AMENDED IN ASSEMBLY AUGUST 24, 2012

AMENDED IN ASSEMBLY AUGUST 8, 2012

AMENDED IN ASSEMBLY AUGUST 7, 2012

AMENDED IN ASSEMBLY JUNE 14, 2012

AMENDED IN SENATE MAY 25, 2012

AMENDED IN SENATE APRIL 11, 2012

SENATE BILL No. 1318

Introduced by Senator Wolk
(Coauthor: Senator Anderson)

February 23, 2012

An act to *amend Section 1248.15 of, to* add Section 1228.5 to, and to repeal and add Section 1288.7 of, the Health and Safety Code, relating to infectious diseases.

LEGISLATIVE COUNSEL'S DIGEST

SB 1318, as amended, Wolk. Health facilities: influenza vaccinations.

Existing law imposes on the State Department of Public Health various duties and responsibilities regarding the regulation of clinics and health facilities, including general acute care hospitals, as defined.

Existing law requires a general acute care hospital to annually offer onsite influenza vaccinations, if available, to all hospital employees. Existing law requires a general acute care hospital to require its employees to be vaccinated, or if the employee elects not to be vaccinated, to declare in writing that he or she declined the vaccination. A violation of these provisions is punishable as a misdemeanor.

This bill would require ~~licensed~~ clinics, *as defined*, and health facilities to institute measures, including aerosol transmissible diseases training, designed to maximize influenza vaccination rates and to prevent onsite health care workers affiliated with the clinic or health facility and persons with privileges on the medical staff from contracting, and transmitting to patients, the influenza virus. *This bill would provide that a clinic includes a licensed clinic, a clinic conducted, operated, or maintained as an outpatient department of a hospital, or an outpatient setting, as defined.*

This bill would require each clinic and health facility to annually offer onsite influenza vaccinations to its employees and to require its onsite health care workers affiliated with the clinic or health facility, as defined, and persons with privileges on the medical staff, as defined, to be vaccinated. This bill would require each clinic and health facility to annually record its vaccination rate, as defined, for each year and to make those records available online or upon request. This bill would require ~~licensed~~ clinics and health facilities to maintain vaccination records of their employees and permit ~~licensed~~ clinics and health facilities to require documentation of vaccination or vaccination refusal from an onsite health care worker or person with privileges on the medical staff. By increasing the responsibilities of clinics and health facilities, and adding instances where a clinic or health facility could be subject to a misdemeanor, this bill would expand the definition of a crime and would impose a state-mandated local program.

This bill would also require each clinic and health facility to develop policies to implement these provisions and to ensure nonmedical staff, as defined, compliance with vaccination requirements. This bill would require the medical staff to develop separate policies to ensure compliance with vaccination requirements imposed by the clinic or health facility. ~~This bill would require clinics and health facilities to report their percentage of employees and medical staff and of medical staff who have been vaccinated for that year to the State Department of Public Health. This~~

This bill would require, commencing January 1, 2015, each clinic and health facility to have a 90% or higher vaccination rate. The bill would require the department, by July 1, 2015, to develop a model mandatory vaccination policy, as specified, and for each year a clinic or health facility does not achieve the 90% or higher vaccination rate, would require the clinic or health facility to adopt the model mandatory vaccination policy for the following ~~flu~~ *influenza* season.

Existing law establishes the Medical Board of California which approves accrediting agencies of outpatient settings. Existing law permits outpatient settings to apply to an accreditation agency for a certificate of accreditation. Existing law requires every outpatient setting which is accredited to be inspected by the accreditation agency.

This bill would require an accrediting agency to ensure that an outpatient setting to which it has issued a certificate is in compliance with these provisions.

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. The Legislature declares that influenza can be a serious disease that can lead to hospitalization and even death, and that increased access to vaccinations is a critical component in the promotion of health and wellness. Because of their contact with patients, many health care workers are at risk for exposure to, and possible transmission of, vaccine-preventable diseases. By getting vaccinated, health care workers can protect themselves, their families, and patients from contracting the ~~flu~~ *influenza virus*. It is the intent of the Legislature in enacting this statute to protect the health, safety, and welfare of health care workers and patients who enter a clinic or health care facility. It is also the intent of the Legislature that health care facilities and clinics institute measures designed to maximize influenza vaccination rates and increase vaccination among health care workers. It is also the intent of the Legislature that the State Department of Public Health develop a model mandatory vaccination policy through a stakeholder process to achieve a 90-percent influenza vaccination compliance rate requirement for health care workers.

