



March 2, 1999

HOUSE BILL No. 1735

DIGEST OF HB 1735 (Updated February 25, 1999 11:06 am - DI 77)

Citations Affected: IC 25-26.

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 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
(Continued next page)

Effective: July 1, 1999.

Welch, Brown C, Becker

January 26, 1999, read first time and referred to Committee on Public Health.
March 1, 1999, amended, reported — Do Pass.

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Digest Continued

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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March 2, 1999

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 "**Counseling**" means **effective communication between a**
9 **pharmacist and a patient concerning the contents, drug to drug**
10 **interactions, route, dosage, form, directions for use, precautions,**
11 **and effective use of a drug or device to improve the therapeutic**
12 **outcome of the patient through the effective use of the drug or**
13 **device.**

14 "Dispensing" means issuing one (1) or more doses of a drug in a
15 suitable container with appropriate labeling for subsequent

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1 administration to or use by a patient.

2 "Drug" means:

3 (1) articles or substances recognized in the official United States
4 Pharmacopoeia, official National Formulary, official
5 Homeopathic Pharmacopoeia of the United States, or any
6 supplement to any of them;

7 (2) articles or substances intended for use in the diagnosis, cure,
8 mitigation, treatment, or prevention of disease in man or animals;

9 (3) articles other than food intended to affect the structure or any
10 function of the body of man or animals; or

11 (4) articles intended for use as a component of any article
12 specified in subdivisions (1) through (3) and devices.

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

25 "**Drug regimen review**" means the retrospective, concurrent,
26 and prospective review by a pharmacist of a patient's drug related
27 history that includes the following areas:

28 (1) Evaluation of prescriptions or drug orders and patient
29 records for drug allergies, rational therapy contradictions,
30 appropriate dose and route of administration, appropriate
31 directions for use, or duplicative therapies.

32 (2) Evaluation of prescriptions or drug orders and patient
33 records for drug-drug, drug-food, drug-disease, and
34 drug-clinical laboratory interactions.

35 (3) Evaluation of prescriptions or drug orders and patient
36 records for adverse drug reactions.

37 (4) Evaluation of prescriptions or drug orders and patient
38 records for proper utilization and optimal therapeutic
39 outcomes.

40 "Drug utilization review" means a program designed to
41 measure and assess on a retrospective and prospective basis the
42 proper use of drugs.



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

4 (1) recognized in the official United States Pharmacopoeia,
5 official National Formulary, or any supplement to them;

6 (2) intended for use in the diagnosis of disease or other conditions
7 or the cure, mitigation, treatment, or prevention of disease in man
8 or other animals; or

9 (3) intended to affect the structure or any function of the body of
10 man or other animals and which does not achieve any of its
11 principal intended purpose through chemical action within or on
12 the body of man or other animals and which is not dependent
13 upon being metabolized for the achievement of any of its
14 principal intended purposes.

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

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

19 "License" and "permit" are interchangeable and mean a written
20 certificate from the Indiana board of pharmacy for the practice of
21 pharmacy or the operation of a pharmacy.

22 "Person" means any individual, partnership, copartnership, firm,
23 company, corporation, association, joint stock company, trust, estate,
24 or municipality, or a legal representative or agent, unless this chapter
25 expressly provides otherwise.

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

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

31 "Pharmacist extern" means a pharmacy student enrolled full-time in
32 an approved school of pharmacy and who is working in a school
33 sponsored, board approved program related to the practice of
34 pharmacy.

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

38 "Pharmacy" means any facility, department, or other place where
39 prescriptions are filled or compounded and are sold, dispensed, offered,
40 or displayed for sale and which has as its principal purpose the
41 dispensing of drug and health supplies intended for the general health,
42 welfare, and safety of the public, without placing any other activity on



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1 a more important level than the practice of pharmacy.

2 "The practice of pharmacy" or "the practice of the profession of
3 pharmacy" or the practice of the "profession of pharmacy" means a
4 **patient oriented health care profession in which pharmacists**
5 **interact and consult with patients and with other health care**
6 **professionals concerning drugs and devices used to enhance**
7 **patients' wellness, prevent illness, and optimize outcomes, by**
8 **accepting responsibility for performing or supervising the**
9 **following acts, services, and operations:**

10 (1) The offering of or performing of those acts, service operations,
11 or transactions incidental to the interpretation, **evaluation, and**
12 **implementation** of a prescription **prescriptions or drug orders.**

13 (2) The compounding, **labeling**, administering, dispensing, or
14 selling of drugs and devices, **including radioactive substances,**
15 whether dispensed ~~on~~ **under a practitioner's prescription or**
16 **drug order**, or sold or given directly to the ultimate consumer. ~~or~~

17 (3) The proper and safe storage and distribution of drugs and
18 devices.

