

A G E N D A WEDNESDAY – JUNE 23RD 2010

ND STATE BOARD OF PHARMACY OFFICE 1906 E BROADWAY AVE – BISMARCK, ND 58501

10:00 AM -CALL TO ORDER

Review and approval of agenda	Agenda
Review and Approval of Board Minutes – May 17-20, 2010	Minute Tab
Examination Candidates for Licensure [5]	Candidates
Conference Room Upgrade Plans	Tab 1
Financial Review – Budget	Budget Tab

Consideration of Final adoption of:

Chapter 61-02-07.1-13 – Pharmacy Technician Reinstatement	Tab 2
Chapter 61-13-02 - Identification Required for Controlled Substances	

Review of Application for Reciprocity: Heriberto Martinez, PharmD – FL
Review Re-instatement Request – David M Legg – ND Technician #410
Family Health Care Center Pharmacy Plans review **Tab 3**
Review Application for Out-of-State Pharmacy Permit Renewal of : Franck’s Pharmacy

Review Re-write of:
 Chapter 61-02-01-03 – Pharmaceutical Compounding Standards

Review plans for Re-write of Wholesale Licensing Requirements

11:00 AM Discussion on priorities for Inspection Visits
ISMP – Integration into Inspections and inspection forms **Tab 4**

11:30 AM Discussion on Dispensing Robots – Chad Nelson, PharmD, R.Ph.

Veterinarians dispensing prescription from other veterinarians-Rule suggested by Dr. John Boyce
To address the veterinary board side of this issue, I drafted a proposed rule change, and sent it to the board members yesterday. They will review it at their next meeting (December 6). It would be the fourth paragraph of 87-04-01-02. I would appreciate it if you would not share this with anyone else at this time, because our board has not had a chance to discuss it, and I am not sure whether this draft accurately captures their thinking on this topic. If you have any comments on it, however, please let me know.

4. A veterinarian may dispense limited quantities of a prescription drug, other than a controlled substance, prescribed by another veterinarian, including a veterinarian licensed in another state, if the prescribing veterinarian does not have an adequate supply of the drug in inventory, or if failure to dispense the drug could interrupt a therapeutic regimen or cause the animal to suffer. The dispensing veterinarian must verify with the prescribing veterinarian, who has established the veterinarian-client-patient relationship, that the drug is appropriate and necessary for the animal, and must comply with the record keeping and labeling requirements of this chapter.

2:00 PM Investigating Committee Meeting

WEDNESDAY - JUNE 23, 2010 Exam Schedule (Four Candidates)

1:15 - 1:30 PM Roll Call and Orientation of Candidates

1:30 - 3:00 PM Laboratory Section 1

3:00 - 3:30 PM Errors and Omissions 1

3:30 - 4:00 PM Oral Examination

4:30 PM Field trip to see Dispensing Robot Demonstration - Optional

The Meeting was called to order by President Elect Rick Detwiller at 10:05 AM on Wednesday June 23rd 2010 in the Conference Room of the ND State Board of Pharmacy located at 1906 E Broadway Ave in Bismarck, ND.

Present were: Pharmacist Rick L. Detwiller; Pharmacist Laurel A. Haroldson; Pharmacist Bonnie J. Thom; Executive Director Howard C. Anderson, Jr, R.Ph.; Legal Intern Dr. Justin Stubstad; Eileen Heidrich and Kathy Zahn.

Absent were: Pharmacist Gary W. Dewhirst; Pharmacist Gayle D. Ziegler

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Agenda as printed. All Board Members present voted aye – motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Board Meeting Minutes of May 17-20, 2010. All Board Members present voted aye – motion carried.

Board Members reviewed the five Candidates for Exam files.

Kathy Zahn presented some options and suggestions for upgrading the Board Conference Room table, chairs and telephone system.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Thom to purchase a telephone conferencing device, a Polycom SoundStation 2™ expandable with display bid by Heinle Telephone Systems at \$696.50. On vote by roll call: Pharmacist Detwiller – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Nays none – the motion carried.

At this time Board Member and President Gayle Ziegler, R.Ph. arrived at the meeting and took over the chair from Pharmacist Detwiller.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to purchase a conference table and 10 chairs from Interiors by France division Office Visions Inc \$2,826.00. On vote by roll call: Pharmacist Detwiller – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler- Aye Nays none – the motion carried.