SEC. 2. Section 1228.5 is added to the Health and Safety Code, to read:

1228.5. (a) A ~~licensed~~ clinic shall institute measures designed to maximize influenza vaccination rates and to prevent persons

with privileges on the medical staff and onsite health care workers affiliated with the clinic from contracting, and transmitting to patients, the influenza virus. These measures shall include, but not be limited to, aerosol transmissible diseases training as described in subdivision (i) of Section 5199 of Title 8 of the California Code of Regulations, as in effect on January 1, 2013.

(b) A ~~licensed~~ clinic shall annually offer its employees onsite influenza vaccinations, if available, at no cost to the employee.

(c) A ~~licensed~~ clinic shall require all onsite health care workers affiliated with the clinic and persons with privileges on the medical staff to either annually receive an influenza vaccination or, as an alternative to the annual influenza vaccination if an onsite health care worker affiliated with the clinic or person with privileges on the medical staff elects not to be vaccinated, he or she shall agree, in writing, to adhere to the most effective measures determined by the clinic in preventing health care workers from contracting and transmitting the influenza virus.

(d) (1) A clinic shall annually record its ~~average~~ vaccination ~~compliance~~ rate, as defined in paragraph (4) of subdivision (i), for that year, and make those records available online or upon request of a government agency, organization, or individual.

(2) The records described in paragraph (1) shall be maintained and made available during any inspection made by the department *or an accrediting agency*.

(e) (1) Commencing January 1, 2015, a clinic shall have a 90-percent or higher vaccination rate. For each year that a clinic does not achieve the 90-percent or higher vaccination rate, the clinic shall adopt for the following ~~flu~~ *influenza* season, as defined by the State *Public* Health Officer, ~~local health officer, or both,~~ the model mandatory vaccination policy described in paragraph (2), to achieve the 90-percent or higher goal. The department *or an accrediting agency* may waive the 90-percent vaccination rate requirement for a clinic that is in substantial compliance.

(2) The department, *in consultation with the California Conference of Local Health Officers,* shall develop a model mandatory vaccination policy, *which has been determined to achieve the 90-percent or higher goal,* through a stakeholder process to be issued through an all facilities letter no later than July 1, 2015.

(3) The department or an accrediting agency may waive the 90-percent vaccination rate requirement for a clinic during any particular year if the clinic is able to show that it is reasonably unable to access the appropriate amount of influenza vaccines necessary to achieve the 90-percent goal for that year.

(f) (1) In meeting the requirements of subdivisions (c), (d), and (e), the clinic shall maintain influenza vaccination records of employees and may maintain influenza vaccination records of the other onsite health care workers who are affiliated with, but are not employees of, the clinic and of persons with privileges on the medical staff. If the clinic does not have records of an onsite health care worker or person with privileges on the medical staff being vaccinated onsite, the clinic may require the worker or medical staff person to either provide documentation of vaccination or documentation that he or she refused the vaccination.

(2) The clinic may include language in its business contracts to require a contract worker to maintain records of the verification of offsite vaccination or documentation that he or she refused the vaccination, which shall be available to the clinic upon request. Nothing in this section shall be construed to require a clinic to maintain separate vaccination records or to provide vaccinations at no cost to a contract worker who is not an employee of the clinic.

(g) Each ~~licensed~~ clinic shall develop policies to implement this section and to ensure its onsite health care workers affiliated with the clinic are in compliance with the vaccination requirements imposed by this section. The medical staff shall also develop policies to ensure that persons who have privileges on the medical staff are in compliance with the vaccination requirements of this section that have been implemented by the clinic.

(h) Subdivisions (f) and (g) shall not be applicable to a dialysis clinic which maintains an influenza immunization log for its patients, health care workers, and medical staff pursuant to an infection control program in compliance with the Medicare "Conditions for Coverage for End-State Renal Disease Facilities," conditions that are promulgated by the *federal* Centers for Medicare and Medicaid Services, if the immunization log *addresses influenza vaccination and* is available for review during routine department inspections or during an inspection in response to a complaint.

(i) For purposes of this section, the following definitions shall apply:

(1) "Employee" means an individual who works for the clinic, is listed on the clinic's payroll records, and is under the clinic's direction and control.

