

Updated 12/14/2020

## Electronic Prescribing of Controlled Substances

In 2019, the Indiana General Assembly passed [SEA 176](#), which generally requires prescribers to issue prescriptions for controlled substances electronically starting Jan. 1, 2021. This law was meant to coincide with a federal law passed in 2018 that requires prescriptions for covered Medicare Part D drugs under a prescription drug plan for a Schedule II, III, IV, or V controlled substance to be “transmitted by a health care practitioner electronically” starting on Jan. 1, 2021 (unless an exception applies).

**\*\*Federal E-Prescribing Update:** On December 1, 2020, the Centers for Medicare and Medicaid Services (CMS) released a [Final Rule](#) for the 2021 Medicare Physician Payment Schedule and Quality Payment Program that has impacted the enforcement date for the federal Jan. 1, 2021 Medicare e-prescribing requirement discussed above.

Specifically, in the Final Rule, CMS states that the Medicare e-prescribing requirement will still take effect on Jan. 1, 2021, but that enforcement of the requirement will be delayed until Jan. 1, 2022. According to CMS, this means that “prescribers who do not implement the. . . standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until Jan[.]1, 2022 will still be considered compliant with the requirement.”

### Indiana E-Prescribing Mandate for Controlled Substance Prescriptions

Starting Jan. 1, 2021, Indiana law requires a prescriber<sup>1</sup> to issue a prescription for a controlled substance in an electronic format and by electronic transmission from the prescriber to the pharmacy. See [Ind. Code § 25-1-9.3-7](#). However, thanks to the ISMA’s

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<sup>1</sup> “Prescriber” means any of the following:

- “(1) A dentist licensed under [IC 25-14](#).
- “(2) A physician licensed under [IC 25-22.5](#).
- “(3) An advanced practice registered nurse licensed and granted the authority to prescribe under [IC 25-23](#).
- “(4) An optometrist licensed under [IC 25-24](#).
- “(5) A physician assistant licensed under [IC 25-27.5](#) and granted the authority to prescribe by the physician assistant’s supervisory physician in accordance with [IC 25-27.5-5-4](#).
- “(6) A podiatrist licensed under [IC 25-29](#).”

[Ind. Code § 25-1-9.3-5](#).

advocacy efforts, there are several exceptions available under the law, as discussed below. In addition to the statutory exceptions, the law also required the Indiana Board of Pharmacy (Board) to adopt rules establishing a separate process for the filing and granting or denying of waivers from the requirement to issue electronically transmitted prescriptions for controlled substances. The waiver process is also discussed below.

### Exceptions

Under [Indiana Code section 25-1-9.3-8](#), a prescriber may issue a prescription for a controlled substance in a written format, a faxed format, or an oral order if any of the following apply:

- 1) The prescriber cannot transmit an electronically transmitted prescription due to temporary technological or electrical failure.
- 2) The prescriber cannot transmit an electronically transmitted prescription due to the technological inability to issue a prescription electronically, including but not limited to failure to possess the requisite technology.
- 3) The prescriber reasonably determines that it would be impractical for the patient to obtain an electronic prescription in a timely manner and the delay would adversely affect the patient's medical condition.
- 4) The prescriber issues a prescription to be dispensed by a pharmacy located outside Indiana.
- 5) The prescriber and the pharmacist are the same entity.
- 6) The prescriber issues a prescription that meets any of the following:
  - The prescription contains elements that are not supported by the technical standards developed by the National Council for Prescription Drug Programs for electronically transmitted prescriptions (NCPDP SCRIPT).
  - The federal Food and Drug Administration requires the prescription to contain certain elements that cannot be supported in an electronically transmitted prescription.
  - The prescription is a non-patient-specific prescription in response to a public health emergency or another instance allowable under state law and that requires a non-patient-specific prescription under:
    - A standing order;
    - Approved protocol for drug therapy;
    - Collaborative drug management; or
    - Comprehensive medication management.
  - The prescription is issued under a research protocol.
- 7) The prescriber has received a waiver or a renewal of a previously received waiver from the Board of Pharmacy in accordance with Board of Pharmacy rules.

8) The Board of Pharmacy has issued a rule providing for another exception not described above.

### Waivers

Under the state e-prescribing law, the Board of Pharmacy (in consultation with the Medical Licensing Board of Indiana) was charged with promulgating rules that include a process to grant or deny waivers or renewals of waivers from the requirement to issue electronically transmitted prescriptions (see items 7 and 8 above) for controlled substances due to (i) economic hardship; (ii) technological limitations outside the control of the prescriber; or (iii) other circumstances determined by the Board of Pharmacy.

On Dec. 14, 2020, the Board of Pharmacy adopted an Emergency Rule formally establishing the waiver process. In addition to setting forth the circumstances under which a waiver may be granted, the Emergency Rule also includes a statement clarifying that prescribers who avail themselves of one of the statutory exceptions set forth in items 1 through 6 above do not require a waiver (see Section 6 of the Emergency Rule).

The following are the circumstances under which the Board of Pharmacy may grant a prescriber a waiver from the e-prescribing requirement:

- 1) A prescriber who demonstrates electronically transmitted prescriptions for controlled substances creates an economic hardship on behalf of the prescriber.
- 2) A prescriber who demonstrates electronically transmitted prescriptions for controlled substances is not possible due to technological limitations that are not reasonably within the control of the prescriber.
- 3) A prescriber who reasonably determines that it would be impractical for the individual involved to obtain an electronically transmitted prescription for controlled substances in a timely manner and such delay would adversely impact the individual's medical condition.
- 4) A prescription issued by a prescriber under an approved research protocol.
- 5) A prescription issued by a prescriber for an individual who receives hospice care and that is not covered under the hospice benefit under 42 U.S. Code 1395 w-104.
- 6) Prescriptions issued by a prescriber for an individual who is a resident of a nursing facility, as defined in 42 U.S. Code 1396r. Waivers are not required for drug orders.
- 7) A prescription issued by a prescriber for an individual who is confined in a city or county jail.
- 8) A prescription issued by a prescriber that is a compounded prescription containing two (2) or more products.

- 9) A prescription issued by a prescriber that is a compounded infusion prescription containing two (2) or more products.

Prescribers subject to the Indiana e-prescribing mandate can apply for a waiver by visiting the Indiana Board of Pharmacy's website at <https://www.in.gov/pla/4102.htm>.

#### Failure to Comply

A prescriber who fails to comply with the e-prescribing law could be subject to disciplinary action by the board governing the prescriber's license. See [Ind. Code § 25-1-9.3-10](#).

***Note: This communication should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own attorney regarding any specific legal questions you may have concerning your situation.***