

**INDIANA BOARD OF PHARMACY
Indiana Government Center South
402 West Washington Street, Room W064
Indianapolis, IN 46204**

MINUTES OF JANUARY 13, 2020

Mark Smosna, R.Ph., President, called the meeting to order at 8:39 a.m. and declared a quorum in accordance with IC 25-26-13-3(d), pursuant to public notice posted at the principal office of the board at least forty-eight (48) hours before the time of the meeting.

Members Present: Mark Smosna, R.Ph., President
Donna Wall, R.Ph., Member
Steven Anderson, R.Ph., Member
Del Fanning, R.Ph., Member (left 10 p.m.)
Winnie Landis, R.Ph., Member
Matt Balla, R.Ph., Vice President

Staff Present: Darren Covington, J.D., Board Director
Professional Licensing Agency
Jody Edens, Assistant Board Director
Professional Licensing Agency
Zaneta Nunnally, Compliance Director
Professional Licensing Agency
Nicole Schuster, J.D., Deputy Attorney General
Office of the Attorney General

The Board voted to adopt the agenda as amended.

Balla/Wall, 6/0/0
Motion carries

The following board members voted aye:
Mark Smosna, Donna Wall, Del Fanning, Steve Anderson, Winnie Landis, Matt Balla
The following board members voted nay: none
The following board members abstained: none

ELECTION OF OFFICERS

The following were voted into office for a one (1) year term beginning February 1, 2020

- Matt Balla, R.Ph., President
- Steve Anderson, R.Ph., Vice President

Smosna/Wall, 6/0/0
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Mark Smosna, Matt Balla, Winnie Landis, Steve Anderson
The following board members voted nay: none
The following board members abstained: none

FULL BOARD APPEARANCES

Rich Palombo, R.Ph., D.Ph. – Express Scripts – Technician Work at Home Pilot Program update:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Winnie Landis, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Matt Balla, R.Ph.

Tara Teachout also appeared regarding this matter.

They started this pilot program one and a half (1 ½) years ago. This will be their last 6 month extension. They inquired what would happen in July if the rule wasn't in place.

Mr. Covington informed them that this specific rule is currently with the Budget Agency and should be effective sometime in 2020. He also indicated that they could apply for a new variance.

They currently have eight (8) technicians working at home. They have very high production and quality.

The program has been very successful.

Rich and Tara both feel it has been very successful and request to continue the pilot for the next six (6) months.

After discussion, the Board moved to APPROVE the Work at Home Pilot Program to continue for another six (6) months.

Wall/Balla, 6/0/0
Motion carries

The following board members voted aye:
Del Fanning, Mark Smosna, Winnie Landis, Donna Wall, Steve Anderson, Matt Balla
The following board members voted nay: none
The following board members abstained: none

**Bill Cover, BSPHarm, R.Ph., Director , Members Relations & Government Affairs,
NAPB – NAPB Wholesale Distributor Inspection Program & VIPPS/.Pharmacy
websites:**

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Winnie Landis, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Matt Balla, R.Ph.

NABP Services for Distributors

- Accreditation
 - *NABP Accredited Drug Distributor Program*
 - *Formerly Verified Accredited Wholesale Distributor® (VAWD®)*
- Inspections
 - *NABP Supply Chain Inspection Program (SCI)*
 - Uniform DSCSA compliance assessment of wholesale distributors
 - Protection of citizens against the ongoing threats to our nation's drug supply

NABP Services for Distributors

- Accreditation and Inspection Programs available for States and Facilities:
 - Wholesale Distributors (including Virtual)
 - Reverse Distributors
 - Third Party Logistics Providers (3PLs)
 - Manufacturers
 - Repackagers
 - 503B (Outsourcer Facilities)

NABP Accredited Drug Distributor Program

- Rebranding of VAWD program in December 2019
- Launched 2005, almost 15 years ago, to assist States with combating proliferation of counterfeit drugs
- Covers prescription drugs and devices
- 640+ Accredited Facilities
- Located in 46 States and 1 Territory
- 24 States recognize NABP Accredited Drug Distributor program
- Time to Accreditation based on preparedness of applicant and willingness to comply with law and criteria.
 - In general, 6 – 9 months
 - 2 – 3 months for facilities that are prepared

Inspections- Supply Chain Inspection Program (SCI)

