

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:	Compounding Medications by Licensed Practical Nurses, Registered Nurses, and Advanced Registered Nurse Practitioners	Number: NCAO 11.0
References:	RCW 18.79 Nursing Care WAC 246-840 Practical and Registered Nursing Nursing Scope of Practice Decision Tree WAC 246-878 Good Compounding Practices WAC 246-330-200 Ambulatory Surgical Centers-Pharmaceutical Services	
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Approved By:	Nursing Care Quality Assurance Commission	

Conclusion Statement

The Nursing Care Quality Assurance Commission concludes that a licensed registered nurse (RN) or a licensed practical nurse (LPN) as directed by a licensed physician and surgeon, dentist, osteopathic physician and surgeon, naturopathic physician, optometrist, podiatric physician and surgeon, physician assistant, osteopathic physician assistant, advanced registered nurse practitioner, or midwife for a patient under the health care practitioner’s care may compound medications for a specific patient. An advanced registered nurse practitioner (ARNP) with prescriptive authority may prescribe or prepare compound medications for a specific patient under the ARNP’s care.

Background

The Nursing Care Quality Assurance Commission (NCQAC) received a request to develop an advisory opinion as to whether it is in the scope of practice for nurses to compound medications. While most compounding occurs in pharmacies, it may not always be feasible to have a licensed pharmacist immediately available. Compounding of drugs by nurses commonly occurs for immediate use in perioperative, emergency care, clinics, health care provider offices, home care, and in other settings when there is a significant gap between ordering and delivering of the compounded medication.

The potential for contamination of compounded products and resulting infections are a serious threat to patient safety. On November 27, 2013, President Obama signed the [Drug Quality and Security Act](#) (Compounding Quality Act) related to the oversight of compounding of human drugs. The impetus for the new law was an incident in 2012 where a commercial pharmacy's compounded sterile preparations (CSPs) injured 271 people and caused 21 deaths in 16 states.¹ The law imposes strict requirements for CSPs that are to be administered into a human being. However, the CSP may be exempt from some provisions of the law if it is compounded for an identified individual patient on the basis of a valid prescription order that a compounded preparation is necessary for that identified patient. Immediate use preparations are frequently used in settings such as emergency rooms, operating rooms, and intensive care. Many compounded medications in surgical settings are not made commercially and required to be mixed immediately prior to use.

The [United States Pharmacopeia \(USP\)](#) defines the following [standards](#) for nonsterile, Chapter 795 (<795>), and sterile preparations, Chapter 797 (<797>), hazardous drugs, Chapter 800 (<800>), and other essential compounding components. Any drug that is recognized in the USP must adhere to USP standards for identity, strength, quality, purity, packaging, and labeling or risk being deemed adulterated or misbranded. Standards apply to all persons who compound sterile preparations and all health care settings. <797> describes the minimum practices and quality standards to be followed when preparing compounded sterile human and animal drugs (compounded sterile preparations, or CSPs) for injections, implants, or other infusions into the human body. These practices and standards must be used to prevent harm, including death, to human and animal patients that could result from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability from the intended strength of correct ingredients, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.² Chapter 797 uses risk assessment categories (immediate use, low risk, low risk with less than twelve hours beyond use date, medium risk, and high risk) to identify risk factors such as the environment, temperature storage, type of product, and when the preparation will be used. Pharmaceutical compounding includes compounding medications to prepare a small quantity of medications as well as manufacturing where a commercial vendor with FDA approval uses mass production to compound bulk quantity of medications.

