

A G E N D A
NORTH DAKOTA STATE BOARD OF PHARMACY
January 4-5-6, 2016
Wingate by Wyndham 4429 19th Ave SW - Fargo ND 58103 (1-701-281-9133)

MONDAY - JANUARY 4, 2016

5:00 PM CALL TO ORDER – President Fran Gronberg

FIRST BUSINESS SESSION

Recite: Mission Statement

Review and approval of agenda

AGENDA TAB

Review and approval of Minutes of November 17, 2015

MINUTE TAB

Assign members to review all paid invoices

Grant Lifetime Licenses and Sign certificates = 10
Sign Pharmacist and RPhTech Original Licenses

TAB 1

Request for CE Approval: Sally M Klabo, PharmD RPh5033

6:30 PM – Dinner– Old Chicago 2551 45th St SW Fargo ND 701-356-8277

President: Donna Kisse	dkisse@thriftywhite.com
Vice-President: Amanda Olauson	amanda.olausoncpht@yahoo.com
Chairperson: Sharon Kupper -	dskup@wil.midco.net
Barbra Lacher – NDSCS -	barbara.lacher@ndscs.edu
Ken Strandberg NDSCS	kenneth.strandberg@ndsu.edu

Discussion Items:

Expanding Role of Technicians in ND: NDAC Chapters 61-02-07.1-05 & 61-02-07.1-06
Standards for registration: Technicians + Technicians-in-Training
Discussion by NAPT Officers of items of interest to NAPT
Promotion of Technician Career to high schools

TUESDAY - JANUARY 5, 2016

8:30 PM CALL TO ORDER – President Fran Gronberg

Exam Schedule Candidates: Svetlana Stukalova – NDSU May 2015 Grad **Candidate**

9:15 - 9:30 PM Roll Call and Orientation of Candidates

9:30 - 11:00 PM Laboratory Section 1

11:00 -11:30 PM Errors and Omissions 1

11:30 -12:00 PM Oral Examination

12:30- 1:30 Lunch Break - Lucky 13

Crosby Drug LLC Report

Yellow Jug Old Drugs Update **TAB 2**

Record Retention Policy **TAB 3**

Year to date Financial Report Budget comparisons **BUDGET TAB**

Board Member Reports

Executive Director's Report

Consider approval of all legal action of the Executive Director

Preparations for May 2016 Exams - move July Board Meeting Date

3:30 PM Investigating Committee Work

6:30 PM Dinner- Grazies – 2000 44th Street SW – Wine Room [701-492-5151]

[20 total]

NDSU President Dean Bresciani; Dean Charles Peterson, Provost Beth Ingram, Mike Schwab
Executive VP NDPhA; Wanda Roden, RPh, President-Elect NDPhA; Kyle DeMontigny, RPh.
President NDPhA; Nicholas Helbling, PharmD, President NDSHP; David J. Olig, R.Ph. for NDPSC, ;
David A. Lindell, Board Attorney

Discussion Items:

Updates from the College of Pharmacy

About the Patient update

Other pharmacy practice issues or concerns

WEDNESDAY – January 6, 2016

8:00 AM Breakfast

Hearings - Meetings with Licensees and Registrants:

9:00 AM – Jayme L Wolf, PharmD – RPh5459

9:00 AM - Advit Shah - Foreign graduate from University of Manitoba

9:20 AM – Thrifty White Pharmacy #078 [old Steiner's] Dickinson relocation plans

9:30 AM – Andrew Norberg – P2 PharmD Student DUI

Discussion Items –

NDAC Chapters	61-02-01-03	Compounding Standards
	61-02-07.1-05	Tasks Technicians <i>MAY</i> perform
	61-02-07.1-06	Tasks Technicians may <i>NOT</i> perform
	61-04-12	Patient consultation requirements
	61-08-01-10	[Out-of-State] Counseling Services

