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**AB-395 Substance use treatment providers.** (2017-2018)

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**Assembly Bill No. 395**

**CHAPTER 223**

An act to amend Sections 11220, 11839.1, 11839.2, 11839.3, 11839.5, and 11839.6 of the Health and Safety Code, and to amend Section 14021.6 of the Welfare and Institutions Code, relating to substance use treatment providers.

[ Approved by Governor September 11, 2017. Filed with Secretary of State September 11, 2017. ]

**LEGISLATIVE COUNSEL'S DIGEST**

AB 395, Bocanegra. Substance use treatment providers.

Existing law requires the State Department of Health Care Services to license narcotic treatment programs to use narcotic replacement therapy in the treatment of addicted persons and makes legislative findings in support of coordinated narcotic treatment programs in this regard. Existing law specifies the controlled substances a licensed narcotic treatment program may use for narcotic replacement therapy by licensed narcotic treatment programs, including federally approved, controlled substances used for narcotic treatment. Existing law authorizes the department to approve an office-based narcotic treatment program in a remote site, if certain conditions are met, that include, among others, a physician at a remote site may treat up to a maximum number of 20 patients, who are provided with a specific pharmacological treatment.

This bill would add the use of medication-assisted treatment as an authorized service by narcotic treatment programs licensed by the department, and would, in that regard, make legislative findings and declarations that it is in the best interest of the health and welfare of the people of this state to also coordinate medication-assisted treatments for substance use disorders. The bill would modify the specific controlled substances authorized for use by licensed narcotic treatment programs for narcotic replacement therapy and medication-assisted treatment to instead allow medication approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment for substance use disorders, and refer to medications, rather than controlled substances, and would authorize the department to implement, interpret, or make specific this provision by means of plan or provider bulletins, or similar instructions and require the department to adopt regulations no later than January 1, 2021. The bill would modify the conditions for the department to authorize an office-based narcotic treatment program in a remote site to authorize a physician to treat a number of patients specified under the United States Drug Enforcement Administration registration and modify the types of authorized pharmacological treatments for narcotic addiction and substance use disorder. The bill would make other conforming changes to related provisions.

Existing law establishes 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 each county for the provision of various alcohol and drug treatment services, including substance use disorder services, narcotic treatment program services, naltrexone services, and outpatient drug-free services, to Medi-Cal beneficiaries. Existing law generally requires bills for service under the Medi-Cal program to be submitted not more than 6 months after the month in which the service is rendered.

This bill would require bills for services under Drug Medi-Cal to be submitted no later than 6 months from the date of service.

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

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

### **SECTION 1.** Section 11220 of the Health and Safety Code is amended to read:

**11220.** At the end of 30 days from the first treatment, the prescribing or furnishing of controlled substances, except medications approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders, shall be discontinued.

### **SEC. 2.** Section 11839.1 of the Health and Safety Code is amended to read:

**11839.1.** The Legislature finds and declares that it is in the best interests of the health and welfare of the people of this state to coordinate narcotic treatment programs to use narcotic replacement therapy and medication-assisted treatments for substance use disorders in the treatment of addicted persons whose addiction was acquired or supported by the use of a narcotic drug or drugs, not in compliance with a physician and surgeon's legal prescription, and to establish and enforce minimum requirements for the operation of all these treatment programs in this state.

### **SEC. 3.** Section 11839.2 of the Health and Safety Code is amended to read:

**11839.2.** The following medications are authorized for use in narcotic replacement therapy and medication-assisted treatment by licensed narcotic treatment programs:

(a) Methadone.

(b) Levo-alpha-acetylmethadol (LAAM) as specified in paragraph (10) of subdivision (c) of Section 11055.

(c) Buprenorphine products or combination of products approved by the federal Food and Drug Administration for maintenance or detoxification of opioid dependence.

(d) Any other medication approved by the federal Food and Drug Administration for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders.

