



Joint Statement from the California Department of Justice, California State Board of Pharmacy, and the Medical Board of California Regarding Secure Prescription Forms

November 19, 2020

RE: AB 149 - NEW REQUIREMENTS FOR CONTROLLED SUBSTANCES PRESCRIPTION FORMS

Assembly Bill (AB) 149 (Cooper, Chapter 4, Statutes of 2019) introduced new security requirements on California controlled substances prescription forms. Specifically, AB 149 imposed new format requirements on the serial number and added a barcode requirement. A transition period was included within AB 149 to support an orderly shift by prescribers to the new forms. This notice is to serve as a reminder of that transition period and the preparations that should be taken as we approach the end of the transition period (December 31, 2020).

Beginning January 1, 2021, the only California controlled substances prescription forms that will remain valid and acceptable by pharmacies will be those possessing a twelve (12) character serial number and corresponding barcode compliant with the requirements introduced in AB 149.

Barcode/Serial Number Example¹



Serial # AAANNNANNNN

As such, the following controlled substances prescription forms will **<u>NO LONGER</u>** be valid and accepted by pharmacies after December 31, 2020:

- Forms valid prior to January 1, 2019, but which do not contain a uniquely serialized number in compliance with Health and Safety Code section 11162.1(a)(15).
- Forms approved by the Department of Justice as of January 1, 2019 when a fifteen (15) character serialized number format was approved by the Department of Justice.

Please keep in mind, however, there are certain limited exceptions² to the requirement that a prescription form comply with the security features of Health & Safety Code section 11162.1, including the new requirements of AB 149.

¹ Please note, this is an example only. Barcodes and serial numbers may vary in size and appearance.

² Exceptions to controlled substance security form requirements include those described within Health and Safety Code (HSC) section 11159.2, HSC section 11159.3, and HSC section 11167.





As part of the transition, no later than January 1, 2020, California-approved security printers were required to exclusively print the twelve (12) character serial number and corresponding barcode on all California controlled substances prescription forms. As such, only these approved forms are available for purchase.

The length of time it may take for orders to be processed and delivered cannot be predicted, especially if the volume of orders increases as the end of the transition period approaches. Therefore, we recommend those who prescribe controlled substances, and who have not acquired forms compliant with AB 149 (as described above), order them as soon as possible.

For more information, please see the Approved List of Security Prescription Printers (<u>https://oag.ca.gov/security-printers/approved-list</u>), and the Department of Justice's California Security Printer Program webpage (<u>https://oag.ca.gov/security-printers</u>).





ASSEMBLY BILL 149: FREQUENTLY ASKED QUESTIONS 11/19/2020

For Prescribers

- 1. What prescription forms for controlled substances are valid (AB 149compliant) beginning January 1, 2021?
 - Beginning January 1, 2021, the only valid (AB 149-compliant) controlled substance paper prescription forms will be those obtained from an Approved Security Prescription Printer containing the required 12-character serial number and corresponding barcode (and all other security features required by Health and Safety Code section 11162.1). (A copy of <u>Health and Safety Code section 11162.1</u>) is attached as Appendix A.) These forms are available for purchase from <u>Approved Security Prescription Printers</u> now. Forms with no serial number and forms with the 15-character serial number that you may currently possess will not be valid (AB 149-compliant) for controlled substances prescriptions on and after January 1, 2021.
- 2. I already use an e-prescribing platform for my prescriptions. Does AB 149 change the way I need to prescribe controlled substances?
 - No. AB 149 only changes the requirements for paper forms used to write controlled substances prescriptions. AB 149 does not affect a prescription for controlled substances written through e-prescribing.
 - You may wish to consider having some paper prescription forms in the office that are compliant with AB 149, should there be a technological impediment that prevents you from submitting the prescription electronically.
- 3. As a prescriber, how do I know if my forms are valid (AB 149-compliant)?
 - Forms are valid (AB 149-compliant) if they conform to all of the security features required by Health and Safety Code section 11162.1, including the 12-character serial number and

corresponding barcode. (A copy of <u>Health and Safety Code</u> <u>section 11162.1</u> is attached as Appendix A.)

