

WYOMING STATE BOARD OF PHARMACY

Board Meeting May 2, 2013

Teleconference

Cheyenne, Wyoming

Present/Absent	Board Member	Title
<i>Present</i>	Randolph A. (Randy) Harrop, R.Ph.	Board President
<i>Present</i>	Bessie McGirr, R.Ph.	Vice President
<i>Present</i>	John R. McPherson, D.D.S.	Board Secretary/Treasurer
<i>Absent</i>	Jim Massengill, R.Ph.	Board Member
<i>Present</i>	Kerri Kilgore, R.Ph.	Board Member
<i>Present</i>	Charles W. Smith	Board Member
<i>Present</i>	Stephanie McAntee, R.P.T.	Board Member, <i>ex-officio</i>

Guests/Observers:

Ken F. Nelson J.D.	Senior Assistant Attorney General
Kelly Roseberry	Assistant Attorney General
Mary K. Walker, R.Ph.	Executive Director, Wyoming State Board of Pharmacy
H. Richard Burton, R.Ph.	Inspector/Compliance Officer, Wyoming State Board of Pharmacy
Phyllis A. Chapman	Senior Office Support Specialist, Wyoming State Board of Pharmacy
Kara Beech, B.S., CHC	Executive Director, Wyoming Pharmacy Association
Stevi Sy, R.Ph.	Wyoming Pharmacy Association
Steve Logan, RPT	Compounding Specialists of Wyoming
Riley Swinchart	US Senate HELP Committee
Sally Sato, R.Ph.	Meds-by-Mail

Call to Order: President Randy Harrop called the meeting to order at 7:30.

Introduction of Kelly Roseberry, Assistant Attorney General: Ken Nelson introduced the new board Assistant Attorney General, Kelly Roseberry. Ms. Roseberry has been with the office for three (3) years now. She will take over the Board of Pharmacy once Mr. Nelson retires on May 31, 2013.

Board email addresses: Mary Walker gave an update on the email addresses for each board member; She suggested we wait until July 1, 2013 to avoid an additional fee. The wyoboard.gov addresses are \$100 each per year. We would save \$800 if we wait. Kerri Kilgore moved to wait until July for the email addresses. Bessie McGirr seconded the motion which passed with a 5-0 vote.

US Senate Committee (HELP) proposed legislation on compounding: President Harrop asked Mary Walker for an update on what the board has been doing. Ms. Walker reviewed the Sterile Compounding task force that met over a year ago. Chapter 17 rules were updated and went into effect January 1, 2012. The inspectors have been using these rules on their inspections. The board office also did an audit on all pharmacies in the state of Wyoming to find out who compounds and who does not. Each location that compounds was required to send a copy of their policies and procedures. The inspectors are also using these as guidelines on inspections. The board staff pharmacists are applying for FDA commissions

to enhance communication. Mary Walker attended an FDA meeting in December where all 50 states were represented and the bill includes many of the recommendations from that meeting.

Riley Swinehart, Senate HELP Committee, mentioned the new bill has restrictions on bulk ingredients and labeling must comply. It does not address OTC vs prescription drug compounding. The bill draws a clear line in the definitions of traditional compounding : "wherein a drug is compounded by a licensed pharmacist in a state-licensed pharmacy; or a licensed physician or licensed veterinarian...that compounds a drug upon receipt of a prescription order for an identified individual patient; or compounds a drug in limited quantities before receipt of a prescription order...based on history...with an established relationship between the licensed pharmacist, licensed physician, or licensed veterinarian and such individual patient for whom the prescription order will be provided."

The new definition of "compounding manufacturer" is an entity "that compounds any sterile drug without receiving a prescription order for such drug prior to beginning compounding and introduces such compounded drug into interstate commerce; or that repackages a drug using sterile preservative-free single-dose vials or by pooling sterile drugs."

President Harrop asked for information on the recent meeting of the boards of medicine and pharmacy where a discussion was held on physician office compounding. Mary Walker stated that the board of medicine told the group that they do not have regulatory authority to inspect offices or clinics unless there is a complaint resulting in an investigation.