(e) 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, interpret, or make specific this section by means of plan or provider bulletins, or similar instructions. The department shall adopt regulations by no later than January 1, 2021.

### **SEC. 4.** Section 11839.3 of the Health and Safety Code is amended to read:

**11839.3.** (a) In addition to the duties authorized by other statutes, the department shall perform all of the following:

(1) License the establishment of narcotic treatment programs in this state to use narcotic replacement therapy in the treatment of addicted persons whose addiction was acquired or supported by the use of a narcotic drug or drugs, not in compliance with a physician and surgeon's legal prescription, except that the Research Advisory Panel shall have authority to approve methadone or LAAM research programs. The department shall establish and enforce the criteria for the eligibility of patients to be included in the programs, program operation guidelines, such as dosage levels, recordkeeping and reporting, urinalysis requirements, take-home doses of controlled substances authorized for use pursuant to Section 11839.2, security against redistribution of the narcotic replacement drugs, and any other regulations that are necessary to protect the safety and well-being of the patient, the local community, and the public, and to carry out this chapter. A program may admit a patient to narcotic maintenance or narcotic detoxification treatment at the discretion of the medical director. The program shall assign a unique identifier to, and maintain an individual record for, each patient of the program. The arrest and conviction records and the records of pending charges against a person seeking admission to a narcotic treatment program shall be furnished to narcotic treatment program directors upon written request of the narcotic treatment program director provided the request is accompanied by a signed release from the person whose records are being requested.

(2) Inspect narcotic treatment programs in this state and ensure that programs are operating in accordance with the law and regulations. The department shall have sole responsibility for compliance inspections of all programs in each county. Annual compliance inspections shall consist of an evaluation by onsite review of the operations and records of licensed narcotic treatment programs' compliance with applicable state and federal laws and regulations and the evaluation of input from local law enforcement and local governments, regarding concerns about the narcotic treatment program. At the conclusion of each

inspection visit, the department shall conduct an exit conference to explain the cited deficiencies to the program staff and to provide recommendations to ensure compliance with applicable laws and regulations. The department shall provide an inspection report to the licensee within 30 days of the completed onsite review describing the program deficiencies. A corrective action plan shall be required from the program within 30 days of receipt of the inspection report. All corrective actions contained in the plan shall be implemented within 30 days of receipt of approval by the department of the corrective action plan submitted by the narcotic treatment program. For programs found not to be in compliance, a subsequent inspection of the program shall be conducted within 30 days after the receipt of the corrective action plan in order to ensure that corrective action has been implemented satisfactorily. Subsequent inspections of the program shall be conducted to determine and ensure that the corrective action has been implemented satisfactorily. For purposes of this requirement, "compliance" shall mean to have not committed any of the grounds for suspension or revocation of a license provided for under subdivision (a) of Section 11839.9 or paragraph (2) of subdivision (b) of Section 11839.9. Inspection of narcotic treatment programs shall be based on objective criteria including, but not limited to, an evaluation of the programs' adherence to all applicable laws and regulations and input from local law enforcement and local governments. Nothing in this section shall preclude counties from monitoring their contract providers for compliance with contract requirements.

(3) Charge and collect licensure fees. In calculating the licensure fees, the department shall include staff salaries and benefits, related travel costs, and state operational and administrative costs. Fees shall be used to offset licensure and inspection costs, not to exceed actual costs.

(4) Study and evaluate, on an ongoing basis, narcotic treatment programs including, but not limited to, the adherence of the programs, to all applicable laws and regulations and the impact of the programs on the communities in which they are located.

(5) Provide advice, consultation, and technical assistance to narcotic treatment programs to ensure that the programs comply with all applicable laws and regulations and to minimize any negative impact that the programs may have on the communities in which they are located.

(6) In its discretion, to approve local agencies or bodies to assist it in carrying out this chapter provided that the department may not delegate responsibility for inspection or any other licensure activity without prior and specific statutory approval. However, the department shall evaluate recommendations made by county alcohol and drug program administrators regarding licensing activity in their respective counties.

