

Date: March 23, 2018	POLICY ANALYSIS PREPARED FOR THE BOARD OF DIRECTORS	 OF NORTHERN LARIMER COUNTY
Staff: Alyson Williams		

HB18-1279: ELECTRONIC PRESCRIBING CONTROLLED SUBSTANCES

Concerning a requirement that certain practitioners prescribe controlled substances electronically.

Details

Bill Sponsors:	House— <i>Esgar (D)</i> , <i>Buckner (D)</i> , <i>Ginal (D)</i> , <i>Kennedy (D)</i> , <i>Liston (R)</i> , <i>McKean (R)</i> , <i>Roberts (D)</i> Senate – <i>Priola (R)</i> and <i>Moreno (D)</i>
Committee:	House Health, Insurance, & Environment
Bill History:	3/7/2018- Introduced in House- Assigned to Health, Insurance, & Environment
Next Action:	3/29/2018- Hearing in House Committee on Health, Insurance, & Environment

Bill Summary

This bill would require podiatrists, dentists, physicians, physician assistants, advanced practice nurses, and optometrists to prescribe controlled substances only through electronic prescribing, with certain exceptions to this mandate. Providers must comply with the requirement by July 1, 2020 unless they serve in a rural community or have a solo practice (deadline of July 1, 2021). These prescribers are required to report their compliance through the license renewal process. Pharmacists are not required to verify if the prescriber has a valid exemption to this mandate if a prescription is transmitted via a written or oral method.

Issue Summary

E-Prescribing Controlled Substances (EPCS)

On June 1, 2010, the Drug Enforcement Administration’s (DEA) rule, “Electronic Prescriptions for Controlled Substances,” became effective.¹ This rule allowed, but did not require, providers to write e-prescriptions for controlled substances (EPCS) and permitted pharmacies to receive, dispense, and archive these e-prescriptions. The rule also mandated stringent and audit requirements for EPCS.

Currently, the process for beginning EPCS consists of four main steps.² First, the provider must purchase a DEA-compliant e-prescribing platform that supports EPCS or utilize an existing solution in an electronic health record (EHR). Then they must go through an identity-proofing process to acquire two-factor authentication tokens in order to sign EPCS prescriptions. These tokens are bound to the provider’s identity. Finally, the prescriber gains access using the EHR or other platforms for EPCS. The DEA’s final rule required prescribers to go through technical steps to approve an e-prescription for a controlled substance. Guidelines have condensed the requirements of the DEA rule into seven main steps³:

1. Prescriber indicates to the information system platform that the EPCS are ready to sign.
2. Prescriber executes signing function, which must include a two-factor authentication protocol (i.e. prescriber enters two separate authentication tokens).⁴

¹ Diversion Control Division, Drug Enforcement Administration, U.S. Department of Justice (2010). *Electronic Prescriptions for Controlled Substances*. Retrieved from https://www.deadiversion.usdoj.gov/e-comm/e_rx/faq/eapplications.htm

² DrFirst (n.d.) *EPCS: Getting Started with Electronic Prescribing of Controlled Substances*. Retrieved from http://www.drfirst.com/wp-content/uploads/EPCS_Infographic_from_DrFirst-1.png

³ Sujansky & Associates, LLC for California HealthCare Foundation (Nov. 24, 2013). *Guidelines for the Electronic Prescribing of Controlled Substances: Identity Proofing, Issuing Authentication Credentials, and Configuring Logical Access Controls*. Retrieved from <http://surescripts.com/docs/default-source/getepcs/pdf-guidelinesepcs.pdf>

⁴ Typically, these tokens are a memorized password plus another token that is uniquely generated by a device (phone, USB, etc.) or by biometrics of the prescriber (fingerprint, retinal pattern).

3. The authentication module of the information system platform checks the prescriber's credentials.
4. The authentication module confirms (or denies) that the authentication tokens correspond to the prescriber's account.
5. The access control module of the information system platform checks that the authenticated prescriber account is permitted to sign controlled substance prescriptions.
6. The access control module confirms (or denies) that the account associated with the prescriber is allowed to sign controlled substance prescriptions.
7. The EPCS is signed.

