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## **Electronic Prescribing of Controlled Substances**

The Indiana electronic prescribing requirement for controlled substances now takes effect on **Jan. 1, 2022**. Continue reading for more information on how the state mandate now aligns with the Medicare e-prescribing requirement, the exceptions available under state law, and the circumstances under which a prescriber may seek a waiver from the state e-prescribing requirement.

### **Background**

In 2019, the Indiana General Assembly passed [SEA 176](#), which generally required 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).

On Dec. 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 impacted the enforcement date for the federal Jan. 1, 2021 Medicare e-prescribing requirement. In the Final Rule, CMS stated that the Medicare e-prescribing requirement would still take effect on Jan. 1, 2021, but that enforcement of the requirement would 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.”

In response to the delayed federal enforcement date, the ISMA successfully advocated for changes to the state’s e-prescribing mandate for controlled substances. Specifically, [HEA 1468 \(2021\)](#), which was signed into law by Governor Eric Holcomb on April 29, 2021, changed the effective date of the state e-prescribing mandate from Jan. 1, 2021 to Jan. 1, 2022. The legislation further amended the statutory exceptions available under the law and clarified information about the waiver process established in the law. The relevant provisions of the law apply retroactively back to Jan. 1, 2021.

***The guidance that follows has been updated to reflect the changes enacted by HEA 1468 (2021).***

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

Starting Jan. 1, 2022, 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 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 in more detail 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 cannot transmit an electronically transmitted prescription due to the inability of the dispensing pharmacy or provider to receive or process an electronically transmitted prescription.
- 4) 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.

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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](#).

- 5) The prescriber issues a prescription to be dispensed by a pharmacy located outside Indiana.
- 6) The prescriber and the pharmacist are the same entity.
- 7) 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.
- 8) 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.
- 9) 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 8 and 9 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. The update to Indiana's e-prescribing statute enacted in HEA 1468 clarifies that prescribers who avail themselves of one of the statutory exceptions set forth in items 1 through 7 above do not require a waiver (see [Ind. Code § 25-1-9.3-9\(d\)](#)).

On Dec. 14, 2020, the Board of Pharmacy adopted an Emergency Rule formally establishing the waiver process. 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 1395w-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 § 25-1-9.3-11](#).

***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.***