- Launched in fourth quarter of 2019
- Developed based on NABP's long established expertise and experience in protecting the nation's drug supply through its Accreditation of Wholesale Distributors
- Inspection focus adopted from NABP Accredited Drug Distributor program
- Snapshot of Wholesaler's operation at a point in time

Supply Chain Inspection (SCI) Program

- Similar to VPP
- WD applies for an inspection
 - Pays fee;
 - Completes application;
 - Submits required documents
 - Agrees to Terms and Conditions:
 - Including that results will be shared with state boards of pharmacy and federal regulators
- Once the application is complete, NABP conducts an unannounced inspection within 8 weeks
- Applicants can apply at sci@nabp.pharmacy
- State boards will be contacted if an SCI inspection will be completed in their state and resident state inspectors can be present to observe.

Benefits of Inspection Program for Member Boards

e-Profile Access

- Inspection sharing across states through e-Profile Connect
- Aids board of pharmacy in making informed decisions

Inspection Services

- Uniform inspection program – Distributors
- Determine compliance with DSCSA, state licensing requirements
- Personalized state inspection projects
- Custom for onsite inspection/audit to verify compliance of desk audits.

NABP Surveyors

- There are currently 50+ surveyors located in 24 states
- Our staff and surveyor and document reviewers' backgrounds include:
 - Distribution Managers for Major Manufacturers and Wholesale Distributors
 - Wholesale drug distribution and supply chain integrity experts
 - Boards of pharmacy and Distributor Regulation Officials - executive officers, board members, compliance officers, and inspectors (current / retired)
 - Community pharmacy, hospital pharmacy, sterile compounding, nuclear pharmacy, home infusion
 - Law enforcement, regulatory compliance, Federal Bureau of Investigations, Drug Enforcement Administration, FDA-OCI, Secret Service, and Internal Revenue Service, including undercover work and criminal investigations for these agencies
 - Military, Department of Health and Human Services, Medicare fraud, and prescription monitoring programming

Michigan Wholesale Distributor Inspection Project

- 45 inspections from 9/20/19 – 10/1/2019
- Presently reviewing findings
- Highlights/Lowlights:
 - Licenses held for decades—without ever having been inspected
 - No air conditioning

- Doors wide open – no security
- Sales into States with no license, especially those selling to physicians.
- Not aware of DSCSA
- Training and education program to assist the state with how to review/manage findings.

Verified Internet Pharmacy Practice Sites® (VIPPS®) Accreditation

- Launched in 1999 as NABP's first accreditation program and is recognized by over twenty state boards of pharmacy
- Established to help the public distinguish between legitimate and illegitimate pharmacy websites
- Pharmacies based in the US with a .pharmacy domain are eligible to apply
 - .Pharmacy is the first step in VIPPS accreditation process
- While VIPPS is a voluntary accreditation program, some states require VIPPS (Indiana, Iowa, Kentucky, North Carolina & Virginia)
- The scope of VIPPS accreditation does not extend to prescription drugs/devices, human or veterinary, that are dispensed to animals
 - Vet-VIPPS program was phased out in August of 2016
 - Veterinary pharmacies are eligible for the NABP *.Pharmacy Top-Level Domain Program*

Currently, there are a total of 72 accredited organizations, accounting for more than 18,500 facilities.

.Pharmacy – Evolution in Online Pharmacy Safety

- **.Pharmacy** is a secure and trustworthy Top-Level Domain (TLD), like .edu or .gov.
 - In 2012, with the support of a global coalition of stakeholders, NABP applied to ICANN to become the registry operator of the new .pharmacy TLD.
 - NABP received approval from ICANN and launched the .Pharmacy Program in 2014.
- **Distinct** from verification sites and certification badges: the “seal of approval” is built into the website's URL.
- **Easy** for consumers to spot a legitimate pharmacy: look to the right of the dot.

.Pharmacy – Recognized by Search Engines and Online Platforms

- Major search engines Google, Yahoo!, & Bing, and social media platforms Snapchat and Twitter have taken notice of the program's powerful simplicity now require a .pharmacy domain to advertise on their platforms

.Pharmacy – Meets Requirements for Visa and Mastercard

- Verification and monitoring through the .Pharmacy Program are recognized by **Visa** and **Mastercard** as meeting requirements for pharmacy merchants conducting card-not-present transactions.
- Provides acquirers with assurance that the pharmacy is operating lawfully and in compliance with Visa and Mastercard rules.

