

TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule
LSA Document #03-154

DIGEST

Amends 856 IAC 1-33-1, 856 IAC 1-33-2, and 856 IAC 1-33-4 concerning patient counseling. Effective 30 days after filing with the secretary of state.

856 IAC 1-33-1
856 IAC 1-33-2
856 IAC 1-33-4

SECTION 1. 856 IAC 1-33-1 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-33-1 Definitions

Authority: IC 25-26-13-4

Affected: IC 25-26-13-4

Sec. 1. ~~As used in~~ **For purposes of this rule, the following definitions apply throughout this rule:**

(1) "Alternative forms of patient information" includes, but is not limited to, written information leaflets, pictograms labels, video programs, or information generated by electronic data processing equipment.

(2) "Clerkship" means:

(A) a pharmacy student in the student's final year of pharmacy school engaged in a school sponsored, board approved program related to the practice of pharmacy; or

(B) an individual who has a professional degree from a school of pharmacy located outside the United States and Canada and who is working to secure additional hours of practice and experience.

(3) "Counseling" means effective communication by a pharmacist, of information between a pharmacist or pharmacist intern/extern engaged in clerkship and a patient or the patient's designee in order to improve therapeutic outcomes by maximizing the proper use of prescription medications and devices.

(4) "Not practicable" means patient variables including, but not limited to, the absence of the patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier. The term does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume.

(Indiana Board of Pharmacy; 856 IAC 1-33-1; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

SECTION 2. 856 IAC 1-33-2 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-33-2 Patient counseling requirements

Authority: IC 25-26-13-4

Affected: IC 25-26-13-16

Sec. 2. **(a) The qualifying pharmacist shall be responsible for developing, implementing, and enforcing policies and procedures to ensure that patients receive appropriate counseling.**

~~(a)~~ **(b) Upon the receipt of a prescription or upon the subsequent refilling of a prescription, and following a review of the patient's prescription medication profile, the pharmacist shall be responsible for the initiation of an offer face-to-face counseling to discuss matters (counsel) which, in the pharmacist's professional judgment, that are significant to optimizing drug therapy. Depending upon the situation, and in the pharmacist's professional judgment, these matters may include, but are not necessarily limited to, the following:**

- (1) The name and description of the medicine.
- (2) The route, dosage form, dosage, route of administration, and duration of drug therapy.
- (3) Special directions and precautions.
- (4) Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
- (5) Techniques for self-monitoring drug therapy.
- (6) Proper storage.
- (7) Prescription refill information.
- (8) Action to be taken in the event of a missed dose.

~~(b)~~ (c) Counseling shall be in person, whenever practicable, or through access to a telephone service ~~which that~~ is toll-free for long distance calls, and be held with the patient, the patient's caregiver, or the patient's representative.

~~(c)~~ (d) **When used in place of face-to-face counseling**, alternative forms of patient information may be used to supplement verbal counseling when appropriate. Examples include, written information leaflets, pictogram labels, and video programs. Nothing in this subsection shall be construed to mean that supplements may be a substitute for verbal counseling when verbal counseling is practicable. **shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call.**

(d) Nothing in this rule shall be construed as requiring a pharmacist to provide counseling when a patient refuses the offer to counsel.

(e) **A combination of face-to-face counseling and alternative forms of counseling is required.**

(f) **Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.**

(g) **A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation must be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.** (*Indiana Board of Pharmacy; 856 IAC 1-33-2; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330*)

SECTION 3. 856 IAC 1-33-4 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-33-4 Institutional patient exception

Authority: IC 25-26-13-4

Affected: IC 25-26-13-4

Sec. 4. The requirements for patient counseling, as described in this rule, shall not apply to patients residing in institutional facilities in Indiana as defined under ~~856 IAC 1-28-1(a)~~ **856 IAC 1-28.1-1(6)**. (*Indiana Board of Pharmacy; 856 IAC 1-33-4; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1177; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330*)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on October 15, 2003 at 10:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room A, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on proposed amendments to revise the requirements for patient counseling. Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W066 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Lisa R. Hayes
Executive Director
Health Professions Bureau