

HOUSE BILL No. 1735

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25-26-13.

Synopsis: Pharmacy law. Eliminates the following requirements: (1) That prescriptions transmitted to a pharmacist from a practitioner by means other than a written order must be immediately reduced to writing by the pharmacist. (2) That not more than four members of the Indiana board of pharmacy may be from the same political party. (3) That one member of the board must be a practicing hospital pharmacist. Eliminates the requirement that a pharmacist must be actively practicing in order to serve on the board, and requires only that the pharmacist hold a current license to practice in Indiana. Prohibits a person employed as a full-time staff member or as a professor at a school of pharmacy from serving on the board. Requires the governor
(Continued next page)

Effective: July 1, 1999.

Welch, Brown C, Becker

January 26, 1999, read first time and referred to Committee on Public Health.

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Digest Continued

to appoint to the board pharmacists from varied practice settings. Allows a person who has obtained a general educational development (GED) diploma to apply for registration as a pharmacist intern or pharmacist extern. Amends structural requirements concerning security and counter size for pharmacies. Requires that all record keeping requirements for pharmacists be consistent with federal law, including requirements concerning the length of time records must be kept.

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Introduced

First Regular Session 111th General Assembly (1999)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 1998 General Assembly.

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HOUSE BILL No. 1735

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 25-26-13-2 IS AMENDED TO READ AS
2 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 2. As used in this
3 chapter:
4 "Board" means the Indiana board of pharmacy.
5 "Controlled drugs" are those drugs on schedules I through V of the
6 Federal Controlled Substances Act or on schedules I through V of
7 IC 35-48-2.
8 "Dispensing" means issuing one (1) or more doses of a drug in a
9 suitable container with appropriate labeling for subsequent
10 administration to or use by a patient.
11 "Drug" means:
12 (1) articles or substances recognized in the official United States
13 Pharmacopoeia, official National Formulary, official
14 Homeopathic Pharmacopoeia of the United States, or any
15 supplement to any of them;



- 1 (2) articles or substances intended for use in the diagnosis, cure,
2 mitigation, treatment, or prevention of disease in man or animals;
3 (3) articles other than food intended to affect the structure or any
4 function of the body of man or animals; or
5 (4) articles intended for use as a component of any article
6 specified in subdivisions (1) through (3) and devices.

7 "Drug order" means a written order in a hospital or other health care
8 institution for an ultimate user for any drug or device, issued and
9 signed by a practitioner, or an order transmitted by other means of
10 communication from a practitioner, which is immediately reduced to
11 writing by the pharmacist, registered nurse, or other licensed health
12 care practitioner authorized by the hospital or institution. The order
13 shall contain the name and bed number of the patient; the name and
14 strength or size of the drug or device; unless specified by individual
15 institution policy or guideline, the amount to be dispensed either in
16 quantity or days; adequate directions for the proper use of the drug or
17 device when it is administered to the patient; and the name of the
18 prescriber.

19 "Device" means an instrument, apparatus, implement, machine,
20 contrivance, implant, invitro reagent, or other similar or related article
21 including any component part or accessory, which is:

- 22 (1) recognized in the official United States Pharmacopoeia,
23 official National Formulary, or any supplement to them;
24 (2) intended for use in the diagnosis of disease or other conditions
25 or the cure, mitigation, treatment, or prevention of disease in man
26 or other animals; or
27 (3) intended to affect the structure or any function of the body of
28 man or other animals and which does not achieve any of its
29 principal intended purpose through chemical action within or on
30 the body of man or other animals and which is not dependent
31 upon being metabolized for the achievement of any of its
32 principal intended purposes.

33 "Investigational or new drug" means any drug which is limited by
34 state or federal law to use under professional supervision of a
35 practitioner authorized by law to prescribe or administer such drug.

36 "Legend drug" has the meaning set forth in IC 16-18-2-199.

37 "License" and "permit" are interchangeable and mean a written
38 certificate from the Indiana board of pharmacy for the practice of
39 pharmacy or the operation of a pharmacy.

40 "Person" means any individual, partnership, copartnership, firm,
41 company, corporation, association, joint stock company, trust, estate,
42 or municipality, or a legal representative or agent, unless this chapter

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1 expressly provides otherwise.

2 "Practitioner" means a physician licensed under IC 25-22.5, a
3 veterinarian licensed under IC 15-5-1.1, a dentist licensed under
4 IC 25-14, a podiatrist licensed under IC 25-29, or any other person
5 licensed by law to prescribe and administer legend drugs in this state.

