

Board Meeting Minutes

Friday, March 27th, 2015; 8:30 AM
Health Professionals Assistance Program; Board Room.
2130 W. 57th St. Suite 111; Sioux Falls, SD 57108

Members Present: Lisa Rave, Diane Dady, Lenny Petrik, and Jeff Nielsen

Staff Present: Executive Director Randy Jones, Inspectors Gary Karel and Paula Stotz, PDMP Director Kari Shanard-Koenders, and Senior Secretary Rita Schulz

Others Present: Brenda Jensen (Compounding Consultants), Cheri Kraemer (Pharmacy Specialties & Clinic, Inc.), Dennis Hedge (SDSU), Maria Eining, and Amanda McKnelly (HPAP)

The meeting was called to order by Lisa Rave at 8:30 AM.

A. Approval of Meeting Minutes

Jeff Nielsen moved for approval of the December 5, 2014 meeting minutes. Motion seconded by Lenny Petrik. Motion carried.

B. Financial Report

The Board Financial Report was reviewed and approved. Executive Director Jones provided an overview and highlighted the remaining balances. It was noted additional costs to SDPhA due to larger SDSU classes and increased number of pharmacists required to be licensed in multiple states. Computers, FileDirector, and a postage machine have been purchased to update our system and provide an electronic filing system going forward. Discussion was also held on the Board's current physical location. The PDMP grant extension was briefly discussed.

C. Staff Reports

1. Employee Update

Melanie Houg transferred to the open part-time PDMP position.
Jessica Neal was hired to fill the part-time position replacing Melanie Houg.

2. Inspector Reports

Paula Stotz:

- Attended FDA 50-State meeting March 18-19, 2015. Discussion was held on draft guides for entities considering whether to register as Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act. Most of the participants voiced they would be unable to sign the MOU in its current form.
- Due to vacation and recent trip to FDA 50-State meeting on Compounding activity report is not up to date. Last entry was 3/4/2015, has now been updated.
- Briefly reported possible movement from paper inspections to electronic inspections, eliminating paper copying, mailing and storage.

Gary Karel:

- Sterile 70% Isopropyl Alcohol must be used when cleaning and disinfecting the compounding area. You cannot use plain Isopropyl alcohol.
- Remember to log Freezer Temperatures if you are stocking Zostavax.
- If you are preparing injectable chemotherapy products they should be stored in a Negative Pressure Room.
- Remember to document/count your outdated controlled substances when you conduct biennial inventory.

- DEA Form 41 has been revised! Please visit the DEA Website: www.deadiversion.usdoj.gov to review the document.
- EPCS (Electronic Prescriptions for Controlled Substances). Must Read!

Go to the following website www.deadiversion.usdoj.gov

- Go to Quick Link & Click on EPCS
- Scroll down to Q & A
- Click on For Pharmacies

3. Statistical Reports

Executive Director Jones provided statistical reports and discussion followed. License permits have not changed dramatically. Pharmacists have increased due to SDSU class size and some increase has been shown in other areas such as wholesalers and nonresidents.

D. Approvals – The following approvals were reported by Executive Director Jones and opened for discussion.

1. Lewis Family Drug #60; Canton – Credit Return of UD from LTCF
2. Lynn's Dakotamart; Pierre – Credit Return of UD from LTCF
3. New Pharmacy Permits (Telepharmacy); Omnicare in Rapid City, Spearfish, and Belle Fourche
4. Omnicare; Omnicell AMDD P&P – Rapid City, Spearfish, and Belle Fourche
5. Bowdle Hospital; Pyxis AMDD P & P

E. Variances – The following variances were reported by Executive Director Jones and opened for discussion.

1. Wal-Mart (Arrowhead-Sioux Falls) 3:1 Tech to Pharmacist Ratio
2. Wal-Mart; Mitchell – 3:1 Tech to Pharmacist Ratio (renewal)
3. Wal-Mart (Stummer Rd-Rapid City) 3:1 Tech to Pharmacist Ratio (renewal)
4. Diamond Pharmacy Svs; Indiana, PA – E-Kit Minnehaha Co. Jail – (renewal)
5. Avera LTC (Tabled until later in meeting.)