.Pharmacy is required for a pharmacy to move forward with VIPPS® Accreditation

The Board thanked Mr. Cover for his presentation

Stephen Tharp, M.D., Commission on Legislation Chair, ISMA – e-prescribing exceptions:

Participating Members: Donna Wall, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Dr. Tharp requested that the Board consider the following when they complete the listing for exceptions for the e-prescribing rule:

- Physician that write no more than one-hundred (100) prescriptions per year
- Locum tenens physicians
- Patients requesting a written prescription so they can compare prices
- Physician determines that a patient can't get the medication in a timely manner
- Physicians that do not have electronic medical records – in rural areas
- Compounded prescriptions
- Physicians volunteering

The Board thanked Dr. Tharp for his input.

Asit Patel, B.Sc., PharmD, Informatics Pharmacist IU Health S Campus – Pharmacy Law/Printed Prescriptions:

Participating Members: Donna Wall, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Mr. Patel presented the following information to the Board in his request to use 8.5x11 size prescription pads.

At IU Health and affiliated clinics/MD offices approximately 20% of prescriptions that are recorded through their EMR are printed. The remaining are transmitted electronically to the pharmacy. A one-day sample showed 2,458 (10.5%) printed prescriptions out of 23,221 written in total.

They expect this percentage to drop as mandatory EPCS comes into effect though the printed method will always have a role in the event of a system failure.

They have kept the two (2) methods for prescribing synchronized in their environment – the same data elements that constitute the prescription are both transmitted electronically as well as printed in the event it is required.

The data elements that are now permitted with the NCPDP2017071 uplift and are required for the EPCS functionality now crowd their printed prescriptions. The crowding may leave to text overtyping the signature lines and the refill related safety feature.

They recognize that other states (Illinois & Michigan) use full page printed prescription for both their Schedule C-II through C-V prescriptions as well as Legend prescriptions. They

see this as an opportunity to enhance improve the legibility and safety of the printed prescriptions.

He submitted a written proposal to the Board as follows:

They propose to amend 856 IAC 1-34-2 and remove paragraph 10. Electronic prescribing of controlled substances (EPCS) (mandatory January 2021) requires a printed solution backup that adds two new elements to the prescription:

- In the event the system is not able to route the prescription, the prescription must indicate it was routed electronically and the destination pharmacy on the face of the prescription.
- In the event the patient wants a copy of the electronically routed prescription for record keeping purposes, the printed prescription must have a statement on the face that it is not to be filled and that it is a copy only.

NCPDP2017071 script uplift – the CMS mandated uplift makes changes to the Script Standard and makes both mandatory and optional changes to the data transmitted electronically to pharmacies and/or 3rd party payers and PBM's.

- Increases the permitted number of characters for SIG to 1,000.
 - Increases the special instructions field to 250 characters – this is the field for patient instructions.
- Requires addition of last charted patient weight and height for pediatric patients and sends it if available for adult patients.
- While there is no legal requirement to include diagnosis on the prescriptions, pharmacists are turning them away when a diagnosis is needed to determine medical legitimacy of the prescription or if 3rd party payers require it for reimbursement. They include the ICD-10 code for the diagnosis
- Do not fill before dates are now permitted for all prescriptions and not just C-II
- Max daily dose and Max daily dose units

Mr. Covington informed Mr. Patel and the Board that the size requirements are set by rule, so it would require a rule change. The rule only applies to paper controlled substance prescriptions.

The Board requested Mr. Covington to look into doing a rule change for the size requirements.

The Board thanked Mr. Patel for his presentation.

Laura Gillespie, PharmD, St. Joseph Health System – Penicillin Skin Testing update:

Participating Members: Donna Wall, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

From the June 10, 2019 Minutes:

"Minutes from the September 2018 meeting are as follows:

Pharmacist Administration of Penicillin Skin Testing Protocol – St. Joseph Health System:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Mark Smosna, R.Ph., Winnie Landis, R.Ph., Steve Anderson, R.Ph., Matt Balla, R.Ph.

Joseph Stoldt, Pharmacist Resident and Jason Jablonski, Pharmacy Director St. Joseph Health System appeared.

