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CHAPTER 9

PATIENT COUNSELING AND PROSPECTIVE DRUG USE REVIEW REGULATIONS

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CHAPTER 9

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Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Definitions.

(a) "Reasonable effort" means that degree of effort which a pharmacist of ordinary prudence and accepted professional duty would exercise in similar circumstances.

Section 3. Patient Profile Records.

(a) A profile record shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The profile record shall provide for the immediate retrieval of information of previously dispensed drugs and devices. The pharmacist shall be responsible for maintaining the following patient information for each new prescription:

- (i) Full name of the patient for whom the drug is intended;
- (ii) Address and telephone number of the patient;
- (iii) Patient's age or date of birth and gender;

(iv) A list of all prescription drug orders obtained at the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, strength of the drug, the quantity, date received and the name of the prescriber;

(v) Pharmacist comments relevant to the individual's drug therapy, including any information peculiar to the specific patient or drug.

(b) Each pharmacist or their agent shall make a reasonable effort to obtain the individual's medical history, any known allergies, drug reactions, idiosyncrasies and chronic conditions or disease states of the patient and the identity of any other medications including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

Section 4. Prospective Drug Use Review.

(a) A pharmacist shall review the patient record and each prescription drug order presented for dispensing by identifying:

- (i) Overutilization or underutilization;
- (ii) Therapeutic duplication;
- (iii) Drug-disease contraindications;
- (iv) Drug-drug contraindications;

- (v) Incorrect drug dosage or duration of drug treatment;
- (vi) Drug-allergy interactions; and
- (vii) Clinical abuse/misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The pharmacist shall document those steps taken.

Section 5. Patient Counseling.

(a) Upon receipt of a prescription and following a review of the patient's record, a pharmacist or a pharmacy intern shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of the patient. Non-resident pharmacies/pharmacists are not exempt from this regulation. Such elements may include the following:

- (i) Name and description of the drug;
- (ii) Dosage form, dose, route of administration, and duration of drug therapy;
- (iii) Intended use of the drug and expected action;
- (iv) Special directions and precautions for preparation, administration, and use by the patient;
- (v) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur;
- (vi) Techniques for self-monitoring drug therapy;
- (vii) Proper storage;
- (viii) Prescription refill information;
- (ix) Action to be taken in the event of a missed dose; and
- (x) Comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug or refusal of counseling.

(b) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation. Every refusal shall be documented by the pharmacist.

(c) Information obtained may be recorded in the patient's manual or electronic profile, in the prescription signature log or in any other system of records and may be considered by the pharmacist in the exercise of professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the offer to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

Section 6. Retrospective Drug Use Review

- (a) “Retrospective drug use review” means the monitoring for:
- (i) Therapeutic appropriateness;
 - (ii) Over-utilization and under-utilization;
 - (iii) Appropriate use of generic products;
 - (iv) Therapeutic duplication;
 - (v) Drug-disease contraindications;
 - (vi) Drug-drug interactions;
 - (vii) Incorrect dosage;
 - (viii) Duration of drug treatment; and
 - (ix) Clinical abuse/misuse after the drug has been dispensed.