

AMENDED IN SENATE JULY 2, 2020
AMENDED IN ASSEMBLY MAY 20, 2019
AMENDED IN ASSEMBLY APRIL 30, 2019
AMENDED IN ASSEMBLY APRIL 4, 2019

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL

No. 1710

Introduced by Assembly Member Wood

February 22, 2019

An act to ~~add Section 26203 to the Business and Professions Code, relating to cannabis~~; amend Section 4052.8 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1710, as amended, Wood. ~~Cannabis~~—*Pharmacy practice: vaccines.*

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime. Existing law authorizes a pharmacist to independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons 3 years of age or older.

This bill would also authorize a pharmacist to independently initiate and administer vaccines approved by the federal Food and Drug

Administration (FDA) under the circumstances described above. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~The Control, Regulate and Tax Adult Use of Marijuana Act (AUMA), an initiative statute approved as Proposition 64 at the November 8, 2016, statewide general election, authorizes a person who obtains a state license under AUMA to engage in commercial adult-use cannabis activity pursuant to that license and applicable local ordinances. The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), among other things, consolidates the licensure and regulation of commercial medicinal and adult-use cannabis activities.~~

~~Existing law provides a local jurisdiction, defined as a city, city and county, or county, with specified powers regarding commercial cannabis activity, including adopting and enforcing local ordinances regulating commercial cannabis activity, including prohibiting that activity. Existing law prohibits a licensing authority from approving an application for a state license if approval will violate the provisions of a local ordinance or regulation.~~

~~This bill would amend AUMA by authorizing the Elk Valley Rancheria, California, a federally recognized Indian tribe, and the County of Del Norte to enter into an agreement, as defined, regarding local authorization for, and tribal regulation of, commercial cannabis activity. The bill would provide that the agreement would satisfy the requirements of MAUCRSA regarding the approval of a local jurisdiction for state license purposes and would require that the licensee or applicant be subject to all of the requirements of MAUCRSA for the applicable license type. The bill would exempt the agreement from the California Environmental Quality Act (CEQA), but would not limit the licensee's requirement to comply with all state laws, including CEQA.~~

~~This bill would make legislative findings and declarations as to the necessity of a special statute for Elk Valley Rancheria and the County of Del Norte.~~

~~AUMA authorizes legislative amendment of its provisions with a $\frac{2}{3}$ vote of both houses of the Legislature, without submission to the voters, to further its purposes and intent.~~

~~This bill would declare that its provisions further specified purposes and intent of the Control, Regulate and Tax Adult Use of Marijuana Act.~~

~~Vote: $\frac{2}{3}$ -majority. Appropriation: no. Fiscal committee: ~~no~~-yes. State-mandated local program: ~~no~~-yes.~~

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

1 SECTION 1. Section 4052.8 of the Business and Professions
2 Code is amended to read:

3 4052.8. (a) In addition to the authority provided in paragraph
4 (11) of subdivision (a) of Section 4052, a pharmacist may
5 independently initiate and administer vaccines *approved by the*
6 *federal Food and Drug Administration (FDA), or listed on the*
7 routine immunization schedules recommended by the federal
8 Advisory Committee on Immunization Practices (ACIP), in
9 compliance with individual ACIP vaccine recommendations, and
10 published by the federal Centers for Disease Control and
11 Prevention (CDC) for persons three years of age and older.

12 (b) In order to initiate and administer an immunization described
13 in subdivision (a), a pharmacist shall do all of the following:

14 (1) Complete an immunization training program endorsed by
15 the CDC or the Accreditation Council for Pharmacy Education
16 that, at a minimum, includes hands-on injection technique, clinical
17 evaluation of indications and contraindications of vaccines, and
18 the recognition and treatment of emergency reactions to vaccines,
19 and shall maintain that training.

20 (2) Be certified in basic life support.

21 (3) Comply with all state and federal recordkeeping and
22 reporting requirements, including providing documentation to the
23 patient’s primary care provider and entering information in the
24 appropriate immunization registry designated by the immunization
25 branch of the State Department of Public Health.

26 (c) A pharmacist administering immunizations pursuant to this
27 section, or paragraph (11) of subdivision (a) of Section 4052, may
28 also initiate and administer epinephrine or diphenhydramine by
29 injection for the treatment of a severe allergic reaction.