They are requesting approval from the Board for a Pharmacist to be able to do skin testing. The pharmacist would be trained and must do a re-training each year to keep their certification up.

Their question to the Board is can a Pharmacist do diagnostic testing? They indicated a Physician will actually order the skin test.

Only hospital inpatients will be tested who have been consulted to the PST/CST team and who have reported penicillin or cephalosporin allergy and a beta-lactam is preferred for the infectious process currently requiring treatment. They must meet the inclusion/exclusion criteria.

They do have a CLIA waiver; and protocol by the institution.

The Board thanked them for their presentation and requested they keep them updated."

Minutes from the June 10, 2019 meeting:

"They are here today to give the Board an update on what they found. The allergy testing program was fully up and operational on January 1, 2019.

They have tested fifty-five (55) individuals so far. Of these, one (1) individual had a positive skin test and four (4) were indeterminate tests. The test results are comparative to what is seen in the literature where over 90% of tested individuals have a negative skin test. The average age of individuals tested was 55 years old. All those who had a negative skin test were able to safely receive a penicillin type antibiotic without incident.

The positive skin test was identified during the scratch test. No systemic or anaphylactic reactions occurred. Positive reaction symptoms included pruritis (itchiness) and erythema (redness) localized at the testing site. The reaction subsided quickly.

A positive cost savings was calculated for the allergy testing program at Saint Joseph Hospital. This cost savings was assessed through a reduction in drug expenditure. Investigators compared cost of therapy patient was on compared to de-escalation to penicillin, cephalosporin, or nothing depending on an individual's specific case. It was assumed if seven (7) patients were tested per week this would equate to a cost savings of \$153,806. This cost savings was reduced when subtracting pharmacist time to \$62,806. However, assuming the allergy testing would help reduce Cdif rates at the hospital (one per quarter), the cost savings increases to \$182,806 – \$230,806."

They have had continued success with the penicillin skin testing and are requesting to do oral challenge and have submitted a written copy of the policies and protocols for the board to review.

They are also requesting if a Pharmacists can do the testing in an outpatient infusion center and in pre-surgical testing.

The Board stated that a Pharmacist must be trained and there must be staff there in case of an emergency.

The Board thanked Ms. Gillespie for her presentation.

Stewart Wilson, Coordinator, National Coalition for Drug Quality & Security (NCDQS):

Participating Members: Donna Wall, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Denise Frank, R.Ph appeared on behalf of this request.

Ms. Frank introduced herself as the President, Founder, Owner, Director of Accreditation and Inspection, Chairman and Member of Accreditation Board.

She is a pharmacist and consultant with extensive experience in pharmacy practice, expertise in accreditation and regulatory compliance including sterile and nonsterile compounding. She has more than 30 years of experience as a pharmacist including owning a rural independent pharmacy before working for a health-system establishing clinic pharmacies. She worked for a major grocery chain as a pharmacy manager and district manager.

She served as a member of the Minnesota Board of Pharmacy for eight years and participated in National Association of Boards of Pharmacy (NABP) committees through 2013. She served as a surveyor consultant for NABP from 2006 until 2013. In 2013, she moved into the full-time position of Accreditation and Inspection Services manager for NABP.

Ms. Frank was heavily involved in the development and implementation of new programs for accreditations and inspections including CPPA®, VPP® and state projects, in training of state board compliance officers, and in maintaining and updating existing NABP accreditation programs to include emerging issues and changes in regulations and standards. She was the subject-matter expert for the accreditation and inspection programs and bore the primary responsibility for the training, supervision and quality improvement of 41 nation-wide contract surveyors/inspectors with a primary goal of protecting public health and improving patient outcomes.

Kansas accepts NCDQS inspections and Iowa approves waivers for Facilities for NCDQS while waiting for VAWD accreditation.

The Board requested transparency on who owns the company and who the Board member are before they will consider the program.

Woodland Hills Pharmacy – License #64001491A – Non Resident Renewal:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Steve Levin, owner of Woodland Hills Pharmacy appeared regarding this matter.

Mr. Levin informed the Board that they are licensed in approximately twenty-three (23) states. They have approximately forty (40) patients a month in Indiana.

