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CALIFORNIA STATE BOARD OF PHARMACY



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

January 10, 2019

As of January 1, 2019, California law requires prescription forms for controlled substances to be printed with a uniquely serialized number. Notices explaining the serial number format and reporting requirements have been released by the Department of Justice (DOJ). Additionally, notices to prescribers and pharmacists were issued by the California State Board of Pharmacy (Pharmacy Board), and by the Medical Board of California (Medical Board), yet questions remain about implementation. This joint statement by DOJ, the Pharmacy Board, and the Medical Board is therefore being issued to provide further clarification and guidance on implementation.

As explained in previous notices from the Pharmacy Board and Medical Board, because of the absence of a grandfathering or transition period in Assembly Bill (AB) 1753 (Low), which enacted this change, as of January 1, 2019, only security forms with unique serialized numbers may lawfully be used to write paper controlled substance prescriptions. As of that date, any paper controlled substance prescription written on a controlled substance security prescription form that does not bear all of the 15 security features will be presumptively invalid.

DOJ has issued guidance to the Security Printers and the pharmacy and direct dispense data reporters regarding the approved serialized number format and reporting requirements. The DOJ has approved 38 security printers that are compliant with the new requirement. However, the signatories to this joint statement recognize that it may take some time for all prescribers to begin using the new, fully-compliant security forms. And that there may be a period of weeks or months during which prescribers continue to use outdated security forms, and those outdated forms are presented to dispensers.

Prescribers are encouraged to procure compliant security forms at their earliest opportunity. In the interim, however, none of the signatory agencies want to see patients denied access to necessary medications during this transition period. With that in mind, the Enforcement Committee of the Pharmacy Board has recommended to the Pharmacy Board and the Executive Officer that, prior to July 1, 2019, enforcement staff not make an enforcement priority of actions against and/or investigations of pharmacists (or their employing pharmacies) who, in the exercise of his or her best professional judgment, determine that it is in the best interest of patient or public health or safety to fill a controlled substance prescription written on a security form that would have been compliant prior to January 1, 2019. Further, to assist pharmacists, pharmacies, and other dispensers with implementation challenges, the Pharmacy Board has told its licensees to consider the following responses to presentation of an outdated form:

- (a) Communicating with the prescriber about the need for a compliant security prescription;
- (b) Advising the prescriber to substitute an electronic prescription;
- (c) Consulting with the prescriber about whether the patient might be terminally ill and eligible for a "11159.2 exemption" prescription under Health and Safety Code section 11159.2;
- (d) Treating prescription orders written on the outdated forms for Schedule III, IV and V medications as oral prescriptions, and verifying the order telephonically with the prescriber's office, pursuant to Health and Safety Code section 11164, subdivision (b);
- (e) Schedule II prescriptions on non-compliant security prescription forms present unique challenges, because of the inability to substitute an oral prescription. It is therefore especially important that pharmacists use their best professional judgment to get needed Schedule II medications to their patients, and the same lack of enforcement priority will be applied to these dispensing decisions until July 1, 2019.
- (f) If failure to dispense may result in loss of life or intense suffering, dispensing pursuant to the emergency situation requirements of Health and Safety Code section 11167, and curing with a compliant controlled substance security prescription form within seven (7) days; or
- (g) Refusing to fill the prescription.

Prescribers should expect to receive calls from dispensers seeking to validate such prescriptions.

Frequently Asked Questions

1. Who is responsible for enforcing the provisions required of the Security Printers?

Answer: The DOJ oversees the Security Printer Program and the approved printers who are required, beginning on January 1, 2019, to print controlled substance prescription forms with uniquely serialized numbers. There is no transition or grace period for printers to become compliant with the requirement to print controlled substance prescription forms with uniquely serialized numbers. Security printers that are not compliant with the new printing requirement, as of January 1, 2019, may have their security printer status suspended.

2. Previous communications have indicated that there is no transition period for prescriptions written after January 1, 2019 without a serial number. Who would enforce provisions against dispensers that determine it is in the best interest of the patient to dispense a medication issued on a form that does not include a serial number?

Answer: The Enforcement Committee of the Pharmacy Board has recommended to the Pharmacy Board and the Executive Officer that, prior to July 1, 2019, investigative staff not make an enforcement priority of actions against and/or investigations of pharmacists (or their employing pharmacies) who, in the exercise of his or her best professional judgment, determine that it is in the best interest of patient or public health or safety to fill a controlled substance prescription written on a security form that would have been compliant prior to January 1, 2019.

The DOJ does not have the authority to enforce such provisions on dispensers.

3. Previous communications have indicated that there is no transition period for prescriptions written after January 1, 2019, without a serial number. Who would enforce provisions against prescribers that determine it is in the best interest of the patient to prescribe on a form that does not include a serial number?

Answer: The Medical Board is responsible for enforcing the provisions related to physician prescribers and is encouraging physician prescribers to obtain and utilize the new controlled substance security prescription forms that contain the serial number as soon as possible. If you are a licensee of another board, you are encouraged to contact the appropriate licensing board for direction.

The DOJ does not have the authority to enforce such provisions on prescribers.

4. As a prescriber, will I be assigned or issued a serial number?

Answer: No, prescribers will not be issued a serial number. The serial number is a number printed on prescription forms produced by approved security printers.

5. Is there a sample of what the new security forms look like?

Answer: The Health and Safety Code establishes the required elements, but does not specify the placement of all security form features. As such, not all forms look the same. The DOJ has a list of approved Security Prescription Printers on its website that can be accessed using the following link - - <https://oag.ca.gov/security-printers/approved-list>. Some of the vendors have a sample of the compliant form on their respective website.

6. Is there a standardized format for the serialized number?

Answer: Yes. The serial number is a 15-digit alphanumeric in the following format:

AAANNNNNNANNNNN (A represents an alpha character and N represents a numeral)

7. Are electronic prescriptions required to include the unique serial number?

Answer: No

8. Who should I contact if I have questions?

Answer: Questions regarding the security printers or the serialized number format should be directed to the DOJ, (916) 210-3216 or securityprinter@doj.ca.gov.

Questions regarding prescriber or pharmacist/dispenser requirements should be directed to the respective board under the Department of Consumer Affairs. The following link can be used to access the respective prescribing boards - - https://www.dca.ca.gov/about_us/entities.shtml.

Questions regarding pharmacy requirements should be directed to the Pharmacy Board, (916) 574-7900.

Please watch for additional advisories to be released as all agencies are working to identify further real-time solutions.

Thank you.

California Department of Justice
California State Board of Pharmacy
Medical Board of California