TAB 4

Vouchers - Adjourn

January 4-5-6, 2016

Fargo, ND

President Fran Gronberg called the meeting to order on January 4th, 2016 at 5:00 PM in the Wingate by Wyndham 4429 19th Ave SW - Fargo ND 58103 (1-701-281-9133)

Present in addition to President Gronberg were: Diane M. Halvorson, RPhTech, Tanya L. Schmidt, PharmD, Steven P. Irsfeld, R.Ph., Shane Wendel, PharmD. - Gayle D Ziegler, R.Ph. –Executive Director Mark J Hardy, PharmD. Also present was Chief Compliance Officer Howard C. Anderson Jr, R.Ph. Absent: Gary W. Dewhirst, R.Ph. was not able to attend the meeting do to another commitment.

President Gronberg read the “*Board of Pharmacy Mission Statement: The Board of Pharmacy protects preserves and promotes the public health and welfare of the citizens of North Dakota by assuring that the highest quality pharmaceutical care is delivered and that appropriate use of pharmaceuticals is upheld through education, communication, licensing, legislation, regulation, and enforcement.*”

Board members signed certificates for use in licensing new pharmacist candidates and registering new technicians, to be used until the next board meeting.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Schmidt to approve the Agenda with the addition of a session with PharmD student Andrew Norberg at 9:30 AM on Wednesday and discussion of changing the July meeting date to better accommodate the Wedding Preparations of Executive Director Hardy and the PDMP Interconnect meeting he chairs at NABP. All Board Members present voted aye – the motion carried.

Board members prepared for tomorrow’s exams. The candidate’s file was reviewed for the exams.

It was moved by Pharmacist Ziegler and seconded by Technician Member Halvorson to approve the minutes of the November 17th, 2015 meeting as printed. All Board Members present voted aye. The motion carried.

President Gronberg appointed Pharmacist Irsfeld and Technician Diane Halvorson to review the paid invoices.

It was moved by Pharmacist Shane Wendel and seconded by Pharmacist Steve Irsfeld to grant lifetime licenses to:

Originally issued on June 5, 1965

RPh2738	ElRoy C Folstad, RPh West Fargo, ND	RPh2739	Sandra G Lane, RPh Brawley, CA
RPh2741	Roger E Kohlman, RPh Bismarck, ND	RPh2743	Adolf L Lilke, RPh Bend, OR
RPh2746	Robert R Mutterer, RPh Redmond, OR	RPh2748	Betty D Patterson, RPh Fargo, ND
RPh2758	Kathleen T Monico, RPh Park Rapids, MN	RPh2760	James W Rystedt, RPh N Fort Myers, FL

Originally issued on November 11, 1965

RPh2763	Gerald E Gamrath, RPh Valley City, ND	RPh2773	Phillip W Wattles, RPh Bedford, TX
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All Board Members present voted aye. The motion carried.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Tanya Schmidt to grant ten hours of continuing education credit to Sally M Klabo, PharmD - RPh5033 for completion of the "About the Patient" program during the time the ACPE accreditation for the program had lapsed. All Board Members present voted aye. The motion carried.

At 6:30 PM the Board moved to Dinner at Old Chicago- 2551 45th St SW - Fargo ND with the Technician Advisory Committee consisting of members of NAPT: President: Donna Kisse, Vice-President: Amanda Olason, Chairperson: Sharon Kupper; and Barbara Lacher and Ken Strandberg of NDSCS.

Executive Director Hardy welcomed everyone and asked Technician Kupper to present a report from the Northland Association of Pharmacy Technicians (NAPT). Technician Kupper reported that their fall conference in October of 2015 was their best ever with an attendance of 114 on Friday and 135 on Saturday, so many that they had to change the venue to accommodate everyone. These numbers were up from 70-75 in 2014.

The constitution and bylaws of NAPT were revised to mirror the practice of NDPhA with a President, Vice-President and Chairperson.