He submitted the following information for the Board's review regarding disciplinary action in other states:

- The California Board of Pharmacy issued a Stipulated Order on February 9, 2018 against the Pharmacy and its PIC Steven Levin effective March 12, 2018 placing both on four (4) years' probation subject to notice, education and other requirements. The violations were for the sale of Amphotericin B and for failure to properly store and deliver Amphotericin B
- The Nevada Board of Pharmacy on April 26, 2018, renewed Steven Levin's license registration and placed him on probation on the following conditions: 1. Comply with the conditions imposed by the CA Board; 2. Notice the Board of any change in license status in CA and 3. Not practice in Nevada without prior authorization of the Executive Secretary of the Board.
- Louisiana Board of Pharmacy issued a Consent Agreement dated May 23, 2018 imposing probation that the pharmacy and the pharmacist Steven Levin abides by conditions imposed by CA Board.
- Oregon Board of Pharmacy issued a Consent Order dated October 2, 2018 imposing probation that the pharmacy and the pharmacist Steven Levin abides by the conditions imposed by CA Board.
- Virginia Board of Pharmacy – Mandatory suspension under Virginia law on July 27, 2018 without a hearing, based upon CA order.
- Texas Board of Pharmacy issued a Stipulated Order December 6, 2018 Discipline imposing probation concurrent with CA order November 3, 2017. The alleged violations were based on out of state orders: California – compounding errors; Louisiana and Virginia - disciplinary action by another Board.
- Colorado Board of Pharmacy issued a letter of Admonishment January 2, 2019 because the pharmacy sold adulterated dangerous drugs that did not conform to standards and tests as to quality and strength.
- Pennsylvania Board has ordered on April 9, 2019 that when the pharmacy license is issued it will be placed on indefinite probation until such time that each and every one of the Applicants pharmacy permits, registrations, licenses or any other authorization to practice in every jurisdiction in which the Applicant possesses such authorizations to practice is active and unencumbered. The license issued July 5, 2019 is Active/Probation.
- Illinois Board issued a Consent Order on July 5, 2019 imposing indefinite probation, must comply with CA Board Order.
- Maryland Board, on April 23, 2019 issued charges against the pharmacy under the Maryland Pharmacy Act charging certain violations of Maryland code. This matter is pending.
- Michigan Board issued an administrative complaint on May 6, 2019 against the pharmacists alleging violations of the Public Health Code. This matter is pending.

After discussing these issues with the Board, the Board moved to APPROVE Woodland Hills license renewal.

Wall/Fanning, 4/0/0
Motion carries

The following board members voted aye:
Del Fanning, Winnie Landis, Donna Wall, Matt Balla
The following board members voted nay: none
The following board members abstained: none

Henry Ford Pharmacy Advantage Southfield – License #64001230A – Non Resident Renewal:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Doug Samojedny, Director of Operations and Brian Jent, J.D. appeared on behalf of this matter.

Mr. Samojedny submitted in part the following information for the Board to review:

- November 28, 2019 the Pharmacy entered into a Consent Order with the Illinois Board. They acknowledged violations of Illinois' rules and regulations based on violations of two (2) other states rules and regulations. The Consent Order officially reprimanded the pharmacy licenses based upon the following Board actions.
- November 14, 2018, the Pharmacy entered into a Consent Agreement with Louisiana Board. They acknowledge and proactively reported dispensing seventeen (17) prescriptions into Louisiana between January 1, 2018 and August 8, 2019 with an expired Louisiana permit. They consented to pay a fine of \$5,000 and to reimburse the Board \$250.00 for administrative costs.
- November 23, 2018, the Pharmacy applied for a license in New Hampshire. The application was submitted nine (9) days after the consent agreement with the Louisiana Board. Within the renewal application they answered "No" to a question regard other state actions. The Pharmacy signed a Notice of Apparent Liability on April 10, 2019 and paid a fine of \$2,000

After discussion, the Board moved to APPROVE Henry Ford Pharmacy Advantage Southfield's license renewal.

Fanning/Wall, 4/0/0
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Winnie Landis, Matt Balla
The following board members voted nay: none
The following board members abstained: none

Wells Pharmacy Network – License #64001355A & 64001422A – Non Resident Renewals:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Cherish Fishman, President appeared on regarding this matter.

