



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

Pharmacy Quality Assurance Commission
Stakeholder Meeting
Pharmacy Compounding Standards
By Videoconference
July 17, 2013

PointPlaza East
310 Israel Rd SE Room
152/153
Tumwater WA 98501

CenterPoint Corporate Park
20435 72nd Ave
Kent, WA 98032

River View Corporate Ctr
Suite 1500 – Room 118
16201 E. Indiana Ave
Spokane Valley WA 99216

Attendees _ Kent:

Mason Bowman, Medicine Mart Pharmacy
Grant Ewing, Ballard Plaza Pharmacy
Jeff Rochon, WA State Pharmacy Association
Nathan Lawless, The Everett Clinic
Valerie Nakagaki, Group Health
Beverly Sheridan, Harborview Medical Center
Denny Burk, Pacific Medical Center
Mike Wright, Central Admixture Pharmacy Services
Cathy McDonald, Harborview Medical Center
Lee Neal, Medicine Mart – Yakima
John Steiner, WSU Student
Tom Hazlet, UW Dean
Stan Jeppesen, Pharmacist
Michell Moser, Makers Compounding Rx
Bonnie Chih, Makers Compounding Rx
Drue Nelson, Harborview Medical Center

Attendees _ Spokane:

Lawrence Timbal, R.Ph., Three Rivers Hospital
Erik Nelson, Sixth Avenue Pharmacy
Cathy Hudek, Riverpoint Pharmacy
Peggy Lamanna, Medicine Shoppe

Attendees _ Tumwater:

Mark Norris, Beall's Compounding Pharmacy
Judy Lim, Kaiser Permanente
Ryan Oftebro, Kelley-Ross Pharmacy
Carmen Collier, Key Compounding Pharmacy
Hee-Joo Park, Key Compounding Pharmacy
Leona Merryman, Halls Drug Center Compounding
Warren Hall, Halls Drug Center
Janet Coleman, Pacific NW Specialty Pharmacy
Christie Stoneback, Albertsons Sav on Pharmacy
Sally Logan, Kaiser Permanente
Nicole Eddins, Mason General Hospital
Cristina Gonzalez, Bartell Drugs
Grant Chester, Pharmacist

Commission Members and Staff:

Chris Barry, Chair
Elizabeth Jensen, Vice Chair
Chris Humberson, Executive Director
Brad Dykstra, Pharmacist Investigator - DOH
Tina Lacey, Pharmacist Investigator - DOH
Bill Kristin, Pharmacist Investigator - DOH
Peggy Crain, Rules Coordinator
Doreen Beebe, Program Manager, Board of Pharmacy

Pre-Meeting Comments:

1. Concerns were expressed that the public and other practitioner were not participating in these meeting/rule development. *Notices inviting stakeholder were distributed to all board, and commission public listservs. Usually interests in the process are heightened once draft language is introduced. We will make sure to include health care practitioner board, commissions, and programs throughout the rule language development. Chris Humberson has also shared updates with the Naturopathic Physician's Board and the Veterinary Board of Governors.*

2. *HB 1800 amends the practice act for pharmacy. Would it be appropriate for the commission to develop rule regarding in-office compounding? The Pharmacy Quality Assurance Commission does not have the authority to limit the scope of practice of other practitioners. A 1980 Attorney General's Office opinion concluded that the "Board" was able to adopt rules affecting practice of other dispenser; however, this was prior to several regulatory reform revisions to the Administrative Procedures Act. Therefore, unless the commission receives specific statutory authority to adopt rules affecting the practice of physicians or other prescribers, the commission cannot establish standards of practice for professions it does not license. One option is to encourage regulatory boards and commissions to consider rulemaking of their own to protect the public.*

Meeting Highlights:

A large part of the meeting focused on federal regulations and pending legislation that will require oversight by the Food and Drug Administration, regarding interstate distribution/dispensing of compounded products – compounding pharmacy versus compounding manufacturer. The workgroup recognized that our work must continue and not wait for the feds to make changes. WA rules, if standards are higher will take precedence over the federal regulations. We need to be mindful to the actions by the federal government, but rules do not need to be written in anticipation of their adoption.

