



STATE OF WASHINGTON

## DEPARTMENT OF HEALTH

*Olympia, Washington 98504*

### **Board of Pharmacy Stakeholder Meeting Pharmacy Compounding Standards**

June 12, 2013

CenterPoint Corporate Park  
20435 72<sup>nd</sup> Ave  
Kent, WA 98032

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

#### ***Attendees \_ Kent:***

Sonia Gale, Hoagland Pharmacy  
Mason Bowman, Medicine Mart Pharmacy  
Grant, Ballard Plaza Pharmacy  
Laura Steinmetz-Malato, Swedish Medical Center  
Ryan Oftebro, Kelley-Ross Pharmacy  
Lisa Beverly, Group Health Infusion  
Jeff Rochon, WA State Pharmacy Association  
Andre Rossi, Dept of Corrections  
Bill Corrison, Key Compounding Pharmacy  
Nathan Lawless, The Everett Clinic  
Valerie Nakagaki, Group Health  
Hee-Joo Park, Key Compounding Pharmacy  
Betsy Faulkner, Woodinville Pharmacy  
Robert Lambert – UW Student  
Kristy Green, Hoagland Pharmacy  
Eric Harvey, Seattle Children's Hospital

#### ***Attendees \_ Spokane:***

Lawrence Timbal, R.Ph., Three Rivers Hospital  
Erik Nelson, Sixth Avenue Pharmacy  
Nick Bruck, Walgreens  
Rory Lambert, Rite Aid  
Garth Fritel, Northwest Health  
Peggy Lamanna., Medicine Shoppe

#### ***Board and Staff:***

Chris Barry, Chair – Board of Pharmacy  
Emma Zavala-Suarez, Public Member, Board of  
Pharmacy (by phone)  
Chris Humberson, Executive Director, Board of  
Pharmacy  
Tyler Varnum, Pharmacist Inspector - DOH  
Tina Lacey, Pharmacist Inspector – DOH  
Julie Faun, Pharmacist Inspector - DOH  
Grant Chester, Chief Pharmacist Inspector - DOH  
Doreen Beebe, Program Manager, Board of Pharmacy

#### ***Key Concepts: –***

Credentialing Issue – separate and distinct credential/endorsement  
National accreditation  
Inspection process  
Pharmacy Compounding verse Manufacturing  
Sterility testing  
Production limits  
Equipment  
Quality assurance  
Environmental standards  
Staff training/qualified requirements  
HB1800 redefining manufacturing

The following is a compilation of the discussion and thoughts shared at the June 12, 2013 stakeholder meeting.

The meeting started with a brief overview of the rulemaking process and an invitation for all interested parties to participate through workshops or input via email. Chris Humberson provided some background on the law passed on May 7, 2013, which amended RCW 18.64.011 and 270 effective immediately. Chris specifically discussed RCW 18.64.270(2), and asked the group how they felt it applies. Subsection 2 states:

(2) 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.

The participants at the meeting expressed that USP 795 and 797 standards to be reasonable and appropriate. There were some concerns that the board needed to clarify the standards to help facilitate the communication of these standards to those that oversee the operations, but may not be directly involved in the pharmacy practice (i.e. hospital administration, etc.). The will help the pharmacy to justify the changes in processes, equipment, space, etc. and to have the ability to demonstrate compliance during the inspection process.

It was noted that simply stating compliance with 797 and 795 may not be clear and the board's direction through rules will make the requirements clear. In addition, 797 and 795 refer to 8 to ten other standards that speak to sterility, labeling, etc.

Pharmacies should be held to comply with the sections of USP that apply to their practice and not all standards may apply. We need to focus on the complexity of the drug being compounded and apply the right USP sections. It was expressed that the language needs to be flexible enough to ensure safety and appropriate enforceable wording that can be measured but not to be outdated or inhibit practice advancements.

**THING TO REMEMBER:** DEA/Controlled Substances, pending federal legislation, WA L&I Hazardous drug laws/rules.

Chris Humberson asked a broader question regarding compounding in non-pharmacy/physician practice sites? There were some strong concerns that we don't know what is happening in these settings and that the USP standards should be universal – the point is patient safety. Although the law is in the pharmacy practice act RCW 18.64, Chris Humberson did state that the information and discussion in the area will be share with other boards and commissions. He has already reached out to the Veterinary Board of Governors.

What are minimum compendium standards and do they need to be in rule? How should the standards be implemented? Could the board set standards higher than those identified in USP?