For license 64001355A, Ms. Fishman gave the Board the following information to review:

- January 16, 2018 the Pharmacy accepted Stipulation and Consent Order from Utah Board based upon a Consent Order they entered into with Alabama Board in 2017.
- July 18, 2018, the Tennessee Board approved a final Consent Order reprimanding the Pharmacy for dispensing compounded hormone pellets in September 2016, which were out of specification. Prior to the

receipt of the June 2018 complaint which the Order is premised upon, on September 20, 2016 the Pharmacy, in conjunction with the FDA, instituted a physician level recall of the affected lot number of products referenced in the Order. March 29, 2017 the recall was closed by the Pharmacy and FDA. To date they have not received an adverse event reports relating to patient's receiving the recalled products.

- January 3, 2019, the Pharmacy received a fully executed Consent Order from the Oregon Board. The Order reprimanded them for alleged unprofessional conduct. This reprimand is based upon two (2) previously reported disciplinary actions to the Board from California on June 6, 2017 and Utah on January 1, 2018.
- May 1, 2019, the Pharmacy received a fully executed MOA with the DEA for recordkeeping infractions stemming from its biennial inspection in September 2018.
- May 29, 2019 the Pharmacy received a fully executed Order from the Kentucky Board. This was based upon reciprocal discipline arising from the Tennessee action. They were issued a fine from Kentucky.
- August 16, 2019, the Pharmacy received a fully executed Stipulation and Consent order from the Idaho Board. Idaho stated that the MOU with DEA violates the states' rules and regs regarding improper recordkeeping, which resulted in a public discipline of their Idaho licenses.
- September 30, 2019, the Pharmacy received a Proposed Settlement Agreement from the Florida Board due to discipline taken in Oklahoma, Tennessee, Idaho and Missouri.
- November 2018, the Texas Board denied the renewal due to the Consent Order executed with the Alabama Board in 2017.

Regarding license 64001422A, she submitted the following information for the Board to review.

- January 16, 2018, the Pharmacy accepted a Stipulation and Consent Order from the Utah Board based upon action taken by the Alabama Board in 2017.
- March 21, 2018 the Pharmacy accepted a Settlement Agreement and Final Order with the Iowa Board. The Iowa Board alleged that Wells did not timely report out of state discipline from Maine; did not timely provide records to the Board; dispensed a prescription without verifying a valid patient-prescriber relationship; compounded drugs which are essentially copies of commercially available products and failure to perform prospective drug use review. In the settlement agreement and Final Order, the Pharmacy agreed to pay a \$12,000 fine within sixty (60) days, remain PCAB accredited, verify prescribers issuing prescriptions to Iowa residents and have an active Iowa medical license, comply with Iowa's rules regarding compounding copies of approved drugs.
- April 20, 2018 the Pharmacy signed a Consent Order with the Oregon Board. This was after the Oregon investigator interviewed and reviewed the Pharmacies disciplinary history. The Pharmacy explained the following regarding the South Carolina discipline and New Hampshire denial: 1. South Carolina presented a Private Order to the Pharmacy. The Pharmacy submitted a copy of the Private Order to the Oregon Board and explained to the Oregon investigator that its understanding was that South Carolina did not intend to publicly release this Order. 2. The New Hampshire Board denied the Pharmacy renewal in March 2018, but the reactivated the license in April 2018.
- As a result of an unrelated inspection of a physician dispenser, the Pharmacy received a complaint from the Oklahoma Board alleging a violation of Oklahoma's "pick up station" statute; a violation of Oklahoma's prohibition of compounding an essential copy of an available FDA-approved drug with patient therapy is not compromised; and 3. Failure to conduct a drug utilization review. The complaint stemmed from a relationship with an Oklahoma clinic that the Pharmacy had been dispensing patient specific non controlled compounded prescriptions until June 2017 when Wells learned that the Clinic had applied for an Oklahoma resident pharmacy license. Upon this discovery Wells ceased its relationship with the clinic. The agreement with the Oklahoma Board was to pay a fine.
- October 1, 2018 the Pharmacy received notification that it has been admonished by the Colorado State Board. This was based upon reciprocal discipline for a previous matter before the Oklahoma Board.
- October 24, 2018 the Pharmacy entered into a Consent Order with Idaho Board and paid an administrative fine of \$14,000.
- October 31, 2018, the Pharmacy entered into a Settlement Agreement with the New Hampshire Board, which imposed a reprimand and fine in the amount of \$4,000 this was based upon reciprocal discipline by the Oklahoma Board.
- October 15, 2019 the Pharmacy entered into a Consent Agreement with the Pennsylvania Board. They were issued a civil penalty based upon discipline by the Idaho Board.
- March 30, 2019, the Pharmacy accepted a Citation and fine from the California Board, based upon reciprocal

action.

