

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

BILL NUMBER: AB 149
AUTHOR: Cooper
BILL DATE: Chaptered, #4
SUBJECT: Controlled Substances: Prescriptions
SPONSOR: California Medical Association
POSITION: Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill allows for a transition period, until January 1, 2021, before the new requirement becomes effective that prescription forms for controlled substances include a uniquely serialized number.

BACKGROUND:

AB 1753 (Low, Chapter 479) was signed into law in 2018 and became effective January 1, 2019. This bill required that all prescription forms include a uniquely serialized number in a manner prescribed by the Department of Justice (DOJ). This bill did not include a transition period to allow time for prescribers to order new prescription forms. This resulted in many prescribers not ordering new forms until right before the new law took effect. This meant that their old prescription forms were not valid on January 1st and they did not have the new forms yet, which resulted in difficulties for patients trying to get prescriptions filled for controlled substances.

To help get information out to prescribers, the Medical Board of California (Board) released a letter regarding the new requirements for prescription forms in December, following statements issued by DOJ and the Board of Pharmacy regarding the new law and their respective plans for enforcing the new law. Due to many calls received by all involved agencies, on January 10, 2019, the Board issued a joint release with DOJ and the Board of Pharmacy to provide further guidance on this issue.

ANALYSIS:

This bill specifies that a prescription for controlled substances written on an otherwise valid prescription form prior to January 1, 2019 that does not comply with the uniquely serialized number requirement, is a valid prescription that may be filled, compounded, or dispensed until January 1, 2021.

In the event that DOJ determines that there is an inadequate availability of compliant prescription forms to meet the demand on or before January 1, 2021, this bill would allow DOJ to extend the period during which prescriptions written on noncompliant prescription forms remain valid for a period no longer than an additional six months.

This bill does not require the uniquely serialized number to be a feature in the printing of new prescription forms until a date determined by DOJ, which shall be no later than January 1, 2020. The specification for the serialized number must be prescribed by DOJ and must be compliant with all state and federal requirements; must be utilizable as a barcode that may be scanned by dispensers; and must be compliant with current National Council for Prescription Drug Program Standards.

This bill includes an urgency clause and took effect when the bill was signed on March 11, 2019.

This bill was needed to allow for a transition period for prescribers to order the new prescription forms. The Board received many calls and emails from prescribers and patients regarding the difficulty of obtaining the new prescription forms and getting prescriptions filled using the old forms. This bill helps ensure that patients receive their medications in a timely manner and the Board was supportive of this bill. The Board has already implemented this bill by posting information on this bill on the Board's website and emailing out information on this bill to all physicians licensed by the Board.

FISCAL: None

SUPPORT: California Medical Association (Sponsor); California Association for Nurse Practitioners; California Academy of Child and Adolescent Psychiatry; California Dental Association; California Pharmacists Association; California Retailers Association; California Society of Anesthesiologists; Kaiser Permanente; Medical Board of California; and National Association of Chain Drug Stores

OPPOSITION: None on file

Assembly Bill No. 149

CHAPTER 4

An act to amend Sections 11162.1 and 11164 of, and to add Section 11162.2 to, the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor March 11, 2019. Filed with Secretary
of State March 11, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

AB 149, Cooper. Controlled substances: prescriptions.

Existing law classifies certain controlled substances into designated schedules. Existing law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the department, as specified. Existing law requires those prescription forms to be printed with specified features, including a uniquely serialized number.

This bill would delay the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2020. The bill would require, among other things, the serialized number to be utilizable as a barcode that may be scanned by dispensers. The bill would additionally make any prescription written on a prescription form that was otherwise valid prior to January 1, 2019, but that does not include a uniquely serialized number, or any prescription written on a form approved by the Department of Justice as of January 1, 2019, a valid prescription that may be filled, compounded, or dispensed until January 1, 2021. The bill would authorize the Department of Justice to extend this time period for a period no longer than an additional 6 months, if there is an inadequate availability of compliant prescription forms.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 11162.1 of the Health and Safety Code is amended to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify themselves as the prescriber by checking the box by the prescriber's name.

(15) A uniquely serialized number, in a manner prescribed by the Department of Justice in accordance with Section 11162.2.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients

in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) Within the next working day following delivery, a security printer shall submit via web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:

(1) Serial numbers of all prescription forms delivered.

(2) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.

(3) The delivery shipment recipient names.

(4) The date of delivery.

SEC. 2. Section 11162.2 is added to the Health and Safety Code, to read:

11162.2. (a) Notwithstanding any other law, the uniquely serialized number described in paragraph (15) of subdivision (a) of Section 11162.1 shall not be a required feature in the printing of new prescription forms produced by approved security printers until a date determined by the Department of Justice, which shall be no later than January 1, 2020.

(b) Specifications for the serialized number shall be prescribed by the Department of Justice and shall meet the following minimum requirements:

(1) The serialized number shall be compliant with all state and federal requirements.

(2) The serialized number shall be utilizable as a barcode that may be scanned by dispensers.

(3) The serialized number shall be compliant with current National Council for Prescription Drug Program Standards.

SEC. 3. Section 11164 of the Health and Safety Code is amended to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(e) (1) Notwithstanding any other law, a prescription written on a prescription form that was otherwise valid prior to January 1, 2019, but that does not comply with paragraph (15) of subdivision (a) of Section 11162.1, or a valid controlled substance prescription form approved by the Department of Justice as of January 1, 2019, is a valid prescription that may be filled, compounded, or dispensed until January 1, 2021.

(2) If the Department of Justice determines that there is an inadequate availability of compliant prescription forms to meet demand on or before the date described in paragraph (1), the department may extend the period during which prescriptions written on noncompliant prescription forms remain valid for a period no longer than an additional six months.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

To immediately confirm the validity of prescriptions for medication written on prescription forms issued, filled, compounded, or dispensed following the enactment of Chapter 479 of the Statutes of 2018 and clarify a timeline for implementation that preserves the continuity of treatment for patients.