- Any forms produced by Approved Security Prescription Printers on or after January 1, 2020, must conform to the requirements of AB 149. Therefore, if your forms were ordered and produced on or after January 1, 2020, they should be AB 149-compliant.
- 4. How do I obtain forms that are valid (AB 149-compliant) for use on or after January 1, 2021?
 - Contact a printer on the Approved List of Security Prescription Printers to order AB 149-compliant forms: <u>https://oag.ca.gov/security-printers/approved-list</u>
 - Please order forms as soon as possible to ensure you have AB 149compliant forms as the amount of time it takes to fulfil an order may vary.
- 5. On or after January 1, 2021, may I continue to write prescriptions for controlled substances on forms that are <u>no longer</u> AB 149-compliant?
 - No. On or after January 1, 2021, you should not continue to write prescriptions for controlled substances on forms that are no longer AB 149-compliant.
- 6. Are AB 149-compliant forms available now and are they accepted by pharmacists now?
 - Yes, AB 149-compliant forms may be purchased from printers on the Approved List of Security Prescription Printers (<u>https://oag.ca.gov/security-printers/approved-list</u>).
 - Yes, AB 149-compliant forms are accepted by pharmacists now.
- 7. What happens if I write a prescription on or before December 31, 2020, on a form that is not AB 149-compliant but my patient does not take it to a pharmacy until on or after January 1, 2021?
 - As required by Health and Safety Code section 11164, pharmacists should not fill prescriptions on or after January 1, 2021, that are not

on AB 149-compliant forms. As January 1, 2021, approaches, prescribers should make every effort to communicate this change to their patients in order to avoid prescriptions being rejected.

- As of January 1, 2021, a pharmacist will only be able to fill a prescription that is not on a compliant form for some exceptions, including filling prescriptions for controlled substances for a terminally ill patient under certain conditions (pursuant to Health and Safety Code section 11159.2), for a patient who cannot access medications as a result of a declared local, state, or federal emergency, with certain restrictions (pursuant to Health and Safety Code section 11159.3), and in an emergency where failure to issue a prescription may result in loss of life or intense suffering (pursuant to Health and Safety Code section 11167).
- 8. May my patient still get refills after December 31, 2020, if the original prescription, filled on or before December 31, 2020, is on a form that is no longer valid (AB 149-compliant) on or after January 1, 2021?
 - No. A patient may not get refills after December 31, 2020, if the original prescription authorizing such refills was on a form that is no longer valid (AB 149-compliant) on or after January 1, 2021. It is recommended that prescribers and dispensers work together to address this potential issue in advance of January 1, 2021, to mitigate potential interruptions in patient care.

For Pharmacists

- 9. What are the new features that distinguish an AB 149-compliant form?
 - New features of the AB 149-compliant form are the 12-character serial number and corresponding barcode. All additional security features set forth in Health and Safety Code section 11162.1 are still required. (A copy of <u>Health and Safety Code section 11162.1</u> is attached as Appendix A.)
- 10. Where are the serial number and barcode located on an AB 149compliant form?

