

AMENDMENTS TO HOUSE BILL NO. 353

Sponsor: SENATOR BAKER

Printer's No. 2066

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

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

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

8 Section 2. Definitions.--* * *

9 (b) As used in this act:

10 * * *

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

20 * * *

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

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

26 * * *

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

34 * * *

35 (vii) Anabolic steroid includes any material, compound,
36 mixture or preparation that includes any of the following or any
37 isomer, ester, salt or derivative of any of the following that

1 acts in the same manner on the human body:

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

5 * * *

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

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

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

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

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

16 Amend Bill, page 2, line 12, by inserting after "available"
17 to be issued or received

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

20 , and in the instance of a temporary technological failure, a
21 practitioner shall, within seventy-two hours, seek to correct
22 any cause for the failure that is reasonably within his or her
23 control;

24 Amend Bill, page 2, lines 17 and 18, by striking out
25 "Internet access OR AN ELECTRONIC HEALTH RECORD SYSTEM;" in line
26 17 and all of line 18 and inserting

27 either of the following:

28 (i) Internet access; or

29 (ii) an electronic health record system;

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

32 ;

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

36 (7) for controlled substance compounded prescriptions and
37 prescriptions containing certain elements required by the Food
38 and Drug Administration or any other governmental agency that

1 are not able to be accomplished with electronic prescribing;
2 (8) for a prescription issued pursuant to an established and
3 valid collaborative practice agreement between a practitioner
4 and a pharmacist, a standing order or a drug research protocol;
5 (9) for a prescription issued in an emergency situation
6 pursuant to Federal or State law and regulations of the
7 department;
8 (10) under circumstances where the pharmacy that receives
9 the prescription is not set up to process electronic
10 prescriptions; or
11 (11) for controlled substances that are not required to be
12 reported to the Prescription Drug Monitoring Program system
13 administered by the department.

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

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

18 Amend Bill, page 2, line 29, by inserting after "may]"
19 , IV or V

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

21 Amend Bill, page 3, line 7, by inserting after "the"
22 All electronic prescription applications shall meet the
23 requirements outlined in 21 C.F.R. § 1311.120.

24 Amend Bill, page 3, lines 17 and 18, by striking out
25 "Internet access OR AN ELECTRONIC HEALTH RECORD SYSTEM;" in line
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37 prescriptions containing certain elements required by the Food
38 and Drug Administration or any other governmental agency that
39 are not able to be accomplished with electronic prescribing;

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

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

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

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

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

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

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

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

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

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

41 (2) If a pharmacist has a reasonable belief that a patient
42 may be seeking a monitored prescription drug for a purpose other
43 than the treatment of an existing medical condition, the
44 pharmacist shall have the responsibility described in 21 C.F.R.
45 § 1306.04 (relating to purpose of issue of prescription).

46 (3) A practitioner shall be subject to the responsibilities
47 described in 21 C.F.R. § 1311.102 (relating to practitioner
48 responsibilities).

49 (b.4) The department shall require the prescription origin
50 to be submitted by dispensers under the authority of the
51 department in compliance with the act of October 27, 2014

1 (P.L.2911, No.191), known as the Achieving Better Care by
2 Monitoring All Prescriptions Program (ABC-MAP) Act.

3 (b.5) A practitioner who violates subsection (a) or (b) is
4 subject to an administrative penalty of one hundred dollars
5 (\$100) for the first through tenth violations and two hundred
6 and fifty dollars (\$250) for each subsequent violation after the
7 tenth violation, up to a maximum of five thousand dollars
8 (\$5,000) per calendar year. Violations shall reset and shall not
9 carry over to subsequent calendar years. The assessment of an
10 administrative penalty pursuant to this subsection by the
11 department to a practitioner alleged to have violated subsection
12 (a) or (b) shall not be reported by the department to the
13 practitioner's appropriate licensing board and shall not be
14 considered a disciplinary action or need to be reported by the
15 practitioner as a violation to the practitioner's appropriate
16 licensing board. A practitioner may appeal the assessment of an
17 administrative penalty pursuant to 2 Pa.C.S. (relating to
18 administrative law and procedure).

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

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

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