

201 KAR 2:210. Patient records and patient counseling.

RELATES TO: KRS 315.191(1), (5), (6), 42 C.F.R. Part 456

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (5), 42 C.F.R. Part 456

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1), (56), 42 CFR Part 456 mandates that pharmacists implement drug utilization reviews and provide patient counseling to those recipients of health-care benefits for which federal funds are allocated. This administrative regulation provides for this mechanism and broadens its magnitude by rendering this valuable service available to all Kentucky's citizenry, equitably.

Section 1. Patient Records. (1)(a) A patient record system shall, with the exercise of professional judgment, be maintained by a pharmacy for patients for whom prescriptive drug orders are dispensed at that pharmacy location.

(b) A pharmacist, with the exercise of professional judgment, shall establish a procedure for obtaining, recording, and maintaining information required for a patient record.

(c) A pharmacist, or his designee, shall obtain, record, and maintain the information for a patient record.

(d) A patient record shall:

1. Be readily retrievable by manual or electronic means;
2. Enable the pharmacist to identify previously dispensed drugs and known disease conditions;
3. Enable the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescriptive drug order; and
4. Be maintained for not less than 180 days from the date of the last entry.

(2) A patient record shall include:

- (a) Full name of patient for whom the drug is intended;
- (b) Address and telephone number of the patient;
- (c) Patient's age or date of birth;
- (d) Patient's gender;
- (e) A list of all prescriptions obtained by the patient at that pharmacy location for the past twelve (12) months by:
 1. Prescription number;
 2. Name and strength of medication;
 3. Quantity;
 4. Date received;
 5. Identity of prescriber; and
 6. Comments or other information as may be relevant to the specific patient or drug; and
- (f) Individual medical history if significant, including known disease states, known allergies, idiosyncrasies, reactions or conditions relating to prospective drug use and drug regimen reviews.

Section 2. Patient Counseling. (1) The pharmacist shall offer to counsel a patient on matters which he believes will optimize drug therapy with each patient or caregiver:

(a) Upon the presentation of an original prescription order; and

(b) On refill prescriptions, as professional discretion dictates.

(2)(a) The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.

(b) If deemed impractical or inappropriate, the offer to counsel may be made:

1. By the pharmacist designee;
2. In written communication;

3. By telephone through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange; or

4. In another manner determined by the pharmacist to be appropriate.

(3) Patient counseling shall be:

(a) In person when practical; or

(b) With reasonable effort, by telephone.

(4) The pharmacist shall include the following elements of patient counseling that he has determined are appropriate:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of therapy;

(c) Special directions and precautions;

(d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;

(e) Techniques for self-monitoring of drug therapy;

(f) Proper storage;

(g) Refill information;

(h) Action to be taken in event of a missed dose;

(i) His comments relevant to the individual's therapy; and

(j) Any other information peculiar to the specific patient or drug.

(5) If a pharmacist determines that it is appropriate, he may supplement patient counseling with additional forms of patient information, such as:

(a) Written or printed information leaflets;

(b) Pictogram labels; and

(c) Video programs.

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

Section 3. Confidentiality. (1) A patient record shall be held in confidence.

(2) It shall be communicated or released:

(a) To the patient;

(b) As the patient directs; or

(c) As prudent, professional discretion dictates.

Section 4. Prospective Drug Use Review. (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.

(2) It shall include an assessment of a patient's drug therapy and the prescription order.

(3) A prospective drug use review shall include a review by the pharmacist of the following:

(a) Known allergies;

(b) Rationale for use;

(c) Proper dose, route of administration, and directions;

(d) Synergism with currently employed modalities;

(e) Interaction or adverse reaction with applicable:

1. Drugs;

2. Foods; or

3. Known disease states;

(f) Proper utilization for optimum therapeutic outcomes; and

(g) Clinical misuse or abuse.

Section 5. Documentation of Counseling. (1) A record that the patient refused the pharmacist's

offer to counsel shall be maintained for one (1) year.

(2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:

(a) The offer to counsel, as required in Section 2 of this administrative regulation, was made and accepted; and

(b) The counseling was provided.

Section 6. The provisions of this administrative regulation shall not apply:

(1) To inpatients of a hospital or institution, if other licensed health-care professionals are authorized to administer the drugs; or

(2) If there is documentation that the patient or caregiver refused consultation. (19 Ky.R. 1694; eff. 2-17-1993; Crt eff. 4-17-2019.)