GOOD COMPOUNDING PRACTICES

WAC 246-878-010 Definitions.
(1) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.
(2) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.
(3) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

WAC 246-878-020 Compounded drug products—Pharmacist.
(1) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace. When a compounded product is to be substituted for a commercially available product, both the patient and also the prescriber must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription or in the computerized patient medication record. The prescriber's authorization shall be in addition to signing on the "substitution permitted" side of a written prescription or advising that substitution is permitted when a verbal prescription is issued.
(2) Pharmacists shall receive, store, or use drug substances for compounding prescriptions that meet official compendia requirements. If these requirements can not be met, and pharmacists document such, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.
(3) Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing.
(4) Pharmacists shall not offer compounded drug products to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.
(5) The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

WAC 246-878-030 Organization and personnel.
(1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.
(2) Pharmacists who engage in drug compounding, and level A pharmacy assistants, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Every pharmacist who engages in drug compounding and any level A pharmacy assistant who assists in compounding, must be aware of and familiar with all details of these good compounding practices.
(3) Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.
(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an

(4/6/94)
apparent illness or open lesions that may adversely affect the 
safety or quality of a drug product being compounded shall 
be excluded from direct contact with components, drug prod-
uct containers, closures, in-process materials, and drug prod-
ucts until the condition is corrected or determined by com-
petent medical personnel not to jeopardize the safety or quality 
of the products being compounded. All personnel who assist 
the pharmacist in compounding procedures shall be 
 instructed to report to the pharmacist any health conditions 
that may have an adverse effect on drug products.

WAC 246-878-040  Facilities. (1) Pharmacies engaging 
in compounding shall have an adequate area for the orderly 
compounding of prescriptions, including the placement of 
equipment and materials. The drug compounding area for 
sterile products shall be separate and distinct from the area 
used for the compounding of nonsterile drug products. The 
area(s) used for compounding of drugs shall be maintained in 
a good state of repair.

(2) Bulk drugs and other chemicals or materials used in 
the compounding of drugs must be stored in adequately 
labeled containers in a clean, dry area or, if required, under 
proper refrigeration.

(3) Adequate lighting and ventilation shall be provided 
in all drug compounding areas. Potable water shall be sup-
plied under continuous positive pressure in a plumbing sys-
tem free of defects that could contribute contamination to any 
compounded drug product. Adequate washing facilities, easily 
accessible to the compounding area(s) of the pharmacy 
shall be provided. These facilities shall include, but not be 
limited to, hot and cold water, soap or detergent, and air dri-
ers or single-use towels.

(4) The area(s) used for the compounding of drugs shall 
be maintained in a clean and sanitary condition. It shall be 
free of infestation by insects, rodents, and other vermin. 
Trash shall be held and disposed of in a timely and sanitary 
manner. Sewage and other refuse in and from the pharmacy 
and immediate drug compounding area(s) shall be disposed 
of in a safe and sanitary manner.

WAC 246-878-050  Sterile pharmaceutical. If sterile 
products are being compounded, the conditions of chapter 
246-871 WAC (Pharmaceutical—Parenteral products for 
nonhospitalized patients) shall be met.

WAC 246-878-060  Radiopharmaceuticals. If radio-
pharmaceuticals are being compounded, the conditions of 
chapter 246-903 WAC shall be met.

WAC 246-878-070  Special precaution products. If 
drug products with special precautions for contamination, 
such as penicillin, are involved in a compounding operation,
appropriate measures, including either the dedication of 
equipment for such operations or the meticulous cleaning of 
contaminated equipment prior to its use for preparation of 
other drugs, must be utilized in order to prevent cross-con-
tamination.

WAC 246-878-080  Equipment. (1) Equipment used in 
the compounding of drug products shall be of appropriate 
design, appropriate capacity, and suitably located to facilitate 
operations for its intended use and for its cleaning and main-
tenance. Equipment used in the compounding of drug prod-
ucts shall be suitable composition so that surfaces that con-
tact components, in-process materials, or drug products shall 
not be reactive, additive, or absorptive so as to alter the 
safety, identity, strength, quality, or purity of the drug prod-
uct beyond that desired.

(2) Equipment and utensils used for compounding shall 
be cleaned and sanitized immediately prior to use to prevent 
contamination that would alter the safety, identity, strength, 
quality, or purity of the drug product beyond that desired. 
In the case of equipment, utensils, and containers/closures used 
in the compounding of sterile drug products, cleaning, steril-
zation, and maintenance procedures as set forth in WAC 
246-871-080.

(3) Equipment and utensils used for compounding drugs 
must be stored in a manner to protect them from contamina-
tion. Immediately prior to the initiation of compounding 
operations, they must be inspected by the pharmacist and 
determined to be suitable for use.

(4) Automatic, mechanical, electronic, or other types of 
equipment other than commercial scale manufacturing or 
testing equipment, may be used in the compounding of drug 
products. If such equipment is used, it shall be routinely 
inspected, calibrated (if necessary), or checked to ensure 
proper performance.

WAC 246-878-090  Control of components and drug 
product containers and closures. (1) Components, drug 
product containers, closures, and bagged or boxed compo-
nents of drug product containers and closures used in the 
compounding of drugs shall be handled and stored in a man-
ner to prevent contamination and to permit unhindered clean-
ing of the work area (e.g., floors) and inspection.

(2) Drug product containers and closures shall not be 
reactive, additive, or absorptive so as to alter the safety, iden-
tity, strength, quality, or purity of the compounded drug 
beyond the desired result. Components, drug product con-
tainers, and closures for use in the compounding of drug 
products shall be rotated so that the oldest stock is used first. 
Container closure systems shall provide adequate protection 
against foreseeable external factors in storage and use that 
can cause deterioration or contamination of the compounded 
Drug product. Drug product containers and closures shall be 
clean and, where indicated by the intended use of the drug, 
sterilized and processed to remove pyrogenic properties to 
assure that they are suitable for their intended use.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-070, 
filed 4/6/94, effective 5/7/94.]

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assure that they are suitable for their intended use.
(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-090, filed 4/6/94, effective 5/7/94.]

WAC 246-878-100 Drug compounding controls. (1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:

(a) Component name; and
(b) Weight or measure.

(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) Capsule weight variation;
(b) Adequacy of mixing to assure uniformity and homogeneity;
(c) Clarity, completeness, or pH of solutions.

(4) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-100, filed 4/6/94, effective 5/7/94.]

WAC 246-878-110 Labeling control of excess products. (1) In the case where a quantity of compounded drug product in excess of that to be initially dispensed in accordance with WAC 246-878-020 is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on shelf or in the refrigerator) to ensure its strength, quality, and purity.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-110, filed 4/6/94, effective 5/7/94.]

WAC 246-878-120 Records and reports. (1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in WAC 246-869-100 for the retention of prescription files.

(2) All records required to be retained under this chapter, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-120, filed 4/6/94, effective 5/7/94.]

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