(7) The director may grant exceptions to the regulations adopted under this chapter if he or she determines that this action would improve treatment services or achieve greater protection to the health and safety of patients, the local community, or the general public. An exception shall not be granted if it is contrary to, or less stringent than, the federal laws and regulations that govern narcotic treatment programs.

(b) It is the intent of the Legislature in enacting this section, in order to protect the general public and local communities, that take-home doses of narcotic replacement therapy medications authorized for use pursuant to Section 11839.2 shall only be provided when the patient is clearly adhering to the requirements of the program, and if daily attendance at a clinic would be incompatible with gainful employment, education, responsible homemaking, retirement or medical disability, or if the program is closed on Sundays or holidays and providing a take-home dose is not contrary to federal laws and regulations governing narcotic treatment programs. The department shall define "satisfactory adherence" and shall ensure that patients not satisfactorily adhering to their programs shall not be provided take-home doses. A narcotic treatment program medical director shall determine whether or not to dilute take-home doses.

(c) There is established in the State Treasury the Narcotic Treatment Program Licensing Trust Fund. All licensure fees collected from the providers of narcotic treatment services shall be deposited in this fund. Except as otherwise provided in this section, if funds remain in this fund after appropriation by the Legislature and allocation for the costs associated with narcotic treatment licensure actions and inspection of narcotic treatment programs, a percentage of the excess funds shall be annually rebated to the licensees based on the percentage their licensing fee is of the total amount of fees collected by the department. A reserve equal to 10 percent of the total licensure fees collected during the preceding fiscal year may be held in each trust account to reimburse the department if the actual cost for the licensure and inspection exceed fees collected during a fiscal year.

(d) Notwithstanding any provision of this code or regulations to the contrary, the department shall have sole responsibility and authority for determining if a state narcotic treatment program license shall be granted and for administratively establishing the maximum treatment capacity of a license. However, the department shall not increase the capacity of a program unless it determines that the licensee is operating in full compliance with applicable laws and regulations.

**SEC. 5.** Section 11839.5 of the Health and Safety Code is amended to read:

**11839.5.** In addition to the duties authorized by other provisions, the department shall be responsible for licensing narcotic treatment programs to use narcotic replacement therapy and medication-assisted treatment in the treatment of addicted persons whose addiction was acquired or supported by the use of alcohol or a narcotic drug or drugs, not in compliance with a physician

and surgeon's legal prescription. No narcotic treatment program shall be authorized to use narcotic replacement therapy and medication-assisted treatment without first obtaining a license as a narcotic treatment program as provided in this chapter. The department may license narcotic treatment programs on an inpatient or outpatient basis, or both. The department may also grant a state narcotic treatment license.

**SEC. 6.** Section 11839.6 of the Health and Safety Code is amended to read:

**11839.6.** (a) The department shall establish a program for the operation and regulation of office-based narcotic treatment programs. An office-based narcotic treatment program established pursuant to this section shall meet either of the following conditions:

(1) Hold a primary narcotic treatment program license.

(2) Be affiliated and associated with a primary licensed narcotic treatment program. An office-based narcotic treatment program meeting the requirement of this paragraph shall not be required to have a license separate from the primary licensed narcotic treatment program with which it is affiliated and associated.

(b) For purposes of this section, "office-based narcotic treatment program" means a program in which interested and knowledgeable physicians and surgeons provide addiction treatment services, and in which community pharmacies or medication units supply necessary medication both to these physicians and surgeons for distribution to patients and through direct administration and specified dispensing services.

(c) Notwithstanding any other law or regulation, including Section 10020 of Title 9 of the California Code of Regulations, an office-based narcotic treatment program in a remote site that is affiliated and associated with a licensed narcotic treatment program may be approved by the department, if all of the following conditions are met:

(1) A physician may provide office-based addiction services only if each office-based patient is registered as a patient in the licensed narcotic treatment program and both the licensed narcotic treatment program and the office-based narcotic treatment program ensure that all services required under Chapter 4 (commencing with Section 10000) of Division 4 of Title 9 of the California Code of Regulations for the management of narcotic addiction are provided to all patients treated in the remote site.