Board Members reviewed the financial data presented by Executive Director Anderson. Executive Director Anderson explained that the migration to the new Great Plains software was nearly complete and a meeting was sent with our auditors and the budget committee to review by the end of the fiscal year.

President Ziegler asked for consideration of final adoption of Chapter 61-02-07.1-13 – Pharmacy Technician Reinstatement. No comments have been received on this rule, neither through its promulgation nor during the comment period following the rule hearing.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to adopt this new section of Chapter 61-02-07.1, Chapter 61-02-07.1-13 Pharmacy Technician Reinstatement, subject to the Attorney General's opinion. All Board Members present voted aye – motion carried.

Consideration of final adoption of Chapter 61-13-02 - Identification Required for Controlled Substances was discussed. Comments were reviewed from CVS Pharmacies, delivered by Pharmacist Robert Hasquet on behalf of their Director of Government Affairs, Michael Ayotte, R.Ph, as well as comments on behalf of the National Association of Chain Drug Stores [NACDS] suggesting that the requirements in this rule might be too restrictive and take additional time and increase costs of filling prescriptions.

Legal Intern Justin Stubstad, PharmD has prepared a response to most of these comments which are included here:

1. Positive identification checks at the point of pick up create workflow problems that could adversely affect delivery of patient care.

Part of providing optimal patient care is preventing controlled substance diversion and abuse. Requiring positive identification checks at the point of pickup for those prescriptions will help to reduce diversion and will attach an identity to each and every controlled substance dispensed. State and federal law already requires positive identification for products containing ephedrine and pseudoephedrine, so pharmacy staff and patients are accustomed to such minor disruptions in workflow.

2. Target scope of the positive identification requirement to remove individuals who are otherwise identifiable and do not pose a significant diversion risk.

The Board has limited the scope of the identification check to patients not otherwise “personally and positively known to a staff member of the pharmacy.”

3. Prescriptions paid for in part or in whole by a third party payor should be excepted from positive identification requirements.

While it is true that many patients who present fraudulent prescriptions typically pay for their drugs out-of-pocket, it is not exclusively so. Often, patients with prescriptions paid for by third party payors or Medicaid are just as willing to abuse the system, filling prescriptions as early and as often as their payor or Medicaid will allow. Further, requiring a positive identification check at the point of pickup helps to

ensure that an identity is attached to the prescription when it leaves the pharmacy as well as when it is processed and filled. Patients known to the payor and traceable by virtue of the relationship with the payor are not necessarily known by the pharmacy staff and must be identified.

4. Positive identification should not be required for refills or for prescriptions presented by patients who have had a prescription for the same controlled substance previously filled by the pharmacy.

In many cases, the person picking up a refill or a new prescription for the same controlled substance previously filled by the pharmacy will be known by a member of the pharmacy staff, and so shall avoid the positive identification requirements. However, often someone not known to the pharmacy staff will be picking up that refill or may have even ordered the refill without the patient's knowledge. In those instances, it is appropriate and necessary to require a positive identification check at the point of sale.

5. Simplify recordkeeping requirements when positive identification is not required.

Staff in a pharmacy is busy and see and speak with numerous people throughout the day. When someone known to the pharmacy staff picks up a prescription covered by this rule, the staff cannot be expected to simply to remember the individual picking up that prescription. The requirement listed in 61-13-02-02(a) ensures that a record of the individual picking up the prescription is still logged in the instance an issue arises.

6. Clarification: military issued identification cards do not contain a signature.

61-13-02-02(b)(1) explicitly allows record of the military branch issuing the identification. Requiring a government identification card with a signature would conflict with that requirement. The language "and the individual's signature" will be struck from the rule.

7. In cases where the patient is unable to produce identification, provide for alternative method to verify that the patient is authorized to receive the prescription so that patient care is not compromised.

There will be cases where an individual simply does not have identification on their person. In those cases, it seems appropriate that a pharmacist would be able to exercise their professional judgment and, after verifying that a legitimate prescription is being dispensed, determine that the prescription should and can be dispensed without a government-issued identification. The individual's identity should still be recorded to the best of the pharmacist's ability to meet the requirements of this section.

Steven McAtee, R.Ph. owner of Rolla Drug indicated that he was concerned that this might give auditors one more excuse to take back from pharmacies if all of the documentation suggested was not followed in every case.

