AMENDMENTS TO HOUSE BILL NO. 353

Sponsor: SENATOR BAKER

Printer's No. 2066

Amend Bill, page 1, line 10, by inserting after "for"

definitions and for

Amend Bill, page 1, lines 14 through 16, by striking out all of said lines and inserting

Section 1. Section 2 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 Food and Drug Administration.
* * *
Section 3. Section 11(a) and (b) of the act is amended and the section is amended by adding subsections to read:

Amend Bill, page 2, line 3, by inserting a bracket before "emergency"

Amend Bill, page 2, line 3, by inserting a bracket after "emergency"

Amend Bill, page 2, line 7, by inserting after "~~the~~"

All electronic prescription applications shall meet the requirements outlined in 21 C.F.R. § 1311.120 (relating to electronic prescription application requirements).

Amend Bill, page 2, line 12, by inserting after "available"

to be issued or received

Amend Bill, page 2, line 13, by striking out the semicolon after "failure" and inserting

, 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;

Amend Bill, page 2, lines 17 and 18, by striking out "Internet access OR AN ELECTRONIC HEALTH RECORD SYSTEM;" in line 17 and all of line 18 and inserting

either of the following:
(i) Internet access; or
(ii) an electronic health record system;

Amend Bill, page 2, line 26, by striking out the period after "condition" and inserting

~~.~~
(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 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 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.

Amend Bill, page 2, line 29, by inserting a bracket before "or"

Amend Bill, page 2, line 29, by striking out the bracket before the comma after "IV"

Amend Bill, page 2, line 29, by inserting after "may]"

, IV or V

Amend Bill, page 3, line 1, by striking out "emergency"

Amend Bill, page 3, line 7, by inserting after "~~the~~"

All electronic prescription applications shall meet the requirements outlined in 21 C.F.R. § 1311.120.

Amend Bill, page 3, lines 17 and 18, by striking out "Internet access OR AN ELECTRONIC HEALTH RECORD SYSTEM;" in line 17 and all of line 18 and inserting

either of the following:

(i) Internet access; or

(ii) an electronic health record system;

Amend Bill, page 3, line 26, by striking out the period after "condition" and inserting

;

(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 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 C.F.R. § 1306.04 (relating to purpose of issue of prescription).

(3) A practitioner shall be subject to the responsibilities described in 21 C.F.R. § 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.

Amend Bill, page 3, line 28, by striking out "2" and inserting

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