

AMENDED NOTICE & AGENDA

Conference Call Meeting of the North Dakota Board of Pharmacy

9:00 PM - THURSDAY – FEBRUARY 25, 2010

Speakerphone located at: 1906 E. Broadway, Bismarck, ND

or

Call 1-800-423-1988

Under the name of: **Howard**

Conference # 1437912

9:00 PM Call to Order – President Gayle Ziegler

1. Altru's Collaborative Agreement
2. Tara's Thrifty White's request for a subclass K
3. Wall's Long Term Care Pharmacy – New Class D Pharmacy
4. Rob Nelson, PharmD – Merit Care Health System – request for a variance to NDAC 61-04-08-03, which limits the number of pharmacists an individual physician can have a collaborative agreement with to 3
5. Rob Nelson, PharmD – Merit Care Health System – Collaborative Agreement: Anticoagulation
Out-patient Dialysis
6. Discussion of rule hearing date
7. Hettinger hospital Plans
8. Consideration of an emergency rule that creates a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

February 25th, 2010

Board of Pharmacy Office

Bismarck, ND

Conference call meeting held on Thursday February 25th, 2010. The speaker phone was located at the Board of Pharmacy office at 1906 E Broadway Ave in Bismarck, North Dakota with others on the telephone via conference call.

President Gayle Zieger, R.Ph. called the meeting to order at 9:00 PM. Present at the meeting via conference call were: Board Members Pharmacist Gary W. Dewhirst; Pharmacist Laurel Haroldson; Pharmacist Bonnie J. Thom and Pharmacist Gayle D. Ziegler Absent: Pharmacist Rick L. Detwiller

Also present on the conference call were: Intern PharmD Student Brandi Hagert; Mike Mullen, Assistant Attorney General; Pharmacist Curt Larson District Manager of CVS; Dr Robert Nelson of Merit Care Health Systems and Jenny Michael of *The Bismarck Tribune*; Dale Wetzler and Julie.

Present in the Office with Executive Director Howard Anderson were: ND Attorney General Wayne Stenehjem; Tom Gerhardt, News Director at KXMB-TV; Cassandra Nickel; William J Nickel and Patrina Elagen all representing Big Willies.

After review of the Agenda – ***it was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Agenda as presented, except that we would move item #8 to the beginning of the list, as most of the visitors at the meeting were concerned about that particular issue. All Board Members present voted aye and the motion carried. The Agenda was approved with the change of item #8 being moved to item #1.***

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

It is now 9:04 PM on Thursday February 25, 2010 on a conference call or in the conference room of the Board of Pharmacy Office at 1906 East Broadway in Bismarck, North Dakota.

This public meeting has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning:
Consideration of an emergency rule that creates a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

Information gathered at this meeting 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, and this meeting is being recorded, 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 meeting for comments:

William J. Nickel of Mandan, North Dakota 58554, expressed concerns that his shop sold some of the products which had been referred to in the public press and in which was eluded might contain some of these chemicals. However, the ingredients on the products he sells does not list any of the chemicals indicated in this rule making. The concern of Mr. Nickel's was primarily that it would be difficult for him to ascertain which of his products actually had the listed chemicals in them and that he felt that he was not responsible for the inappropriate use of his products by the people who purchased them. Mr. Nickel asked what the disposition of suspect products might be, if this rule passed tonight.

It was pointed out that once the rule was published by the Legislative Council, in it's present form, any products containing any of these ingredients would be illegal and would not be able to be sold or possessed.

Wayne Stenehjem, North Dakota Attorney General spoke, expressing support for the proposed Emergency Rule. General Stenehjem said that his Bureau of Criminal Investigation Agents, the State Crime Lab and other Law Enforcement Departments have found North Dakota citizens using these products in an inappropriate manner and that in several instances it has been reported that significant harm and hospitalizations have occurred as a result of use of products containing some of these substances. He also indicated that he supported the adoption of this rule and that he felt that those selling products, which the State Lab had identified as containing these dangerous chemicals, either knew or should know, by the high price asked of these products relative to ordinary Incense or Bath Oil Salts, these products were being used inappropriately. General Stenehjem pointed out that the roll of his office and the Board of Pharmacy in supporting and hopefully adopting this rule was for the protection of the public health. Individuals using these products intentionally by inappropriate methods, or by inhaling the smoke or vapors from these products in legitimate fashion, not realizing that they contain dangerous chemicals were a significant risk to the public health. Scheduling these substances and thus making it known that they cannot be added as ingredients to what would otherwise appear to be safe products, will serve to protect the public from these chemicals, whether the individuals using them know they are in the products or if they are using them without knowing that these dangerous chemicals are included in the products.