Richard Burton mentioned that WY pharmacies are compliant to the compounding rules and are updating policy/procedures. He mentioned that the recent newsletters from the National Assn of Board of Pharmacy (NAB P) do not distinguish between OTC and Prescription drug compounding.

Bessie McGirr asked a series of questions:

1. If a compounder is to notify the FDA secretary prior to the date of compounding for drug shortages there could be delays resulting in harm to patients. Recent drug shortages of Tamiflu, plo gels, promethazine, and lorazepam were mentioned.
2. Drugs that cannot be compounded will be listed in the federal register which is a huge document and cumbersome to use.
3. Bessie went over that reconstituting an antibiotic for a child is not compounding but mixing several ingredients together is compounding.
4. What about selling to veterinarians or physicians one product for a patient to be given in the office? Is this compounding manufacture or traditional compounding?
5. Will the FDA be inspecting all the compounding manufacturers? Each of them will have a licensed pharmacist but not be licensed as a pharmacy? Will the FDA be contacted if problems?

Riley Swinehart stated the following:

He will check on notification, the intent is to make it as least burdensome as possible. The Federal Register is the traditional place for official notification. FDA will list drug shortages and drugs not to be compounded. Inspections will be done by FDA personnel for compounding manufacturers licensed

under the new definition where there is no prescription, interstate business, or as repackagers. Inspections of traditional compounding with the patient-physician-pharmacist relationship will continue to be by states.

Mary Walker mentioned the FDA in December wanted to improve their website and increase communication. The FDA commissions for Mary, Richard, and Hank should facilitate communication.

Steve Logan asked if the new bill prohibits a technician from compounding. Riley stated that the oversight of a pharmacist will still be required, the bill does not change that.

Charlie Smith mentioned that as the public member he understands this bill is a reaction to the fungal meningitis outbreak that included failure of inspection and enforcement in Massachusetts. He recommends a strong review process of the bill so as not to add regulation on top of regulation. Riley commented that Senator Enzi agrees with that statement 100%.

Mary Walker asked if anyone on the telephone knew of a compounding pharmacy in Wyoming that employed more than 25 people. No one did. The fee schedule for inspection and re-inspection is listed in the bill. Bessie mentioned that re-inspection is not capped and could be more than the initial inspection. The \$15,000 fee (or \$5000 for 25 employees) is based on the research that compounding manufacturers are usually licensed in most states and the inspection would be every 3 to 4 years, even though that is not specifically stated in the bill. If the inspection fails there would be a re-inspection.

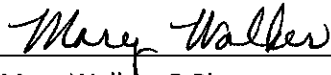
Rules revisions requested by Governor Mead: President Harrop stated the spreadsheet provided is an excellent idea. We will report to the Governor that each year the board of pharmacy reviews rules and we will do a thorough review this year. People can choose which rules they want to work on, keep track of time spent working on them and send ideas for revisions to the board office by June 1, 2013, to be compiled for the June meeting.

NABP call for committee members due by May 17, 2013: NABP has called for committee members to work on various issues in the next year. Mary Walker stated that NABP usually meets for 1-2 days in Chicago and reimburses the travel. This is a good way to meet board members from other states and be involved in creating the NABP model rules. Board members can send a letter to NABP stating their interest.

President Harrop Mentioned the next board meeting will be June 19, 20, 2013 prior to the WPHA convention in Laramie.

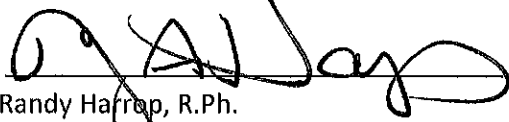
Bessie McGirr moved to adjourn the meeting at 8:20 am. Kerri Kilgore seconded the motion which passed with a 5-0 vote.

Respectfully submitted on May 28, 2013
Notes by Phyllis Chapman, Senior Office Support Specialist
Respectfully submitted and reviewed:



Mary Walker, R.Ph.
Executive Director

Minutes approved and entered into record:



Randy Harrop, R.Ph.
Board President