

A G E N D A NORTH DAKOTA STATE BOARD OF PHARMACY
January 12-14, 2022

Club House Hotel & Suites - 4400 15th Ave South – Regency 3 Room Fargo ND 58103 (1-701-282-5777)

WEDNESDAY – JANUARY 12, 2022

5:00 PM CALL TO ORDER – Tyler Lannoye, President

Recite: Mission Statement

Review and approval of agenda

**AGENDA TAB
MINUTE TAB**

Review and approval of Minutes of November 18, 2021

Assign members to review all paid invoices and Reconciled Bank Statements

Grant Lifetime Licenses and Sign certificates = **26**

TAB 1

Sign Pharmacist and RPhTech Original Licenses

6:30 PM – Technician Advisory Dinner– *Regency 3 Room - Club House Hotel & Suites - 4400 15th Ave South – Fargo ND 58103 701-282-5777*

Chairperson: Lindsay Cizek-Cribb lindsaycizek@hotmail.com

President: Mandy Chase ajchase_75@hotmail.com

Vice President: Adelle Casavant acasavant5@gmail.com

Melissa Krava –NDSCS melissa.krava@ndscs.edu

Discussion Items:

ND Legislative Session

Administration Authorization Rule for Technicians

Workforce and Recruitment of Technicians

Discussion by NAPT Officers of items of interest to NAPT

Thursday January 13, 2022

8:30 AM CALL TO ORDER – Tyler Lannoye, President

9:00 AM Phar539 Sanford South University Dispensing of Paxlovid and Molnupiravir
Monte Roemmich PharmD BCPS - Pharmacy Manager

TAB 2

Request Add Class K - Remodeling: Phar949 Crosby Drug - 30 Main Street North

TAB 3

10:00 AM Presentation: National Coalition for Drug Quality & Security

TAB 4

11:30 AM Lunch Lucky 13s

1:00 PM ONE Program Final Summary Report 2021

TAB 5

Heidi Eukel, PharmD - Mark Strand, PhD

NEW Pharmacy Thrifty White Pharmacy #085 Fargo

Old Thrifty Drug Southgate location

Discussion Items:

Interim Legislative Meeting

Update on PCMA vs Wehbi

Board Office remodel or relocation

Wholesale and 3PL License fee increase related to HB 1032

Board Member Reports

Executive Director's Report

Consider approval of all legal action of the Executive Director

Preparations for May 16-18, 2022 Exams -

Approval of Paid Invoices and Reconciled Bank Statements

Year to date Financial Report Budget comparisons

BUDGET TAB

Investigating Committee Work

5:30 PM Profession of Pharmacy Dinner– *Regency 3 Room - Club House Hotel & Suites
4400 15th Ave South – Fargo ND 58103 701-282-5777*

Representatives of: NDSU – NDPHA – NDPSC - NDSHP

Discussion Items: NDSU Center for Collaboration and Advancement in Pharmacy [CAP]

ACPE Accreditation

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Page 1

Expansion of Pharmacist Authorities

Challenges and Solutions in the Profession

Friday January 14, 2022

8:00 AM CALL TO ORDER – Tyler Lannoye, President

Discussion

Vouchers - Adjourn

President Tyler Lannoye called the meeting to order on Wednesday January 12, 2022, at 5:10 PM while board members continued to sign certificates for future use.

Present in the Regency 3 Meeting Room were Executive Director Mark J Hardy, PharmD, Board Members: Tyler Lannoye, PharmD; Steven Irsfeld, RPh; Public Member Ron Horner; Carolyn Bodell, RPh; Technician Member Diane Halvorson and Howard C Anderson, Jr, RPh, Senior Compliance Officer

Present remotely: Tanya Schmidt, PharmD

Absent: Shane Wendel, PharmD

President Lannoye read the 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.*

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the meeting Agenda with the additions of a New Pharmacy, Thrifty White Pharmacy #085 in the old Thrifty Drug Southgate location in Fargo and review of Wholesale and 3PL License fee Increases related to HB 1032. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

It was moved by Technician Member Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the minutes of November 18, 2021 Board Meeting as printed. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

President Lannoye assigned Pharmacist Steve Irsfeld and Pharmacist Carolyn Bodell to review the paid invoices and the bank statements.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Carolyn Bodell to grant lifetime licenses to the following individuals:

- | | |
|----------------------------------|-----------------------------------|
| RPh3080 Gary W Boehler, RPh | RPh3081 David O Bucholz, RPh |
| RPh3084 Barbara S Jones, RPh | RPh3086 Connie J Dunbar-Webb, RPh |
| RPh3095 Wade M Hopkins, RPh | RPh3099 Robert W Leitner, RPh |
| RPh3100 Michael J Lillestol, RPh | RPh3101 Barbara Wessling, PharmD |
| RPh3103 Douglas K Macy, RPh | RPh3105 Dwight R Mundy, RPh |
| RPh3106 Bruce A Nelson, RPh | RPh3107 Larry P Oliver, RPh |
| RPh3111 Fred G Paavola, RPh | RPh3115 Rodney G Rosenau, RPh |
| RPh3118 James M Schumacher, RPh | RPh3121 Alvin C Selleck, RPh |
| RPh3122 Cale S Shipman, RPh | RPh3123 Madelon A Streeter, RPh |
| RPh3124 Donald M Stutrud, RPh | RPh3127 Larry P Calhoun, RPh |

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- | | |
|------------------------------|---------------------------------|
| RPh3134 Janis K Johnson, RPh | RPh3143 Patricia A Kramer, RPh |
| RPh3146 Ryn M Pitts, RPh | RPh3149 Kenneth F Schwandt, RPh |
| RPh3150 Mike Vettel, RPh | RPh3154 Ivar Jakobson, RPh |

On vote by roll call Public Member Ron Horner -Aye- Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

At 6:30 PM President Lannoye welcomed members of the Technician Advisory Committee to Dinner

President of the Northland Association of Pharmacy Technicians (NAPT) Mandy Chase an NDSCS alum from Valley City and Vice President Adelle Casavant an NDSCS alum working at Sanford in Fargo were able to join us for the meeting. Grandfathered Technician Joan Anderson and Technician Board Member Diane Halvorson were also present for the discussion. Everyone introduced themselves with Mandy Chase asking Public Member Ron Horner what the public member did. Mr. Horner explained that the public member was there to give a perspective from someone with no direct financial or family interest in pharmacy. Other Board members reinforced that the Public Member has proven to be a valuable asset to the Board.

Executive Director Hardy reviewed recent PREP Act Authorities from the Federal level and subsequent laws passed by the 2021 North Dakota Legislature along with the recently adopted rules effective January 1, 2022 which expanded the role of properly trained technicians to administer medications when working with an authorized pharmacist, even under telepharmacy supervision. Mandy Chase pointed out that 80 technicians took advantage of recent training to become qualified to be able to participate in administration of vaccines. Technician Member Halvorson indicated we are at the one-year anniversary of the PREP act authorization and it would be good to know just how many technicians were actively doing administrations. Tyler Lannoye explained this has been an excellent policy and provided opportunity for technicians to administer many vaccines and booster shots in his practice.

Technician Diane Halvorson requested feedback on if data collection could show how the practice is progressing. It was the consensus of the Board that the data would be valuable and to consider adding questions on wages as well.

Pharmacist Schmidt said Thrifty White is looking at Technicians doing vaccinations at their telepharmacy sites.

Workforce and recruitment were discussed. Pharmacist Irsfeld said he has noticed that many of our pharmacies seem to be pharmacist heavy, thus not utilizing technicians as much as they might to expand services to the patients.

Pharmacist Bodell asked how competencies were maintained in the retail setting and heard that the technician training modules are available for review to keep skills up to date.

Relative to recruitment issues, Technician Mandy Chase reminded the board they have sponsored recruitment videos used at high schools and career fairs.

Discussion followed about the Career and Technical Education programs expanding around the state. Technicians coming out of high school ready to go to work would be a great asset to many communities having difficulty recruiting.

Technician Chase reported the Fall Conference of NAPT was very successful with many technicians taking training on administration of medications. Next years program is scheduled for September 2022, in Bismarck.

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Technician Member Halvorson reported 12 states with Technicians on their Boards, with Oregon having two technician members.

President Lannoye recessed the meeting until tomorrow morning at 8:30 AM

President Lannoye reconvened the Board Meeting at 8:30 AM on January 13, 2022 and read the 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.*

Pharmacist Shane Wendel was now present in person at the meeting this morning in addition to Pharmacist Tanya Schmidt and all other board members.