Cassandra Nickel of Bismarck, ND 58504 pointed out that the selling of these products in their shop, which were purported to contain some of these chemicals, never indicated that these products should be used inappropriately. Most of these products are labeled as Incense or Bath Oil Salts and are labeled not for human consumption.

The State Board of Pharmacy Members offered comments, indicating that they supported their role in the protection of the public health. The scheduling of these substances is necessary to protect those individuals either using them inappropriately or using the products without knowing that these chemicals were contained in the products.

Board Members also pointed out that if legitimate medical uses could be found for these products, they could be moved to an appropriate schedule. But, at this time there is no legitimate medical use for these products. They are used primarily in research for medical purposes. This research can continue under the Schedule I placement of these products until such time as legitimate uses are properly researched and the safety and effectiveness of the products documented.

Mike Mullen Assistant Attorney General pointed out that the rule will affect these products much like a food recall would affect a product that was determined to be adulterated by chemicals not listed on the packaging.

Howard Anderson, Jr, R.Ph., Executive Director of the ND State Board of Pharmacy pointed out some grammatical corrections in the Rule version that was sent out as part of the Notice, where two extra letters had been inserted in the chemical name of HU-211 and a couple of parentheses and brackets had been omitted. Also, Charles Peterson, Dean of NDSU College of Pharmacy had submitted a written comment in which he pointed out that he felt that "or injecting" should be added after ingesting to 61-13-01-01 – Purpose and Scope as how one of the ways users might abuse these substances. This suggestion was included in the final draft.

At the suggestion of Mike Mullen the table under 61-13-01-03 Scheduling was revised slightly to group into group 1 and group 2 the products being scheduled and the history, general authority and law implemented between the two groups eliminated.

A final copy with the above documented corrections was distributed at the meeting and was emailed to the Members of the Board of Pharmacy prior to final action.

CLOSING

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

At this point, I will close the discussion on new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Bonnie Thom to adopt this interim final Rule represented by the corrected copy. On a vote by Roll Call: Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Pharmacist Detwiller – was absent from the Meeting The interim final rule was passed and declared adopted.

Title 61 STATE BOARD OF PHARMACY

SECTION 1. There is hereby created a new Article 61-13 of title 61 of the North Dakota Administrative Rules as follows:

Article 61-13

CONTROLLED SUBSTANCES

Chapter

61-13-01 Controlled Substances Schedules

Section

61-13-01-01 Purpose and Scope

61-13-01-02 Definitions

61-13-01-03 Scheduling

61-13-01-01 Purpose and Scope

The purpose of this rule is to schedule substances which have an actual or relative potential for abuse; and which bear risk to the public health by unknown individuals using them by inhaling the smoke, vapors or by ingesting or injecting the substances.

History: Effective February 25, 2010

General Authority: NDCC 19-03.1-02; NDCC 19-03.1-05

Law Implemented: NDCC 19-03.1-02

61-13-01-02 Definitions.

The definitions under this rule have the meaning as set forth in Chapter 19-03.1 and Chapter 43-15.

History: Effective February 25, 2010

General Authority: NDCC 19-03.1-02; NDCC 19-03.1-05

Law Implemented: NDCC 19-03.1-02

61-13-01-03 Scheduling.

