CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT - PROFESSIONAL PRESCRIPTION, ADMINISTRATION AND DISPENSING

Act of Oct. 24, 2018, P.L. 662, No. 96 **Cl. 35**

Session of 2018
No. 2018-96

HB 353

AN ACT

Amending the act of April 14, 1972 (P.L.233, No.64), entitled "An act relating to the manufacture, sale and possession of controlled substances, other drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health, and a newly created Pennsylvania Drug, Device and Cosmetic Board; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing an act," further providing for definitions and for professional prescription, administration, and dispensing.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2(b) of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, is amended by adding a definition to read:

Section 2. Definitions.--* * *

(b) As used in this act:

* * *

"Temporary technological or electrical failure" means any failure of a computer system, application or device, or the loss of electrical power to that system, application or device, or any other service interruption to a computer system, application or device in a manner that reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this act and Federal requirements.

* * *

Section 2. Section 4(3)(vii)1 of the act is amended to read:

Section 4. Schedules of Controlled Substances.--The following schedules include the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated.

* * *

(3) Schedule III--In determining that a substance comes within this schedule, the secretary shall find: a potential for abuse less than the substances listed in Schedules I and II; well documented and currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence or high psychological dependence. The following classes of controlled substances are included in this schedule:

* * *

(vii) Anabolic steroid includes any material, compound, mixture or preparation that includes any of the following or any isomer, ester, salt or derivative of any of the following that acts in the same manner on the human body:

1. Chorionic gonadotropin, **except when used for injection or implantation in cattle or any other nonhuman species and when that use is approved by the Federal Food and Drug Administration.**

* * *

Section 3. Section 11(a) and (b) of the act are amended and the section is amended by adding subsections to read:

Section 11. Professional Prescription, Administration, and Dispensing.--(a) Except when dispensed or administered directly to the patient by a practitioner or his authorized agent, other than a pharmacist, to an ultimate user, no controlled substance in Schedule II[, may] **shall** be dispensed without [the written] **an electronic** prescription of a practitioner, except in [emergency] situations, as prescribed by the secretary by regulation. No prescription for a controlled substance in Schedule II may be refilled. **All electronic prescription applications shall meet the requirements outlined in 21 CFR § 1311.120 (relating to electronic prescription application requirements). The electronic prescription requirement under this subsection shall not apply if the prescription is issued :**

(1) by a veterinarian;

(2) under circumstances when an electronic prescription is not available to be issued or received due to a temporary technological or electrical failure, and, in the instance of a temporary technological failure, a practitioner shall, within seventy-two hours, seek to correct any cause for the failure that is reasonably within his or her control;

(3) by a practitioner and dispensed by a pharmacy located outside this Commonwealth;

(4) by a practitioner who or health care facility that does not have either of the following:

(i) Internet access; or

(ii) an electronic health record system;

(5) by a practitioner treating a patient in an emergency department or a health care facility under circumstances when the practitioner reasonably determines that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;

(6) for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;

(7) for controlled substance compounded prescriptions and prescriptions containing certain elements required by the Federal Food and Drug Administration or any other governmental agency that are not able to be accomplished with electronic prescribing;

(8) pursuant to an established and valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;

(9) in an emergency situation pursuant to Federal or State law and regulations of the department;

(10) under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions; or

(11) for controlled substances that are not required to be reported to the Prescription Drug Monitoring Program system administered by the department.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in Schedule III [or IV, may], **IV or V shall** be dispensed without [a written or oral] **an electronic** prescription **of a practitioner, except in situations, as prescribed by the secretary by regulation.** Such prescriptions shall not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. **All electronic prescription applications shall meet the requirements outlined in 21 CFR § 1311.120. The electronic prescription requirement under this subsection shall not apply if the prescription is issued :**

(1) by a veterinarian;

(2) under circumstances when an electronic prescription is not available due to a temporary technological or electrical failure;

(3) by a practitioner and dispensed by a pharmacy located outside this Commonwealth;

(4) by a practitioner who or health care facility that does not have either of the following:

(i) Internet access; or

(ii) an electronic health record system;

(5) by a practitioner treating a patient in an emergency department or a health care facility u nder circumstances when the practitioner reasonably determines that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition ;

(6) for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;

(7) for controlled substance compounded prescriptions and prescriptions containing certain elements required by the Federal Food and Drug Administration or any other governmental agency that are not able to be accomplished with electronic prescribing;

(8) for a prescription issued pursuant to an established and valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;

(9) for a prescription issued in an emergency situation pursuant to Federal or State law and regulations of the board;

(10) under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions; or

(11) for controlled substances that are not required to be reported to the Prescription Drug Monitoring Program system administered by the department.

(b.1) (1) A practitioner, pharmacy or health care facility that does not meet an exception to the electronic prescribing requirements under subsection (a) or (b) and is unable to timely comply with the electronic prescribing requirements may petition the department for an exemption from the requirements based upon economic hardship, technical limitations or exceptional circumstances.

(2) The department shall adopt rules establishing the form and specific information to be included in a request for an exemption.

(3) The department may approve an exemption for a period of time determined by the department not to exceed one year from the date of approval and may be renewed annually upon request subject to department approval.

(4) The department may grant additional exemptions beyond the exemptions provided for in subsections (a) and (b), subject to the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act."

(b.2) A prescription generated on an electronic system and printed or transmitted via facsimile is not an electronic prescription.

(b.3) (1) A pharmacist who receives a written, oral or faxed prescription shall not be required to verify that the prescription properly falls under one of the exceptions provided in subsections (a) and (b) from the requirement to electronically prescribe. A pharmacist may continue to dispense medications from the otherwise valid written, oral or faxed prescriptions that are consistent with current laws and regulations.

(2) If a pharmacist has a reasonable belief that a patient may be seeking a monitored prescription drug for a purpose other than the treatment of an existing medical condition, the pharmacist shall have the responsibility described in 21 CFR § 1306.04 (relating to purpose of issue of prescription).

(3) A practitioner shall be subject to the responsibilities described in 21 CFR § 1311.102 (relating to practitioner responsibilities).

(b.4) The department shall require the prescription origin to be submitted by dispensers under the authority of the department in compliance with the act of October 27, 2014 (P.L.2911, No.191), known as the "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act."

(b.5) A practitioner who violates subsection (a) or (b) is subject to an administrative penalty of one hundred dollars ($100) for the first through tenth violations and two hundred and fifty dollars ($250) for each subsequent violation after the tenth violation, up to a maximum of five thousand dollars ($5,000) per calendar year. Violations shall reset and shall not carry over to subsequent calendar years. The assessment of an administrative penalty pursuant to this subsection by the department to a practitioner alleged to have violated subsection (a) or (b) shall not be reported by the department to the practitioner's appropriate licensing board and shall not be considered a disciplinary action or need to be reported by the practitioner as a violation to the practitioner's appropriate licensing board. A practitioner may appeal the assessment of an administrative penalty pursuant to 2 Pa.C.S. (relating to administrative law and procedure).

(b.6) The department, within one hundred eighty days of the effective date of this subsection, shall promulgate regulations necessary to implement the requirements of this act.

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Section 4. This act shall take effect in one year.

APPROVED--The 24th day of October, A.D. 2018.

TOM WOLF