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WSR 23-20-115

PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Transfer practices for a dispensed prescription drug for the purpose of re-dispensing or subsequent administration to a patient. The Pharmacy Quality Assurance Commission (commission) is proposing to create a new section(s) in chapter 246-945 WAC related to the regulation of the practices of "white bagging" and "brown bagging" or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005

Reasons why rules on this subject may be needed and what they might accomplish: According to a 2018 report prepared by the National Association of Boards of Pharmacy, "white bagging" refers to "the distribution of patient-specific medication from a pharmacy... to the physician's office, hospital, or clinic for administration" and "brown bagging" refers to "the dispensing of a medication from a pharmacy... directly to the patient, who then transports the medication(s) to the physician's office for administration." Certain drugs are often the subject of white bagging and brown bagging practices. In 2015, 28% of medical benefit drugs—drugs that are injected or infused by a healthcare professional in an infusion center—were distributed to physician offices via brown bagging. As of 2016, 28% of oncology drugs were distributed through white bagging and brown bagging practices. There is currently a lack of clear regulatory standards on these practices in Washington state.

These drug transfer practices represent a different approach to the traditional chain-of-custody for prescribed medications. Concerns have been raised over ensuring the integrity and quality of these medications is maintained if such practices are used by prescribers, hospitals, or patients because these practices can create an unknown chain of custody.

Following discussions held at commission business and subcommittee meetings, the commission determined that it needed to consider adding more robust regulatory standards to ensure product integrity and patient safety in its rules chapter.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Office of the Insurance Commissioner (OIC) oversees the registration and regulation of pharmacy benefit managers (PBMs), who in turn manage the use of benefits and health care services by patients, including the practices of white bagging and brown bagging. The commission will contact the OIC as the commission considers collecting data and drafting rule language related to practices for which PBMs and the OIC have specialized knowledge and experience.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative rulemaking

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

	(If necessary)
Name: Joshua Munroe	Name:
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Other:	Other:

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: https://public.govdelivery.com/accounts/WADOH/subscriber/new. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

Date: October 3, 2023 **Name:** Kenneth Kenyon, PharmD, MBA **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:**