1 *SEC. 2. No reimbursement is required by this act pursuant to*
2 *Section 6 of Article XIII B of the California Constitution because*
3 *the only costs that may be incurred by a local agency or school*
4 *district will be incurred because this act creates a new crime or*
5 *infraction, eliminates a crime or infraction, or changes the penalty*
6 *for a crime or infraction, within the meaning of Section 17556 of*
7 *the Government Code, or changes the definition of a crime within*
8 *the meaning of Section 6 of Article XIII B of the California*
9 *Constitution.*

10 ~~SECTION 1. Section 26203 is added to the Business and~~
11 ~~Professions Code, to read:~~

12 ~~26203. (a) The Elk Valley Rancheria, California, a federally~~
13 ~~recognized Indian tribe, and the County of Del Norte may enter~~
14 ~~into an agreement regarding commercial cannabis activities on the~~
15 ~~tribe's trust lands. An agreement that was entered into by the tribe~~
16 ~~and the county prior to January 1, 2020, remains valid if it~~
17 ~~otherwise complies with this section.~~

18 ~~(b) The agreement shall satisfy the requirement of this chapter~~
19 ~~regarding the approval of a local jurisdiction for state license~~
20 ~~purposes. The agreement shall require that the licensee or applicant~~
21 ~~is subject to all of the requirements of this division for the~~
22 ~~applicable license type.~~

23 ~~(c) The execution of an agreement pursuant to this section does~~
24 ~~not constitute a project and shall be exempt from the California~~
25 ~~Environmental Quality Act (Division 13 (commencing with Section~~
26 ~~21000) of the Public Resources Code). This exemption does not~~
27 ~~limit the requirement of the licensee to comply with all state laws,~~
28 ~~including the California Environmental Quality Act, that are~~
29 ~~applicable to them as a licensee.~~

30 ~~(d) For purposes of this section, "agreement" means a~~
31 ~~memorandum of understanding, intergovernmental agreement joint~~
32 ~~powers agreement, or other type of agreement regarding local~~
33 ~~authorization for, and tribal regulation of, commercial cannabis~~
34 ~~activity.~~

35 ~~SEC. 2. The Legislature finds and declares that a special statute~~
36 ~~is necessary and that a general statute cannot be made applicable~~
37 ~~within the meaning of Section 16 of Article IV of the California~~
38 ~~Constitution because of the unique circumstances facing the Elk~~
39 ~~Valley Rancheria and the County of Del Norte.~~

1 ~~SEC. 3.—The Legislature finds and declares that this act furthers~~
2 ~~the purposes and intent of the Control, Regulate and Tax Adult~~
3 ~~Use of Marijuana Act.~~

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Supporting California's COVID-19 Response: Pharmacist Testing and Immunization

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COVID-19 Testing

- April 8 2020: OASH issued guidance pursuant to the PREP Act (42 U.S.C. § 247d-6d) and the HHS' PREP Act Declaration (Mar. 10, 2020) authorizing pharmacists to 'order and administer COVID-19 tests, including serology tests, that the FDA has authorized,' thus, qualifying pharmacists as "covered persons" for the purposes of PREP Act immunity.
- April- May 2020: CPhA and NACDS worked with the Board of Pharmacy and the DCA staff to issue the waivers of law under Governor Newsom's Executive Order to authorize pharmacists to perform (i.e. order and administer) COVID-19 testing under state law.
 - Currently, there are about 3 COVID-19 test sites available per 100,000 people and over 18,200 community pharmacists in the chain and independent setting that could potentially be performing (i.e. ordering and administering) COVID-19 testing.
- May 14: The DCA issued a pharmacy law waiver that temporarily allows pharmacists to independently order COVID-19 tests for patients as well as conduct collection of specimens from patients. However, there are still some barriers for pharmacists to administer COVID-19 tests.

The Problem

- Pharmacists can only participate in administering COVID-19 tests under CA state law, aside from specimen collection, by contracting with a laboratory director specifically to oversee COVID testing.
 - Some COVID-19 tests are classified as CLIA-waived tests, which requires a CLIA-waiver certificate to order and administer. In some states, pharmacists may order and administer tests when done under a pharmacy's CLIA-waiver certificate. However, it is our understanding that CDPH is currently denying CLIA waiver-certificates to pharmacies.
 - More so, even if pharmacies were issued CLIA-waiver certificates, pharmacists may not be able to administer tests:
 - **BPC 1206.5:** Pharmacists can only perform CLIA-waived tests under the overall operation and administration of a laboratory director.
 - *Exception- Community pharmacists can independently perform CLIA tests involving blood glucose, hemoglobin A1C, and cholesterol.*
 - **BPC 1209:** Definition of Laboratory Directors
 - Pharmacists currently are not authorized to be laboratory directors.
 - The requirement is cost-prohibitive and difficult, especially for smaller community pharmacies.

Clarification of Federal Guidance

- On May 19th, HHS' Office of the General Counsel issued an advisory opinion, which states that the PREP Act and associated federal action (i.e. Apr. 8th guidance) preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 test.
- *See* 42 U.S.C. § 247d-6d(b)(8)(A); *see also* Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, *available at* <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.

Proposed Solution

- Governor Newsom should sign an Executive Order removing existing lab barriers that prevent pharmacists from conducting the full COVID-19 testing process.
 - Despite Governor Newsom's repeated support for increased testing and tracing to safely re-open California, CDPH has actively prevented increased testing capacity in California by excluding pharmacies.
- The Board of Pharmacy and the DCA should enhance advocacy efforts and continue conversations with the Administration authorizing pharmacists to administer COVID-19 tests.
 - Currently, 40+ other states allow pharmacies to perform such CLIA-waived tests and California pharmacists should have the ability to do so too.

QUESTIONS?