Variations occur in the definition of compounding from various organizations and in state law:

- The Washington State Pharmacy Quality Assurance Commission (PQAC) statute and rule, [RCW 18.64.011\(6\)](#) and [WAC 246-878-010\(1\)](#), define compounding as combining two or more

¹ ASHP Guidelines on Compounding Sterile Preparations (June 2, 2013): <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx>

² The USP is currently reviewing public comments to its proposed revisions to General Chapter 797 (<797>). The proposed revisions are available at: <http://www.uspnf.com/notices/general-chapter-797-proposed-revision>. The proposed revisions define a compounded sterile preparation (CSP) as: "A preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise adulterating a drug product or bulk drug substance. A product produced by reconstituting a conventional manufactured product for an individual patient strictly in accordance with the directions contained in the approved labeling provided by the product manufacturer is not considered a CSP for the purposes of this chapter." The proposed rules recognize that nurses also prepare CSPs. The proposed rule requires that the employer and all employees must be trained and qualified, demonstrating proficiency in core competencies; must ensure that the practices and standards are correctly applied; and must proactively identify and remedy potential problems. <http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision>. The final rule may not be published until March 2017 or later. <http://www.usp.org/frequently-asked-questions/pharmaceutical-compounding-sterile-preparations>

ingredients in the preparation of a prescription. Chapter 246-878 WAC, Good Compounding Practices, dates from 1994 and will be revised as a result of the passage of HB 1800, Chapter 146, Laws of 2013, which amended RCW 18.64.270. RCW 18.64.270 requires that any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products.³

- The [United States Food and Drug Administration \(FDA\)](#) is still developing draft guidance on implementing the changes to its law, which defines compounding as “the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.” Compounding Quality Act, Sec. 503B(d)(1). Compounding, the combining or altering of ingredients of two or more drugs, may be necessary to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA-approved. Under Section 503A of the [Federal Food, Drug, and Cosmetic Act \(FDAC\)](#), a compounded drug product may be eligible for exemption from additional regulation if it is “compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order (this includes orders that a physician writes in the charts of his or her patients) that a compounded product is necessary for the identified patient.”⁴ The FDAC rule states that compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions in approved labeling provided by the product’s manufacturer and other manufacturer direction consistent with that labeling. 21 CFR §353(f). However, the USP indicates that mixing and reconstituting processes following package insert directions will be subject to USP standards.
- The USP defines compounding of nonsterile preparations in <795> as the “preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.”⁵ Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components. Some differences include ISO-classified air environments; personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and

³ In 2013, the PQAC declared its intention to write updated rules on compounding as a result of the change in USP guidelines. <http://apps.leg.wa.gov/documents/laws/wsr/2013/11/13-11-096.htm>

⁴ Draft Prescription Requirement under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, April 2016, at 5. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>

⁵ The definition continues, with examples of what compounding includes: “Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
- Preparation of drugs or devices for the purposes of, or incident to, research (clinical or academic), teaching, or chemical analysis
- Preparation of drugs and devices for prescriber’s office use where permitted by federal and state law.” http://www.pharmacist.com/sites/default/files/files/Allen_20Chap_201_Art%2C%20Science%20and%20Technology%20of%20Pharmaceutical%20Compounding%2C%204e.pdf

sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces. The standards apply to those preparations prepared to the manufacturers' labeled instructions and other manipulations when preparing sterile preparations that may expose the original content to potential contamination, as well as preparations that contain nonsterile ingredients or employ nonsterile components and devices that must be sterilized before use. USP does not differentiate between compounding and reconstituting medications. (Subject to revision: see fn. 2).

- The [American Pharmacists Association \(APhA\)](#) defines compounding as the mixing of ingredients, including dilution, admixture, repackaging, reconstitution, and other manipulations of sterile products, to prepare a medication for patient use.

The Infusion Nurses Society (INS) standard 17.1 states that, "Compounding of parenteral solutions and medications is in accordance with state and federal regulations, the American Society of Health-System Pharmacists (ASHP), the Drug Quality and Security Act, and the USP National Formulary (FM), including but not limited to General Chapter <797>." According to the ASHP guidelines, the "term *compounding personnel* refers to any individual involved in compounding sterile preparations, regardless of profession. Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, sorted, dispensed, distributed, and disposed of if not used. Emphasis should be on the need to maintain quality standards for the control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs." [ASHP Guidelines on Compounding Sterile Preparations \(June 2, 2013\)](#).

