Chapter 246-899 WAC
PHARMACEUTICAL—DRUG PRODUCT SUBSTITUTION

Last Update: 5/28/92

WAC

WAC 246-899-020 Dispensing responsibilities. When the pharmacist dispenses, with the practitioner's authorization, a therapeutically equivalent drug product, the following information shall be noted:

(a) On oral prescriptions, the pharmacist shall indicate on the permanent prescription record, if substitution is permitted.

(b) The manufacturer or distributor of the drug product actually dispensed or its national drug code number or short name code or trade name shall be noted on the permanent record, or on the patient medication record if this document is utilized for providing and recording refills. This requirement shall also apply to refill prescriptions when a different distributor or manufacturer's product is used.

(c) The generic or trade name of the drug actually dispensed shall be noted on the prescription label or package label. For combination drug products, the generic names of the drugs combined or the trade name of the manufacturer or distributor shall be noted on the prescription label. For prescriptions compounded with multiple ingredients, the label designation will be left to the discretion of the pharmacist.

(d) For institutionalized and closed system patients, the pharmacist may identify the manufacturer or distributor of the product actually dispensed through pharmacy purchasing records or packaging records, and a published formulary designation may be used on the label.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-899-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.180. WSR 79-12-063 (Order 152), § 360-49-010, filed 11/29/79; Order 143, § 360-49-010, filed 12/9/77.]

WAC 246-899-030 Product selection responsibilities. (1) The determination of the drug product to be dispensed on a prescription is a professional responsibility of the pharmacist, and the pharmacist shall not dispense any product that in his/her professional opinion does not meet adequate standards.

(2) Pharmacists may utilize as the basis for their decisions on therapeutically equivalent drug products:

(a) Available drug product information from federal and state agencies, official compendia, and drug manufacturers, or

(b) Other scientific or professional resources, or

(c) The federal food and drug administration "approved drug products" as a board approved reference for a positive formulary of therapeutically equivalent products within the limitations stipulated in that publication.

(3) Those pharmacies that fill prescriptions based on prior authorization for therapeutically equivalent drug substitution must have available for inspection and review such authorization documentation in the institutional records or in the pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-899-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.180. WSR 79-12-063 (Order 152), § 360-49-020, filed 11/29/79; Order 143, § 360-49-020, filed 12/9/77.]

WAC 246-899-040 Manufacturers, wholesalers, distributors, pharmacy location, requirement that drug products offered for sale comply with 21 U.S.C. 355—Immediate suspension and subsequent revocation of licenses authorized for violation. (1) In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety when generic drugs are substituted for brand name drugs pursuant to RCW 69.41.110 through 69.41.180 drug products which are offered for sale by, or stored at the premises of, any manufacturer, distributor, wholesaler or pharmacy location must have an approved new drug application (NDA) or abbreviated new drug application (ANDA) designation by the Federal Food and Drug Administration pursuant to 21 U.S.C. 355 unless they are exempt from the requirements for such a designation.

(2) In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety drug products offered for sale by, or stored at the premises of, a manufacturer, wholesaler, distributor or pharmacy location which do not have the required NDA or ANDA, or exemption therefrom referenced in subsection (1) of this section, are hereby declared to be contraband and subject to surrender to and destruction by the Washington state board of pharmacy. This surrender and destruction shall take place as specified below.

(3) The board shall publish in its newsletter the source from which the current list compiled by the Federal Food and Drug Administration of generic drugs which do not have an NDA or ANDA and are not exempt from such a requirement and are therefore contraband as provided in subsection (2) of this section may be obtained. The board shall also respond to both written and telephone inquiries from any source regarding the status of any generic drug.

(4) Whenever it is made to appear to the board that a manufacturer, wholesaler, distributor or pharmacy location within he [the] state of Washington is in possession of a stock of drugs which are contraband as defined in subsection (2) of this section, a representative of the board shall confirm with the Federal Food and Drug Administration, by telephone, that the particular drug or drugs involved do not have the required NDA or ANDA and that they are not exempt from this requirement. Upon receipt of this confirmation, the board shall direct such of its investigative personnel as it deem necessary to proceed to the premises of the manufacturer, wholesaler, distributor or pharmacy location and to then inform the owner, or person in charge, of the contraband status of the drugs in question.

(5) The pharmacy board investigative personnel shall offer the owner, or person in charge, of the premises at which the drug products are being kept the opportunity to immediately voluntarily surrender to

the board all stocks of the drug products whether kept at the premises of the manufacturer, wholesaler, distributor, or pharmacy location, or at any separate storage facility under the control of the manufacturer, wholesaler, distributor or retailer, which are contraband under subsection (2) of this section. A receipt shall be given to the owner, or person in charge, for all drug products voluntarily surrendered.

(6) All drug products voluntarily surrendered pursuant to subsection (5) of this section shall be destroyed by the board of pharmacy unless they are ordered returned to the manufacturer, wholesaler, distributor or pharmacy location by order of a court of competent jurisdiction. No destruction of any drug products surrendered will be accomplished until thirty days after the date of their surrender to the board.

(7) Retention, dispensing, promotion or advertisement, of any drug products by a manufacturer, wholesaler, distributor or pharmacy location, either at their business premises or at any separate storage facility after notification of their contraband status under subsection (2) of this section shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the immediate summary suspension and subsequent revocation of any license issued by the board of pharmacy to the manufacturer, wholesaler, distributor or pharmacy location and will also constitute good and sufficient cause for revocation of any license issued by the board of pharmacy to the owner of any manufacturer, wholesaler, distributor or pharmacy location or any person in charge thereof who knowingly retains, dispenses, promotes or advertises, any drug products which are contraband under subsection (2) of this section after notification of their status.

[Statutory Authority: RCW 69.41.180. WSR 92-12-035 (Order 277B), § 246-899-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-899-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), § 360-49-040, filed 9/2/87. Statutory Authority: RCW 69.41.180. WSR 80-14-012 (Order 157, Resolution No. 9/80), § 360-49-040, filed 9/22/80; WSR 80-02-113 (Order 153, Resolution No. 1/80), § 360-49-040, filed 1/28/80.]

WAC 246-899-050 Out-of-state prescriptions. (1) When dispensing a prescription issued by a practitioner licensed in a state other than Washington, and recognized in RCW 69.41.030, the pharmacist must honor the instructions of the practitioner regarding substitution. These instructions may be on a prescription blank different than that required for Washington practitioners by RCW 69.41.120 and may include the use of the words "dispense as written," words of similar meaning, a check-off box, or some other indication of intent.

(2) If the practitioner has not clearly provided instructions regarding substitution, a pharmacist may substitute a therapeutically equivalent generic drug only if the pharmacist has determined substitution is permitted by one of the following means:

(a) The pharmacist has personal knowledge and is familiar with the laws and rules regarding substitution in the state of origin; or

(b) The pharmacist obtains oral or written authorization from the practitioner; or

(c) The pharmacist obtains current information regarding the manner in which an out-of-state practitioner provides instruction from:

(i) The Washington state board of pharmacy; or

(ii) The board of pharmacy in the state, other than Washington, in which the practitioner practices; or

(iii) Some other professional source.

(3) Drug product selection shall be based on Washington law and rule as set forth in WAC 246-899-030.

[Statutory Authority: RCW 69.41.180. WSR 92-12-035 (Order 277B), § 246-899-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-899-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-13-004 (Order 174B), § 360-49-050, filed 6/7/91, effective 7/8/91.]