

*Department of Health
Pharmacy Quality Assurance Commission*

Interpretive Statement

Revised – 10/18/11

<i>Title:</i>	Clarification of “emergency medical reason” and wholesaler licensure requirements	<i>Number: I001.1</i>
<i>References:</i>	RCW 18.64.046(1), WAC 246-945-001(81)(e)	
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<i>Effective Date:</i>	March 8, 2019 (reaffirmed August 28, 2020)	
<i>Supersedes:</i>	WSR 19-07-062 (March 8, 2019)	
<i>Approved By:</i>	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

This interpretive statement is intended to clarify and confirm current rule, WAC 246-945-001(81)(e), which does not require pharmacies to obtain a state wholesaler license when transferring prescription drugs for “emergency medical reasons.”

The Pharmacy Quality Assurance Commission (commission) new rule defines “emergency medical reasons” and the pharmacist on duty no longer has to rely on his or her professional judgment, to make the determination of whether the transfer is for an “emergency medical reason.”

However, the “emergency medical reasons” exception is limited in rule. Per WAC 246-945-001(81)(e), when applying the “emergency medical reasons” exception, no transfer can amount to more than five percent of “total prescription drug sale revenue of either the transferor or transferee” during any twelve consecutive month period. In addition, the pharmacist on duty must ensure compliance with all federal laws and regulations that govern the transfer of medications.

BACKGROUND:

The commission has received inquiries around the need to obtain a wholesaler’s license when transferring drugs between pharmacies not under common ownership. Under RCW 18.64.046(1), a wholesaler’s license is required for entities that are engaged in the wholesale distribution of drugs. The commission has defined wholesale distribution in rule, as well as exceptions:

WAC 246-945-001(81)"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

- (a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription:
- (b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or
- (c) The sale, purchase, or trade of blood and blood components intended for transfusion.
- (d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner.
- (e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for *emergency medical reasons*; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

If the conduct of a pharmacy falls within one of the five exceptions to the definition of "wholesale distribution," then obtaining licensure as a wholesaler is not necessary. If a pharmacy sells drugs to another pharmacy, the pharmacy would have to ascertain whether one of the exceptions listed in WAC 246-945-001(81) applies.

The commission has received specific questions regarding when the "emergency medical reason" exception applies under WAC 246-945-001(81)(e).

The "emergency medical reasons" exception in WAC 246-945-001(81)(e) allows a retail pharmacy to sell, purchase, or trade prescription drugs to another retail pharmacy for "emergency medical reasons." The rule provides that an "emergency medical reason" can include transfers to "alleviate a temporary shortage". The commission also interprets this rule to allow transfers of prescription drugs between pharmacies in a situation that in the professional judgment of the responsible pharmacist on duty is an "emergency medical reason." When making this professional judgment, the responsible pharmacist on duty should consider that any transfer cannot amount to more than five percent of "total prescription drug sale revenue of either the transferor or transferee" during any twelve consecutive month period.

While the commission provides this interpretive statement to assist individuals and entities evaluating the need for state licensure as a wholesaler, individuals and entities should consider their obligations to federal regulators when making a transfer of prescription drugs between pharmacies. Interested parties should contact applicable federal regulators for that information.

When prescription drugs are transferred for emergency medical reasons as defined in WAC 246-945-001(81)(e) between two pharmacies, and it is the professional judgment of the pharmacist on duty, state licensure as a wholesaler is not necessary. Federal restrictions may apply.



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

NOTICE OF ADOPTION OF AN INTERPRETIVE STATEMENT

Title of Interpretive Statement: Clarification of “emergency medical reason” and wholesaler license requirements. | IS Number I001.1

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This statement clarifies the Pharmacy Quality Assurance Commission’s rule that a pharmacy is not required to obtain a wholesaler license when transferring prescription drugs for “emergency medical reasons.”

Effective Date: August 28, 2020

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