(2) "Medical staff" means professional medical personnel who are approved and given privileges to provide health care to patients while onsite in a clinic and who are responsible for the adequacy and quality of care rendered to patients. Medical staff includes, but is not limited to, physicians and surgeons, and, if dental or podiatric services are provided, dentists or podiatrists.

(3) "Onsite health care worker affiliated with the clinic" means a person who is either a volunteer or is employed by, paid by, or receives credit or any other form of compensation from the clinic, who performs some or all of his or her duties in a patient care area of the facility. The patient care area of the facility shall be determined by the clinic and is where onsite health care workers and medical staff are within close proximity to patients receiving care. An onsite health care worker affiliated with the clinic includes, but is not limited to, employees, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff, and registry staff who perform direct patient care duties but are not employed by the clinic.

(4) "Vaccination rate" means the percentage of a clinic's onsite health care workers who are employees and persons with privileges on the medical staff who receive influenza vaccination during a specific year or influenza season.

(j) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by sending letters or similar instruction to all applicable facilities without taking regulatory action.

(k) This section does not ~~to~~ prevent a clinic or local jurisdiction from instituting additional measures or policies to maximize influenza vaccination rates and to prevent health care workers affiliated with the clinic from contracting and transmitting the influenza virus.

(*l*) This section does not require the department to perform any additional ~~duties to ensure compliance that are separate from its existing~~ *surveillance for the purpose of ensuring compliance with*

this section that is above and beyond its routine licensing survey ~~activity~~ *schedule* or other statutory requirements.

(m) Clinic, for purposes of this section, includes a clinic licensed pursuant to this chapter, a clinic that is conducted, operated, or maintained as an outpatient department of a hospital, as defined in Section 1250, and an outpatient setting, as defined in Section 1248.

(n) Accrediting agencies approved by the Medical Board of California shall be solely responsible for ensuring that outpatient settings, as defined in Section 1248, are in compliance with this section.

~~(m)~~

(o) Implementation of this section is exempt from the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

SEC. 3. Section 1248.15 of the Health and Safety Code is amended to read:

1248.15. (a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.

(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.

(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:

(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.

(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having

admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.

(D) In addition to the requirements imposed in subparagraph (C), the outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:

(i) Notify the individual designated by the patient to be notified in case of an emergency.

(ii) Ensure that the mode of transfer is consistent with the patient's medical condition.

(iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.

(iv) Continue to provide appropriate care to the patient until the transfer is effectuated.

(E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.

(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under

Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.

(4) Outpatient settings shall have a system for maintaining clinical records.

(5) Outpatient settings shall have a system for patient care and monitoring procedures.

(6) (A) Outpatient settings shall have a system for quality assessment and improvement.

(B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.

(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.

(7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.

(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.

(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.

(10) Outpatient settings shall have a written discharge criteria.

(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.

(d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.

(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

(f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.

(g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.

(h) An outpatient setting shall be subject to the reporting requirements in Section 1279.1 and the penalties for failure to report specified in Section 1280.4.

(i) An accrediting agency shall ensure that an outpatient setting to which it has issued an accreditation certificate is in compliance with Section 1228.5.

~~SEC. 3.~~

SEC. 4. Section 1288.7 of the Health and Safety Code is repealed.

~~SEC. 4.~~

SEC. 5. Section 1288.7 is added to the Health and Safety Code, to read:

1288.7. (a) A licensed health facility shall institute measures designed to maximize influenza vaccination rates and to prevent persons with privileges on the medical staff and onsite health care workers affiliated with the health facility from contracting, and transmitting to patients, the influenza virus. These measures shall include, but not be limited to, aerosol transmissible diseases training as described in subdivision (i) of Section 5199 of Title 8 of the California Code of Regulations, as in effect on January 1, 2013.

(b) A licensed health facility shall annually offer its employees onsite influenza vaccinations, if available, at no cost to the employee.

(c) A licensed health facility shall require all onsite health care workers affiliated with the health facility and persons with privileges on the medical staff to either annually receive an influenza vaccination or, as an alternative to the annual influenza vaccination if the onsite health care worker affiliated with the health facility or person with privileges on the medical staff elects not to be vaccinated, he or she shall agree, in writing, to adhere to the most effective measures determined by the health facility in preventing health care workers from contracting and transmitting the influenza virus.

(d) (1) A health facility shall annually record its vaccination rate, as defined in paragraph (4) of subdivision (i), for that year, and make those records available online or upon request of a government agency, organization, or individual.

(2) The records described in paragraph (1) shall be maintained and made available during any inspection made by the department.