Controlled Substances in Colorado

Colorado has 1,089 pharmacies, 42,371 prescribers, and over 1.4 million unique patients that either dispensed, prescribed, or consumed a controlled substance (i.e. a drug that has been classified as a Schedule II-V substance).⁵ More than 96 percent of Colorado pharmacies are enabled to handle EPCS; however, only 13.3 percent of prescribers are ready.⁶ In 2016, only 6.9 percent of controlled substances were prescribed electronically.⁶

The Colorado Controlled Substances Act of 2013 implemented an inventory of Schedule I to V drugs.⁷ Statute defines Schedule I substances as those that have a high potential for abuse, no currently accepted medical use in treatment, and lack accepted safety for use under medical supervision.⁸ Some of the listed substances under this category include some synthetic opiates, heroin, LSD, and peyote.⁸ Schedule II drugs are those that have a high potential for abuse, has currently accepted medical use in treatment or currently accepted medical use with severe restrictions, and the abuse of the substance may lead to severe psychological or physical dependence.⁹ Examples of Schedule II substances are morphine, cocaine, some synthetic opiates (i.e. fentanyl and methadone), and amphetamines.⁹ The statute defines Schedule III drugs as those substances that have a potential for abuse less than that for schedule I and II drugs, have currently accepted medical use for treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence.¹⁰ Commonly known Schedule III drugs include anabolic steroids, ketamine, and drugs with limited amounts of opiates.¹⁰ Schedule IV substances are accepted for medical use and low potential for abuse as well as limited physical or psychological dependence relative to Schedule III.¹¹ Notable substances in this schedule are the chemicals that are in the brand name drugs Valium®, Ambien®, and Klonopin®.¹¹ Finally, Schedule V drugs are substances that have a low potential for abuse, currently accepted for medical use, and abuse may lead to limited physical or psychological dependence.¹² Common drugs in this category include buprenorphine and compound drugs that include a limit dosage of a narcotic (i.e. codeine) but also have another nonnarcotic medicinal ingredient.¹² Colorado's schedule categorization typically mirrors the scheduling that has occurred at the federal level by the DEA.¹³

National Standards for E-Prescribing

The National Council for Prescription Drug Programs (NCPDP) creates and updates standards for the pharmacy and pharmaceutical industry. The NCPDP SCRIPT Standard was first created in 1997 and is

⁵ Colorado Department of Public Health and Environment (July 2017). *Colorado Prescription Drug Profile*. Retrieved from https://www.colorado.gov/pacific/sites/default/files/PW_ISVP_Colorado%20Rx%20Drug%20Data%20Profile.pdf

⁶ Surescripts (Jan. 2018). *Electronic Prescribing for Controlled Substances*. Retrieved from <http://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-of-controlled-substances/>

⁷ C.R.S. 18-18-203-207

⁸ C.R.S. 18-18-203

⁹ C.R.S. 18-18-204

¹⁰ C.R.S. 18-18-205

¹¹ C.R.S. 18-18-206

¹² C.R.S. 18-18-207

¹³ Diversion Control Division, Drug Enforcement Administration, U.S. Department of Justice (2018). *Controlled Substances Schedules* Retrieved from <https://www.deadiversion.usdoj.gov/schedules/index.html>

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updated at least annually.¹⁴ SCRIPT was established to facilitate the electronic transfer of prescription data between prescribers, pharmacies, payers, and other necessary entities. This data can include new prescriptions, refill requests, cancellations, prior authorizations, medical history, and other transactions.

Legislation in Other States

Eight states (Arizona, Connecticut, Maine, Minnesota, New York, North Carolina, Rhode Island, and Virginia) have required e-prescribing for all controlled substances or just opioids, with at least fourteen others considering such a mandate.¹⁵ New York mandates e-prescribing for all substances as of March 2016, with exceptions for practitioners in certain circumstances.¹⁶ New York is the first state to impose fines and other penalties for failing to comply with the e-prescribe mandate.¹⁶ Minnesota was the first state to require e-prescribing of controlled substances but it does not penalizing for noncompliance.¹⁷ Other states have mandated EPCS in a more targeted manner. In 2017, North Carolina passed legislation requiring e-prescribing of Schedule II and III drugs that are opioids/opioid derivatives or are combination drugs that contain opioids, but with exceptions for certain circumstances.¹⁸ Furthermore, North Carolina's law clarifies that pharmacists are not required to check if an e-prescribe exemption is valid if they receive a prescription through different means.¹⁸

This Legislation

This bill requires podiatrists, dentists, physicians, physician assistants, advance practice nurses, and optometrists to prescribe controlled substances through an electronic prescription (e-prescribe). The prescribers must comply with this requirement by July 1, 2020. The exceptions to the e-prescribing requirement are:

- E-prescribe is not available due to technical or electrical failure.
- The prescription will be dispensed at an out-of-state pharmacy.
- The prescription is being dispensed by the prescriber.
- The prescription has elements that are not supported by the most recent version of the National Council for Prescription Drug Programs SCRIPT Standard.
- The Food and Drug Administration requires the prescription have elements that cannot be met with e-prescribe.
- The prescription is not for a specific patient but allows for the dispensing of a controlled substance under a standing order, approved protocol of drug therapy, collaborative drug management, comprehensive medication management plan, response to a public health emergency, or other circumstances that allow such a prescription.
- The prescription is for a research protocol.
- The prescription is to be administered to a patient in a hospital, nursing care facility, hospice care facility, dialysis treatment clinic, or assisted living residence.
- The prescriber reasonably determines that the patient could not obtain their prescription in a timely manner and that delay would adversely affect the patient's medical condition.