F. Complaints, Investigations, Disciplinary Actions, Loss / Theft Reports – The following were reported by Executive Director Jones and Inspector Gary Karel. Discussion followed.

1. Wal-Mart, Mitchell; Loss / Theft Report X 5 (in-transit)
2. Walgreen's, Rapid City (Mt. View); Loss / Theft (in-transit)
3. Avera McKennan Hospital, Sioux Falls; Loss / Theft X 3
4. Lewis Drug-Flandreau; Loss / Theft
5. Milbank Area Hospital; Loss / Theft (in-transit)
6. Shopko 101; Sioux Falls; Loss / Theft
7. Wal-Mart, Brookings; Loss/Theft Report (in-transit)
8. Wal-Mart, SF (Arrowhead); Loss/Theft (in-transit)
9. Philip Hospital; Non-DEA 106 Theft
10. Lewis Drug (SE); Sioux Falls; Loss / Theft
11. Avera Flandreau Hospital; Loss / Theft
12. Hy-Vee S. Minnesota-Sioux Falls; Complaint
13. Avera McKennan Hospital, Sioux Falls; Loss/Theft

G. SD Pharmacists Association – Sue Schaefer

Sue was unable to attend but did submit a report highlighting the items below. If any questions please contact Sue or Executive Director Jones. The report includes information on the following:

1. Activity Report
 - Legislative Session
 - Legislative Days/January 27/28, 2015
 - Spring District Meetings
 - Immunization Training (May 30th at Sheraton Hotel in Sioux Falls)

- South Dakota Pharmacists Association Meeting – Annual Meeting (*September 18-19, 2015 at the Lodge in Deadwood*)
 - Board of Pharmacy providing article on electronic prescriptions for controlled substances in the next *South Dakota Pharmacist* journal
 - APhA Annual Meeting – March 27-31, 2014
 - The National Scene – introduced Legislation to US House and Senate to recognize pharmacists as providers under Medicare Part B
 - H.R. 244 – MAC Transparency Act
 - H.R. 1021 – Protecting the Integrity of Medicare
 - S.776, The Medication Therapy Management Empowerment Act of 2015
 - H.R. 793 – Any Willing Provider Legislation introduced
 - DEA Issues Nationwide Alert on Fentanyl
 - FDA Release Draft Guidance on Sterile Product Compounding
 - C&L Fund
 - SDPhA Office Update – New Website
2. Financial Report

H. Other Reports

SDSU College of Pharmacy – Dennis Hedge

The Accreditation Council for Pharmacy Education Board of Directors has extended the accreditation term for the SDSU Doctor of Pharmacy program until June 30, 2023, which is the full eight-year cycle allowed between self-studies. The academic year for the next currently scheduled review of the Doctor of Pharmacy program for purposes of continued accreditation is 2022-2023. The College of Pharmacy extends a sincere “thank you” to the SD Board of Pharmacy and the pharmacists across the state for their support throughout the reaccreditation process.

The Pharm.D. program admissions process for the incoming Fall 2015 P1 Class (80 students) was recently completed. Consistent with national trends, total applications for admission to the Pharm.D. program was down slightly this past year. The good news, however, is that the number of applications from students on the SDSU campus and from other institutions in the region remained very steady. Once again, the academic profile of students entering the Doctor of Pharmacy program at SDSU is incredibly strong. The academic statistics of the incoming class include an average ACT score of 27.2 and an average cumulative college GPA of 3.79.

Nationally, there are now 130 pharmacy colleges/schools with just under 15,000 students admitted into pharmacy programs across the country each year. These numbers have grown dramatically since 2000. Although more students are now graduating with pharmacy degrees, SDSU pharmacy graduates are still very successful in regard to job and residency program placement. Job placement for pharmacy graduates in some portions of the country has become more difficult, however.

The USD-SDSU collaborative Master of Public Health program successfully launched this past January. Eleven students have been admitted into the MPH program and are currently taking courses. The College is currently exploring the feasibility of a Pharm.D./MPH dual degree opportunity.

Finally, the College of Pharmacy extends an invitation to a representative of the SD Board of Pharmacy to lead the SDSU Pharm.D. Class of 2015 as they recite the Oath of a Pharmacist during the Pharm.D. Hooding Ceremony on May 8, 2015. The ceremony is part of commencement weekend events on the SDSU campus.