- July 3, 2019, the Pharmacy was placed on probation by the Missouri Board resolving allegations arising from the Pharmacies practice of pharmacy in Missouri.
- May 14, 2019, the Pharmacy received notification the Nebraska Board denied their license renewal due to previous action taken by other states.
- July 22, 2019 the Pharmacy received a Proposed Settlement Agreement from the Iowa Board of Pharmacy alleging that Wells violated its 2018 Consent Order by compounding essential copies of approved drugs. Well requested a hearing regarding this issue and it's scheduled for November 2019.
- November 2018, the Texas Board denied the renewal due to the consent order entered into by Wells with the Alabama Board in 2017.

After discussion, the Board moved to APPROVE both license renewals for Wells Pharmacy Network.

Landis/Fanning, 4/0/0
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Winnie Landis, Matt Balla
The following board members voted nay: none
The following board members abstained: none

Caremark Florida Mail Pharmacy – License #64000536A – Non Resident Renewal:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Dora Rebelo appeared regarding this matter.

The Illinois Board of Pharmacy took action based upon sister state action. This issues from the other states took place from 2010 to 2016 and they purchased the pharmacy in 2018 correcting all issues.

After discussion, the Board moved to APPROVE Caremark Florida Mail Pharmacy's license renewal.

Wall/Fanning, 3/0/1, with Ms. Landis abstaining
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Matt Balla
The following board members voted nay: none
The following board members abstained: Winnie Landis

Diamond Pharmacy – License # 64000035A – Non Resident Renewal:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph.

Gerald O'Brian, J.D, General Counsel for Diamond Pharmacy and Derek Peterson, J.D.

appeared regarding this matter.

They submitted the following information for the Board to review:

- September 24, 2019, the Alabama Board placed Diamond on probation for three (3) years and issued an administrative fine of \$13,000 due to the orders issued by Oklahoma Board in 2015, Louisiana Board in 2018, Texas Board in 2018, Colorado Board in 2017 and the Consent Judgement by the US District Court of Northern District of Ohio in 2018.

After discussion, the Board moved to APPROVE Diamond Pharmacy's license renewal.

Wall/Fanning, 4/0/0
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Winnie Landis, Matt Balla
The following board members voted nay: none
The following board members abstained: none

Genoa Healthcare – Remote Dispensing Facility/CSR Application:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph.

Nick Vucurevich appeared regarding this matter.

Mr. Vucurevich informed the Board that the remote dispensing facility will be inside a community health facility. They will only fill prescriptions from the physicians that practice in the community health facility.

They will be open from 8am to 5pm which is the same as the physician offices.

They currently only have one (1) technician that will be working in the facility but are training two (2) others at this time. A Pharmacist will visit the facility every two (2) weeks and the PIC will visit at least once a month.

After discussion, the Board moved to APPROVE the Remote Dispensing Facility/CSR Application.

Wall/Landis, 6/0/0
Motion carries

The following board members voted aye:
Donna Wall, Del Fanning, Winnie Landis, Matt Balla, Steve Anderson, Mark Smosna
The following board members voted nay: none
The following board members abstained: none

Thorntown Pharmacy – Remote Dispensing Facility/CSR Application:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph.

Saumiin Calcuttawala appeared regarding this matter.

He indicated the remote dispensing facility will be inside a primary care facility.

He indicated it would be open to the public. The Board determined it met the 10 mile rule.

After discussion, the Board moved to APPROVE the Remote Dispensing Facility/CSR App.

Wall/Anderson, 6/0/0
Motion carries

The following board members voted aye:

Donna Wall, Del Fanning, Winnie Landis, Matt Balla, Steve Anderson, Mark Smosna

The following board members voted nay: none

The following board members abstained: none

Janki Pharmacy d/b/a Clay City Pharmacy – Remote Dispensing Facility/CSR Application:

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Matt Balla, R.Ph., Winnie Landis, R.Ph., Mark Smosna, R.Ph., Steve Anderson, R.Ph.