President Lannoye followed up from last evening by reinforcing the Board will continue to work on CTE inclusion of technician programs and ask the NDSU School of Pharmacy CAP program to help with the technician survey design.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Diane Halvorson to approve the remodeling plans and addition of a subclass K permit for Crosby Drug Phar949 at 30 Main Street North in Crosby, ND. It is intended to connect with Tioga Drug and Dakota Drug in Stanley. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel -Aye -Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson - Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

Executive Director Hardy and Pharmacist Tanya Schmidt explained the request for a new pharmacy permit for Thrifty White #085 to be located at the former Thrifty Drug Southgate location in Fargo. The former pharmacy has closed, and the files transferred to Phar6 Linson Pharmacy. Coburn's, the owner of the Hornbacher's Grocery Store has done an analysis and has offered the lease to Thrifty White.

It was moved by Pharmacist Carolyn Bodell and seconded by Technician Member Diane Halvorson to approve the issuance of a permit to Thrifty White #085 at 1532 32nd Ave South in Fargo, contingent upon Executive Director Hardy receiving an acceptable lease for the site. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel -Aye - Pharmacist Tanya Schmidt – Recused herself as she is employed by Thrifty White - Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

At 9 AM Executive Director Hardy summarized the request of Sanford Phar539 South University for Dispensing of Paxlovid and Molnupiravir to all patients. Monte Roemmich PharmD BCPS - Pharmacy Manager and Morgan Thompson, PhmD were present to discuss the request.

These two drugs are for oral treatment of Covid-19. They are new therapies on limited supply and currently limited distribution through the State Department of Health. Dr. Roemmich explained that currently 80% of the request for therapy was coming from the urgent care clinic near the location of this hospital pharmacy. There is not a retail pharmacy permit there and he is requesting they be allowed to use the hospital pharmacy to dispense to all patients for whom their providers are prescribing these drugs. The intention would be that once a positive test is received by the clinic, the prescription is issued and then could be dispensed at the Pharmacy.

It was noted that many patients go home after their test is done, await a call from the clinic and then return for their

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prescription. The hospital pharmacy is currently licensed to dispense only to patients of the hospital upon discharge or who are seen in the hospital emergency room. Board Members understood the State is working to get supplies of the drug to other pharmacies in the Fargo area and patients often go home to await the call. Patients could eventually go to their regular pharmacy for the service and inventory could be worked through a cooperative effort with the pharmacy which usually serves those patients.

Executive Director Hardy introduced Denise Frank, RPh who is a partner in the National Coalition for Drug Quality & Security. Pharmacist Frank gave a presentation to the board on the company's program for accreditation of wholesalers and others who might be seeking licensure in North Dakota or other states. Pharmacist Frank previously worked with the NABP VAWD program, currently required by North Dakota, and went independent from NABP in 2016 to develop her own accreditation program. She reported they currently have 22 wholesalers accredited and six in process. Board Members did not reach a decision and asked for further information from Pharmacist Frank and Executive Director Hardy.

At 11:36 Board members went to Lucky 13's for lunch.

At 1:00 PM the board reconvened to hear a report from Dr. Mark Strand, Dr Oliver Frenzel and Alyssa Hodges BS, who is working on her Masters of Public Health Degree. Dr. Strand provided a handout with statistics gleaned from the program as it has been implemented by Pharmacies to screen patients for Opioid Misuse and Accidental Overdose. The program has been a very successful one, has gained national attention and is being implemented by Idaho and West Virginia.

Pharmacist Tanya Schmidt asked if manufacturers of naloxone have provided support to which Dr. Strand responded, he would not be able to take funds from them as it would be a conflict of interest. The program has been showcased at NABP and will be again, live, if North Dakota provides student support at the poster session this year. Technician Diane Halvorson encouraged a presentation at the NAPT fall conference as much of the patient interaction and follow-up can be provided by pharmacy technicians.

Executive Director Hardy proceeded with the discussion items on the agenda:

Interim legislative meetings have discussed PBM issues in detail and has resulted in a request for the Board of Pharmacy, The Attorney General and the Insurance Commissioner to suggest changes in the law to make PBM regulation work more effectively. Licensure (registration), complaint investigation and resultant prosecution is disconnected now and relies on local states attorneys to prosecute cases, which does not work effectively.