1. The following substances are hereby placed in Schedule I of the Controlled Substances Act NDCC 19-03.1-05 Schedule I subsection 5 Hallucinogenic substances:
 - a. CP 47,497 and homologues 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol)
 - b. HU-210[(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol)].
 - c. HU-211 (dexanabinol, (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)(-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol)
 - d. JWH-018 1-Pentyl-3(1-naphthoyl)indole
 - e. JWH-073 1-Butyl-3-(1-naphthoyl)indole.
2. The following substances are hereby placed in Schedule I of the Controlled Substances Act NDCC 19-03.1-05 Schedule I subsection 7 Stimulant substances:
 - a. Mephedrone (2-methylamino-1-*p*-tolylpropan-1-one).[3] also known as 4-methylmethcathinoe (4-MMC), 4-methylephedrone.
 - b. 3,4-Methylenedioxypropylvalerone (MDPV)

History: Effective February 25, 2010

General Authority: NDCC 19-03.1-02; NDCC 19-03.1-05

Law Implemented: NDCC 19-03.1-02

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Bonnie Thom to Approve the Collaborative Agreement submitted by the following Pharmacist and physicians of the Anticoagulation Clinic at Altru Health Systems:

<u>Pharmacist</u>	<u>Doctor</u>
Cairns, Melanie	Brosseau, James Chan, Paul Deere, Joshua Eickman, Jeff Funk, Peter Grissom, Doug Johnson, Eric
Oakland, Dan	Millette, Keith Nygard, Shane Riaz, Freaha Walz, Joel
Renfrow, Kari	Zaks, William

All Board Members present voted aye and the motion carried.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the addition of the Subclass K – Telepharmacy to Tara’s Thrifty White, LLC at 610 Main Ave in Oakes, North Dakota. All Board Members present voted aye and the motion carried.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Haroldson to approve the new Class D Long-Term-Care Pharmacy Permit for Wall’s LTC Pharmacy Inc at 1020 S Washington Street in Grand Forks, ND. All Board Members present voted aye and the motion carried.

ND Pharmacist #4666 Robert Nelson, PharmD was present on the call and discussed the two Collaborative Agreements submitted on behalf of Merit Care Health Systems.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the Anticoagulation Collaborative Agreement for Merit Care Health Systems, contingent upon the approval of the Board of Medical Examiners for a variance allowing 4 pharmacists to work with each physician. All Board Members present voted aye, with Pharmacist Ziegler disclosing that she is employed with Merit Care Health Systems and intended to vote - the motion carried.

It was moved by Pharmacist Haroldson and seconded by Pharmacist Dewhirst to approve the Renal Dialysis Collaborative Agreement for Merit Care Health Systems, contingent upon the approval of the Board of

Medical Examiners for a variance allowing 4 pharmacists to work with each physician. All Board Members present voted aye, with Pharmacist Ziegler disclosing that she is employed with Merit Care Health Systems and intended to vote - the motion carried.

It was agreed to hold the Rule Hearing for the Emergency Rules approved tonight on Saturday April 24th, 2010 at 2:00 PM in the Grand International Hotel located at 1505 North Broadway in Minot during the North Dakota Pharmacists Convention.

The other rules that are in process such as the USP 797 and 795 Compounding Rules; the requirement of Positive Identification for patient's receiving controlled substances prescriptions and the rule for Reinstatement for Registered Pharmacy Technicians, as well as any others will be presented at the April North Dakota Pharmacists Convention, with their rule hearing to be held on Thursday May 20th, 2010 at 11:00 AM at the Candlewood Suites -1831 NDSU Research Park Drive - Fargo ND 58102.

Pharmacist Susan Hallen of West River Regional Medical Center in Hettinger spoke with Executive Director Anderson to discuss the remodeling floor plans she submitted for their pharmacy. Board Member Gary Dewhirst also had spoken with Pharmacist Hallen and explained the Hettinger plans to the Board.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Thom to approve the remodeling plans for West River Regional Medical Center Pharmacy – 1000 Highway 12 in Hettinger, contingent upon Executive Director Anderson determining compliance with our new intended rules for sterile compounding. All Board Members present voted aye and the motion carried.

Board members asked about the take-back program for pharmaceuticals, which was previously approved.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to move ahead with the take-back program and to fund the \$38,000 necessary for that program, and to make that adjustment in the Budget. On a vote by roll call: Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye – the motion carried. [Pharmacist Detwiller was absent]

The meeting was 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.