Mr. Patel appeared regarding this matter.

This is currently a full pharmacy and they are requesting to convert it to a remote dispensing facility.

There isn't a pharmacy within a seventeen (17) mile radius.

The parent store is in Terre Haute and the Pharmacists will visit twice a week.

After discussion, the Board moved to APPROVE the Remote Dispensing Facility/CSR Application.

Fanning/Wall, 6/0/0
Motion carries

The following board members voted aye:

Donna Wall, Del Fanning, Winnie Landis, Matt Balla, Steve Anderson, Mark Smosna

The following board members voted nay: none

The following board members abstained: none

PROBATIONARY APPEARANCES

Participating Members: Donna Wall, R.Ph., Del Fanning, R.Ph., Steve Anderson, R.Ph., Winnie Landis, R.Ph., Matt Balla, R.Ph., Mark Smosna, R.Ph.

The following made their probationary appearance:

Phillip Simpson
David Ringel
Stephen Potts
Susan Adams
Mikhail Galperin
Lucas Sweet
Estil Caton

Jennifer Coy – did not appear again.

After discussion, the Board moved to issue an Order to Show Cause in this matter.

Wall/Balla, 5/0/0
Motion carries

The following board members voted aye:
Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis
The following board members voted nay: none
The following board members abstained: none

The Board thanked Ms. Nunnally for her report.

PERSONAL APPEARANCES

During the Full Board Appearances, the Board divided up into two Committees with two (2) members on the Compliance Committee which met in Room A of the Conference Center doing people personal appearances. The Standing Committee stayed in W064 and consisted of four (4) members and they completed the Facility appearances. Once the Board was back together as a full board they voted on all the personal appearances that appeared before the Compliance Committee.

The following did not appear for their scheduled personal appearance:

- Amanda Walker – MPJE repeat exam app
- Alicia Minniear – Technician in Training app
- Teresa Smith – Technician in Training online app

Kara Sermersheim – MPJE Retake Exam App:

Ms. Sermersheim appeared before the Compliance Committee and discussed her studying habits with the Committee.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Ms. Sermersheim's MPJE retake exam application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Diana Karas – MPJE Retake Exam App:

Ms. Karas appeared before the Compliance Committee and discussed her studying habits with the Committee.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Ms. Karas's MPJE retake exam application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Cameron Allen – NAPLEX Retake Exam App:

Mr. Allen appeared before the Compliance Committee and discussed his studying habits with the Committee.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Mr. Allen's MPJE retake exam application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Saljalben Patel – MPJE Retake Exam App:

Ms. Patel appeared before the Compliance Committee and discussed her studying habits with the Committee.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Ms. Patel's MPJE retake exam application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Jacob Neiman – Intern Permit Renewal:

Mr. Neiman appeared before the Compliance Committee and was not represented by counsel.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL on INDEFINITE PROBATION with terms and conditions of Mr. Neiman's intern permit renewal.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Evelyn Choe – Intern Permit App:

Ms. Choe appeared before the Compliance Committee and was not represented by counsel.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Ms. Choe's intern permit application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Thomas Manewitz – Technician in Training App:

Mr. Manewitz appeared before the Compliance Committee and was not represented by counsel.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended APPROVAL of Mr. Manewitz's technician in training application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Isaac Holliday – Technician in Training App:

Mr. Holliday did not appear before the Compliance Committee and was not represented by counsel.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended DENIAL of Mr. Holliday's technician in training application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none

Mercedes Rodriguez – Technician in Training App:

Ms. Rodriguez did not appear before the Compliance Committee and was not represented by counsel.

Compliance Committee Participating Members: Mark Smosna, R.Ph., Steve Anderson, R.Ph.

After discussion, the Compliance Committee recommended DENIAL of Ms. Rodriguez's technician in training application.

The Compliance Committee's recommendation was presented to the full Board. After discussion, the full Board moved to APPROVE the recommendation.

Balla/Anderson, 5/0/0

Motion carries

The following board members voted aye:

Mark Smosna, Donna Wall, Steve Anderson, Matt Balla, Winnie Landis

The following board members voted nay: none

The following board members abstained: none