not intended or
- 12 approved for the resident’s underlying medical condition.
- 13 *Antipsychotic drugs are a subclass of psychotherapeutic drugs.*
- 14 (d) The United States Food and Drug Administration (FDA)
- 15 has issued black box warnings for the antipsychotic drugs most
- 16 commonly provided to nursing facility residents. The warnings
- 17 state that these antipsychotic drugs greatly increase the risk of
- 18 death for seniors with dementia.

1 (e) Nursing facility residents and resident's representatives
2 rarely see the medication inserts that provide the black box
3 warnings and often do not receive sufficient information about the
4 side effects of medications.

5 (f) Nursing facility residents and resident's representatives must
6 be well-informed in advance about the risks of proposed
7 antipsychotic drugs and their consent must be obtained before
8 medications are used.

9 (g) California's existing regulations on informed consent for
10 nursing facility residents are rarely enforced.

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

13 (1) Codify provisions that establish a resident's right to informed
14 consent concerning the use of psychotherapeutic drugs.

15 (2) Specify that residents and their representatives must be
16 informed in writing about the content of black box warnings for
17 proposed drugs and whether the drug's proposed use has been
18 approved by the FDA.

19 (3) Require the State Department of Public Health to evaluate
20 nursing facility compliance with these provisions during periodic
21 state licensing inspections.

22 SEC. 3. Section 1418.9 of the Health and Safety Code is
23 amended to read:

24 1418.9. (a) If the attending physician and surgeon of a resident
25 in a skilled nursing facility or *intermediate care facility* prescribes,
26 orders, or increases an order for an antipsychotic medication for
27 the resident, the physician and surgeon shall do both of the
28 following:

29 (1) Obtain the informed consent, in accordance with the
30 requirements of subdivision (j) of Section 1599.1 and Section
31 1599.15, of the resident for purposes of prescribing, ordering, or
32 increasing an order for the medication.

33 (2) Seek the consent of the resident to notify the resident's
34 interested family member, as designated in the medical record. If
35 the resident consents to the notice, the physician and surgeon shall
36 make reasonable attempts, either personally or through a designee,
37 to notify the interested family member, as designated in the medical
38 record, within 48 hours of the prescription, order, or increase of
39 an order.

(b) Notification of an interested family member is not required under paragraph (2) of subdivision (a) if any of the following circumstances exist:

(1) There is no interested family member designated in the medical record.

(2) The resident has been diagnosed as terminally ill by his or her physician and surgeon and is receiving hospice services from a licensed, certified hospice agency in the facility.

(3) The resident has not consented to the notification.

(c) As used in this section, the following definitions shall apply:

(1) “Resident” means a patient of a skilled nursing facility who has the capacity to consent to make decisions concerning his or her health care, including medications.

(2) “Designee” means a person who has agreed with the physician and surgeon to provide the notice required by this section.

(3) “Antipsychotic medication” means a medication approved by the United States Food and Drug Administration for the treatment of psychosis.

(4) “Increase of an order” means an increase of the dosage of the medication above the dosage range stated in a prior consent from the resident.

(d) This section shall not be construed to require consent from an interested family member for an attending physician and surgeon of a resident to prescribe, order, or increase an order for antipsychotic medication.

SEC. 4. Section 1599.1 of the Health and Safety Code is amended to read:

1599.1. Written policies regarding the rights of patients shall be established and shall be made available to the patient, to any guardian, next of kin, sponsoring agency or representative payee, and to the public. Those policies and procedures shall ensure that each patient 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 patient 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 patient.

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

3 (d) The facility shall provide an activity program staffed and
4 equipped to meet the needs and interests of each patient and to
5 encourage self-care and resumption of normal activities. Patients
6 shall be encouraged to participate in activities suited to their
7 individual needs.

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

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

15 (g) (1) If a facility has a significant beneficial interest in an
16 ancillary health service provider or if a facility knows that an
17 ancillary health service provider has a significant beneficial interest
18 in the facility, as provided by subdivision (a) of Section 1323, or
19 if the facility has a significant beneficial interest in another facility,
20 as provided by subdivision (c) of Section 1323, the facility shall
21 disclose that interest in writing to the patient, or his or her
22 representative, and advise the patient, or his or her representative,
23 that the patient may choose to have another ancillary health service
24 provider, or facility, as the case may be, provide any supplies or
25 services ordered by a member of the medical staff of the facility.

26 (2) A facility is not required to make any disclosures required
27 by this subdivision to any patient, or his or her representative, if
28 the patient is enrolled in an organization or entity that provides or
29 arranges for the provision of health care services in exchange for
30 a prepaid capitation payment or premium.

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

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

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

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

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

15 (i) Effective July 1, 2007, Sections 483.10, 483.12, 483.13, and
16 483.15 of Title 42 of the Code of Federal Regulations in effect on
17 July 1, 2006, shall apply to each skilled nursing facility and
18 intermediate care facility, regardless of a resident's payment source
19 or the Medi-Cal or Medicare certification status of the skilled
20 nursing facility or intermediate care facility in which the resident
21 resides, except that a noncertified facility is not obligated to provide
22 notice of Medicaid or Medicare benefits, covered services, or
23 eligibility procedures.