(e) (1) Commencing January 1, 2015, a health facility shall have a 90-percent or higher vaccination rate. For each year that a health facility does not achieve the 90-percent or higher vaccination rate, the health facility shall adopt for the following ~~flu~~ *influenza* season, as defined by the State *Public* Health Officer, ~~local health officer, or both,~~ the model mandatory vaccination policy described

in paragraph (2), to achieve the 90-percent or higher goal. The department may waive the 90-percent vaccination rate requirement for a health facility that is in substantial compliance.

(2) The department, *in consultation with the California Conference of Local Health Officers,* shall develop a model mandatory vaccination policy, *which has been determined to achieve the 90-percent or higher goal,* through a stakeholder process to be issued through an all facilities letter no later than July 1, 2015.

(3) The department may waive the 90-percent vaccination rate requirement for a health facility during any particular year if the health facility is able to show that it is reasonably unable to access the appropriate amount of influenza vaccines necessary to achieve the 90-percent goal for that year.

(f) (1) In meeting the requirements of subdivisions (c), (d), and (e), the health facility shall maintain influenza vaccination records of employees and may maintain influenza vaccination records of the other onsite health care workers who are affiliated with, but are not employees of, the health facilities and of persons with privileges on the medical staff. If the health facility does not have records of an onsite health care worker or person with privileges on the medical staff being vaccinated, the health facility may require the worker or medical staff person to either provide documentation of vaccination or documentation that he or she refused the vaccination.

(2) The health facility may include language in its business contracts to require a contract worker to maintain records of the verification of offsite vaccination or documentation that he or she refused the vaccination, which shall be available to the health facility upon request. Nothing in this section shall be construed to require a health facility to maintain separate vaccination records or to provide vaccinations at no cost to a contract worker who is not an employee of the health facility.

(g) Each licensed health facility shall develop policies to implement this section and to ensure its onsite health care workers affiliated with the health facility are in compliance with the vaccination requirements imposed by this section. The medical staff shall develop policies to ensure that persons who have privileges on the medical staff are in compliance with the

vaccination requirements of this section that have been implemented by the health facility.

(h) In addition to other requirements of this section, general acute care hospitals shall take all of the following actions:

(1) Institute respiratory hygiene and cough etiquette protocols, develop and implement procedures for the isolation of patients with influenza, and adopt a seasonal influenza plan.

(2) Revise an existing or develop a new disaster plan that includes a pandemic influenza component. The plan shall also document any actual or recommended collaboration with local, regional, and state public health agencies or officials in the event of an influenza pandemic.

(i) For purposes of this section, the following definitions shall apply:

(1) "Employee" means an individual who works for the health facility, is listed on the health facility's payroll records, and is under the health facility's direction and control.

(2) "Medical staff" means professional medical personnel who are approved and given privileges to provide health care to patients in a health facility and who are responsible for the adequacy and quality of care rendered to patients. Medical staff includes, but is not limited to, physicians and surgeons, and, if dental or podiatric services are provided, dentists or podiatrists.

(3) "Onsite health care worker affiliated with the health facility" means a person who is either a volunteer or is employed by, paid by, or receives credit or any other form of compensation from the health facility, who performs some or all of his or her duties in a patient care area of the facility. The patient care area of the facility shall be determined by the health facility and is where onsite health care workers and medical staff are within close proximity to patients receiving care. An onsite health care worker affiliated with the health facility includes, but is not limited to, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff, and registry staff performing direct patient care duties but are not employed by the health facility.

(4) "Vaccination rate" means the percentage of a health facility's onsite health care workers who are employees and persons with

privileges on the medical staff who receive an influenza vaccination during a specific year or influenza season.

(j) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by sending letters or similar instruction to all applicable facilities without taking regulatory action.

(k) This section does not apply to correctional treatment centers as defined in subdivision (j) of Section 1250.

(*l*) This section does not prevent a health facility or local jurisdiction from instituting additional measures or policies to maximize influenza vaccination rates and to prevent health care workers affiliated with the health facility from contracting and transmitting the influenza virus.

(m) This section does not require the department to perform any additional ~~duties to ensure compliance that are separate from its existing~~ *surveillance for the purposes of ensuring compliance with this section that is above and beyond its routine* licensing survey ~~activity~~ *schedule* or other statutory requirements.

(n) Implementation of this section is exempt from the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

~~SEC. 5.~~

SEC. 6. 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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