(2) A physician in an office-based narcotic treatment program may provide treatment for an appropriate number of patients under the appropriate United States Drug Enforcement Administration registration. The primary licensed narcotic treatment program shall be limited to its total licensed capacity as established by the department, including the patients of physicians in the office-based narcotic treatment program.

(3) The physicians in the office-based narcotic treatment program shall dispense or administer pharmacologic treatments for narcotic addiction or a substance use disorder that have been approved by the federal Food and Drug Administration for the purpose of narcotic replacement therapy or medication-assisted treatment of substance use disorders.

(4) Office-based narcotic treatment programs, in conjunction with primary licensed narcotic treatment programs, shall develop protocols to prevent the diversion of medication. The department may develop regulations to prevent the diversion of medication.

(d) For purposes of this section, "remote site" means a site that is geographically or physically isolated from any licensed narcotic treatment program. Therefore, the requirements in this subdivision regarding a remote site do not apply to an office-based narcotic treatment program that holds a primary narcotic treatment program license.

(e) In considering an office-based narcotic treatment program application, the department shall independently weigh the treatment needs and concerns of the county, city, or areas to be served by the program.

(f) Nothing in this section is intended to expand the scope of the practice of pharmacy.

**SEC. 7.** Section 14021.6 of the Welfare and Institutions Code is amended to read:

**14021.6.** (a) For the fiscal years prior to fiscal year 2004–05, and subject to the requirements of federal law, the maximum allowable rates for the Drug Medi-Cal Treatment Program shall be determined by computing the median rate from available cost data by modality from the fiscal year that is two years prior to the year for which the rate is being established.

(b) (1) For the fiscal year 2007–08, and subsequent fiscal years, and subject to the requirements of federal law, the maximum allowable rates for the Drug Medi-Cal Treatment Program shall be determined by computing the median rate from the most recently completed cost reports, by specific service codes that are consistent with the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Sec. 300gg).

(2) For the fiscal years 2005–06 and 2006–07, if the State Department of Health Care Services determines that reasonably reliable and complete cost report data are available, the methodology specified in this subdivision shall be applied to either or both of those years. If reasonably reliable and complete cost report data are not available, the State Department of Health Care Services shall establish rates for either or both of those years based upon the usual, customary, and reasonable charge for the services to be provided, as the department may determine in its discretion. This subdivision is not intended to modify subdivision (h) of Section 14124.24, which requires certain providers to submit performance reports.

(c) Notwithstanding subdivision (a), for the 1996–97 fiscal year, the rates for nonperinatal outpatient methadone maintenance services shall be set at the rate established for the 1995–96 fiscal year.

(d) Notwithstanding subdivision (a), the maximum allowable rate for group outpatient drug free services shall be set on a per person basis. A group shall consist of a minimum of 2 and a maximum of 12 individuals, at least one of which shall be a Medi-Cal eligible beneficiary. For groups consisting of two individuals, if one of the individuals is ineligible for Medi-Cal, the individual who is ineligible for Medi-Cal shall be receiving outpatient drug free services for a substance use disorder diagnosed by a physician.

(e) The department shall develop individual and group rates for extensive counseling for outpatient drug free treatment, based on a 50-minute individual or a 90-minute group hour, not to exceed the total rate established for subdivision (d).

(f) The department may adopt regulations as necessary to implement subdivisions (a), (b), and (c), or to implement cost containment procedures. These regulations may be adopted as emergency regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The adoption of these emergency regulations shall be deemed an emergency necessary for the immediate preservation of the public peace, health and safety, or general welfare.

(g) Bills for services under the Drug Medi-Cal Treatment Program shall be submitted no later than six months from the date of service.