Missouri Dental Association

Clarifying Requirements for Missouri Electronic Prescribing for Controlled Substances Updated December 21, 2020

In the September/October 2020 *Focus MDA* issue an article was published titled, *Surprising Ways e-prescribing Can Speed Up Your Workflow*. The article referred to a Missouri Statute that became effective August 2019 and states, "beginning January 1, 2021, no person shall issue any prescription in this state for any Schedule II, III, or IV controlled substance unless the prescription is made by electronic prescription from the person issuing the prescription to a pharmacy."

The article also incorrectly stated, "beginning January 1, 2021, all doctors are *federally* mandated to only use electronic prescriptions for any Schedule II, III or IV controlled substances."

While there is a state statute, the Missouri statute is different from the federal rule with the same start date. The Missouri statute requires the use of e-prescribing for Schedule II-IV controlled substances for all prescribers (but provides exceptions and waivers, which we will discuss following). In contrast, the federal e-prescribing final rule pertains only to Medicare Part D prescriptions per the electronic Real-Time Benefit Tool (RTBT).

The following questions and answers seek to clarify current laws and how Missouri dentists can respond to those.

1) What does the Missouri Electronic Prescribing for Controlled Substances (EPCS) statute require?

The Missouri statute states "beginning January 1, 2021, no person shall issue any prescription in this state for any Schedule II, III, or IV controlled substance unless the prescription is made by electronic prescription from the person issuing the prescription to a pharmacy."

2) What is electronic prescribing or e-prescribing?²

- e-prescribing requires a special software program, connected to a private, secure network that transmits directly to the pharmacy's secure network
- Prescribers access this special software through a computer device such as a desktop computer, laptop, tablet or phone
- e-prescribing is a doctor's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy

3) Does this include fax, phone, scanned or emailed prescriptions?

¹ https://revisor.mo.gov/main/OneSection.aspx?section=195.550 (Missouri statute)

https://www.healthit.gov/faq/what-electronic-prescribing

No. As explained in #2, special software must be used to transmit an electronic prescription. Thus, e-prescribing meets an entirely different set of security regulations set forth by the Drug Enforcement Agency (DEA).³ Fax, phone, scans and emails do not meet these requirements.

4) Is the Missouri statute different from the federal rule with the same start date?

Yes, they are different. The Missouri statute requires the use of e-prescribing only for Schedule II-IV controlled substances for all prescribers. The federal e-prescribing final rule pertains only to Medicare Part D prescriptions per the electronic Real-Time Benefit Tool (RTBT).⁴

5) Are there exceptions to the state statute?

The exceptions outlined in the Missouri statute are as follows:5

- (1) Issued by veterinarians;
- (2) Issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;
- (3) Issued by a practitioner to be dispensed by a pharmacy located outside the state;
- (4) Issued when the prescriber and dispenser are the same entity;
- (5) Issued that include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;
- (6) Issued by a practitioner for a drug that the federal Food and Drug Administration requires the prescription to contain certain elements that are not able to be accomplished with electronic processing;
- (7) Issued by a practitioner allowing for the dispensing of a nonpatient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a nonpatient specific prescription;
- (8) Issued by a practitioner prescribing a drug under a research protocol;
- (9) Issued by practitioners who have received an annual waiver, or a renewal thereof, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the department of health and senior services, due to economic hardship, technological limitations, or other exceptional circumstances demonstrated by the practitioner.⁶
- (10) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subsection, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition; or
- (11) Issued where the patient specifically requests a written prescription.

³ https://ecfr.federalregister.gov/current/title-21/chapter-II/part-1311 (standards), https://ecfr.federalregister.gov/current/title-21/chapter-II/part-1300/section-1300.03 (definitions)

⁴https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f

⁵ https://revisor.mo.gov/main/OneSection.aspx?section=195.550

⁶ https://revisor.mo.gov/main/OneSection.aspx?section=195.550

6) Is there a waiver process?

Yes. Prescribers who meet certain "exceptional circumstances" may be eligible for a waiver delaying implementation of an e-prescribing tool, as noted in #5, Sections 9, 10 and 11 of the Missouri statute.

