

A G E N D A
April 24th, 2010 Grand International Hotel – Executive Room
1505 North Broadway - Minot, ND 58703

Call to Order – President Gayle Ziegler

2:00 PM Rule Hearing on: New Section 61-13-01
Emergency Controlled Substance Scheduling Rule

Sign Original Certificates: Registered Pharmacy Technicians

Remodeling plans for: Bilden Pharmacy – Northwood
Churchill Pharmacy - Bismarck
Drayton Drug – Telepharmacy
Family Practice Pharmacy – NDSU
Jamestown Hospital Pharmacy

Proposed Pharmacy Services - MedCenter One Walk-in-Clinic
Questions on placement of Automated Dispensing Devices in Nursing Homes-McGarvey

Minutes of the ND State Board of Pharmacy April 24, 2010 Minot, ND

President Gayle Ziegler called the meeting to order at 2:00 PM in the Executive Room of the Grand International Hotel in Minot, ND. Present were: Pharmacist Rick L. Detwiller; Pharmacist Gary W. Dewhirst; Pharmacist Laurel A. Haroldson; Pharmacist Bonnie J. Thom; Pharmacist Gayle D. Ziegler and Executive Director Howard C. Anderson, Jr, R.Ph. Also present were Pharmacist Dan Churchill and the individuals who signed the attendance sheet and are listed in the Hearing Summary.

PUBLIC HEARING FORMAT

I am Gayle Ziegler, President of the Board of Pharmacy and I will be acting as hearing officer for this public hearing.

It is now 2:00 PM on Saturday, April 24, 2010 in the Executive Room of the Grand International Hotel at 1505 North Broadway in Minot, North Dakota 58703.

This public hearing has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:

Consideration of Rules to implement; **Article 61-13 Controlled Substances**

The comments received at this hearing will be considered with any written comments that are received. Information gathered at this hearing will be used by the Board of Pharmacy for it's deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting; this hearing is being taped so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the hearing for comments:

Attorney General Wayne Stenehjem expressed his support for continuing the rule as passed in emergency form and the continued scheduling of these seven substances as Schedule I Controlled Substances. General Stenehjem discussed incidents where Bureau of Criminal Investigation Agents have seized these products and several publicly reported incidents where people had been hospitalized as a result of using either spice cannabinoids or the injectable stimulants listed in the rule. [Full statement in Addendum A- attached to these minutes.]

Ernie Thurman Security Director at MedCenter One in Bismarck, North Dakota spoke about several incidents where people came into the Emergency room after using these substances, being very combative, hard to control and a danger to themselves and others. Mr. Thurman pointed out that when these products are sold with no active ingredients listed, and yet contain these now controlled substances, it makes it very difficult for the hospital staff to effectively treat them, as the etiology of their problems is unknown.

An individual expressed his concern that making these controlled substances would make it difficult, if not impossible to conduct medical research as to their effectiveness to treat pain or disease in actual patients.

Executive Director Anderson pointed out that scheduling these substances does not prevent medical research, but would make sure that if it were to be conducted in North Dakota, it would have to be under a Letter of Authorization from his office, done according to an FDA protocol and approved by an institutional review board, if the research were to be conducted on human or animal subjects. We do this for many other drugs and the process is well known to researchers.

A Bureau of Criminal Investigation Agent was present with samples of the marketed products, which were demonstrated by analysis by the State Crime Lab to contain one or more of the substances listed in this rule. None of these marketed products listed any of the active ingredients on their labels.

CLOSING

Thank you all for coming. The Board of Pharmacy will use all of the information gathered at this hearing, in making their decision.

The record will be held open for written comment through May 17th, 2010.

At this point, I will close the hearing on: Article 61-13 Controlled Substances

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

Along with the full Board of Pharmacy and the following individuals were in attendance and signed the sheet at the Meeting:

<u>Last Name</u>	<u>First Name</u>	<u>Address</u>	<u>City</u>	<u>State</u>	<u>Zip</u>
Anstadt	Jill	701 32nd Ave N #204	Fargo	ND	58102
Behm	Cody	570 4th Ave SW	Dickinson	ND	58601
Berg-Gibbens	Erin E	4330 47th St S Unit L	Fargo	ND	58104

Born	Megan	1704 Dakota Dr #104	Fargo	ND	58102
Boyer	Julie	4303 9th Ave Cir #201	Fargo	ND	58103
Browne	Robert		Minot		
Buck	Samantha	1405 25th Ave S #302	Fargo	ND	58103
Craham	William H	1412 31st Ave SW #2	Minot	ND	58702
Hardy	Mark	418 Main Street	Neche	ND	58265
Hendrickson	Garrett	107 University Village	Fargo	ND	58102
Hursman	Allison	4963 19th Ave W	West Fargo	ND	58078
Jacobson	Eric	2202 35th Ave S	Fargo	ND	58104
Lothspeich	Taviah	2201 33rd Ave S #206	Fargo	ND	58104
Miller	Erin E	1541 5th Street N	Fargo	ND	58102
Ness	Jan	7001 Highway 83 N	Minot	ND	58703
Ness	Loren	7001 Highway 83 N	Minot	ND	58703
O'Gorman	Brendan	1605 N Univeristy Dr B	Fargo	ND	58102
Olsen	John	3285 Broadway #6	Fargo	ND	58102
Sandgren	Daniel	4303 9th Ave Cir #201	Fargo	ND	58102
Schaaf	Andrew	4339 9th Ave Cir S #34	Fargo	ND	58102
Thurman	Ernie	300 N 7th Street	Bismarck	ND	58501
Welder	Anton	1314 Bayview Court	Bismarck	ND	58504
Wolf	Jordan	1605 N Univeristy Dr B	Fargo	ND	58102

President Ziegler presided over the Rule Hearing protocols at the appointed time of 2:00 PM. After the close of the hearing and a brief period of time where participants were allowed to view the sample products brought by the Attorney General, the Board Members continued with the Agenda for the meeting.