During the New England Compounding Center's tragedy we discovered we could not readily identify which pharmacies licensed and located in Washington provided compounding services. Should the department issue a separate and distinct license to pharmacies engaging in compounding? What steps, if any, should the board take to prepare for the passage of U.S. Senate Bill 959 which would require entities shipping compounded drugs across state lines to be licensed as compounding manufacturers?

How do we handle non-resident pharmacies that ship into Washington? Currently there is not a requirement to be inspected by Washington or for the pharmacists practicing at these sites to hold a WA credential. All non-resident pharmacies must be license in their resident state and provide a copy of the initial inspection at the time of licensure – if the board conducts one.

The group felt strongly that all pharmacies must be held to the same standards – resident and non-resident alike. How do we verify that non-resident pharmacies meet the same inspection requirements? The National Association of Boards of Pharmacy (NABP) is currently involved in a national inspection project. The challenge is each state has independent standards. It is likely that NABP will develop a model/sample inspection process. NABP recently passed a resolution to also adopt the USP standards. Once developed, their process and policies will be reviewed by the board before it will consider for adoption/approval.

U.S Senate Bill 959 placing oversight of pharmacies that compound and ship across stateliness under the federal Food and Drug Administration - Good Compounding Practices. How does this impact or change the verification of an out-of-state pharmacy? This legislation only speaks to sterile compounding.

The ability to identify those firms doing high risk or sterile compounding was seen as important. Julie Faun suggested for inspection purposes it is important for the inspector to know what practices are carried out by the pharmacy prior to inspection. Separate endorsements would allow the inspector to survey specific to the practice/operations of that pharmacy.

Will there be additional fees associated with a new license or endorsement? On a regulatory level we need to know what is going on in WA. Special designation or endorsement will help use to notify affected practice to improve and to ensure appropriate standards for the protection of public health. We need to understand and know how many pharmacies are doing sterile versus non-sterile – subcategory - second license. The focus is high risk/batch compounding - to identify and assist the practice with changes and compliance with standards.

Endorsement concept – the act of drug compounding is a “core function” within the practice of a pharmacist. If you are not endorsed for compounding would that mean you could not compound if presented with a prescription? The initial thoughts are that simple compounds like “magic mouthwash” or simple ointment – simple essential compounding would not require an endorsement. Endorsements may be limited to moderate -high-risk sterile compounding – similar to the events and practices being evaluated by the FDA which includes primarily sterile compounding and repackaging of sterile products.

1. How do we identify pharmacies engaging in the practice of moderate to high-risk compounding?
2. How do we accurately apply the appropriate chapter to the applicable pharmacy practice? (Not rewrite USP).
3. How will the public know who is authorized? DOH Provider Credential Search - endorsement/designation for compounding pharmacy and pharmacist.

How do we define compounding? Low versus high risks – mixing two or more commercially available products but anytime you start to weighting, measuring, powders, mixing instructions and move the practice into another category. However, even mixing two or more commercially products require specific labeling requirements under USP.

Everyone should be able to follow USP 797 and 795 – minimum standards – if you can’t comply, you should not be compounding.

RCW 18.64.011(2) 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;

What is a small, reasonable quantity? An example of the “magic number” 30 was stated as being the number inspectors would evaluate. Small reasonable quantities may be based on production units verse

number sold to multiple prescribers. Remember this is applicable to **repackaging** for office use. The focus should be on the quality assurance rather than the quantity.

Potential for harm even if 1% error rate when the lot size is so huge is significant. Apply 797 but when you're making 10,000 in a lot with 1% error rate that is huge! It is an irrelevant question. What business are they ultimately in if you're dispensing more than 10% or 5% of your total dispensing activities? How the board ultimately defines "small, reasonable quantities" will determine if it is appropriate for a pharmacy versus a manufacturer. The statement is clarifying what is not manufacturing.

Things to consider – if additional standards reduces the number of pharmacies engaging in this practice will it increase the volume for those that continue to provide the services. What about the impact of drug shortages and the cost of drugs, how might these contribute to what is a "small, reasonable quantity?"

We know what manufacturing is when we see it. It's just difficult to quantify where to define that line.

New Jersey – passed compounding rules on June 3, 2013 suggest we review language.

Training/Qualifications:

Establish in policies and procedures – with minimum requirements in rules. The group discussed Pharmacy Compounding Accreditation Board PCAB certification, which was explained to mean that you are meeting USP standards. The discussion included on requiring additional CE hours on compounding for pharmacists/technicians engaging in sterile compounding.

