



## Alerts

### Attention Pharmacies and Prescribers: New California Controlled Substances Prescription Form and CURES Reporting Requirements Are Coming

November 19, 2020

*Health Care Alert*

Compliance with prescription drug controlled substances prescribing and dispensing rules is essential for pharmacies and prescribers, as penalties for non-compliance are severe and can result in State Board of Pharmacy and U.S. Drug Enforcement Administration (DEA) investigations and enforcement actions. To help ensure ongoing compliance, both pharmacies and controlled substance providers should adopt and implement the new controlled substances requirements outlined below.

### New Controlled Substance Prescription Form Requirements

#### New Serialized Prescription Forms

California controlled prescription forms are required to contain several security features and identifying markers. Before January 1, 2019, having a unique serial number was not a required feature, making prescriptions written on stolen or fraudulent prescription pads difficult to identify and track. As of January 1, 2021—under [Assembly Bill 1753](#) and [Assembly Bill 149](#), as codified and amended in [Health and Safety Code Section 11162.1](#)—prescribers of controlled substances will be required to use new, compliant tamper-resistant prescription forms, which include a 12-character serial number and corresponding barcode that link to corresponding records in the [Controlled Substance Utilization Review and Evaluation System \(CURES\)](#). Additionally, the prescription forms must be compliant with National Council for Prescription Drug Program (NCPDP) standards, as well as federal and state requirements. With the exception of limited emergency situations, pharmacies and pharmacists will be unable to fill a prescription for a controlled substance that is not on a serialized number compliant form starting January 1, 2021.

#### Electronic Prescribing Option

As an alternative to the new prescription forms, prescribers can also use electronic prescribing, a process which will become mandatory in 2022 under [Assembly Bill 2789](#), as codified in [Business and Professions Code Section 688](#).

#### Attorneys

Michael A. Dowell



Specifically, by 2022, all healthcare practitioners authorized to issue prescriptions must be able to electronically transmit prescriptions to a pharmacy selected by the patient, for both controlled and non-controlled substances, unless specified exceptions are met.

The DEA adopted the rule establishing the electronic prescribing controlled substances procedures in June 2010. These include: (1) third-party certification that prescription software applications meet DEA requirements; (2) identify-proofing of prescribers; (3) two-factor authentication when signing prescriptions; and (4) access controls established by software users. Notably, after January 1, 2022, a prescriber who issues a prescription for a controlled substance, but does not transmit the prescription as an electronic prescription must document the reason in the patient's medical record as soon as practicable, and within 72 hours of the end of the technological or electrical failure that prevented e-prescribing.

## Loss or Theft of Prescription Pads

Under [Health and Safety Code Section 11165.3](#), the theft or loss of any tamper-resistant prescription forms must be reported by the prescriber to the California Department of Justice (DOJ) CURES program within three days of discovering the theft or loss. A law enforcement agency report number is required when submitting a report of lost or stolen prescription forms to CURES. The required notification may be accomplished electronically by logging into the prescriber's CURES account, or by emailing [SecurityPrinter@doj.ca.gov](mailto:SecurityPrinter@doj.ca.gov) to obtain a report to file with the California DOJ. Prescribers should also notify the California State Board of Pharmacy at [BOPcomplaint@dca.ca.gov](mailto:BOPcomplaint@dca.ca.gov). The Board of Pharmacy maintains [a list](#) of physicians whose prescription pads have been reported lost or stolen.

## Controlled Substance Prescription Reporting Requirements for Pharmacies and Dispensers

In California, CURES is an electronic tracking program that reports all pharmacy (and other specified types of prescribers) dispensing of certain schedules of controlled drugs by drug name, quantity, prescriber, patient, and pharmacy. Data from CURES is managed by the DOJ. Information tracked in CURES contains the patient name, prescriber name, pharmacy name, drug name, amount, and dosage, and is available to law enforcement agencies, regulatory bodies, prescribers, dispensers, and qualified researchers. CURES information may help prescribers identify if a person is "doctor shopping" by visiting multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs. The new CURES requirements summarized below are applicable to all pharmacies and prescribers who dispense controlled substances.

### CURES Reporting Time Frame

As of January 1, 2021—under [Assembly Bill 528](#), as codified in [Health and Safety Code Sections 11164.1, 11165, 11165.1, and 11165.4](#)—the dispensing of a controlled substance must be reported to CURES 2.0 within **one working day** after the medication is released to the patient or the patient's representative. Previously, the deadline to report was seven days after dispensing.

### CURES Querying Time Frame

Beginning January 1, 2021, under [Assembly Bill 528](#), the timeline for which a prescriber must re-query the CURES database prior to renewing a prescription for Schedule II-IV drugs will be changed. It will shift from once every four months to once every six months, as long as opioids remain part of the treatment and are being renewed.

## Controlled Substance Drug Schedules Reportable to CURES

Starting January 1, 2021, under [Assembly Bill 528](#), the direct dispensing of a Schedule V drug, in addition to the prior requirements applicable to Schedules II, III, and IV, must be reported to CURES.



## Compliance Steps to be Taken by Pharmacies and Prescribers

Prescribers and dispensers should develop or revise controlled substances policies and procedures to incorporate the new controlled substances prescription form and reporting requirements. They should also educate and train their staff on the new and updated policies and procedures.

Any prescribers who do not already have the new serialized prescription pads should place an order as soon as possible from a [Department of Justice-approved security prescription printer](#) to ensure they have compliant prescription pads before January 1, 2021. Additionally, prescribers should always remember to keep all prescription pads and forms under lock and key, or within the prescriber's immediate control and view.

Dispensers should make sure their CURES software reporting vendor has the ability to upload all required controlled substances data points with accuracy. They should also make sure that the software vendor will include Schedule V controlled substances in CURES reporting uploads no later than January 1, 2021. Developing a daily, automated CURES reporting process is strongly encouraged, as it will assist dispensers in complying with the one business day CURES reporting format. In addition, dispensers should maintain adequate books and records regarding CURES reporting compliance, including maintenance of copies of the Atlantic Associates confirmation emails regarding successful CURES reporting uploads.