Beginning December 16, 2020, DHSS/BNDD has established a system to issue waivers for electronic prescribing. Practitioners may:

- Visit the BNDD website at health.mo.gov/safety/bndd
- At the top of the page, click on the link <u>Applications for Electronic Prescribing Waivers</u>
 - o From this page, you will find documents including a copy of the statute, the emergency rule to push back compliance until March 31, 2021, a copy of the emergency waiver and the BNDD rule.
 - o Also from that page is an Application for Prescribing Waiver. The application is one page and asks limited questions. IMPORTANT—The form must be saved and submitted to a specific email address. Applications will be handled in the order in which they are received, to begin being processed January 1, 2021.

The BNDD has stated that during the next year, the waiver questions will be added to the annual application that registrants complete and submit once a year when they get a new registration.

7) Will pharmacies accept paper prescriptions for controlled substances after January 1?

The law calls for pharmacies to follow e-prescribing protocol outside the statute exceptions listed in #5, but it is not possible to accurately predict which pharmacies will and will not fill controlled substance prescriptions that are not transmitted electronically.⁷

One of the exceptions noted in the state statute (Section 1.11) is when a script for a designate controlled substance is, "Issued where the patient specifically requests a written prescription"; another, under Section 2 states, "A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with state and federal laws and regulations."

The MDA has communicated with the Missouri Pharmacy Association to ensure the association communicates with its member pharmacists about their ability to continue to accept paper scripts at the request of the patient, and therefore a universal rejection of paper scripts—and requirement of e-prescribing for these listed controlled substances—is not allowed.

8) Does this law apply to non-controlled substances?

No. The Missouri statute does not pertain to non-controlled substances.⁸ However, if you implement electronic prescribing for some medications, it may be faster and simpler to adapt a

⁷ https://revisor.mo.gov/main/OneSection.aspx?section=195.550

⁸ https://revisor.mo.gov/main/OneSection.aspx?section=195.550

consistent workflow for all prescriptions. The law does not require nor preclude you from using the same technology for non-controlled substances.

9) Should I implement an EPCS program in my practice, what are the basic DEA guidelines for e-prescribing software?

In order for an EPCS system to be considered in compliance with the DEA requirements, it must include:9

- Authentication: The system must enable a recipient to positively verify the signer without direct communication with the signer and subsequently demonstrate to a third party, if needed, that the sender's identity was properly verified
- Nonrepudiation: The system must ensure that strong and substantial evidence is available to the recipient of the sender's identity, sufficient to prevent the sender from successfully denying having sent the data. This criterion includes the ability of a third party to verify the origin of the document
- Message integrity: The system must ensure that the recipient, or a third party, can
 determine whether the contents of the document have been altered during transmission
 or after receipt
- Digital signatures using Public Key Infrastructure (PKI) technology
- Two-factor authentication for providers who sign an EPCS prescription
- EHR/e-prescribing application certification
- ID proof to verify a provider has the authorization to prescribe controlled substances
- Detailed reporting that comprehensively shows compliance and identifies auditable events and any incidents around breaches of security

10) How do I choose an e-prescribing software that adheres to the Missouri statute?

Look for a software vendor that meets the DEA criteria for electronic prescriptions as outlined in #9 and that will personally assist you in the registration and setup process. Additionally, some software companies have e-prescribing services that improve your workflow, such as e-prescribing all medications, integrating with your practice management system and providing accessibility on any computer or device.

Summary

The MDA regrets that in its original publication, it did not provide enough information for members about all aspects of the current statute. The MDA Board of Trustees is further researching this issue, including having discussions with other state healthcare associations, to best advocate for our member dentists. We will provide updates and information as available.

As stated previously, while the statue is in effect, current rules have not been written to apply the statute, and thus the Bureau of Narcotics and Dangerous Drugs has stated that doctors can continue to prescribe as they have previously—including by paper or by e-prescribe, if it is a technology they already have implemented into their practice.

Should a doctor not currently use e-prescribe and/or EPCS technology, but wish to do so, they should inquire with their current dental practice software about built-in technology or software

⁹ https://ecfr.federalregister.gov/current/title-21/chapter-II/part-1311

integration. Members can receive discounts through iCoreConnect, an MDA Perks Program participant that offers iCoreRx which meets EPCS requirements and integrates with Dentrix, Eaglesoft, Open Dental and other practice management systems. The iCoreConnect team can discuss with members what iCoreRx interaction looks like with their particular PM software. You can learn more at icoreconnect.com/modental-about.