19 (4) The maintenance of proper records of **the receipt, storage,**
20 **sale, and dispensing of** drugs and devices.

21 (5) ~~and the responsibility for~~ **Counseling**, advising, and
22 **educating patients, patients' care givers, and health care**
23 **providers and professionals**, as necessary, as to the contents,
24 therapeutic values, ~~hazards;~~ **uses, significant problems, risks,**
25 and appropriate manner of use of drugs ~~or~~ **and** devices.

26 (6) **Assessing, recording, and reporting events related to the**
27 **use of drugs or devices.**

28 (7) **Obtaining and maintaining patient profiles, patient drug**
29 **histories relating to therapy, other pharmacy records, and**
30 **other patient health records.**

31 (8) **Monitoring, recording, and reporting drug therapy and**
32 **use.**

33 (9) **Performing drug evaluation, drug utilization review, and**
34 **drug regimen review.**

35 (10) **Participation in the selection, storage, and distribution of**
36 **drugs, dietary supplements, and devices.**

37 (11) **Participation in drug or drug related research.**

38 (12) **Provision of the professional acts, professional decisions,**
39 **and professional services necessary to maintain all areas of a**
40 **patient's pharmacy related care as specifically authorized**
41 **under this article.**

42 "Prescription" means a written order **or an order transmitted by**



1 **other means of communication from a practitioner** to or for an
 2 ultimate user for any drug or device containing the name and address
 3 of the patient, the name and strength or size of the drug or device, the
 4 amount to be dispensed, adequate directions for the proper use of the
 5 drug or device by the patient, and the name of the practitioner issued
 6 and signed by a practitioner. ~~or an order transmitted by other means of~~
 7 ~~communication from a practitioner and which is immediately reduced~~
 8 ~~to writing by the pharmacist.~~

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

14 "Sale" means every sale and includes:

- 15 (1) manufacturing, processing, transporting, handling, packaging,
 16 or any other production, preparation, or repackaging;
- 17 (2) exposure, offer, or any other proffer;
- 18 (3) holding, storing, or any other possession;
- 19 (4) dispensing, giving, delivering, or any other supplying; and
- 20 (5) applying, administering, or any other using.

21 SECTION 2. IC 25-26-13-3 IS AMENDED TO READ AS
 22 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 3. (a) The Indiana
 23 board of pharmacy is created. It shall consist of seven (7) members ~~not~~
 24 ~~more than four (4) of whom may be from the same political party;~~
 25 appointed by the governor for terms of four (4) years. One (1) member
 26 of the board, to represent the general public, must be a resident of this
 27 state who has never been associated with pharmacy in any way other
 28 than as a consumer. Except for the member representing the general
 29 public, the members must be pharmacists in good standing of
 30 recognized experience and ability ~~who are actively engaged in the~~
 31 ~~practice of pharmacy. One (1) member of the board must be a~~
 32 ~~practicing hospital pharmacist. who hold a current license to practice~~
 33 **pharmacy in Indiana and who represent varied practice settings.**
 34 A person ~~connected in any manner with~~ **employed as a full-time staff**
 35 **member or as a professor at** a school of pharmacy may not serve on
 36 the board. If a member leaves the board for any reason before the end
 37 of the member's term, the member's successor shall serve for the
 38 unexpired portion of the term.

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



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

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

9 (e) Each member of the board is entitled to compensation as
 10 determined by the rules of the budget agency for each day the member
 11 is actually engaged in business of the board, together with necessary
 12 travel and other expenses incurred in the performance of the member's
 13 duties.

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

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

25 (b) A registration issued under subsection (a) of this section is valid
 26 for six (6) years from the date of issuance and may be renewed by the
 27 board for an additional five (5) years for good cause shown.

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

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

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

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

40 (3) Except as provided in section 19 of this chapter, a registered
 41 pharmacist will be in personal attendance and on duty in the
 42 licensed premises at all times when the practice of pharmacy is

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1 being conducted and that the pharmacist will be responsible for
2 the lawful conduct of the pharmacy.

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

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

11 (A) be stationary;

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

15 ~~(C)~~ **have entry doors capable of being securely locked to**
16 **prevent be sufficiently secure, either through electronic or**
17 **physical means, or a combination of both, to protect the**
18 **products contained in the pharmacy and to detect and**
19 **deter** entry during those times when the pharmacy is closed;

20 ~~(D)~~ (C) be well lighted and ventilated with clean and sanitary
21 surroundings;

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

25 ~~(F)~~ (E) have a prescription compounding counter providing a
26 minimum of sixteen (16) square feet of unobstructed working
27 area for one (1) pharmacist or twenty-four (24) square feet of
28 unobstructed area if two (2) or more pharmacists are on duty
29 at the same time; and the floor area extending the full length
30 of the prescription compounding counter shall be clear and
31 unobstructed for a minimum of thirty (30) inches from the
32 counter edge; **filling area of sufficient size to permit the**
33 **practice of pharmacy as practiced at that particular**
34 **pharmacy; and**

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

39 A pharmacy licensed under IC 25-26-10 (before its repeal on July 1,
40 1977) on June 30, 1977, must comply with the provisions of this clause
41 before December 31, 1982, unless for good cause shown the board
42 grants a waiver or otherwise exempts it.

