246-919-XXX/246-918-XXX

(1) Purpose. The purpose of this rule is to promote effective collaboration between physicians and pharmacists and establish consistent standards that promote patient safety. The commission establishes the following rule for a physician licensed under this chapter who establish collaborative drug therapy agreements with a pharmacist licensed under chapter 18.64 RCW. The Commission takes notice of the requirements for all collaborative drug therapy agreements mandated by the pharmacy quality assurance commission and wishes to supplement those requirements in certain circumstances.

(2) Definitions. The following terms used in this subsection apply throughout this section unless the context clearly indicates otherwise:

(a) “Black box warning” means the warning placed on medication packaging that indicates the United States Food and Drug Administration has found the use of the medication carries a risk of serious or life-threatening adverse effects.

(b) “Collaborative drug therapy agreements” or “CDTA” means a written agreement that is filed with the pharmacy quality assurance commission between a physician and pharmacist that permits the pharmacist to exercise prescriptive authority under the physician’s authorization.

(c) “Diagnosis” means the assessment of a patient to determine whether or not a patient has a disease or condition through identification of symptoms or distinguishing characteristics.

(d) “Health care entity” means a location licensed by the pharmacy quality assurance commission pursuant to WAC 246-945-245.

(e) “Hospital pharmacy associated clinics” means a location licensed by the pharmacy quality assurance commission pursuant to WAC 246-945-233.

(f) “Initiate drug therapy” means the selection of medication to treat a disease or condition and includes the dosage amount and dosage frequency.

(g) “Off-label use” means the prescribed use of a medication other than that stated in its United States Food and Drug Administration-approved labelling.

(h) “Vaccination” means the administration of a vaccine in order to promote immunization against disease.

(3) Exemptions. This rule does not apply to physicians when:

(a) The pharmacist is exercising prescriptive authority in treating patients at hospitals, health care entities, or hospital pharmacy associated clinics.

(b) The pharmacist is exercising prescriptive authority in administering vaccinations.

(4) Requirements. In addition to requirements mandated by the pharmacy quality assurance commission under WAC 246-345-350, a physician must ensure that for any CDTA into which the physician enters, the CDTA must include the following provisions:

(a) The ability for the physician and pharmacist to communicate directly on a one-to-one basis and exchange and review treatment records contemporaneously;

(b) Allowance for the physician to ascertain that the pharmacist’s educational background and experience is sufficient to allow for safe and effective collaboration in the modification or initiation of drug therapy after the physician makes a diagnosis;

(c) There must be a statement that that authorization to exercise prescriptive authority is between the individual physician and the individual pharmacist and explicit prohibition that the pharmacist may not delegate any aspect of treatment provided to a pharmacy technician or pharmacy assistant;

(d) There must be an explicit prohibition that states the pharmacist may not perform diagnosis of a patient, only modify or initiate drug therapy after the physician makes a diagnosis;

(e) There must be an explicit prohibition that states the pharmacist may not prescribe medication for off-label use;

(f) There must be an explicit prohibition that states the pharmacist may not prescribe medication in contravention to a black box warning; and

(g) There must be a requirement that, during the first year of the CDTA, semiannually obligates the physician and pharmacist to review the patient care provided under the physician’s authorization. The review must include discussion of any adverse events and the physician must maintain documentation regarding the review.

(5) Prohibition. With regard to authorization of a pharmacist’s prescriptive authority, a physician may not receive compensation based on the quantity or type of medication administered or dispensed.

(6) Enforcement. Physicians must comply with the terms of each CDTA they enter into with a pharmacist. If physicians discovers that a pharmacist is not complying with the terms of a CDTA, then they must either terminate their authorization or take other steps to ensure the pharmacist complies with the terms of the CDTA.

(7) Reporting. If a physician participating in a CDTA discovers that a pharmacist is not complying with the terms of their CDTA and the physician terminates the authorization for the pharmacist to use prescriptive authority, then that physician must file a complaint with both the commission and the pharmacy quality assurance commission that details the circumstances of the termination.

(8) Effective date. To allow for reformation of existing CDTAs, the effective date of these rules shall be [nine months after they have been filed with the code reviser/whatever the formal APA rule-making phase is called].

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For PA rules, the only addition is that the supervision agreement with the MD must specifically allow for the PA to enter into CDTAs.