PCMA vs Wehbi is mostly finalized in the 8th Circuit Court, with PCMA appealing a provision on Accreditation Standards and recertification requirements.

Executive Director Hardy reported on the Board office remodeling or relocation plans. Board Members again agreed a relocation will be in our best interest. It will avoid remodeling costs and put the Board in a better Office area, although it will increase our rent expense. The Board may be able to view the new space at the March meeting and may be to move in sometime in May 2022.

Dr. Hardy circulated copies of a letter going to the wholesale licensees who will be paying the extra \$600 decreed by HB 1032 to give them notice of the coming increase. These extra dollars will be transferred to the State Treasurer's office for the use of the insurance commissioner for the operation of the Prescription Drug Cost Transparency Program.

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Technician Member Diane Halvorson suggested we review rules related to display of license certificates as this is extra work, especially when a person works in more than one location. She also asked if we needed any additional requirements to ensure patients with poor eyesight or another language can read a label. Public Member Ron Horner suggested that no one actually looks at those posted certificates for information.

Pharmacist Carolyn Bodell suggested we look at the issue of "*White Bagging*", where medication is sent to a hospital by a specialty pharmacy for administration to a hospital patient, "*Brown Bagging*", where medication is sent to the patient with the expectation it is stored properly and brought to the hospital for administration, and "*Clear Bagging*", when a drug is dispensed from the hospital's own pharmacy for administration.

Executive Director Hardy reported there are updates being finalized for USP 795 and USP 797. This brought questions about what happens when the rule has been adopted and the standard changes. The answer was that licensees can only be held to the standard in place at the time the rule or law is adopted, as North Dakota does not allow outside groups to change North Dakota laws or rules.

Executive Director reported on the DEA request for comments relative to Telepharmacy and shared what he submitted on behalf of the Board.

The inspection process is ongoing. Compliance Officer Judith Swisher has not been able to perform inspections due to her health so other inspectors are taking on the load. We are hearing some burnout comments on inspections and pharmacies are under a lot of pressure as PBMs continue to take more out of pharmacy reimbursement.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Member Diane Halvorson to approve all the legal actions of Executive Director Hardy. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel -Aye -Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye - Aye. The motion carried.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Carolyn Bodell to approve the reviewed paid invoices and the bank statements. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel -Aye -Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye - Aye. The motion carried.

Dr. Hardy reviewed the financial statements pointing out a \$87,000 refund will be received from the Department of Human Services. He noted the continued expenses of the PCMA lawsuit and the possibility our rent will rise with the new location.

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Shane Wendel to approve the financials as presented. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel - Aye -Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

Dr. Hardy reviewed the exam process for the May meeting to help the two new Board Members understand their participation and remind everyone of the responsibility to review portfolios and have their portion of the exam prepared.

The Investigating Committee met to review and consider some complaints.

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The Profession of Pharmacy Dinner was moved up to 4:55 to allow those who wished to leave before the snowstorm scheduled to arrive tonight.

Present for the dinner were: Dean Charles Peterson and Dr. Elizabeth Skoy of NDSU School Pharmacy, Maari Loy, Pharm D of the North Dakota Society of Health Systems Pharmacists, Steve Boehning, RPh of the North Dakota Pharmacy Service Corporation, and Jeff Jacobson, PharmD President of the North Dakota Pharmacists Association. Everyone introduced themselves.

Dr. Skoy lead off with an explanation of the Center for Collaboration and Advancement in Pharmacy (CAP Center) and explained the four principles, which are: Education and Training; Programs and Implementation; Coaching and Support; Data and Outcomes. All designed to advance patient care. They have received a grant of five million dollars over a three-year period to support their work.

Dean Charles Peterson followed and reported the recent accreditation process went very well with the College of Pharmacy receiving an eight-year accreditation through June 30, 2028. Budget cuts and an enrollment decline did trigger some monitoring as they had five open faculty positions at the time of the five-person team visit. Enrollment is a huge concern given there are currently 54 incoming students in the professional program instead of our previous 85. This will cause financial constraints.

NDSU has received recognition as a Carnegie R1 status of Doctoral Universities with very high research activity. This is due in large part to the performance of the Pharmaceutical Sciences Department at the School of Pharmacy

with over 40 million in highly competitive research funding over the last five years in addition to 50 million in philanthropic donor support.