6 "Pharmacist" means a person licensed under this chapter.

7 "Pharmacist extern" means a pharmacy student enrolled full-time in
8 an approved school of pharmacy and who is working in a school
9 sponsored, board approved program related to the practice of
10 pharmacy.

11 "Pharmacist intern" means a person who is working to secure
12 additional hours of practice and experience prior to making application
13 for a license to practice as a pharmacist.

14 "Pharmacy" means any facility, department, or other place where
15 prescriptions are filled or compounded and are sold, dispensed, offered,
16 or displayed for sale and which has as its principal purpose the
17 dispensing of drug and health supplies intended for the general health,
18 welfare, and safety of the public, without placing any other activity on
19 a more important level than the practice of pharmacy.

20 "The practice of pharmacy" or "the practice of the profession of
21 pharmacy" ~~or the practice of the "profession of pharmacy"~~ means a
22 **patient oriented health care profession in which pharmacists**
23 **interact and consult with patients and with other health care**
24 **professionals to enhance patients' wellness, prevent illness, and**
25 **optimize outcomes, by accepting responsibility for performing or**
26 **supervising acts, services, and operations including:**

- 27 (1) the offering of or performing of those acts, service operations,
28 or transactions incidental to the interpretation, **evaluation, and**
29 **implementation of a prescription prescriptions or drug orders;**
30 (2) the compounding, **labeling**, administering, dispensing, or
31 selling of drugs and devices, **including radioactive substances**,
32 whether dispensed ~~on~~ **under a practitioner's prescription or**
33 **drug order**, or sold or given directly to the ultimate consumer; ~~or~~
34 (3) the proper and safe storage and distribution of drugs and
35 devices;
36 (4) the maintenance of proper records of **the receipt, storage,**
37 **sale, and dispensing of** drugs and devices;
38 (5) ~~and the responsibility for~~ **counseling, advising, and educating**
39 **patients, patients' care givers, and health care providers and**
40 **professionals**, as necessary, as to the contents, therapeutic values,
41 ~~hazards,~~ **uses, significant problems, risks**, and appropriate
42 manner of use of drugs ~~or~~ **and** devices;



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- 1 **(6) assessing, recording, and reporting events related to the**
 2 **use of drugs or devices;**
 3 **(7) obtaining and maintaining patient profiles, patient drug**
 4 **histories relating to therapy, other pharmacy records, and**
 5 **other patient health records;**
 6 **(8) monitoring, recording, and reporting drug therapy and**
 7 **use;**
 8 **(9) performing drug evaluation, drug utilization review, and**
 9 **drug regimen review;**
 10 **(10) participation in the selection, storage, distribution, and**
 11 **administration of drugs, dietary supplements, and devices;**
 12 **(11) participation in drug or drug related research; and**
 13 **(12) provision of the professional acts, professional decisions,**
 14 **and professional services necessary to maintain all areas of a**
 15 **patient's pharmacy related care.**

16 "Prescription" means a written order **or an order transmitted by**
 17 **other means of communication from a practitioner** to or for an
 18 ultimate user for any drug or device containing the name and address
 19 of the patient, the name and strength or size of the drug or device, the
 20 amount to be dispensed, adequate directions for the proper use of the
 21 drug or device by the patient, and the name of the practitioner issued
 22 and signed by a practitioner. **or an order transmitted by other means of**
 23 **communication from a practitioner and which is immediately reduced**
 24 **to writing by the pharmacist.**

25 "Record" means all papers, letters, memoranda, notes, prescriptions,
 26 drug orders, invoices, statements, patient medication charts or files,
 27 computerized records, or other written indicia, documents or objects
 28 which are used in any way in connection with the purchase, sale, or
 29 handling of any drug or device.

30 "Sale" means every sale and includes:

- 31 (1) manufacturing, processing, transporting, handling, packaging,
 32 or any other production, preparation, or repackaging;
 33 (2) exposure, offer, or any other proffer;
 34 (3) holding, storing, or any other possession;
 35 (4) dispensing, giving, delivering, or any other supplying; and
 36 (5) applying, administering, or any other using.