At this time Chad Nelson, PharmD, R.Ph. arrived to later discuss dispensing robots. Accompanying Dr. Nelson was Mr. Jason Spears LTC Market Director for Talyst, a remote dispensing device. Dr Nelson indicated that he felt that something needed to be done relative to positive identification for controlled substances and offered his pharmacies as a pilot for such a requirement.

It was moved by Pharmacist Detwiller to table final action on Chapter 61-13-02 – Identification Required for Controlled Substances until the next meeting of the Board. This motion was seconded by Pharmacist Thom – All Board Members present voted aye – motion carried and the action was tabled.

An Application for Reciprocity to North Dakota from Florida by Heriberto Martinez, PharmD was reviewed.

It was moved by Pharmacist Detwiller to ask Pharmacist Martinez to appear before the Board to discuss his convictions and arrests which were reported in his Application for Reciprocity, with the Board of Pharmacy, as we have asked others to do under similar circumstances. The motion was seconded by Pharmacist Thom – All Board Members present voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the registration reinstatement request of David M Legg, ND Pharmacy Technician #410. All Board Members present voted aye – motion carried.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Detwiller to approve the remodeling floor plans for Family Health Care Center Pharmacy located at 306 4th Street North in Fargo. All Board Members present voted aye – motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Detwiller approve the renewal application of Out-of-State Pharmacy Permit #485 issued to Franck's Lab dba Franck's Compounding Pharmacy, indicating that we had reviewed the disciplinary actions taken by Florida disclosed with the renewal, which would be maintained in their file for future reference if any other incidents occur. All Board Members present voted aye – motion carried.

Since the re-write of Chapter 61-02-01-03 – Pharmaceutical Compounding Standards was not complete; this agenda item will be deferred to a later meeting.

Discussion followed on the addition of medical gas suppliers and durable medical equipment suppliers relative to the Wholesale Licensing law re-write. No draft is ready at this time.

Legal Intern Justin Stubstad, PharmD reviewed the requirements for “name tags” included in the current rules and laws. Dr. Stubstad made some suggestions for modification of our rules, to reinforce our requirement that personnel in a pharmacy be properly identified on their name tag, as to whether they were Technicians, interns or pharmacists.

Discussion followed on priorities for Inspection Visits by our Compliance Officers, with direction to include some of the questions from the Institute for Safe Medications Practices [ISMP] in our annual Inspection Visits to our pharmacies.

Brendan K. Joyce, PharmD, RPh, Administrator, Pharmacy Services, ND Department of Human Services asked that we include a question on our Inspection Forms that asked about the

compliance with the Medicaid requirement for using tamper evident prescription pads on Medicaid prescriptions. This will be done as well.

Chad Nelson, PharmD, R.Ph and Mr. Jason Spears representing "Talyst" discussed with the Board Members the use of automatic dispensing devices in nursing homes. It was mentioned that Texas and Maryland had regulations in reference to these devices. Pharmacist Nelson is looking at establishing one in Rosewood Nursing facility and Villa Maria.

Board Members reiterated that they were in support of the use of technology. Utilization of this particular device seems to offer benefits to the pharmacy and to the patient. The use of this device and installation of it by the pharmacy does not appear to raise any flags relative to anti-kickback provisions under North Dakota Board of Pharmacy Regulations. The installing pharmacy and the Long Term Care facility do need to keep in mind that there are Center for Medicare and Medicaid Services anti-kickback rules and regulations, which need to be complied with, as well. There would need to be a lease in place for the space, a controlled substances number for the location of the device to facilitate an issuance of a DEA Registration and the concomitant adequate security required for double locking provisions when controlled substances are on site.

It is the policy of the Board of Pharmacy that pharmacy technicians or pharmacists must perform the restocking and removal of medications from the devices.

Pharmacist Nelson invited the Board Members to view the device at a local nursing facility, where it was awaiting approval, but no Board Members could make the schedule today.

At 1:15 PM the candidates for exam arrived and Board Members administered the North Dakota portions of the examinations for licensure to the five candidates.

At the end of the day, the scores were tabulated and all five candidates received passing scores.

There being no further business, the meeting was adjourned.

Gayle D. Ziegler, R.Ph.
President

Gary W. Dewhirst, R.Ph.
Member

Member
Laurel A. Haroldson, R.Ph.

Member
Bonnie J. Thom, R.Ph.

Member
Rick L. Detwiller, R.Ph

Executive Director
Howard C. Anderson Jr. R.Ph.