Jeff Rochon also offered a tool by The International Academy of Compounding Pharmacists (IACP) - the *Compounding Pharmacy Assessment Questionnaire (CPAQ™)* for patients, prescriber, hospitals, etc. to help them evaluate which compounding pharmacies to use.

Comments should be sent to the Board's mailbox [WSBOP@doh.wa.gov](mailto:WSBOP@doh.wa.gov) - or after July 29, [WSPQAC@doh.wa.gov](mailto:WSPQAC@doh.wa.gov)



# PREPROPOSAL STATEMENT OF INQUIRY

**CR-101 (June 2004)**  
(Implements RCW 34.05.310)  
Do **NOT** use for expedited rule making

**Agency:** Department of Health- Board of Pharmacy

**Subject of possible rule making:** Chapter 246-878 WAC Good Compounding Practices; Chapter 246-871 WAC Pharmaceutical -- Parenteral Products for Non-Hospitalized Patients; Chapter 246-903 WAC Nuclear Pharmacies and Pharmacists; and Chapter 246-873 WAC Hospital Pharmacy Standards. The Board of Pharmacy will evaluate nationally recognized compounding standards to update and set enforceable practice and quality standards for the compounding of sterile and non-sterile preparation in all practice settings.

**Statutes authorizing the agency to adopt rules on this subject:** RCW 18.64.005 State Board of Pharmacy -- Powers and duties; RCW 18.64A.030 Rules -- Duties of technicians, assistants; RCW 18.64.410 Nonresident pharmacies -- Rules; and HB 1800 (Chapter 146, Laws of 2013)

**Reasons why rules on this subject may be needed and what they might accomplish:** In 2008, US Pharmacopeia Convention, a nonprofit organization that sets guidelines for drug standards, adopted minimum practice and quality standards for sterile compounding known as USP 797 and later USP 795 for non-sterile compounding. Washington State rules on compounding practices for pharmacies were last adopted in 1994. Updated rules will ensure that standards are appropriate, clear, and enforceable to protect the public's health and safety from hazardous practices similar to recent events involving hundreds of cases of fungal meningitis and other infections due to the administration of contaminated medications produced using unsafe compounding techniques.

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:**  
None.

**Process for developing new rule (check all that apply):**

- Negotiated rule making  
 Pilot rule making  
 Agency study  
 Other (describe) The Board of Pharmacy will use a collaborative rule-making process to develop new and amended rules.

**How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:**

(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Interested parties will receive notice of rulemaking and stakeholder workshops, and will have the opportunity to submit written comments on the proposed rules. The Board of Pharmacy will use listservs to notify interested parties. Interested parties will have the opportunity to comment and the Board of Pharmacy will take public testimony during the official public rules hearing. For more information, please contact: Doreen Beebe, Program Manager with the Washington State Department of Health, Board of Pharmacy, PO Box 47852, Olympia WA 98504; by phone 360-236-4834; by email: [wsbop@doh.wa.gov](mailto:wsbop@doh.wa.gov).

**DATE**  
5/20/2013

**NAME (TYPE OR PRINT)**  
Chris Humberson, R.Ph

**SIGNATURE**

**TITLE**  
Executive Director, Board of Pharmacy

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE:** May 20, 2013

**TIME:** 10:41 AM

**WSR 13-11-096**



CERTIFICATION OF ENROLLMENT

**HOUSE BILL 1800**

Chapter 146, Laws of 2013

63rd Legislature  
2013 Regular Session

PHARMACISTS--DRUG COMPOUNDING--DISTRIBUTION OR RESALE

EFFECTIVE DATE: 05/07/13

Passed by the House April 22, 2013  
Yeas 95 Nays 0

FRANK CHOPP

\_\_\_\_\_  
**Speaker of the House of Representatives**

Passed by the Senate April 17, 2013  
Yeas 48 Nays 0

BRAD OWEN

\_\_\_\_\_  
**President of the Senate**

Approved May 7, 2013, 2:02 p.m.

JAY INSLEE

\_\_\_\_\_  
**Governor of the State of Washington**

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **HOUSE BILL 1800** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BARBARA BAKER

\_\_\_\_\_  
**Chief Clerk**

FILED

May 7, 2013

**Secretary of State  
State of Washington**

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HOUSE BILL 1800

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AS AMENDED BY THE SENATE

Passed Legislature - 2013 Regular Session

State of Washington

63rd Legislature

2013 Regular Session

By Representatives Cody, Morrell, and Schmick

Read first time 02/11/13. Referred to Committee on Health Care & Wellness.