37 SECTION 2. IC 25-26-13-3 IS AMENDED TO READ AS
 38 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 3. (a) The Indiana
 39 board of pharmacy is created. It shall consist of seven (7) members **not**
 40 **more than four (4) of whom may be from the same political party;**
 41 appointed by the governor for terms of four (4) years. One (1) member
 42 of the board, to represent the general public, must be a resident of this



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1 state who has never been associated with pharmacy in any way other
 2 than as a consumer. Except for the member representing the general
 3 public, the members must be pharmacists in good standing of
 4 recognized experience and ability ~~who are actively engaged in the~~
 5 ~~practice of pharmacy. One (1) member of the board must be a~~
 6 ~~practicing hospital pharmacist. who hold a current license to practice~~
 7 **pharmacy in Indiana and who represent varied practice settings.**
 8 A person ~~connected in any manner with~~ **employed as a full-time staff**
 9 **member or as a professor at** a school of pharmacy may not serve on
 10 the board. If a member leaves the board for any reason before the end
 11 of the member's term, the member's successor shall serve for the
 12 unexpired portion of the term.

13 (b) Not later than ten (10) days after a member's appointment, the
 14 member must subscribe by oath or affirmation to faithfully uphold the
 15 duties of the member's office. If a member fails to qualify as provided,
 16 a new member shall be appointed in the member's place.

17 (c) At the first meeting of each year the board shall elect from
 18 among its members a president and vice president who shall perform
 19 duties and have powers as the board prescribes.

20 (d) The board shall meet at least eight (8) times per year at such
 21 times and places as the board selects. At each meeting the board shall
 22 continue in session from day to day, for not more than five (5) days,
 23 until the business of the meeting is complete. Four (4) members of the
 24 board shall constitute a quorum.

25 (e) Each member of the board is entitled to compensation as
 26 determined by the rules of the budget agency for each day the member
 27 is actually engaged in business of the board, together with necessary
 28 travel and other expenses incurred in the performance of the member's
 29 duties.

30 (f) Approval by a majority of the quorum is required for any action
 31 to be taken by the board.

32 SECTION 3. IC 25-26-13-10 IS AMENDED TO READ AS
 33 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 10. (a) An applicant for
 34 registration as a pharmacist intern or pharmacist extern must furnish
 35 proof satisfactory to the board that ~~he the applicant~~ is a high school
 36 graduate **or has obtained a general educational development (GED)**
 37 **diploma** and is enrolled in a pre-pharmacy or pharmacy curriculum at
 38 an accredited school of pharmacy. The board may require the applicant
 39 to successfully complete an examination prior to registering ~~him the~~
 40 **applicant** as a pharmacist intern or pharmacist extern.

41 (b) A registration issued under subsection (a) of this section is valid
 42 for six (6) years from the date of issuance and may be renewed by the

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1 board for an additional five (5) years for good cause shown.

2 (c) An application for registration or renewal must be accompanied
3 by the appropriate fee.

4 SECTION 4. IC 25-26-13-18 IS AMENDED TO READ AS
5 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 18. (a) To be eligible
6 for issuance of a pharmacy permit, an applicant must show to the
7 satisfaction of the board that:

8 (1) Persons at the location will engage in the bona fide practice of
9 pharmacy. The application must show the number of hours each
10 week, if any, that the pharmacy will be open to the general public.

11 (2) The pharmacy will maintain a sufficient stock of emergency
12 and frequently prescribed drugs and devices as to adequately
13 serve and protect the public health.

14 (3) Except as provided in section 19 of this chapter, a registered
15 pharmacist will be in personal attendance and on duty in the
16 licensed premises at all times when the practice of pharmacy is
17 being conducted and that the pharmacist will be responsible for
18 the lawful conduct of the pharmacy.

19 (4) One (1) pharmacist will have not more than four (4)
20 unlicensed persons under the pharmacist's immediate and
21 personal supervision at any time. As used in this clause,
22 "immediate and personal supervision" means within reasonable
23 visual and vocal distance of the licensed person.

24 (5) The pharmacy will be located ~~in a room~~ separate and apart
25 from any area containing merchandise not offered for sale under
26 the pharmacy permit. ~~which room will~~ **The pharmacy will:**

27 (A) be stationary;

28 (B) ~~have a complete enclosure extending from floor to ceiling~~
29 ~~level enclosing all the products offered for sale under the~~
30 ~~pharmacy permit;~~

31 ~~(C) have entry doors capable of being securely locked to~~
32 ~~prevent be sufficiently secure, either through electronic or~~
33 ~~physical means, or a combination of both, to protect the~~
34 ~~products contained in the pharmacy and to detect and~~
35 ~~deter entry during those times when the pharmacy is closed;~~

36 ~~(D) (C) be well lighted and ventilated with clean and sanitary~~
37 ~~surroundings;~~

38 ~~(E) (D) be equipped with a sink with hot and cold running~~
39 ~~water or some means for heating water, a proper sewage outlet,~~
40 ~~and refrigeration;~~

