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AB-941 Clinics: licensure and regulation: exemption. (2015-2016)

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Assembly Bill No. 941

CHAPTER 502

An act to amend Section 1206 of the Health and Safety Code, relating to clinics.

[Approved by Governor October 05, 2015. Filed with Secretary of State October 05, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 941, Wood. Clinics: licensure and regulation: exemption.

Existing law provides for the regulation and licensure of clinics, as defined, by the State Department of Public Health. Under existing law, specified types of clinics are exempted from these licensing provisions, including a clinic that is conducted, maintained, or operated by a federally recognized Indian tribe and is located on land recognized as tribal land by the federal government.

This bill would expand that exemption to also include a clinic conducted, maintained, or operated by a federally recognized Indian tribe under a contract with the United States pursuant to federal law, without regard to the location of the clinic, except that if the clinic chooses to apply to the department for a state facility license, then the department would retain authority to regulate that clinic as a primary care clinic.

This bill would incorporate additional changes to Section 1206 of the Health and Safety Code proposed by AB 1130 that would become operative if this bill and AB 1130 are chaptered and this bill is chaptered last.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

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

SECTION 1. Section 1206 of the Health and Safety Code is amended to read:

1206. This chapter does not apply to the following:

(a) Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) of subdivision (b) of Section 1204, any place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, regardless of the name used publicly to identify the place or establishment.

(b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department

from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

(c) (1) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

(2) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, under a contract with the United States pursuant to the Indian Self-Determination and Education Assistance Act (Public Law 93-638), regardless of the location of the clinic, except that if the clinic chooses to apply to the State Department of Public Health for a state facility license, then the State Department of Public Health will retain authority to regulate that clinic as a primary care clinic as defined by subdivision (a) of Section 1204.

(d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.

(e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).

(f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art.

(h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 20 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.

(i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).

(j) Student health centers operated by public institutions of higher education.

(k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

(l) A clinic operated by 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, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.

(m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.

(n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.

(o) A community mental health center, as defined in Section 5601.5 of the Welfare and Institutions Code.

(p) (1) A clinic operated by 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, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:

(A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.

(B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.

(C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

(D) Received grants and contracts from the National Institutes of Health.

(E) Held and licensed patents on medical technology.

(F) Received charitable contributions and bequests totaling at least five million dollars (\$5,000,000).

(G) Provides health care services to patients only:

(i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.

(ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.

(H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.

(I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

(2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.

SEC. 1.5. Section 1206 of the Health and Safety Code is amended to read:

1206. This chapter does not apply to the following:

(a) Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) of subdivision (b) of Section 1204, any place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, regardless of the name used publicly to identify the place or establishment.

(b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

(c) (1) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

(2) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, under a contract with the United States pursuant to the Indian Self-Determination and Education Assistance Act (Public Law 93-638), regardless of the location of the clinic, except that if the clinic chooses to apply to the State Department of Public Health for a state facility license, then the State Department of Public Health will retain authority to regulate that clinic as a primary care clinic as defined by subdivision (a) of Section 1204.

(d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.

(e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).

(f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art.

(h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 30 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.

(i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).

(j) Student health centers operated by public institutions of higher education.

(k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

(l) A clinic operated by 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, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.

(m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.

(n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.

(o) A community mental health center, as defined in Section 5667 of the Welfare and Institutions Code.

(p) (1) A clinic operated by 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, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:

(A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.

(B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.

(C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

(D) Received grants and contracts from the National Institutes of Health.

(E) Held and licensed patents on medical technology.

(F) Received charitable contributions and bequests totaling at least five million dollars (\$5,000,000).

(G) Provides health care services to patients only:

(i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.

(ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.

(H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.

(I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

(2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.

SEC. 2. Section 1.5 of this bill incorporates amendments to Section 1206 of the Health and Safety Code proposed by both this bill and Assembly Bill 1130. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2016, (2) each bill amends Section 1206 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 1130, in which case Section 1 of this bill shall not become operative.