1 AN ACT Relating to compounding of medications; amending RCW  
2 18.64.270; reenacting and amending RCW 18.64.011; and declaring an  
3 emergency.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 **Sec. 1.** RCW 18.64.011 and 2009 c 549 s 1008 are each reenacted and  
6 amended to read as follows:

7 Unless the context clearly requires otherwise, definitions of terms  
8 shall be as indicated when used in this chapter.

9 (1) "Administer" means the direct application of a drug or device,  
10 whether by injection, inhalation, ingestion, or any other means, to the  
11 body of a patient or research subject.

12 (2) "Board" means the Washington state board of pharmacy.

13 (3) "Compounding" shall be the act of combining two or more  
14 ingredients in the preparation of a prescription.

15 (4) "Controlled substance" means a drug or substance, or an  
16 immediate precursor of such drug or substance, so designated under or  
17 pursuant to the provisions of chapter 69.50 RCW.

18 (5) "Deliver" or "delivery" means the actual, constructive, or

1 attempted transfer from one person to another of a drug or device,  
2 whether or not there is an agency relationship.

3 (6) "Department" means the department of health.

4 (7) "Device" means instruments, apparatus, and contrivances,  
5 including their components, parts, and accessories, intended (a) for  
6 use in the diagnosis, cure, mitigation, treatment, or prevention of  
7 disease in human beings or other animals, or (b) to affect the  
8 structure or any function of the body of human beings or other animals.

9 (8) "Dispense" means the interpretation of a prescription or order  
10 for a drug, biological, or device and, pursuant to that prescription or  
11 order, the proper selection, measuring, compounding, labeling, or  
12 packaging necessary to prepare that prescription or order for delivery.

13 (9) "Distribute" means the delivery of a drug or device other than  
14 by administering or dispensing.

15 (10) The words "drug" and "devices" shall not include surgical or  
16 dental instruments or laboratory materials, gas and oxygen, therapy  
17 equipment, X-ray apparatus or therapeutic equipment, their component  
18 parts or accessories, or equipment, instruments, apparatus, or  
19 contrivances used to render such articles effective in medical,  
20 surgical, or dental treatment, or for use or consumption in or for  
21 mechanical, industrial, manufacturing, or scientific applications or  
22 purposes, nor shall the word "drug" include any article or mixture  
23 covered by the Washington pesticide control act (chapter 15.58 RCW), as  
24 enacted or hereafter amended, nor medicated feed intended for and used  
25 exclusively as a feed for animals other than human beings.

26 (11) "Drugs" means:

27 (a) Articles recognized in the official United States pharmacopoeia  
28 or the official homeopathic pharmacopoeia of the United States;

29 (b) Substances intended for use in the diagnosis, cure, mitigation,  
30 treatment, or prevention of disease in human beings or other animals;

31 (c) Substances (other than food) intended to affect the structure  
32 or any function of the body of human beings or other animals; or

33 (d) Substances intended for use as a component of any substances  
34 specified in (a), (b), or (c) of this subsection, but not including  
35 devices or their component parts or accessories.

36 (12) "Health care entity" means an organization that provides  
37 health care services in a setting that is not otherwise licensed by the

1 state. Health care entity includes a freestanding outpatient surgery  
2 center or a freestanding cardiac care center. It does not include an  
3 individual practitioner's office or a multipractitioner clinic.

4 (13) "Labeling" shall mean the process of preparing and affixing a  
5 label to any drug or device container. The label must include all  
6 information required by current federal and state law and pharmacy  
7 rules.

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

11 (15) "Manufacture" means the production, preparation, propagation,  
12 compounding, or processing of a drug or other substance or device or  
13 the packaging or repackaging of such substance or device, or the  
14 labeling or relabeling of the commercial container of such substance or  
15 device, but does not include the activities of a practitioner who, as  
16 an incident to his or her administration or dispensing such substance  
17 or device in the course of his or her professional practice, personally  
18 prepares, compounds, packages, or labels such substance or device.  
19 "Manufacture" includes the distribution of a licensed pharmacy  
20 compounded drug product to other state licensed persons or commercial  
21 entities for subsequent resale or distribution, unless a specific  
22 product item has approval of the board. The term does not include:

23 (a) The activities of a licensed pharmacy that compounds a product  
24 on or in anticipation of an order of a licensed practitioner for use in  
25 the course of their professional practice to administer to patients,  
26 either personally or under their direct supervision;

27 (b) The practice of a licensed pharmacy when repackaging  
28 commercially available medication in small, reasonable quantities for  
29 a practitioner legally authorized to prescribe the medication for  
30 office use only;

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

35 (d) The delivery of finished and appropriately labeled compounded  
36 products dispensed pursuant to a valid prescription to alternate  
37 delivery locations, other than the patient's residence, when requested

1 by the patient, or the prescriber to administer to the patient, or to  
2 another licensed pharmacy to dispense to the patient.

3 (16) "Manufacturer" shall mean a person, corporation, or other  
4 entity engaged in the manufacture of drugs or devices.

5 (17) "Master license system" means the mechanism established by  
6 chapter 19.02 RCW by which master licenses, endorsed for individual  
7 state-issued licenses, are issued and renewed utilizing a master  
8 application and a master license expiration date common to each  
9 renewable license endorsement.

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

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

15 (20) "Pharmacist" means a person duly licensed by the Washington  
16 state board of pharmacy to engage in the practice of pharmacy.

17 (21) "Pharmacy" means every place properly licensed by the board of  
18 pharmacy where the practice of pharmacy is conducted.

19 (22) The word "poison" shall not include any article or mixture  
20 covered by the Washington pesticide control act (chapter 15.58 RCW), as  
21 enacted or hereafter amended.

22 (23) "Practice of pharmacy" includes the practice of and  
23 responsibility for: Interpreting prescription orders; the compounding,  
24 dispensing, labeling, administering, and distributing of drugs and  
25 devices; the monitoring of drug therapy and use; the initiating or  
26 modifying of drug therapy in accordance with written guidelines or  
27 protocols previously established and approved for his or her practice  
28 by a practitioner authorized to prescribe drugs; the participating in  
29 drug utilization reviews and drug product selection; the proper and  
30 safe storing and distributing of drugs and devices and maintenance of  
31 proper records thereof; the providing of information on legend drugs  
32 which may include, but is not limited to, the advising of therapeutic  
33 values, hazards, and the uses of drugs and devices.

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

37 (25) "Prescription" means an order for drugs or devices issued by

1 a practitioner duly authorized by law or rule in the state of  
2 Washington to prescribe drugs or devices in the course of his or her  
3 professional practice for a legitimate medical purpose.

4 (26) "Secretary" means the secretary of health or the secretary's  
5 designee.

6 (27) "Wholesaler" shall mean a corporation, individual, or other  
7 entity which buys drugs or devices for resale and distribution to  
8 corporations, individuals, or entities other than consumers.

9 **Sec. 2.** RCW 18.64.270 and 2003 c 53 s 137 are each amended to read  
10 as follows:

11 (1) Every proprietor of a wholesale or retail drug store shall be  
12 held responsible for the quality of all drugs, chemicals or medicines  
13 sold or dispensed by him or her except those sold in original packages  
14 of the manufacturer and except those articles or preparations known as  
15 patent or proprietary medicines.

16 (2) Any medicinal products that are compounded for patient  
17 administration or distribution to a licensed practitioner for patient  
18 use or administration shall, at a minimum, meet the standards of the  
19 official United States pharmacopeia as it applies to nonsterile  
20 products and sterile administered products.

21 (3) Any person who shall knowingly, willfully or fraudulently  
22 falsify or adulterate any drug or medicinal substance or preparation  
23 authorized or recognized by an official compendium or used or intended  
24 to be used in medical practice, or shall willfully, knowingly or  
25 fraudulently offer for sale, sell or cause the same to be sold for  
26 medicinal purposes, is guilty of a misdemeanor, and upon conviction  
27 thereof shall be punished by a fine in any sum not less than seventy-  
28 five nor more than one hundred and fifty dollars or by imprisonment in  
29 the county jail for a period of not less than one month nor more than  
30 three months, and any person convicted a third time for violation of  
31 this section may suffer both fine and imprisonment. In any case he or  
32 she shall forfeit to the state of Washington all drugs or preparations  
33 so falsified or adulterated.

34 NEW SECTION. **Sec. 3.** This act is necessary for the immediate  
35 preservation of the public peace, health, or safety, or support of the

1 state government and its existing public institutions, and takes effect  
2 immediately.