41 ~~(F) (E) have a prescription compounding counter providing a~~
42 ~~minimum of sixteen (16) square feet of unobstructed working~~

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1 area for one (1) pharmacist or twenty-four (24) square feet of
 2 unobstructed area if two (2) or more pharmacists are on duty
 3 at the same time; and the floor area extending the full length
 4 of the prescription compounding counter shall be clear and
 5 unobstructed for a minimum of thirty (30) inches from the
 6 counter edge; **filling area of sufficient size to permit the**
 7 **practice of pharmacy as practiced at that particular**
 8 **pharmacy; and**

9 ~~(G)~~ (F) have such additional fixtures, facilities, and equipment
 10 as the board requires to enable it to operate properly as a
 11 pharmacy in compliance with federal and state laws and
 12 regulations governing pharmacies.

13 A pharmacy licensed under IC 25-26-10 (before its repeal on July 1,
 14 1977) on June 30, 1977, must comply with the provisions of this clause
 15 before December 31, 1982, unless for good cause shown the board
 16 grants a waiver or otherwise exempts it.

17 (b) Prior to opening a pharmacy after receipt of a pharmacy permit,
 18 the permit holder shall submit the premises to a qualifying inspection
 19 by a representative of the board and shall present a physical inventory
 20 of the drug and all other items in the inventory on the premises.

21 (c) At all times, the wholesale value of the drug inventory on the
 22 licensed items must be at least ten percent (10%) of the wholesale
 23 value of the items in the licensed area.

24 SECTION 5. IC 25-26-13-25 IS AMENDED TO READ AS
 25 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 25. (a) All original
 26 prescriptions, **whether in written or electronic format**, shall be
 27 numbered and ~~filed~~ **maintained** in numerical and chronological order,
 28 or in a manner approved by the board. ~~and preserved for at least two (2)~~
 29 ~~years in the pharmacy~~. The files shall be open for inspection to any
 30 member of the board or its duly authorized agent or representative. **All**
 31 **record keeping requirements must be consistent with federal law,**
 32 **including requirements concerning the length of time records must**
 33 **be kept.**

34 (b) A prescription for any drug, the label of which bears the legend,
 35 "Caution: Federal law prohibits dispensing without prescription", may
 36 not be refilled without written or oral authorization of a licensed
 37 practitioner.

38 (c) The refill record shall include:

- 39 (1) the date of the refill;
 40 (2) the quantity dispensed if other than the original quantity; and
 41 (3) the dispenser's identity on:
 42 (A) the original prescription form; or



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- 1 (B) another board approved, uniformly maintained, readily
 2 retrievable record.
- 3 (d) The original prescription form or the other board approved
 4 record described in subsection (c) must indicate by the number of the
 5 original prescription the following information:
 6 (1) The name and dosage form of the drug.
 7 (2) The date of each refill.
 8 (3) The quantity dispensed.
 9 (4) The identity of the pharmacist who dispensed the refill.
 10 (5) The total number of refills for that prescription.
- 11 (e) A prescription is valid for not more than one (1) year after the
 12 original date of filling.
- 13 (f) A pharmacist may not knowingly dispense a prescription after
 14 the demise of the practitioner, unless in the pharmacist's professional
 15 judgment it is in the best interest of the patient's health.
- 16 (g) A pharmacist may not knowingly dispense a prescription after
 17 the demise of the patient.
- 18 (h) A pharmacist or a pharmacy shall not accept medication that is
 19 returned for resale or redistribution unless the medication:
 20 (1) was dispensed to a patient residing in an institutional facility
 21 (as defined in 856 IAC 1-28-1(a));
 22 (2) was properly stored and securely maintained according to
 23 sound pharmacy practices;
 24 (3) is returned unopened and:
 25 (A) was dispensed in the manufacturer's original:
 26 (i) bulk, multiple dose container with an unbroken tamper
 27 resistant seal; or
 28 (ii) unit dose package; or
 29 (B) was packaged by the dispensing pharmacy in a:
 30 (i) multiple dose blister container; or
 31 (ii) unit dose package;
 32 (4) was dispensed by the same pharmacy as the pharmacy
 33 accepting the return;
 34 (5) is not expired; and
 35 (6) is not a controlled substance (as defined in IC 35-48-1-9),
 36 unless the pharmacy holds a Type II permit (as defined in
 37 IC 25-26-13-17).
- 38 (i) A pharmacist may use the pharmacist's professional judgment as
 39 to whether to accept medication for return under subsection (h).

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