The [Centers for Medicare and Medicaid Services \(CMS\)](#) aligned the State Operations Manual for hospitals with the USP standards. The October 30, 2015 CMS revision recognizes that nurses commonly prepare medications for immediate use. CMS recognizes the INS standards of practice for nurses.

Analysis

The commission may adopt rules or issue advisory opinions in response to questions put to it by professional health associations, nursing practitioners, and consumers in this state concerning the authority of various categories of nursing practitioners to perform particular acts. RCW 18.79.110(1). The Washington State nursing law does not specifically prohibit compounding medications by an RN or LPN. The practice of nursing includes carrying out a medical regimen. [RCW 18.79.040](#). A RN may, at or under the general direction of a licensed physician and surgeon, dentist, osteopathic physician and surgeon, naturopathic physician, optometrist, podiatric physician and surgeon, physician assistant, osteopathic physician assistant, advanced registered nurse practitioner, or midwife acting within the scope of his or her license, 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 which are within the scope of registered nursing practice. [RCW 18.79.260](#). An LPN may, under the direction of a licensed physician and surgeon, dentist, osteopathic physician and surgeon, naturopathic physician, optometrist, podiatric physician and surgeon, physician assistant, osteopathic physician assistant, advanced registered nurse practitioner, midwife or under the direction and supervision of a RN 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](#). 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 definition of compounding in the pharmacy law and rule, [RCW 18.64.011\(6\)](#) and [WAC 246-878-010\(1\)](#), means “the act of combining two or more ingredients in the preparation of a prescription.” [RCW 18.64.020](#) restricts the practice of pharmacy to licensed pharmacists. The "practice of pharmacy" includes “the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.” However, the pharmacy laws do not restrict the scope of authorized practice of any practitioner other than a pharmacist, duly licensed as such under the laws of this state. [RCW 18.64.255](#). The Legend Drug Act, [RCW 69.41.030](#), does not apply to a practitioner acting within the scope of his or her 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 his or her 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 his or her care. Neither the pharmacy law nor the nursing law prohibits a licensed health care practitioner with prescriptive authority from directing a RN or LPN to compound medications for the practitioner’s patient. It is a recognized and long-accepted practice for nurses to compound medications.

Recommendations

The NCQAC recommends health care settings use compounding pharmacy services or compounding manufacturers whenever possible. Nurses compounding medications are responsible for ensuring the medication is compounded according to USP guidelines. The nurse must have the training, knowledge, skills, and abilities (competency) to prepare compound medications safely in accordance with state and federal laws, regulations, guidelines, and other standards of care.

The nurse must be familiar with regulations, guidelines, and practices that aim to reduce contamination that can occur during the compounding process. The nurse must determine whether the setting is appropriate to compound and administer the medication safely following all compounding regulations, guidelines, and practices. The nurse must follow State and Federal regulations, infection control standards, [Occupational Safety and Health Administration](#) requirements, and the [Washington Industrial Safety and Health Act](#).

Conclusion

Awareness of standards and following recommended practices will decrease the likelihood of an adverse event. The NCQAC concludes that it is within the scope of practice of a properly trained nurse to compound medications for a specific patient pursuant to an order by a licensed provider with prescriptive authority.

References

ASHP Guidelines on Compounding Sterile Preparations (June 2, 2013): <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx>

Centers for Disease Control and Prevention and the Safe Injection Practices Coalition, One & Only Campaign: http://www.oneandonlycampaign.org/safe_injection_practices

FDA Compounding Quality Act Title I of the Drug Quality and Security Act of 2013:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

FDA Compounding Questions and Answers:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm>

Infusion Nurses Society: <https://www.ins1.org/default.aspx>

Institute for Safe Medication Practices Preparation of Compounded Sterile Preparations (2016):

<http://www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf>

Just the Facts: Compounding, APhA: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3627035/>

Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf>

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<http://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/Pharmacy/PharmacyCompoundingStandards>

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http://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc795.pdf