After the pharmacy remodeling plans were reviewed and discussed the following motions were made:

It was moved by Pharmacist Thom and seconded by Pharmacist Detwiller to require a consultation room with the remodeling of Paul Bilden Pharmacy located at 10 North Main Street in Northwood, ND. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to approve remodeling plans for Churchill Pharmacy located at 1190 W Turnpike Ave in Bismarck, ND as presented. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the plans for a Class K - Telepharmacy Permit at Drayton Drug located at 104 E HWY 66 in Drayton, ND; with the understanding that this Pharmacy would be operated as a full Class K – Telepharmacy with prescription drug inventory on site and registered pharmacy technicians preparing the prescriptions for dispensing by a pharmacist via the telepharmacy links. The plan drawn by Chuck McGuire of Dakota Drug was acceptable, indicating that the lock box for filled prescriptions would be accessible only from the outside of the prescription drug storage area, should the prescription be dispensed when the technician is out of the pharmacy and a supportive person is needed to connect the patient with the pharmacist for dispensing and counseling via the telepharmacy link.

This scenario would rarely be utilized, and only when the pharmacy technician would not be available over lunch. The drug storage and prescription preparation areas would need to be secured whenever the Registered Pharmacy Technician is out of the pharmacy. All Board Members voted aye – motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller to approve the preliminary designs of the Family Practice Pharmacy – NDSU in Fargo, ND, as far as the location as the bathrooms and pharmacy waiting area. Final approval will await specific plans and current lease agreement. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and Seconded by Pharmacist Haroldson to approve the plans for the new Jamestown Hospital Pharmacy. All Board Members voted aye – motion carried.

Pharmacist Curtis McGarvey's request for clarification on the use of Automatic Dispensing Devices in a nursing home situation was considered and discussed. The consensus of the Board of Pharmacy was to reassert our established policy – *“that we are not interested in inhibiting progress via technology or otherwise. New ideas are always acceptable and solicited by our Board of Pharmacy. The introduction of Automatic Dispensing Devices in a nursing home setting must be mitigated by the requirement that no kickbacks can occur. Each of these situations is unique, as the specifics must be reviewed to be determined who benefits from the placement of the Automatic Dispensing Device. Is the pharmacy benefiting by avoiding some costs they would otherwise have? Is the nursing home benefiting by obtaining a more efficient and friendly medication dispensing system? Does the patient benefit by improved accuracy within the system and by avoiding some of the costs, which might occur should medications, particularly controlled substances, be wasted because they have been dispensed and cannot be returned?”*

Board members also reiterated their previous position that no non-pharmacy personnel would be permitted to restock or refill the Automatic Dispensing Devices in these settings. A pharmacist or a registered pharmacy technician either employed or contracted by the pharmacy must be used for this purpose so that their license or registration is under the control of the Board of Pharmacy, ensuring that all patient concerns can be protected.

A letter from Pharmacist Thomas Simmer, Director of Pharmacy at MedCenter One asking for the best option for pharmacy services to their walk-in-clinic, which is under construction on Broadway Avenue in Bismarck, was discussed.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to specify that the Board wants to see a protocol and Policies and Procedures, relative to Option A as delineated in Pharmacist Simmer's letter. As indicated by Pharmacist Simmer, the MedCenter One Pharmacy could offer the service that if a patient wanted to have prescription filled at the MedCenter One main pharmacy, MedCenter One could have the prescription delivered over to the walk-in-clinic and the pharmacist would give it to the patient and do the medication counseling at that time. The pharmacist can always deliver the medication to the patient at any location and then provide the medication counseling. All Board Members voted aye – motion carried.

Board Members had the opportunity to meet with Pharmacist Wade Bilden during breakfast on Sunday Morning and agreed to readdress the issue of his remodeling. The Board Members express their concern about the need for a counseling room in the remodeling of Paul Bilden Pharmacy in Northwood. Pharmacist Bilden told the Board Members that he had said the same thing to Mr. Chuck McGuire when he was preparing the floor plans. Pharmacist Bilden and the Board Members agreed that a counseling room could be added near the pharmacy that could serve the patient counseling, immunization needs and medication therapy management needs, as well as future telepharmacy applications.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Haroldson to approve the remodeling plans of Paul Bilden Pharmacy with the addition of the counseling room. Executive Director Anderson will review the updated draft of plans, once the counseling room has been added and submitted. All Board Members voted aye – motion carried.

Having concluded the agenda, the meeting adjourned.

President
Gayle D. Ziegler, R.Ph.

Member
Gary W. Dewhirst, R.Ph.

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.