AMENDED IN SENATE APRIL 21, 2014

SENATE BILL No. 966

Introduced by Senator Lieu

February 10, 2014

~~An act to amend Section 14124.24 of the Welfare and Institutions Code, relating to Medi-Cal.~~ *An act to add Section 2216.5 to the Business and Professions Code, and to amend Sections 1204, 1248.15, 1248.3, and 1248.35 of the Health and Safety Code, relating to outpatient settings.*

LEGISLATIVE COUNSEL'S DIGEST

SB 966, as amended, Lieu. ~~Drug Medi-Cal.~~ *Outpatient settings: surgical clinics.*

Existing law provides for the licensure and regulation of clinics by the State Department of Public Health. A violation of those provisions is a misdemeanor. Existing law provides that certain types of specialty clinics, including surgical clinics, as defined, are eligible for licensure.

This bill would clarify that surgical clinics are eligible for licensure by the department regardless of physician or dentist ownership.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law provides that it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with specified provisions. Existing law prohibits an association, corporation, firm, partnership, or person from operating, managing, conducting, or maintaining an outpatient setting in the state unless the setting is one of the specified settings, which includes, among others, a surgical clinic licensed by the State Department of Public Health or an outpatient setting accredited by an accreditation agency

approved by the Division of Licensing of the Medical Board of California.

Existing law provides that an outpatient setting that is accredited shall be inspected by the accreditation agency and may be inspected by the Medical Board of California. Existing law requires that the inspections be conducted no less often than once every 3 years by the accreditation agency and as often as necessary by the Medical Board of California to ensure quality of care provided. Existing law requires that certificates for accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than 3 years.

This bill would require that all subsequent inspections after the initial inspection for accreditation be unannounced. This bill would require an outpatient setting accredited by the division to pay certain fees and to comply with certain data submission requirements. The bill would also instead require that initial certificates of accreditation by an accreditation agency be valid for not more than 2 years and that renewal certificates be valid for not more than 3 years.

~~Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law establishes the Drug Medi-Cal Treatment Program (Drug Medi-Cal) under which the department is authorized to enter into contracts with counties for the provision of various drug treatment services to Medi-Cal recipients, or is required to directly arrange for the provision of these services if a county elects not to do so. Existing law defines Drug Medi-Cal reimbursable services for purposes of these provisions.~~

~~This bill would make technical, nonsubstantive changes to that definition.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

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

SECTION 1. Section 2216.5 is added to the Business and Professions Code, to read:

2216.5. An outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code is subject to the requirements

of Section 1216, subdivision (f) of Section 127280, and Section 128737 of the Health and Safety Code.

SEC. 2. Section 1204 of the Health and Safety Code is amended to read:

1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics and specialty clinics.

(a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:

(A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.

(B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

(2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose

services are reimbursed by third-party payers, or from entering into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.

(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:

(1) *(A)* A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or ~~establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.~~ *establishment.*

(B) Physicians or dentists may, at their option, apply for licensure. Surgical clinics shall be eligible for licensure by the department regardless of physician or dentist ownership.

(2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.

(3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

(4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

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~~ *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.

SEC. 4. Section 1248.3 of the Health and Safety Code is amended to read:

1248.3. (a) ~~Certificates~~ *Initial certificates* of accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than *two years and renewal certificates shall be valid for not more than* three years.

(b) The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership, including, but not limited to, a merger, change in majority interest, consolidation, name change, change in scope of services, additional services, or change in locations.

(c) Except for disclosures to the division or to the Division of Medical Quality under this chapter, an accreditation agency shall not disclose information obtained in the performance of accreditation activities under this chapter that individually identifies patients, individual medical practitioners, or outpatient settings. Neither the proceedings nor the records of an accreditation agency or the proceedings and records of an outpatient setting related to performance of quality assurance or accreditation activities under this chapter shall be subject to discovery, nor shall the records or proceedings be admissible in a court of law. The prohibition relating to discovery and admissibility of records and proceedings does not apply to any outpatient setting requesting accreditation in the event that denial or revocation of that outpatient setting's accreditation is being contested. Nothing in this section shall prohibit the accreditation agency from making discretionary

disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting.

SEC. 5. Section 1248.35 of the Health and Safety Code is amended to read:

1248.35. (a) Every outpatient setting ~~which~~ *that* is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided. *After the initial inspection for accreditation, all subsequent inspections shall be unannounced.*

(3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

(3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.

(4) Suspend or revoke the outpatient setting's certification of accreditation.

(d) (1) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board and to the California State Board of Pharmacy if an outpatient setting is licensed pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code. The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

(2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.

(e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation. If an outpatient setting has been issued a license by the California State Board of Pharmacy pursuant to Article 14

(commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code, the accreditation agency shall also send this report to the California State Board of Pharmacy within 24 hours.

(f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

(g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed, shall be public records open to public inspection.

(h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.

(i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:

(1) Notify the board of the action.

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

(3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.

(j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.

