

Legislation and regulations affecting pharmacists' practice guidelines vary according to the legislative styles and practices of each state. The following information highlights the legislative elements that can expand the scope of pharmacy practice to include collaborative drug therapy agreements that can be used to increase access to emergency contraceptive pills (ECPs).

Easy access to services is essential to maximizing the public health impact of emergency contraception. Legislation and regulations that enable community pharmacists to initiate therapy are essential to achieving this goal. As the following information indicates, the wording and content of revised statutes and regulations must be carefully considered if their purpose is to be achieved.

Collaborative Drug Therapy

Adding collaborative drug therapy to the pharmacist's scope of practice is performed on a state level by revising the definition of the practice of pharmacy. The following information discusses the wording and content necessary to expand access to ECPs through collaborative drug therapy agreements.

Model Legislation

Statute

The statute can be revised to define the practice of pharmacy as including the practice of and responsibility for:

“initiating, modifying, or discontinuing drug therapy in accordance with written protocols or agreements established and approved by a practitioner authorized to prescribe drugs”

OR

“drug therapy management pursuant to a written protocol or agreement between a pharmacist and practitioner.”

In the latter case, “drug therapy management” is defined as initiating, modifying, or discontinuing drug therapy.

Practice Act

Both of the definitions above can be bolstered with a statement concerning “monitoring drug therapy” in the practice act. This term may be defined in statute or regulation to include *collecting and reviewing patient drug histories, conducting clinical assessments, and ordering and evaluating laboratory tests.*

Example:

"Practice of pharmacy" includes the practice of and responsibility for: interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; **the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs;** the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

Clearly, the goal is a general definition that is inclusive. Additions that incorporate the following elements **should be avoided**:

Additions That Create Barriers

- Limitation to specific practice sites.
- Ties to therapeutic substitution activities.
- Approval on a patient-by-patient basis.
- Certification as a pharmacist practitioner.
- Approval beyond the authorizing practitioner.

These additions institute barriers that run counter to the goal of increasing ECP access through collaborative drug therapy agreements.

Regulation

A regulation promulgated by the State Board of Pharmacy provides a means of defining the content of collaborative drug therapy protocols or agreements and of quality assurance. It is consistent with the Board's role to regulate the practice of pharmacy and ensure public health and safety concerning the use of drugs.

Collaborative drug therapy regulations include the following:

- A statement identifying the prescribing practitioner(s) and the pharmacist(s) who are participating in the protocol or agreement.
- A statement concerning the type of drug therapy management decisions that the pharmacist is allowed to make. This is defined through two statements: (1) a detailed statement about the diseases, drugs, or drug categories involved; and (2) a detailed statement about the methods, procedures, decision criteria, and plan the pharmacist is to follow.
- A statement describing the manner in which the pharmacist's activities are documented and the method of communication, feedback, and reporting to the authorizing practitioner.
- A statement outlining how the practitioner will supervise the pharmacist(s) and perform quality assurance of the drug decision-making process.
- A statement regarding the time period for the protocol or agreement (usually one to two years).

Other issues also may be addressed in the regulation. These include identification of any specific additional pharmacist training, a private area for patient consultation, identification of the patient population to be served, and the reporting of adverse events.

The use of collaborative drug therapy to provide public health services such as emergency contraception, immunizations, and smoking cessation are different than many other collaborative approaches in one important respect: in these situations, there may be no pre-existing authorized prescriber relationship. The pharmacist may be the patient's entry point to care. These services are fundamentally different than the traditional collaborative relationships where authorized prescribers and pharmacists care for the acutely and chronically sick individuals. The agreements and protocols for public health services need to include patient referral, when indicated.

An illustration of legislation on collaborative drug therapy management is found in the regulation below. For purposes of discussion, sections that are “disabling,” or potentially so, in terms of emergency contraception services are printed in bold, and explanatory notes and commentary have been added in italics.

Oregon Administrative Rules
Chapter 855, Division 041 – Board of Pharmacy
Collaborative Drug Therapy Management

855-041-0400

- (1) A pharmacist shall engage in collaborative drug therapy management only under a written protocol that includes:
- (a) The identification, either by name or by description, of the participating pharmacist(s);
 - (b) The identification, by name, of the participating practitioner(s);
 - (c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;
 - (d) A detailed description of the collaborative role the pharmacist(s) shall play, including but not limited to:
 - (A) Written protocol for specific drugs pursuant to which the pharmacist will base drug therapy management decisions for an individual patient;**
 - *Each agreement for collaborative drug therapy management must be made in advance for each **individual** patient [as referenced in Sect (2) of this rule] for specific drugs and filed with the Board of Pharmacy.*
 - *Emergency contraceptive pill (ECP) patients, by the inherent unpredictability and emergent nature of their needs, would not find it feasible/realistic to have such agreements on file in advance of those needs.*
 - (B) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for new prescription orders and reports of patients’ therapeutic responses or adverse effects;**
 - *In the case of ECP services, this statement would require a pharmacist to contact a physician to receive a new prescription order. This is not collaborative drug therapy management but rather just a standard “called in” prescription. If the physician were not available, access would not be increased.*
 - *These regulations appear to assume that there is a patient/practitioner relationship in every collaborative drug therapy agreement. In other words, practitioners will only be signing agreements for individuals who are already their patients. Without this practitioner/patient relationship, adherence to this section would result in breaches of patient confidentiality.*

(C) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary;

- *Although this statement will not, in itself, preclude the provision of ECP services by pharmacists, if the training/competency requirement becomes excessive or controlled by an outside board with a conflicting agenda, approval of the protocol could become a political issue.*

(D) Quality assurance and periodic review by a panel of the participating pharmacist(s) and practitioner(s).

- (e) Authorization by the practitioner(s) for the pharmacist(s) to participate in collaborative drug therapy;
- (f) A provision for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years; and
- (g) A description of the mechanism for the pharmacist(s) to communicate to the practitioner(s) and for documentation of the implementation of the collaborative drug therapy.

(2) Collaborative drug therapy management is valid only when initiated upon the prescription order of a participating practitioner for each individual patient.

- *Pharmacists will not be able to increase patient access to ECP services if they are **unable to initiate** ECP prescriptions.*
- *This precludes ECP access and appropriate/timely initiation of treatment when each therapy initiation requires a new prescription from the participating practitioner.*

(3) Nothing in this rule shall be construed to allow therapeutic substitution.

- *This statement could restrict a pharmacist from making the most objective and appropriate therapeutic choice for each patient's circumstances. It reflects the influence of pharmaceutical industry interest groups (such as the Pharmaceutical Research and Manufacturers of America [PhRMA]) on legislation more than it reflects medical/health concerns.*

(4) The collaborative drug therapy protocol must be filed with the Board of Pharmacy, kept on file in the pharmacy, and made available to the Board Inspector upon request.

Although not specifically stated, this Oregon regulation assumes that collaborative drug therapy agreements would only occur between a patient and her own physician and/or pharmacist. In the case of ECP services, there must be an allowance for patients to seek care where it is most accessible.

This regulation does not allow for preventative public health services, such as ECPs or immunizations. All collaborative drug therapy management services in Oregon need to be established in advance of service delivery for each patient and therefore will not increase ECP access by enabling pharmacists to provide ECP services directly to women.

