

902 KAR 55:130. Electronic prescribing of controlled substances.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 218A.182

STATUTORY AUTHORITY: KRS 218A.182

NECESSITY, FUNCTION, AND CONFORMITY: In accordance with KRS 218A.182, which takes effect on January 1, 2021, electronic prescribing for all schedule II-V controlled substances is required by each practitioner who issues the prescription to a pharmacy. KRS 218A.182(1) identifies certain prescriptions that are exempt from the electronic prescribing mandate, including a temporary waiver for entities that demonstrate economic hardship, technological limitations, or other exceptional circumstances. KRS 218A.182(3) requires the cabinet to promulgate administrative regulations to implement the electronic prescribing mandate, including enforcement mechanisms, waivers of requirements, and the appropriate penalties for violations. This administrative regulation establishes requirements related to the electronic prescribing of controlled substances (EPCS).

Section 1. Prescription Requirements. (1) Beginning January 1, 2021, a prescription for a controlled substance shall:

(a) Be transmitted electronically to a pharmacy, except as provided by KRS 218A.182(1)(a)-(l); and

(b) Contain the:

1. Full legal name, gender, address, and date of birth of the person for whom the controlled substance is intended;

2. Name, address, Drug Enforcement Administration (DEA) registration number, telephone number, and electronic signature of the prescribing practitioner;

3. Drug name, strength, dosage form, quantity prescribed, specific directions for use, and number of refills (if authorized); and

4. Date upon which the prescription was issued and signed electronically by the prescribing practitioner.

(2) In accordance with KRS 218A.182(2), a pharmacist who receives a written, oral, or faxed prescription for a controlled substance:

(a) Shall not be required to verify that the prescription is subject to an exception provided in KRS 218A.182(1)(a)-(l); and

(b) May dispense a controlled substance pursuant to an otherwise valid written, oral, or fax prescription.

Section 2. Waiver from the EPCS Mandate. (1) A practitioner who is unable to comply with the EPCS mandate may petition the cabinet for a temporary waiver based upon:

(a) Economic hardship;

(b) Technological limitations that are not reasonably within the control of the practitioner; or

(c) Other exceptional circumstances.

(2) A practitioner seeking an initial waiver from the EPCS mandate shall submit a completed Temporary Exemption Form, no later than November 1, 2020.

(3) A request for renewal of an approved waiver shall be submitted on the Temporary Exemption Form at least sixty (60) days in advance of the expiration of the waiver.

(4) A completed Temporary Exemption Form shall include:

(a) The name, practice address, phone number of the practice point of contact, professional license number, and Drug Enforcement Administration (DEA) registration number of the practitioner seeking the waiver;

(b) The practitioner's current electronic prescribing capabilities;

(c) The reason the practitioner is seeking the waiver;
(d) Supporting documentation to justify the reason for the waiver, including the following mandatory documentation:

1. For an economic hardship exemption:

- a. Attestation of the practitioner's current gross annual income; and
- b. At least two (2) quotes documenting the cost to the practitioner of implementing EPCS;

2. For a technological limitation exemption:

a. Documentation showing the:

- (i) Available internet service providers;
- (ii) Speed and bandwidth available from each provider; and
- (iii) Any data caps imposed by the internet service provider; and

b. Documentation showing the minimum technological requirements from at least two (2) electronic prescribing platform vendors;

(e) The anticipated date of compliance with the EPCS mandate; and

(f) If the practitioner is requesting renewal of an approved waiver:

1. Information relating to the practitioner's actions during the previous waiver period to work toward compliance with the EPCS mandate; or

2. An explanation as to why no progress has been made.

(5) Upon consideration of all information provided by the practitioner on a Temporary Exemption Form, the cabinet shall approve or deny the request for an initial or renewal waiver based on the criteria established by this subsection.

(a) If the reason for the waiver is economic hardship and the cost, to the practitioner, of compliance with the EPCS mandate would exceed five (5) percent of the practitioner's gross annual income as self-reported, the cabinet shall approve the request.

(b) If the reason for the waiver is technological limitations and the internet service providers available do not have the technological capabilities required by the electronic prescribing platform, the cabinet shall approve the request.

(c) If the reason for the waiver is other exceptional circumstances, the cabinet shall evaluate the description of the exceptional circumstances on a case-by-case basis.

(d) If the practitioner seeks renewal of a previous waiver, the cabinet shall consider:

1. Updated information as it relates to the practitioner working toward compliance with the EPCS mandate; or

2. The explanation as to why no progress has been made.

(6)(a) The cabinet may approve a waiver, or the renewal of a current waiver, for a specified period of time not to exceed one (1) year from the date of approval.

(b) The cabinet shall not approve more than two (2) renewal waivers.

Section 3. Enforcement. It shall be the duty of the cabinet to enforce the provisions of this administrative regulation.

Section 4. Penalties. (1) The cabinet shall make a referral to the appropriate professional licensing board and impose a fine of \$1,000 against a practitioner for each violation, not to exceed \$2,000 during a twelve (12) month period, in which the cabinet substantiates that the practitioner has:

(a) Falsified information on the Temporary Exemption Form or the form's supporting documentation;

(b) Failed to request a timely waiver in accordance with KRS 218A.182(1)(i) and Section 2(1) to (4) of this administrative regulation and the practitioner is noncompliant with the EPCS mandate; or

(c) Failed to transmit a prescription for a controlled substance electronically to a pharmacy after expiration of the practitioner's waiver, except for prescriptions that meet the exemption criteria of KRS 218A.182(a)-(h) and (j)-(l).

(2) A practitioner may file an appeal with the cabinet within twenty (20) calendar days of the cabinet's written notice of the violation and fine.

(3) If the practitioner requests an administrative hearing, the cabinet shall:

(a) Appoint a hearing officer; and

(b) Proceed pursuant to KRS 13B.050.

(4) The administrative hearing shall be conducted by a hearing officer appointed by the secretary and held in accordance with KRS 13B.080, 13B.090, and 13B.110.

(5) The secretary shall issue a final order in accordance with KRS 13B.120.

Section 5. Incorporation by Reference. (1) The OIG 55:130, "Temporary Exemption Form", October 2019 edition, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (17 Ky.R. 719; eff. 10-14-1990; 20 Ky.R. 1694; eff. 2-2-1994; 22 Ky.R. 358; 725; eff. 10-5-1995; 26 Ky.R. 2320; 27 Ky.R. 962; eff. 10-16-2000; 35 Ky.R. 1894; 2223; eff. 5-1-2009; Crt eff. 7-1-2019; 46 Ky.R. 1760, 2640; eff. 6-30-2020.)