The question arose at their meeting about whether ACPE Accreditation is necessary for their CE offerings. It is costing \$1000 this year and will increase to \$2400 to provide CE for the upcoming conference attendees. The Board responded that they felt ACPE Accredited CE was the best way to validate quality and process. It does cost someone to do that and Assistant Program Director Lacher of NDSCS said she would need to hire help to do it through her office, as well.

Technician Donna Kisse spoke about a marketing video NAPT would like to produce to help recruit new people into the technician field. The Video could be used by high schools and technician programs, as well as placed on the web site and through you tube. She said the cost is projected to be about ten thousand dollars and asked the Board to consider half of that cost. [Technician Kisse also stated that PTCB is changing to once a month for recertification from the current quarterly schedule.] Executive Director Hardy encouraged all technicians to establish a CPE profile through NABP as the Board is beginning to use this as an audit mechanism to determine if technicians have their required ten hours of CE per year. Upon review of their CPE profile, if an individual does not appear to have the required amount they are sent a letter requiring them to submit their credits.

Assistant Program Director Barb Lacher stated that NDSCS needs to do some marketing of the new cohort group planned for BSC this fall. Her recent trip as a member of the ACPE advisory committee provided information that two different types of rotations are no longer a requirement, although NDSCS plans to keep their program the same. There will still be 80 hours of lab required. Entry requirements for credit earning courses have been increased slightly across all higher education programs in North Dakota. For the PATSIM program certification of minimum abilities in math, reading and writing can be accomplished by a letter from their potential employer.

Program Director Ken Strandberg said there is an agreement in principal, with a few details to be worked out, to have a cohort group of students enrolled in the NDSCS program at Bismarck State

College [BSC] but taking general courses and attending classes via computer at BSC or at home by the fall semester of 2016. There is a need for \$30,000 to furnish equipment for the lab at BSC and another \$20,000 for marketing of the new program there. It is hoped that BSC will provide the part time proctor needed for the program through their staff. Director Strandberg said funds will be raised through the NDSCS development foundation for both programs and asked if the Board could consider providing the \$30,000 for the lab.

Executive Director Hardy discussed the potential changes to allow Registered Technicians to screen patients for counseling as proposed in NDAC 61-02-07.1. There may be a hearing scheduled at the NDPhA and Technician Convention with the goal that the new rules might be in place within nine months. Discussion followed that there will need to be clear distinction for boundaries between what technicians and supportive personnel are expected to do. The screening could be done by Registered Technicians and perhaps the NAPT fall conference could address this topic.

Executive Director Hardy also discussed that we have talked with the Career and Technical Education Department at the Capitol about getting more technician education opportunities in High Schools.

The evening adjourned with much table discussion following.

President Fran Gronberg reconvened the Board meeting at 8:30 AM Tuesday, January 5th in the Wingate Hotel.

It was moved by Pharmacist Tanya Schmidt to amend the budget and authorize up to \$5000 for the Northland Association of Pharmacy Technicians to produce a recruitment video to help alleviate the technician shortage in North Dakota. The motion was seconded by Technician Diane Halvorson. On vote by roll call: Public Member Gronberg - Aye Technician Halvorson - Aye Pharmacist Irsfeld - Aye Pharmacist Schmidt - Aye Pharmacist Wendel - Aye Pharmacist Ziegler - Aye Nays none - the motion carried.

It was moved by Pharmacist Gayle Ziegler and seconded by Technician Diane Halvorson to support the concept of extending the North Dakota State College of Science [NDSCS] technician program to Bismarck State College and via computer connections across the state. We will need a formal request in writing along with a proposed budget before committing funding to the project. All Board Members present voted aye. The motion carried.

Board members made final preparations and welcomed recent NDSU graduate Svetlana Stukalova for the practical exam.