- There is presently no fixed location requirement, except that the barcode must appear on the front of the form and the serial number should be located directly below it. The barcode and serial number may appear either in a horizontal or vertical position.
- 11. What is the format of an AB 149-compliant serial number?
 - The serial number is 12 characters in length, in the following format: Three alpha characters followed by three numeric characters followed by one alpha character followed by five numeric characters. Example: AAANNNANNNN
- 12. Are there any prescriptions for controlled substances I can fill that are not subject to the requirements of AB-149 effective January 1, 2021?
 - Yes, there are exceptions to the controlled substance security form requirements, including permission to fill prescriptions for controlled substances for a terminally ill patient under certain conditions (pursuant to Health and Safety Code section 11159.2), for a patient who cannot access medications as a result of a declared local, state, or federal emergency, with certain restrictions (pursuant to Health and Safety Code section 11159.3), and in an emergency where failure to issue a prescription may result in loss of life or intense suffering (pursuant to Health and Safety Code section 11167).
- 13. May I fill a prescription for controlled substances issued on a paper form without the 12-character serial number and barcode (provided the form is otherwise valid), if the prescriber wrote the prescription before January 1, 2021, but the patient did not bring it to the pharmacy until on or after January 1, 2021?
 - No. A prescription written on a prescription form that was otherwise valid prior to January 1, 2019, but that does not contain the required unique serialized number, 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 (Health and Safety Code section 11164(e)(1)). Accordingly, a form without the required unique serialized number cannot be filled on or after January 1, 2021, unless an exception applies. Exceptions to controlled substance security form requirements include those described within Health and Safety Code (HSC) section 11159.2, HSC section 11159.3, and HSC section 11167. See response to question #12, above.

- 14. May I fill a prescription for controlled substances issued on a paper form without the 12-character serial number and barcode (provided the form is otherwise valid), if I received the paper form before January 1, 2021, but I am unable to fill it until on or after January 1, 2021?
 - No, you many not fill a prescription for controlled substances issued on a paper form without the 12-character serial number and barcode absent emergency circumstances. Reasonable attempts should be made to fill, compound, or dispense before January 1, 2021, since the paper form was valid when provided. Pharmacists who receive a prescription on a paper form that will be invalid effective January 1, 2021 and that they believe cannot be filled prior to January 1, 2021, should inform the patient that the prescription cannot be filled prior to the January 1, 2021, and that the patient needs a new prescription form from the prescriber on an AB 149-compliant form. Pharmacists may also want to consider an oral prescription if permitted under existing law.
- 15. May I fill a prescription for controlled substances issued on a paper form without the 12-character serial number and barcode (provided the form is otherwise valid), if the prescriber wrote the prescription on or after January 1, 2021?
 - No, you may not fill a prescription for controlled substances issued on a paper form without the 12-character serial number and barcode (provided the form is otherwise valid), if the prescriber wrote the prescription on or after January 1, 2021.
 - As of January 1, 2021, a pharmacist will only be able to fill a prescription that is not on a compliant form for some exceptions, including filling prescriptions for controlled substances for a terminally ill patient under certain conditions (pursuant to Health and Safety Code section 11159.2), for a patient who cannot access medications as a result of a declared local, state, or federal emergency, with certain restrictions (pursuant to Health and Safety Code section 11159.3), and in an emergency where failure to issue a prescription may result in loss of life or intense suffering (pursuant to Health and Safety Code section 11167).
- 16. What do I, as the dispenser, report to CURES as the serial number if the prescription I filled is an e-prescription?

- The serial number field is not reported on an e-prescription. The Electronic Prescription Reference Number needs to be reported on an e-prescription.
- 17. What do I, as a California dispenser, report to CURES for the serial number if the prescription I filled is from an out-of-state prescriber and there is no serial number or barcode?
 - If the prescription is from an out-of-state prescriber and there is no serial number or barcode, the serial number field should be left blank when reporting to CURES.

<u>APPENDIX A</u>

HEALTH AND SAFETY CODE - HSC

DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 - 11651] (Division 10 repealed and added by Stats. 1972, Ch. 1407.)

CHAPTER 4. Prescriptions [11150 - 11209] (Chapter 4 added by Stats. 1972, Ch. 1407.)

ARTICLE 1. Requirements of Prescriptions [11150 - 11180] (Article 1 added by Stats. 1972, Ch. 1407.)

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.

(Amended by Stats. 2019, Ch. 4, Sec. 1. (AB 149) Effective March 11, 2019.)