¹⁴ National Council for Prescription Drug Programs (May 2014). *E-Prescribing Fact Sheet*. Retrieved from <https://www.ncpdp.org/NCPDP/media/pdf/EprescribingFactSheet.pdf>

¹⁵ Dr First (2018). *E-Prescribing Mandate Map*. Retrieved from <http://www.drfirst.com/resources/e-prescribing-mandate-map/>

¹⁶ New York State Department of Health. (Dec. 2017). *Electronic Prescribing*. Retrieved from https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/

¹⁷ Minnesota Department of Health (Sept. 2017). *Frequently Asked Questions on E-Prescribing of Controlled Substances*. Retrieved from <http://www.health.state.mn.us/e-health/eprescribing/docs/faqforepcs.pdf>

¹⁸ North Carolina Board of Pharmacy (July 2017). *Guidance to Pharmacists on Implementation of the Strengthen Opioid Misuse Prevention ("STOP") Act*. Retrieved from <http://www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf>

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The bill extends that deadline for compliance until July 1, 2021, if the provider practices in a rural area¹⁹ or is in a practice that consists of a sole provider. The Podiatry Board, Dental Board, Medical Board, Board of Nursing, and Board of Optometry are each to adopt rules that define what constitutes a technical or electrical failure and specify the requirements for a podiatrist who claims an exception to the e-prescribe mandate. Each board must include a question on its license renewal questionnaire that asks whether the provider is complying with the e-prescribe mandate. If the provider does not answer the questionnaire accurately or fails to comply with the e-prescribe mandate, the respective board for that prescriber has the grounds for discipline.

The bill clarifies that if a pharmacist receives a prescription for a controlled substance that is not transmitted electronically they are not required to verify the applicability of one of the aforementioned exceptions. Therefore, they can dispense the prescribed controlled substance to the patient if the prescription is otherwise valid and consistent with the requirements of current laws.

Reasons to Support

Increased e-prescribing of prescription drugs can decrease the possibility of prescribing errors or adverse drug events. Due to this potential benefit of e-prescribing, the U.S. Institute of Medicine in 2006 recommended that by 2010 all providers and pharmacies should have e-prescribing capabilities implemented.²⁰ Beyond ensuring the safety of the patient, the cost-savings of the reduction of adverse drug events can be beneficial for both the consumer and the health care system as a whole. Increased efficiency at the pharmacy and in the provider's office means less effort for the patient if issues arise. Fewer issues and less effort decrease the barriers to prescription drug adherence or having a script filled. E-prescribing of controlled substances (EPCS) can assist in preventing "doctor shopping" by making it easier to see a patient's past prescriptions for controlled substances from other providers. Additionally, EPCS can aid in preventing prescription fraud by eliminating paper prescription pads that can be stolen, altered, or forged.

Supporters

- Anthem Blue Cross Blue Shield
- Colorado Foundation for Universal Health Care
- Colorado Mental Wellness Network

Reasons to Oppose

The cost of implementing and upkeep of a system may present a barrier to practices. While confidentiality protections exist in electronic prescribing systems, there is a small possibility that a breach of these systems could occur and protected patient information could be stolen. Smaller, community, or rural pharmacies may not be ready to accept e-prescriptions and the cost of implementing such a system may be prohibitive. If there is a technological failure or an emergency that inhibits the use of the platform, paper prescription pads will be necessary and with this mandate some offices may not have adequate supplies remaining.

Opponents

- Colorado Medical Society

¹⁹ A rural area is a county with a population less than 3,000 people, a municipality that has a population less than 1,000 that is located more than 10 miles from a municipality that has a population greater than 1,000, or an unincorporated part of a county that is located more than 10 miles from a municipality that has a population greater than 1,000.

²⁰ Roehr, B. (July 2006). Institute of Medicine report strives to reduce medication errors. *BMJ*; 333(7561): 220. doi: 10.1136/bmj.333.7561.220-f

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About this Analysis

This analysis was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. For more information about this summary or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.