The examinations were completed and President Gronberg reconvened the Board meeting at 1:30 PM

Executive Director Hardy reported on the progress of the effort to transition J. Co. Drug in Crosby to new ownership. He reported that both he and Howard C. Anderson Jr., R.Ph. are investors in the Crosby Drug, LLC that is buying the drug store from I. J. Jacobson and his wife.

Mark reported on the progress of the Yellow Jugs Old Drugs program. We have seen some of the first installations and they look good. Shane Wendel reported that the public is already using the one

installed in his store. We should have opportunity for 100 locations using the Jugs when the next 50 are manufactured.

It was moved by Pharmacist Irsfeld and seconded by Pharmacist Schmidt to adopt the Record Retention Policy as presented by Executive Director Hardy. All Board Members present voted aye. The motion carried.

It was moved by Pharmacist Ziegler and seconded by Pharmacist Wendel to accept and file the financial report as presented by Executive Director Hardy. On vote by roll call: Public Member Gronberg - Aye Technician Halvorson - Aye Pharmacist Irsfeld - Aye Pharmacist Schmidt - Aye Pharmacist Wendel - Aye Pharmacist Ziegler - Aye Nays none - the motion carried.

Board Member Reports:

Technician Member Halvorson has heard questions from technicians about the required retention time for perpetual inventory logs. Executive Director Hardy responded that since there is no requirement to keep the logs we do not have any requirement for retention but suggested that they might be kept for two years, the same as DEA records, if the pharmacy chooses to use them.

Pharmacist Irsfeld asked if we have guidance on how best to fill and bill a prescription with two NDC numbered products. Discussion followed, with the consensus that Board requirements would be met with adequate documentation about what happened. However, billing procedures are more complicated and avoiding rejections based on appearing to fill two prescriptions on the same day, make the choice difficult. Since insurance companies, PBMs and Medicaid get rebates based on which NDC is used there is always a chance an auditor will consider whatever is done fraudulent, even when legal and patient care standards have been met in full. Filling a partial days supply on the first day and then refilling the prescription when that supply is used up may be the only way to avoid this risk even though it raises cost to the pharmacy and creates more work for the patient.

Pharmacist Schmidt asked about the case of the young lady being denied admittance to NDSU College of Pharmacy. Executive Director Hardy responded that the minutes of the Board are clear when she visited with the Board of Pharmacy. She also asked about any requirements for filling a prescription, e.g. for birth control medication, when the pharmacist has a conscientious objection to their use. Executive Director Hardy responded that we ask that the pharmacist ***take care of the patient*** and refer to someone where they can get care. A pharmacy could also post their objections so the public knows. Pharmacist Schmidt also inquired about the application of the technician ratio to the use of interns and supportive personnel. Executive Director Hardy responded that we do not apply the ratio to include interns and supportive personnel.

Pharmacist Ziegler inquired about the use of a nurse in the hospital to transcribe a prescription for a schedule 3-5 controlled substance taken orally from a clinic physician for a discharge patient. It was discussed and agreed that unless the nurse and the physician have the same employer, or have a written agent agreement, they should not act as the agent of the prescriber for a controlled substance prescription. Pharmacist Ziegler also said that she is on her last year of her first full five year appointment after being appointed to fill the unexpired term of Dewey Schlittenhard.

Board members encouraged her to go to the Governor's web site and submit her application for reappointment, as there are no term limits and the choice is up to the Governor.

Executive Director's Report: Executive Director Hardy reminded the Board that the no-cost software agreement with NABP and Appriss for the PDMP program will end this year and we are looking at an approximate cost of \$6,000 per month in the next budget cycle. The PDMP requirement for registration and use by prescribers, mandated by legislation, is in place for pharmacists and is working its way through the administrative rule process for the other boards. We are looking at a good way to eliminate the requirement for a notary in the registration process without compromising security. Executive Director said he is planning a trip to Winnipeg to meet with Ron Guse about reciprocity between Manitoba and North Dakota for pharmacist licensure, before Ron retires at the end of January.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Gayle Ziegler to approve all legal actions of the Executive Director since the last such motion was passed. On vote by roll call: Public Member Gronberg – Aye Technician Halvorson – Aye Pharmacist Irsfeld – Aye Pharmacist Schmidt – Aye Pharmacist Wendel – Aye Pharmacist Ziegler – Aye Nays none – the motion carried.

