Situation:
Staff are recommending another approach to adopting compounding standards to alleviate the uncertainty of continued delays by the Unites States Pharmacopeia’s (USP) compounding standards that are required to be followed by Commission licensees. Additionally, staff have a recommendation on potential changes to HB 1352 in the event the Commission is asked for technical assistance on the bill.

Background:
RCW 18.64.270(2) requires those credentialed by the Commission who are engaged in compounding to be in compliance with USP chapters related to compounding standards.

Over the last two years the USP Expert Committee has been in the process of updating and making revising chapters related to the USP chapters on compounding, these include:

- USP chapter <795> - Nonsterile Compounding (revision published 6/1/19)
- USP chapter <797> - Sterile Compounding (revision published 6/1/19)
- USP chapter <800> - Handling of Hazardous Drugs (revision published 2/1/16)
- USP chapter <825> - Radiopharmaceutical Compounding (revision published 6/1/19)

Revisions were published to USP <800> in February 2016, but had an effective date of July 28, 2018. During that time USP <795> and <797> were out for public comment, and based on the number of comments received the USP Expert Committee pulled back the proposed revisions and began to rework them. This resulted in USP delaying the effective date of USP 800 to December 1, 2019 to coincide with the publishing of the updates to USP <795> and <797>.

On September 23, 2019, USP delayed the effective date of the revised chapters and made USP 800 informational only pending appeals on the revised chapters. This delay has resulted in additional uncertainty in how to regulate and enforce compounding standards in WA. This is large part due to reconstitution of preparations being included in the definition of compounding in WA in RCW 18.64.011.

HB 1352 was introduced in the 2019 session to address the definition of compounding and would have given the Commission specific rulemaking authority to adopt the versions of USP that are applicable in WA State. The Commission supported the bill and provided technical assistance when requested. The bill did not move out of committee due to stakeholder concerns on the use of the term “active” in the proposed updated definition, and were concerned that the Commission might reduce the standards around compounding instead of USP remaining the minimum standard in WA.
Commission SBAR Communication

Assessment:
Staff are suggesting the Commission use its general rulemaking authority in RCW 18.64.005(7) which states:

The Commission shall:

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the commission;

Adopting the versions of USP through the rules re-write will alleviate the uncertainty the Commission has had on enforceable standards because they would no longer be relying on a third-parties effective date, but rather a date set by the Commission. (See attached.)

Staff are also recommending potential language on HB 1352 if the Commission or staff are asked to provide technical assistance or amendments to the bill. Staff have not heard whether the bill will be introduced, but wanted to be ready in the even the Commission is approached on the bill. (See attached.)

Recommendation:
1. Approve the draft rule language adopting 4 USP compounding standard chapters and incorporate that language in the final rule re-write language to be filed with a CR-102.
2. Approve or provide feedback regarding suggested technical assistance language on the definition of compounding in the event the Commission or Commission staff are asked to provide technical assistance on HB 1352 if it is reintroduced this session.
Potential Technical Assistance on HB 1352

RCW 18.64.011
Definitions.

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

1. "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.
2. "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.
3. "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.
4. "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.
5. "Commission" means the pharmacy quality assurance commission.
6. "Compounding" means the act of combining two or more ingredients in the preparation of a prescription. Compounding does not include reconstitution of a non-sterile preparation according to manufacturer’s labeling.
7. "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.
8. "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.
9. "Department" means the department of health.
10. "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.
11. "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.
12. "Distribute" means the delivery of a drug or device other than by administering or dispensing.
13. "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.
14. "Drugs" means:
   (a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;
(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or
(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(15) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

(16) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

(17) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.

(18) "Labeling" means the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(19) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(20) "Long-term care facility" means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW.

(21) "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, personally prepares, compounds, packages, or labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;
(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;
Potential Technical Assistance on HB 1352

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(22) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(23) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(24) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(25) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

(26) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

(27) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(28) "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.

(29) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(30) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs.

(31) "Reconstitution" means the process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension. (32) "Secretary" means the secretary of health or the secretary's designee.

(33) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, or reviewing chart orders.

(34) "Wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.
WAC 246-XXX-XXX Compounding – Minimum Standards

(1) 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:
   (a) USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations,
   (b) USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations,
   (c) USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, and
   (d) USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters listed in subsection (1) are available for public inspection at the Commission's office at Department of Health, Town Center 2, 111 Israel Road SE, Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.