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TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule

LSA Document #03-326

DIGEST

Amends 856 IAC 1-33-1 to revise the definition of counseling and to add the definitions of offer and patient. Adds 856 IAC 1-33-1.5 to establish the requirements for an offer. Amends 856 IAC 1-33-2 to revise the requirements for patient counseling. Amends 856 IAC 1-33-4 to revise the institutional patient exception. Adds 856 IAC 1-33-5 to establish the grounds for discipline for patient counseling violations. Effective 30 days after filing with the secretary of state.

856 IAC 1-33-1

856 IAC 1-33-4

856 IAC 1-33-1.5

856 IAC 1-33-5

856 IAC 1-33-2

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~~ **The following definitions apply throughout** this rule:

(1) "Counseling" means ~~effective~~ **appropriate** communication, by a pharmacist, **to a patient, as defined in subdivision (3),** of information ~~in order to improve for the purpose of improving~~ therapeutic outcomes by maximizing the proper use of ~~prescription medications~~ **drugs and devices dispensed pursuant to prescriptions.**

(2) "Offer" means a statement that is verbal or, only if necessary for an individual patient, nonverbal, for example, printed or written, that clearly informs the patient that a pharmacist is available, at the time the offer is made, to counsel the patient, including, but not limited to, giving information to or answering questions, or both, from the patient.

(3) "Patient" means the following:

(A) The individual for whom a prescription was issued.

(B) The caregiver of the individual for whom a prescription was issued.

(C) The agent of the individual for whom a prescription was issued.

(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 1-33-1.5 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-33-1.5 Offer requirements

Authority: IC 25-26-13-4

Affected: IC 25-26-13-10

Sec. 1.5. (a) The following can satisfy an offer:

(1) A pharmacist counseling the patient.

(2) A pharmacist intern/extern registered under IC 25-26-13-10 if:

(A) permitted by the pharmacist; and

(B) the counseling by the pharmacist intern/extern is followed by a bona fide offer for the pharmacist to counsel the patient and if the patient or patient's representative desires such counseling.

(3) A written notice containing the pharmacy's phone number and a bona fide offer when:

- (A) a patient is not present and has not authorized the giving of information to another; or
 - (B) the drug or device is delivered by the United States Postal Service, parcel delivery, or hand delivery.
- (4) Any personnel in the prescription department, as defined in 856 IAC 1-13-3(b)(3), making an offer to counsel, as defined in section 1(2) of this rule.

(b) The following cannot satisfy an offer:

- (1) Making an offer for the patient to ask questions.
 - (2) Any other method that serves to shift the responsibility from the pharmacists to the patient for initiating the counseling or for selecting the informational content of the counseling.
 - (3) Relaying information through an intermediary, unless needed for translations, hearing impaired, or other situation beyond the control of the pharmacist.
 - (4) Using signs or other types of written notices or written information given to the patient with each drug dispensed.
- (Indiana Board of Pharmacy; 856 IAC 1-33-1.5)*

SECTION 3. 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) 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, **as set forth in section 1.5(a) of this rule**, to ~~discuss matters~~ counsel ~~which~~, **the patient on matters that**, in the pharmacist's professional judgment, are significant to optimizing drug therapy. Depending upon the situation, 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) 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) 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.

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

(e) Requesting or accepting, or both, a waiver for counseling for all prescriptions both present and future is not permitted. An offer must be made with each prescription-dispensing visit.

(f) The patient's declining of counseling must be documented in either written or electronic format. The required documentation may be on the same form as or with another pharmacy-related authorization, only if it is clear to the patient that the documentation form also contains the patient's intent to decline (waive) counseling. The documentation subject to this section shall be retained in the pharmacy licensed area or in a secure area under the pharmacy's control, which is readily available for inspection, for a period of not less than two (2) years. *(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 4. 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 25-1-9

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*)

SECTION 5. 856 IAC 1-33-5 IS ADDED TO READ AS FOLLOWS:

856 IAC 1-33-5 Patient counseling violations

Authority: IC 25-26-13-4

Affected: IC 25-26-13-4

Sec. 5. Violation of this rule shall be grounds for discipline by the board under either IC 25-1-9 or 856 IAC 1-20. (*Indiana Board of Pharmacy; 856 IAC 1-33-5*)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on April 12, 2004 at 10:00 a.m., at the Health Professions Bureau, Indiana Government Center-South, 402 West Washington Street, Conference Center Room W064, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on proposed amendments to revise the definition of counseling and to add the definitions of offer and patient, to revise the requirements for patient counseling, to revise the institutional patient exception, to establish the requirements for an offer, and to establish the grounds for discipline for patient counseling violations. 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