Passed by the House April 22, 2013.

Passed by the Senate April 17, 2013.

Approved by the Governor May 7, 2013.

Filed in Office of Secretary of State May 7, 2013.



# United States Senate

## **Bipartisan HELP Senators Unveil Major Effort to Clarify Oversight for Pharmaceutical Compounding; Ensure Consumer Safety**

*"This legislation is a significant step forward in protecting the public from unsafe compounded products. By clarifying FDA authority over high-risk compounding practices, this bill will enhance protections for patients taking compounded drugs and help prevent crises like last year's tragic meningitis outbreak." – Chairman Tom Harkin (D-IA)*

*"Last year's meningitis outbreak was a nightmare for Tennesseans, and this legislation will help ensure that it never happens again. Our goal with this bill is to put an end to FDA inaction and make it clear who is on the flagpole—who is in charge and accountable for oversight of these pharmacies and manufacturers." – Ranking Member Lamar Alexander (R-Tenn.)*

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Following the recent illnesses and deaths from contaminated compounded drug products, a bipartisan group of HELP Committee Senators led by Chairman Tom Harkin (D-Iowa), Ranking Member Lamar Alexander (R-Tenn.), Sen. Pat Roberts (R-Kan.), and Sen. Al Franken (D-Minn.) have released draft legislation. Their proposal would help improve the safety of compounded human and animal drugs by making clear the oversight responsibilities of state and federal authorities.

### **Among the highlights of their draft legislation:**

- The draft establishes a clear boundary between traditional compounders and compounding manufacturers, which make sterile products without or in advance of a prescription and sell those products across state lines. It clarifies a national, uniform set of rules for compounding manufacturers while preserving the states' primary role in traditional pharmacy regulation. The draft creates a similar structure for oversight of compounded animal drugs, and clarifies the law on compounding from bulk chemicals for animals.
- The draft clarifies that compounded drugs are new drugs subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), and specifies which provisions of the law will apply to traditional compounders, and which will apply to compounding manufacturers. A compounding manufacturer is an entity that compounds a sterile drug prior to or without receiving a prescription and introduces such drug into interstate commerce, with the exception that interstate shipment within a hospital system will not cause a hospital pharmacy to be considered a compounding manufacturer. Any entity that pools sterile products, or that repackages sterile, single-use, preservative-free vials is also a compounding manufacturer. In order to maintain clear accountability, compounding manufacturers cannot be licensed as pharmacies.

# United States Senate

## Bipartisan HELP Senators Unveil Major Effort to Clarify Oversight of Compounding Pharmacies; Ensure Consumer Safety – Page 2

- The draft defines the Food and Drug Administration's (FDA's) role in oversight of compounding manufacturers. It calls on compounding manufacturers to register with the FDA and tell the agency what products they have made, make products under a pharmacist's oversight and in compliance with Good Manufacturing Practices, investigate and report adverse events, and label products to indicate that they are compounded and to specify other identifying information. A compounding manufacturer will pay an annual establishment fee to defray the cost of compounding oversight (e.g. inspections), and will cover the agency's costs for any needed reinspections.
- The draft legislation preserves the states' primary role in oversight of traditional pharmacy, while ensuring the compounded products meet certain minimum standards. It prohibits compounding of certain drug products, including those identified by regulation as being demonstrably difficult to compound (such as complex dosage forms and biologics), marketed FDA-approved drugs that are not in shortage, variations of marketed FDA-approved drugs unless they fulfill a specific patient need, or products subject to certain risk evaluation and management strategies unless the compounder utilizes comparable safety controls. Wholesale distribution of compounded products is also not permitted.
- The draft enhances current bulk chemical requirements for the ingredients used in all compounded products. It affirms, with minor modifications, the existing restrictions on bulk compounding of human drugs. The same restrictions apply to compounding animal products from bulk chemicals for minor species, such as exotic animals. The FDA must affirmatively list bulk chemicals for compounding products for food-producing animals and major species (horses, dogs, cats).
- Finally, the draft encourages communication among states and increases communication between states and the FDA. If the FDA receives a complaint from a state regulatory agency about a traditional pharmacy in another state, the FDA must promptly relay that information to the relevant state pharmacy board.

With the release of this draft, Senators Harkin, Alexander, Roberts, and Franken and other members of the HELP Committee are requesting that stakeholders provide feedback on the policy merits, potential unintended consequences, and opportunities to improve the legislative language.