Department of Health
Nursing Care Quality Assurance Commission

Advisory Opinion

The Nursing Care Quality Assurance Commission (NCQAC) issues this advisory opinion in accordance with WAC 246-840-800. An advisory opinion adopted by the NCQAC is an official opinion about safe nursing practice. The opinion is not legally binding and does not have the force and effect of a duly promulgated regulation or a declaratory ruling by the NCQAC. Institutional policies may restrict practice further in their setting and/or require additional expectations to assure the safety of their patient and//or decrease risk.

Title:	Registered Nurse and Licensed Practical Nurse: Compounding and Reconstituting Medications	*Number:* NCAO 11.01
References:	RCW 18.79 Nursing Care WAC 246-840 Practical and Registered Nursing Interactive Scope of Practice Decision Tree See Page 5 for additional References	
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Conclusion Statement

The appropriately trained and competent licensed registered nurse (RN) and licensed practical nurse (LPN) may compound or reconstitute medications for a specific patient as directed by an authorized health care practitioner with prescriptive authority. It is a recognized and long-accepted practice for nurses to compound and reconstitute medications for immediate use. The nurse must follow state and federal laws, rules, and best practice standards.

Background

Effective July 25, 2021, Washington State amended the Washington State Pharmacy Quality Assurance Commission law to define the difference between compounding and reconstitution. "Compounding" means the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of:

- Sterile products according to the Federal Food and Drug Administration (FDA)-approved labeling does not constitute compounding if prepared pursuant to a prescription an administered immediately or in accordance with package labeling, and;
- Nonsterile products according to the Federal FDA-approved labeling does not constitute compounding if prepared pursuant to a prescription. RCW 18.64.011 (6)

All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

- USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations,
- USP General Chpater <795> Pharmaceutical Compounding – Sterile Preparations,
- USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings, and
- USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging. WAC 246-945-100.

The Washington State nursing law does not prohibit the RN or LPN from compounding medications. Neither the pharmacy nor the nursing law prohibits an authorized health care practitioner with prescriptive authority from directing an RN or LPN to compound medications for the practitioner's patient:

- The RN, under the general direction of an authorized health care practitioner, acting within the scope of their license, may administer medications, treatments, tests, and inoculations, whether or not the severing or penetrating of tissues is involved and whether or not a degree of independent judgment and skill is required. Such direction must be for acts that are within the scope of registered nursing practice. RCW 18.79.260. Registered nursing practice also includes the performance of such additional acts requiring education and training that are recognized by the medical and nursing professions as proper and recognized by the commission to be performed by registered nurses RCW 18.79.240.
- The LPN under the direction of an authorized health care practitioner, or under the direction and supervision of the RN may administer drugs, medication, treatments, tests, injections, and inoculations, whether or not piercing of the skin is involved and whether or not a degree of independent judgment and skill is required. RCW 18.79.270.

The Legend Drug Act, RCW 69.41.030, does not apply to a practitioner acting within the scope of their license whose possession of any legend drug is in the usual course of business or employment. This exempts any licensed practitioner acting within the scope of their license from the law's prohibition of the sale, delivery, or possession of legend drugs. A licensed health practitioner with prescriptive authority may compound medications for a patient under their care.

Compounded Medications

Compounding provides access to medication for patients who may not be able to use commercially available formulations because of dosing requirements, allergies, rare diseases, or other health conditions. Compounded medications can be sterile or nonsterile. Although compounding is essential to meeting specific patient healthcare needs, compounded drugs made without standards of care may lead to the exposure of contaminants and risk of infection. Compounded sterile preparations are potentially more hazardous to patients because they're more likely to be administered into the sterile body. These spaces are typically microbe-free, and the introduction of contaminants can lead to adverse events, In addition, incorrect ingredients or incorrect quantities of ingredients can result in medicine that is not therapeutically effective or is toxic to the patient (Becker S, Jinger L, 2019).

Compounded drugs are not FDA approved for safety, effectiveness, and quality. Most compounding occurs in pharmacies, but it may not always be feasible to have a licensed pharmacist immediately available. Compounding medications by the nurse commonly occurs for immediate or emergency use in a range of practice settings when there may be limited access to pharmacy support or a significant gap between ordering and delivering the compounded medication.

