SENATE BILL No. 303

Introduced by Senator Alquist

February 25, 2009

An act to amend Sections 1418.9 and 1599.1 of, to add Section 1599.15 to, and to repeal and add Section 1599.3 of, the Health and Safety Code, relating to nursing facility residents.

LEGISLATIVE COUNSEL'S DIGEST

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

Existing law provides that patients of skilled nursing facilities and intermediate care facilities shall 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, a physical restraint, or the prolonged use of a device that may lead to the inability of a resident to regain use of a normal bodily function.

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

Existing law prescribes the persons to whom the rights of a resident of a skilled nursing or intermediate care facility devolve if the resident is judicially determined to be incompetent, or who is found by his or her physician to be medically incapable of understanding his or her

rights or the nature and consequences of proposed treatment, or who exhibits a communication barrier.

This bill would repeal these provisions, and, instead, would provide that a resident's representative, as defined, shall have the rights of a resident of a skilled nursing or intermediate facility who lacks the capacity to understand his or her rights or the nature and consequences of proposed treatment. The resident's incapacity would be determined by a court in accordance with state law or by the resident's physician unless the physician's determination is disputed by the resident or the resident's representative.

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:

SECTION 1. This act shall be known, and may be cited, as the Nursing Facility Resident Informed Consent Protection Act of 2009.

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) Almost 60 percent of California nursing facility residents are prescribed psychoactive drugs, many of which have dangerous side effects.

(c) Nearly 20 percent of California nursing facility residents are receiving powerful antipsychotic drugs that are not intended or approved for the resident's underlying medical condition.

(d) The United States Food and Drug Administration (FDA) has issued black box warnings for the antipsychotic drugs most commonly provided to nursing facility residents. The warnings state that these antipsychotic drugs greatly increase the risk of death for seniors with dementia.

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

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

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

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

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

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

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

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

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

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

(2) Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record. If the resident consents to the notice, the physician and surgeon shall make reasonable attempts, either personally or through a designee,

to notify the interested family member, as designated in the medical record, within 48 hours of the prescription, order, or increase of 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.

(c) The facility shall provide food of the quality and quantity to meet the patients' 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 patient and to encourage self-care and resumption of normal activities. Patients 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 patients. Extension cords to each patient's bed shall be readily accessible to patients 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 patient, or his or her representative, and advise the patient, or his or her representative, that the patient 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 any patient, or his or her representative, if the patient 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 his or her rights to readmission pursuant to bed hold provisions, or readmission rights of either state or federal law, and the facility refuses to readmit him or her, 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) Effective July 1, 2007, Sections 483.10, 483.12, 483.13, and 483.15 of Title 42 of the Code of Federal Regulations in effect on July 1, 2006, 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.

(j) The resident shall have the right to receive all information that is material to an individual's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability of the resident to regain use of a normal bodily function shall include the disclosures required by Section 1599.15.

SEC. 5. 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) "Attending physician" means the physician chosen by the resident or the resident's representative to be responsible for the medical treatment of the resident in the facility.

(2) "Informed consent" means the voluntary agreement of a patient or a resident's representative to accept a treatment or 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.

(4) "Physical restraint" means any physical or mechanical device or material attached or adjacent to a resident's body that the resident cannot remove easily, which has the effect of restricting the resident's freedom of movement. Physical restraint does not include the use of the least restrictive immobilization reasonably necessary to administer necessary treatment of a therapeutic, noncontinuous nature, such as a single injection of antibiotics, and where the immobilization is removed upon the administration of that treatment. This exception shall not include immobilizations for continuously administered treatments such as intravenous therapy.

(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, physical restraint, or the prolonged use of a device that may lead to the inability of the resident to regain use of a normal bodily function, 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, physical restraints, or the prolonged use of a device that may lead to the inability of the resident to regain use of a normal bodily function, facility staff shall verify with the resident or the resident's representative that the resident has been fully informed about the proposed treatment or procedure and has consented. This verification shall be specifically documented in the resident's health record. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the resident's health record.

(e) Residents' rights policies and procedures established under this section concerning consent, informed consent, and refusal of treatments or procedures shall specify how the facility will verify that the resident provided informed consent or refused treatment or procedure pertaining to the administration of psychotherapeutic drugs, physical restraints, or the prolonged use of a device that may lead to the inability of the resident to regain the use of a normal bodily function.

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

(g) The State Department of Public Health shall inspect nursing facilities for compliance with this section during the periodic inspections required under Section 1422 and, as appropriate, during complaint investigations required under Section 1420. This inspection requirement shall not limit the department's authority in other circumstances to cite for violations of this section or to inspect for compliance with this section.

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

SEC. 6. Section 1599.3 of the Health and Safety Code is repealed.

~~1599.3. Any rights under this chapter of a patient judicially determined to be incompetent, or who is found by his physician to be medically incapable of understanding such information, or who exhibits a communication barrier, shall devolve to such patient's guardian, conservator, next of kin, sponsoring agency, or representative payer, except when the facility itself is the representative payer.~~

SEC. 7. Section 1599.3 is added to the Health and Safety Code, to read:

1599.3. (a) If a resident lacks the capacity to understand his or her rights or the nature and consequences of a proposed treatment, the resident's representative shall have the rights specified in this chapter to the extent the right may devolve to another, unless the representative's authority is otherwise limited. The resident's incapacity shall be determined by a court in accordance with state law or by the resident's physician unless the physician's determination is disputed by the resident or resident's representative.

(b) As used in this chapter, the term "resident's representative" means a conservator, as authorized by Parts 3 and 4 (commencing with Section 1800) of Division 4 of the Probate Code, a person designated as attorney in fact in the resident's valid durable power of attorney for health care, the resident's next of kin, other appropriate legally recognized health care decisionmaker designated consistent with statutory and case law, a person appointed by a court authorizing treatment pursuant to Part 7 (commencing with Section 3200) of Division 4 of the Probate

Code, or, if the resident is a minor, a person lawfully authorized to represent the minor.

SEC. 8. 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.

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