

Emergency Rule
LSA Document #20-628(E)

DIGEST

Temporarily adds provisions to establish the process for the filing and granting or denying waivers from the requirement to issue electronically transmitted prescriptions for controlled substances. Statutory authority: [IC 25-1-9.3-9](#). Effective January 1, 2021.

SECTION 1. The definitions of this SECTION apply throughout this document:

- (1) "Prescriber" has the meaning set forth in [IC 25-1-9.3-5](#).
- (2) "Board" is defined as the Indiana board of pharmacy.
- (3) "Controlled substance" has the meaning set forth in [IC 25-1-9.3-3](#).
- (4) "Electronically transmitted" has the meaning set forth in [IC 25-1-9.3-4](#).
- (5) "Prescription" has the meaning set forth in [IC 25-1-9.3-6](#).

SECTION 2. The purpose of this document is to facilitate implementation and compliance with [IC 25-1-9.3-9](#) by establishing procedures for the application, granting, or denying of waivers on the requirement to issue electronically transmitted prescriptions for controlled substances.

SECTION 3. (a) The board shall accept applications for waivers filed in compliance with this document.

(b) To apply for a waiver, a prescriber must apply for a waiver on a form prescribed by the board.

(c) A prescriber may apply for a waiver for each controlled substance registration which requires or qualifies for a waiver.

(d) All waivers will expire on the date the prescriber's controlled substance registration expires.

(e) Upon expiration of the waiver, a prescriber may submit a renewal application form to renew the prescriber's waiver request.

(f) Upon review of an application for a waiver or a renewal application for a waiver, the board may:

- (1) approve the application;**
- (2) deny the application; or**
- (3) request additional information on the application.**

SECTION 4. The board recognizes the following as exceptions to the requirement to issue electronically transmitted prescriptions for controlled substances:

- (1) Prescriber who demonstrates electronically transmitted prescriptions for controlled substances creates an economic hardship on behalf of the prescriber.**
- (2) 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) 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) Prescription issued by a prescriber under an approved research protocol.**
- (5) 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) Prescription issued by a prescriber for an individual who is confined in a city or county jail.**
- (8) Prescription issued by a prescriber that is a compounded prescription containing two (2) or more products.**
- (9) Prescription issued by a prescriber that is a compounded infusion prescription containing two (2) or more products.**
- (10) All other exceptions found in [IC 25-1-9.3](#).**

SECTION 5. (a) A prescriber who has obtained or applied for a waiver under this rule *[document]* is required to indicate on the written or oral prescription:

- (1) the waiver number or indicate that a waiver has been applied for; and
- (2) the prescriber's controlled substance registration (CSR) number and Drug Enforcement Administration (DEA) number.

A prescriber is not required to provide the circumstances for the waiver on the written or oral prescription.

(b) The pharmacist may contact a prescriber for confirmation of the reason or reasons for failing to electronically transmit a prescription for a controlled substance and not including the prescriber's waiver number or that a waiver has been applied for.

(c) The pharmacist shall exercise the pharmacist's professional judgment in the best interest of the patient's health when engaging in the practice of pharmacy, in accordance with [IC 25-26-13-16](#).

SECTION 6. A prescriber who utilizes a statutory exception listed in [IC 25-1-9.3-8\(1\)-\(4\)](#) or (7) *[IC 25-1-9.3-8(1) through IC 25-1-9.3-8(4) or IC 25-1-9.3-8(7)]* is not required to obtain a waiver under this rule *[document]*.

SECTION 7. The application for waiver denials or waiver renewal denials is not subject to administrative review under [IC 4-21.5](#).

SECTION 8. This document expires July 1, 2023.

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