~~SECTION 1. Section 14124.24 of the Welfare and Institutions Code is amended to read:~~

~~14124.24. (a) For purposes of this section, "Drug Medi-Cal reimbursable services" means the substance use disorder services described in the California State Medicaid Plan and includes, but is not limited to, all of the following services, administered by the department, and to the extent consistent with state and federal law:~~

~~(1) Narcotic treatment program services, as set forth in Section 14021.51.~~

~~(2) Day care rehabilitative services.~~

~~(3) Perinatal residential services for pregnant women and women in the postpartum period.~~

~~(4) Naltrexone services.~~

~~(5) Outpatient drug-free services.~~

~~(6) Other services upon approval of a federal Medicaid state plan amendment or waiver authorizing federal financial participation.~~

~~(b) (1) While seeking federal approval for any federal Medicaid state plan amendment or waiver associated with Drug Medi-Cal services, the department shall consult with the counties and stakeholders in the development of the state plan amendment or waiver.~~

~~(2) Upon federal approval of a federal Medicaid state plan amendment authorizing federal financial participation in the following services, and subject to appropriation of funds, "Drug Medi-Cal reimbursable services" shall also include the following services, administered by the department, and to the extent consistent with state and federal law:~~

~~(A) Notwithstanding subdivision (a) of Section 14132.90, day care habilitative services, which, for purposes of this paragraph, are outpatient counseling and rehabilitation services provided to persons with alcohol or other drug abuse diagnoses.~~

~~(B) Case management services, including supportive services to assist persons with alcohol or other drug abuse diagnoses in gaining access to medical, social, educational, and other needed services.~~

~~(C) Aftercare services.~~

~~(c) (1) The nonfederal share for Drug Medi-Cal services shall be funded through a county's Behavioral Health Subaccount of the Support Services Account of the Local Revenue Fund 2011, and any other available county funds eligible under federal law for federal Medicaid reimbursement. The funds contained in each county's Behavioral Health Subaccount of the Support Services Account of the Local Revenue Fund 2011 shall be considered state funds distributed by the principal state agency for the purposes of receipt of the federal block grant funds for prevention and treatment of substance abuse found at Subchapter XVII of Chapter 6A of Title 42 of the United States Code. Pursuant to applicable federal Medicaid law and regulations including Section 433.51 of Title 42 of the Code of Federal Regulations, counties may claim allowable Medicaid federal financial participation for Drug Medi-Cal services based on the counties certifying their actual total funds expenditures for eligible Drug Medi-Cal services to the department.~~

~~(2) (A) If the director determines that a county's provision of Drug Medi-Cal treatment services are disallowed by the federal government or by state or federal audit or review, the impacted county shall be responsible for repayment of all disallowed federal funds. In addition to any other recovery methods available, including, but not limited to, offset of Medicaid federal financial participation funds owed to the impacted county, the director may offset these amounts in accordance with Section 12419.5 of the Government Code.~~

~~(B) A county subject to an action by the director pursuant to subparagraph (A) may challenge that action by requesting a hearing in writing no later than 30 days from receipt of notice of the department's action. The proceeding shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the director has all the powers granted therein. Upon a county's timely request for hearing, the county's obligation to make payment as determined by the director shall be stayed pending the county's~~

~~exhaustion of administrative remedies provided herein but no longer than will ensure the department's compliance with Section 1903(d)(2)(C) of the federal Social Security Act (42 U.S.C. Sec. 1396b).~~

~~(d) Drug Medi-Cal services are only reimbursable to Drug Medi-Cal providers with an approved Drug Medi-Cal contract.~~

~~(e) Counties shall negotiate contracts only with providers certified to provide Drug Medi-Cal services.~~

~~(f) The department shall develop methods to ensure timely payment of Drug Medi-Cal claims.~~

~~(g) (1) A county or a contracted provider, except for a provider to whom subdivision (h) applies, shall submit accurate and complete cost reports for the previous fiscal year by November 1, following the end of the fiscal year. The department may settle Drug Medi-Cal reimbursable services, based on the cost report as the final amendment to the approved county Drug Medi-Cal contract.~~

~~(2) Amounts paid for services provided to Drug Medi-Cal beneficiaries shall be audited by the department in the manner and form described in Section 14170.~~

~~(3) Administrative appeals to review grievances or complaints arising from the findings of an audit or examination made pursuant to this section shall be subject to Section 14171.~~

~~(h) Certified narcotic treatment program providers that are exclusively billing the state or the county for services rendered to persons subject to Section 1210.1 or 3063.1 of the Penal Code or Section 14021.52 of this code shall submit accurate and complete performance reports for the previous state fiscal year by November 1 following the end of that fiscal year. A provider to which this subdivision applies shall estimate its budgets using the uniform state daily reimbursement rate. The format and content of the performance reports shall be mutually agreed to by the department, the County Alcohol and Drug Program Administrators' Association of California, and representatives of the treatment providers.~~

~~(i) Contracts entered into pursuant to this section shall be exempt from the requirements of Chapter 1 (commencing with Section 10100) and Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.~~

~~(j) Annually, the department shall publish procedures for contracting for Drug Medi-Cal services with certified providers~~

~~and for claiming payments, including procedures and specifications for electronic data submission for services rendered.~~

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