In the spring of 2020 63.4% of the graduates were licensed in North Dakota. Dean Peterson invited the profession to identify areas of needed training or retraining and the college will look at them for curriculum additions.

Dr. Maari Loy cited Covid-19 as the biggest challenge for the hospitals during the last two years. Recruitment has been a challenge for all health professions. Also, many drugs are on allocation which has prompted more networking among hospital pharmacists to attempt to solve these problems. She responded to questions that pharmacists with a residency are usually hired at one step up from those without that experience.

Pharmacist Steve Boehning identified PBM pressure on reimbursements as the chief problem of retail pharmacy. Almost all prices are now rebate driven. The Pharmacy Service Corporation, along with NDPhA are looking to develop a billing service to help pharmacies move into the new service areas of MTM, testing, immunizations, and other new patient care services. The demand of PBMs to get involved in 340B reimbursement disadvantages both the pharmacy and the 340B clinic or hospital.

Pharmacist Jeff Jacobson spoke for NDPhA. They are looking at a health insurance product that all pharmacies can use. The convention is in Bismarck this year. He said the morale of pharmacists needs some help as everyone is over worked and reimbursement pressure.

Pharmacist Tanya Schmidt said we are at risk of losing pharmacies because of reimbursement issues. Access to services is a risk as prescription filling is not making money. For them Central fill and ancillary services is keeping the doors open right now.

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President Lannoye recessed the meeting so those who wished to leave could head to where they are going before the snowstorm hit. A Zoom link will be available for tomorrow's meeting.

Friday January 14, 2022

President Lannoye called the meeting to order at 8:06 AM and read the 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.

Present in the Regency 3 Room of the Club House Hotel and Suites were Pharmacist Tanya Schmidt, Technician Member Diane Halvorson and Pharmacist Howard C. Anderson Jr. Present via Zoom were Executive Director Mark Hardy, Pharmacist Carolyn Bodell, Pharmacist Tyler Lannoye, Public Member Ron Horner, Pharmacist Steve Irsfeld and Pharmacist Shane Wendel.

President Lannoye invited Board Members to comment on the meeting with the profession held last night and the meeting with the Technician Advisory Committee on Wednesday evening.

The Technician Survey was discussed. Dr. Skoy offered the CAP Center to help design the questionnaire and perhaps the use of the Qualtrics toll they use for tabulation of responses. Technician Member Diane Halvorson will work with Executive Director Hardy to involve the CAP Center in the work. Pharmacist Tyler Lannoye volunteered his technicians to report on their immunization activities at the NAPT Conference next fall.

Everyone supported the efforts of the CAP Center to help move pharmacy services into the economic stream of pharmacy to build the sustainability model of those services.

Pharmacist Steve Irsfeld reported his pharmacy has a somewhat unique model. With the reimbursement on prescriptions leading to a net profit on many prescriptions under \$2.00, he had decided they can no longer service those PBM contracts.

Executive Director Hardy suggested policy makers look at setting a baseline reimbursement for the patient service and safety expectations to protect patients.

Pharmacist Tanya Schmidt offered that as pressure comes on the payers to eliminate DIR fees, they morph the language into other strategies to continue to take money out of the Pharmacy's pocket.

The goal of the Board is to get every prescription filled accurately, safely and provide the service the public expects from their pharmacist.

It was moved by Pharmacist Tanya Schmidt and seconded by Technician Member Diane Halvorson to adjourn the meeting. On vote by roll call Public Member Ron Horner -Aye- Pharmacist Shane Wendel -Aye - Pharmacist Tanya Schmidt – Aye- Pharmacist Steve Irsfeld – Aye – Pharmacist Carolyn Bodell – Aye – Technician Member Diane Halvorson -Aye- Pharmacist Tyler Lannoye -Aye. The motion carried.

President Lannoye adjourned the meeting.

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President
Tyler G Lannoye, PharmD

Technician Member & Senior Member
Diane M. Halvorson, RPhTech

Member
Steven P Irsfeld, RPh

Member
Tanya L Schmidt, PharmD

Member
Shane R. Wendel, PharmD

Public Member
Ron J Horner

Member
Carolyn R Bodell, RPh

Executive Director
Mark J. Hardy, PharmD