The group agreed that standards must be applicable to all pharmacies, in state and non-resident pharmacies. Standards such as requiring pharmacists to be licensed in WA, documentation of inspection or other process to verify compliance with policies and procedures/third-party audit, etc. Can a pharmacy be required to hold multiple credentials if it engages in interstate distribution? Yes, many pharmacies already hold multiple credentials to accommodate various business practices.

Designation of Compounding practice – Would it be useful to delineate between pharmacies engaging in sterile compounding versus non-sterile? Will hospitals need a special designation or endorsement or does their current credential authorize this practice? Should special verification or documentation be required to renew an endorsement for compounding? At what level of practice would an endorsement be required?

An endorsement could have a separate renewal/approval process allowing the commission to deny or discipline the authority under the endorsement independent from the pharmacy license if appropriate.

Key Areas for delineation in rule:

- Beyond use dating – must require documentation to justify/prove the basis for establishing the expiration dating.
- Consider limiting office use/non-patient specific compounded products for distribution to in-state pharmacies.
- Rules must be specific and standalone. They must address the core elements:
 - Training – based on level of complexity within 797.
 - Quality Assurance
 - Sterility Testing
 - Facility/Environment
 - Equipment
 - Beyond Use Dating
 - Non-specific compounding for office-use
 - Credentialing/accreditation
- Important to consider a implementation/enforcement of the rules to be phased in to optimize/ensure compliance.
- Do not develop new terminology – be consistent with USP 797 and 795.

Post-Meeting Comments:

1. **Comment:** Would there be difficulties in implementing HB1800, which redefines manufacture, specifically repackaging since it appears to be in opposition to the FDA definition in 21CFR210.3? Response/Exemption provided by Stan Jeppesen.

CFR210.3 (12) *Manufacture, processing, packing, or holding of a drug product* includes packaging and labeling operations, testing, and quality control of drug products.

RCW 18.64.011 (15 (b)) manufacture excludes "the practice of repackaging, by a licensed pharmacy, commercially available medication in small reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only."

Exemptions 21CFR 207.10:

(a) Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail. The supplying of prescription drugs by these pharmacies to a practitioner licensed to administer these drugs for his or her use in the course of professional practice or to other pharmacies to meet temporary inventory shortages are not acts that require pharmacies to register.

(b) Hospitals, clinics, and public health agencies that maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy or medicine and that regularly engage in dispensing prescription drugs, other than human blood or blood products, upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care.

(c) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture or process drugs solely for use in their professional practice.

Title 21 USC §360 Registration of producers of drugs or devices (g) Exclusions from application of section

The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

2. **Comment:** Shouldn't referencing the FDA's Compliance Policy Guide (CPG) and United States Pharmacopeia (USP) be sufficient to implement 797 and 795 standards? RCW 69.40.012 and 69.41.010(9) already refers to USP or any supplement, which should be sufficient to say that any updated versions are already part of the law.

Response: RCW 69.40.012, and 69.41.010(9), are **general** references defining drugs. Case law requires sufficient public notice of law/rule changes as well as prohibits the legislature, and the commission from delegating their authority to the federal government.

Incorporation by reference. Incorporation by reference of statutes from other jurisdictions or of other materials, such as building or fire codes, should be drafted to refer to a specific statute or edition as it existed at a particular point in time. The state supreme court has indicated that an attempt to incorporate future changes in federal laws or regulations would be an invalid delegation of legislative power. See *State v. Dougall*, 89 Wn.2d 118 (1977). Also see: *State ex rel. Kirschner v. Urquhart*, 50 Wn.2d 131, 137 (1957); *Yelle v. Bishop*, 55 Wn.2d 286, 303 (1959); *State v. Reader's Digest*, 81 Wn.2d 259, 275 (1972). The same rationale would apply to other source material.

Follow-up Issues:

- Review other state's rule
- Refer to [Hazardous Drugs Handling – WAC 296-62-500](#)

Comments should be sent to the Commission's mailbox WSPQAC@doh.wa.gov
[WSPQAC's Rules in Progress Webpage](#)