At 3:15 PM board members discussed preparations and assignments for the May exams. It was explained that the list of competencies is public, but the questions are not.

It was moved by Technician Member Halvorson and seconded by Pharmacist Schmidt to change the July 2016 meeting date to the 14th to accommodate Executive Director Hardy's chairing a Prescription Drug Monitoring Program [PDMP] interconnect meeting at NABP as well as his and Katherine's wedding preparations. Congratulations Mark and Katherine. All Board Members present voted aye. The motion carried.

At 3:30 PM the Board recessed for some Investigative Committee work.

At 6:30 PM the Board met for Dinner at Grazies – 2000 44th Street SW – Wine Room with NDSU President Dean Bresciani; Dean Charles Peterson, Mike Schwab Executive VP NDPhA; Kyle DeMontigny, RPh. President NDPhA; Nicholas Helbling, PharmD, President NDSHP; David J. Olig, R.Ph. for NDPSC, ; David A. Lindell, Board Attorney. Provost Beth Ingram was out of the country and Wanda Roden, RPh, President-Elect NDPhA could not attend.

Discussion Items: Updates from the College of Health Professionals - About the Patient update - Other pharmacy practice issues or concerns

President Gronberg welcomed everyone and turned things over to Executive Director Hardy for introductions.

Nicholas Helbling, PharmD, President NDSHP spoke first about the many new and exciting things NDSHP is doing. They have increased their membership by 50%, have a newly designed web site with chat rooms where members can learn from each other and are conducting information sessions on a monthly bases for their members.

Mike Schwab Executive VP NDPhA spoke on behalf of NDPhA and NDPSC. There are multiple PBM

issues that are preventing pharmacies from serving their patients and they are looking at some legislation in the 2017 session to address those issues. The “*About the Patient*” program is growing stronger, adding more Medication Therapy Management areas and increasing their services. He stressed that Dr. Wendy Brown at the college has been a great resource for the program.

NDSU President Dean Bresciani spoke about the success NDSU has had in bringing research to Fargo, the value it adds to the state by bringing students from around the country who, when graduating, stay in North Dakota to help expand the economy here. He broached the idea that they might even consider asking the state to reduce the tuition for out of state students to take advantage of the economic benefit they bring.

NDSU President Dean Bresciani deferred to Dean Charles Peterson who spoke about the expansion of the College of Health Professionals where the School of Pharmacy now resides. The addition of the nursing program in Bismarck is helping to train more nurses for the workforce and already has eight Doctor of Nursing Science students ready to graduate in the spring and he hopes they can all be placed in North Dakota. The pharmacy program is very strong with the Pharmaceutical Sciences department contributing greatly to the research and graduate program at NDSU. The new Pharmacy Practice chair, Dr. Marketa Marvanova has great credentials, is enthusiastic and is ready and willing to work with the About the Patient program and the pharmacists of the state. The Dean handed out a one page summary of the plans and need for the addition to Sudro Hall and asked for help in moving that project forward through private funding and the legislative process.

President Gronberg called the meeting back to order at 8:30 AM on Wednesday, January 6th at the Wingate Hotel. Board attorney David A. Lindell was present, but Pharmacist Shane Wendel was not, as he had family commitments in Aberdeen, SD. Pharmacist Steve Irsfeld was a bit late, as he had a flat tire after exercising.