24 (j) The resident shall have the right to receive all information
25 that is material to an individual's decision concerning whether to
26 accept or refuse any proposed treatment or procedure. The
27 disclosure of material information for administration of
28 psychotherapeutic drugs shall include the disclosures required by
29 Section 1599.15.

30 SEC. 5. Section 1599.15 is added to the Health and Safety
31 Code, to read:

32 1599.15. (a) As used in this section, the following definitions
33 shall apply:

34 (1) "Attending physician" means the physician chosen by the
35 resident or the resident's representative to be responsible for the
36 medical treatment of the resident in the facility.

37 (2) "Informed consent" means the voluntary agreement of a
38 patient or a resident's representative to accept a treatment or
39 procedure after receiving information in accordance with

subdivisions (b) to (f), inclusive, and subdivision (j) of Section 1599.1.

(3) “Psychotherapeutic drug” means a medication to control behavior or to treat thought disorder processes.

(b) It is the responsibility of the attending physician to determine what information a reasonable person in the resident’s condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician.

(c) The information material to a decision concerning the administration of a psychotherapeutic drug shall include, but not be limited to, the following:

(1) The reason for the treatment and the nature and seriousness of the resident’s illness.

(2) The nature of the procedure to be used in the proposed treatment, including the procedure’s probable frequency and duration.

(3) The probable degree and duration, whether temporary or permanent, of improvement or remission expected with or without the proposed treatment.

(4) The nature, degree, duration, and probability of the side effects and significant risks that are commonly known by the health professions. Information on risks associated with psychotherapeutic drugs shall include, but not be limited to, whether a proposed medication is being prescribed for a purpose or medical condition other than the purpose or medical condition for which the United States Food and Drug Administration (FDA) has specifically approved that medication. Information on risks of a proposed medication shall also include, in writing, any current boxed warning labels and accompanying detailed information regarding contraindications, warnings, and precautions required by the FDA.

(5) The reasonable alternative treatments and risks, and why the health professional is recommending a particular treatment.

(6) That the resident has the right to accept or refuse the proposed treatment, and, if he or she consents, the right to revoke his or her consent for any reason at any time.

(d) Before initiating the administration of psychotherapeutic drugs, facility staff shall verify that the resident’s health record

1 contains a notation by the attending or prescribing physician and
2 surgeon that the physician and surgeon has obtained the informed
3 consent of the resident to the proposed treatment or procedure.
4 Facility staff shall also verify with the resident or the resident's
5 representative that the resident has voluntarily agreed to accept
6 the proposed treatment or procedure after receiving information
7 from the attending physician and surgeon and shall document this
8 verification in the resident's health record. *If the resident or the*
9 *resident's representative indicates to facility staff that he or she*
10 *did not voluntarily agree to accept the proposed treatment or*
11 *procedure, or that he or she is now refusing treatment, the*
12 *treatment shall be withheld from the resident. If the resident or*
13 *the resident's representative has questions or concerns about the*
14 *risks or benefits of, or alternatives to, the treatment, the facility*
15 *staff shall promptly refer those questions or concerns to the*
16 *resident's attending or prescribing physician and surgeon. The*
17 facility shall also ensure that all decisions concerning the
18 withdrawal or withholding of life sustaining treatment are
19 documented in the resident's health record.

20 (e) Residents' rights policies and procedures established under
21 this section concerning consent, informed consent, and refusal of
22 treatments or procedures shall specify how the facility will verify
23 that the resident provided informed consent or refused treatment
24 or procedure pertaining to the administration of psychotherapeutic
25 drugs.

26 (f) This section shall not be construed to require obtaining
27 informed consent each time a treatment or procedure is
28 administered unless material circumstances or risks change.

29 (g) The State Department of Public Health shall inspect ~~nursing~~
30 ~~facilities~~ *skilled nursing facilities as defined in subdivision (c) of*
31 *Section 1250 and intermediate care facilities as defined in*
32 *subdivision (d) of Section 1250* for compliance with this section
33 during the periodic inspections required under Section 1422 and,
34 as appropriate, during complaint investigations required under
35 Section 1420. This inspection requirement shall not limit the
36 department's authority in other circumstances to cite for violations
37 of this section or to inspect for compliance with this section.

38 (h) A violation of the informed consent rights provided for in
39 this section may constitute a class "B," "A," or "AA" violation
40 pursuant to the standards established in Section 1424.

1 (i) Nothing in this section shall impair or otherwise alter other
2 nonconflicting statutory or regulatory requirements, including, but
3 not limited to, requirements contained in paragraphs (e) to (h),
4 inclusive, of Section 72528 of Title 22 of the California Code of
5 Regulations or otherwise related requirements for informed consent
6 for the administration of psychotherapeutic drugs.

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