The USP provides standards for compounding non-sterile and sterile preparations of medications, and handling hazardous drugs to help reduce risks. Washington's regulation for compounding standards requires all licensed health care practitioners to comply with the USP guidelines when compounding nonsterile and sterile products. WAC 246-945-100.

Reconstituted Medications

Reconstituted medications include mixing, reconstituting medications approved by the FDA following the directions by the product's manufacturer and other manufacturer directions consistent with that labeling. For example, correct reconstitution of vaccines is critical to safe injection practices. Safe and effective use of reconstituted vaccines requires storage of vaccines and diluents at appropriate temperatures, mixing of vaccines only with specific diluents, the ability to identify contaminated vaccines, and the knowledge of when to discard the reconstituted medication.

Recommendations

NCQAC recommends health care settings use compounding pharmacy services or compounding manufacturers whenever possible. The nurse compounding medications is responsible for ensuring the medication is compounded according to the standards of USP guidelines. The nurse must follow FDA-approved recommendations when mixing or reconstituting medications. The nurse must have the training, knowledge, skills, and abilities (competency) to prepare compounded or reconstituted medications safely following state and federal laws, regulations, guidelines, and other standards of care. It is essential that the nurse is competent in the preparation and reconstitution of a wide variety of drugs pertinent to their clinical area. This requires an extensive knowledge of pharmacological agents and their applications. The nurse must be familiar with their employer/facility regulations, guidelines, policies, procedures, and practices. The nurse must be aware of relevant health and safety issues and follow Occupational Safety and Health Administration requirements, and the Washington Industrial Safety and Health Act.

Conclusion

The NCQAC concludes that it is within the scope of practice of a properly trained nurse to compound or reconstitute medications for a specific patient under the direction of an authorized health care practitioner with prescriptive authority. Understanding the risks inherent in each and incorporating established standards into daily clinical practice is essential to patient safety.

References and Resources

Laws and Rules

RCW 18.64.011 Pharmacy - Definitions
RCW 18.64.255 Pharmacy - Authorized practices
RCW 18.64.270 Pharmacy - Responsibility for drug purity—Compounding—Adulteration—Penalty
Chapter 69.41 RCW Legend Drugs - Prescription Drugs

WAC 246-945-100 Pharmacy - Compounding Minimum Standards
WAC 246-330-200 Ambulatory Surgical Centers-Pharmaceutical Services
WAC 182-530 Health Care Authority Prescription Drugs

Other References and Resources

American Society for Hospital Pharmacist: Compounding Sterile Preparations - ASHP

Becker S, Jinger L. "USP Compounding Standards: Prepare with Care." American Nurse Association (2019): https://www.myamericannurse.com/usp-compounding-standards-prepare-care/

Center for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (2019), Medication Preparation Questions: Medication Preparation Questions | Injection Safety

Gorski, L. A., Hadaway, L., Hagle, M. E., & et al. (2021). Infusion Therapy standards of Practice. *Journal of Infusion Nursing*, *44*(4), S59–S62: https://doi.org/10.1097/nan.0000000000000436

Institute for Safe Medication Practices (2016). Guidelines for Safe Preparation of Compounded Sterile Preparations: ismp-hosp-temp-MASTER.qxd

National Home Infusion Association: Sterile Compounding Resource Center |Best Practices and methods

Occupational Safety and Health Administration: Hazardous Drugs - Controlling Occupational Exposure to Hazardous Drugs

Spacer D. (2020). American Nurse Journal. Standardizing Intravenous Push Administration: Bridging education and practice: myamericannurse.com

United States Department of Labor, Occupational Safety and Health Administration: Hazardous Drugs - Controlling Occupational Exposure to Hazardous Drugs | Occupational Safety and Health Administration

United States Food and Drug Administration Human Drug Compounding: Human Drug Compounding

- United States Food and Drug Administration Center for Drug Evaluation and Research: *Compounding and the FDA*: Compounding and the FDA: Questions and Answers
- United States Food and Drug Administration: Title I Compounding Quality Act
- United States Food and Drug Administration, Center for Drug Evaluation and Research. (2020). *Provisions that apply to human drug compounding*: https://www.fda.gov/drugs/human-drug-compounding/fdc-act-provisions-apply-human-drug-compounding

U.S. Pharmacopeia Website

Washington State Department of Health Pharmacy Commission Website