At 9 AM Advit Shah, a 2010 University of Manitoba Faculty of Pharmacy Graduate who has been working in Manitoba met with the board. He has taken the Foreign Pharmacy Graduate Equivalency Examination and the internet based Test of English as a Foreign Language test and asked the Board what they would like him to do for internship before sitting for the North Dakota exams.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to grant Pharmacist Shah 1250 hours of credit for his work in Canada, require 250 hours of internship be earned in North Dakota and a report from his preceptor. He has secured an internship at Wall Drug in Grand Forks. All Board Members present voted aye. The motion carried.

Pharmacist Jayme L. Wolf, PharmD arrived at the meeting along with Agnes Harrington of the PharmAssist Committee to discuss her progress and explain a positive drug test for amphetamine metabolites received Monday of this week. She explained that she had taken a pseudoephedrine product and used an inhaler which had levmetamfetamine as its active ingredient. Agnes said she thought Jayme was doing well and Gayle Ziegler did as well. The board did ask that she go to her counseling sessions before she returns to meet with the Board at the May 2016 meeting in Fargo.

Andrew Norberg, a P2 pharmacy student who attended the technician program at NDSCS arrived to discuss his self-reported DUI received in August 2015. He has met with both Agnes Harrington

and Larry Nelson of the PharmAssist Committee.

It was moved by Pharmacist Irsfeld and seconded by Technician Member Halvorson to approve the relocation plans for Thrifty White Pharmacy #078 (formerly Steiner's) in King's Plaza to 506 West Villard Street in Dickinson. Pharmacist Schmidt disclosed that she works for Thrifty White and intends to vote. All Board Members present voted aye. The motion carried.

NDSCS Assistant Program Director Barb Lacher arrived at the meeting to discuss the proposed changes to NDAC 61-02-07.1-05, 06 and the patient consultation requirements in the new section 61-04-12.

Executive Director Hardy explained the changes proposed to Chapter 61-02-01-03 Compounding Standards with the intention of requiring compliance to USP 795 & 797 Compounding Standards. Board members reviewed the draft and although agreed with it, felt there were a few changes in the risk levels in the sterile compounding section to facilitate the updated chapter in 797. Executive Director Hardy indicated that he would run the proposed changes by Compliance Officer Dennis DelaBarre to assure there is no conflict with USP 795 & 797 standards.

Executive Director Hardy presented the proposed changes to Chapter 61-02-07.1-05; 61-02-07.1-06; 61-04-12 Patient consultation requirements and 61-08-01-10 [Out-of-State] Counseling Services. Board members had many questions and had a very lengthy discussion about these changes and the impact they would have on the practice of pharmacy in North Dakota. All felt that it would be an improvement in level of services and sets a standard that can be strictly enforced for pharmacies providing medications to patients. They discussed the impact on Out-of-State mail order pharmacies and how they would comply to the rule; specifically requiring them to provide communication with the patient in each prescription dispensed. Board Members felt that with a new prescription it was important that a pharmacist talk with that patient in both retail and mail order locations and that the standard should be consistent. They also thought there should be initial communication from the pharmacy to the patient; especially when the patient had never used the mail order pharmacy in the past.

It was the consensus of the Board to move the proposed rule changes forward and that it is important to hear from the pharmacists, technicians and pharmacies that will be affected by these changes and for any clarification in the context of the rules.

It was moved by Pharmacist Ziegler and seconded by Technician Member Halvorson to make the modifications discussed and move forward with the rule hearing process, preferably at the NDPhA convention in April 2016. All Board Members present voted aye. The motion carried.

President Gronberg called for any further business, none forthcoming she adjourned the meeting.

President – Public Member
Fran Gronberg

Gary W. Dewhirst, R.Ph.
Senior Member

Member
Diane M. Halvorson, RPhTech.

Member
Gayle D. Ziegler, R.Ph.

Member
Shane R. Wendel, PharmD.

Member
Steven P Irsfeld, R.Ph.

Member
Tanya L Schmidt, PharmD

Executive Director
Mark J. Hardy, PharmD