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

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

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

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

22 (c) The refill record shall include:

- 23 (1) the date of the refill;
 24 (2) the quantity dispensed if other than the original quantity; and
 25 (3) the dispenser's identity on:
 26 (A) the original prescription form; or
 27 (B) another board approved, uniformly maintained, readily
 28 retrievable record.

29 (d) The original prescription form or the other board approved
 30 record described in subsection (c) must indicate by the number of the
 31 original prescription the following information:

- 32 (1) The name and dosage form of the drug.
 33 (2) The date of each refill.
 34 (3) The quantity dispensed.
 35 (4) The identity of the pharmacist who dispensed the refill.
 36 (5) The total number of refills for that prescription.

37 (e) A prescription is valid for not more than one (1) year after the
 38 original date of filling.

39 (f) A pharmacist may not knowingly dispense a prescription after
 40 the demise of the practitioner, unless in the pharmacist's professional
 41 judgment it is in the best interest of the patient's health.

42 (g) A pharmacist may not knowingly dispense a prescription after

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- 1 the demise of the patient.
- 2 (h) A pharmacist or a pharmacy shall not accept medication that is
- 3 returned for resale or redistribution unless the medication:
- 4 (1) was dispensed to a patient residing in an institutional facility
- 5 (as defined in 856 IAC 1-28-1(a));
- 6 (2) was properly stored and securely maintained according to
- 7 sound pharmacy practices;
- 8 (3) is returned unopened and:
- 9 (A) was dispensed in the manufacturer's original:
- 10 (i) bulk, multiple dose container with an unbroken tamper
- 11 resistant seal; or
- 12 (ii) unit dose package; or
- 13 (B) was packaged by the dispensing pharmacy in a:
- 14 (i) multiple dose blister container; or
- 15 (ii) unit dose package;
- 16 (4) was dispensed by the same pharmacy as the pharmacy
- 17 accepting the return;
- 18 (5) is not expired; and
- 19 (6) is not a controlled substance (as defined in IC 35-48-1-9),
- 20 unless the pharmacy holds a Type II permit (as defined in
- 21 IC 25-26-13-17).
- 22 (i) A pharmacist may use the pharmacist's professional judgment as
- 23 to whether to accept medication for return under subsection (h).

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1735, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, between lines 7 and 8, begin a new paragraph and insert:

""Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device."

Page 2, between lines 18 and 19, begin a new paragraph and insert:

""Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

- (1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.
- (2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.
- (3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.
- (4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs."

Page 3, line 24, after "professionals" insert **"concerning drugs and devices used"**.

Page 3, line 26, after "supervising" insert **"the following"**.

Page 3, line 26, delete "including".

Page 3, line 27, delete "the" and insert "The".

Page 3, line 29, delete ";" and insert ".".

Page 3, line 30, delete "the" and insert "The".

Page 3, line 33, delete ";" and insert ".".

Page 3, line 34, delete "the" and insert "The".

Page 3, line 35, delete ";" and insert ".".

Page 3, line 36, before "maintenance" delete "the" and insert "The".

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Page 3, line 37, delete ";" and insert ".".
Page 3, line 38, delete "counseling" and insert "**Counseling**".
Page 3, line 42, delete ";" and insert ".".
Page 4, line 1, delete "assessing" and insert "**Assessing**".
Page 4, line 2, delete ";" and insert ".".
Page 4, line 3, delete "obtaining" and insert "**Obtaining**".
Page 4, line 5, delete ";" and insert ".".
Page 4, line 6, delete "monitoring" and insert "**Monitoring**".
Page 4, line 7, delete ";" and insert ".".
Page 4, line 8, delete "performing" and insert "**Performing**".
Page 4, line 9, delete ";" and insert ".".
Page 4, line 10, delete "participation" and insert "**Participation**".
Page 4, line 10, before "distribution" insert "**and**".
Page 4, line 10, after "distribution" delete ", **and**".
Page 4, line 11, delete "administration".
Page 4, line 11, delete "; and" and insert ".".
Page 4, line 12, delete "participation" and insert "**Participation**".
Page 4, line 12, delete "; and" and insert ".".
Page 4, line 13, delete "provision" and insert "**Provision**".
Page 4, line 15, after "care" insert "**as specifically authorized under this article**".

and when so amended that said bill do pass.

(Reference is to HB 1735 as introduced.)

BROWN C, Chair

Committee Vote: yeas 11, nays 0.

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