SD Society of Health System Pharmacists – Report was submitted by Andrea Aylward, SDSHP President. The report includes information on the following:

- 39th Annual SDSHP Conference to be held April 17th & 18th at the Ramkota Hotel and Conference Center in Sioux Falls. Event will provide 11 hours of ACPE accredited continuing education and will also offer a technician track on Saturday morning.

- SDSHP has been awarded the ASHP/ASHP Foundation State Affiliate Workshop grant with focus on the Pharmacy Practice Model Initiative. The event will be held May 16th at University Center North.

SD Association of Pharmacy Technicians – No Report

HPAP Update – Maria Eining and Amanda McKnelly

Maria reported on the HPAP Contract for the Boards with Midwest Health Management. It is felt the new business and location reduces the barriers for clients and enables early intervention and in doing so provides better client outcomes. The sustained HPAP contract provides a planned budget for the participating boards. It was noted with the new contract participating students will pay themselves. Discussion followed on the benefits and outcomes of the program and the ability to immediately assist those in need.

The Board also thanked them for providing the meeting room along with refreshments for the meeting and a tour of the new space.

Variance Continued:

6. **Avera LTC** - Discussion was held on the variance Mark Gerdes submitted at the December 2014 meeting. Further clarification was requested at that meeting and a new listing of medications was provided and reviewed.

Diane Dady motioned to approve the variance. Motion seconded by Lenny Petrik. All approved.

Executive Director Jones will issue a letter.

I. Old Business

1. Technician to Pharmacist Ratio

Discussion was held on the ratio that is currently in place along with the number of current variances and the ratio in other states. Discussion was held keeping patient safety as the primary concern in addition to pharmacist survey results.

Jeff Nielsen motioned to change the Technician to Pharmacist Ratio to 3 to 1 for retail pharmacies and the ratio for other pharmacy environments to be determined by the PIC providing the required criteria in Administrative Rule is met. The criteria will be provided to the Board prior to the next Board meeting for review. Motion seconded by Lenny Petrik. All approved.

2. Continuing Education Requirements

Discussion was held regarding an increase in continuing education requirements and in what format the additional CE's should be received.

Diane Dady motioned to increase to 15 continuing education requirements. Motion was seconded by Jeff Nielsen. Motion carried.

**A Rules hearing will be required to address #'s 1 and 2 under Old Business.*

3. FDA Draft MOU – 503A & 503B

A copy of the draft was provided and discussion was held. There are major concerns with this document as drafted. Information will be gathered and provided to pharmacies by Executive Director Jones. Comments on the website will be taken until June 18th and it is highly recommended to review this information and provide comments.

J. New Business

1. Main Street Family Pharmacy; Tennessee

Executive Director Jones provided information on Main Street Pharmacy located in Tennessee. The pharmacies license was revoked by the Tennessee Board of Pharmacy for not following proper compounding regulations. This could have turned into another NECC debacle but thankfully it did not. This situation demonstrates how easily these things may happen if the resident board is not providing timely inspections.

2. RCRH E-kit Pennington Co. Jail – Waiver request

Discussion was held on the E-kit waiver. This waiver may be a bridge to automation.

Diane Dady motioned to approve the waiver. The motion seconded by Lenny Petrik. Motion carried.

K. Other Business – (This report was provided earlier in the meeting.)

1. Prescription Drug Monitoring Program updates – Kari Shanard-Koenders (PDMP Director)

- South Dakota Prescription Drug Monitoring Program Statistical Information February 2015 was provided to the Board including:

February Most Prescribed Drugs	RX's	Quantity	Days Supply	Quantity/Rx
Hydrocodone BIT/Acetaminophen	20,964	1,459,620	275,810	70
Tramadol HCl	12,951	1,022,224	241,391	79
Zolpidem Tartrate	7,843	251,592	248,808	32
Lorazepam	7,258	369,415	170,083	51
Clonazepam	6,452	422,792	194,859	66
Alprazolam	4,826	279,043	124,084	58
Dextroamphetamine/Amphetamine	4,764	212,978	143,948	45
Methylphenidate HCL	4,687	207,073	141,019	44
Oxycodone HCl	4,077	348,494	79,254	85
Oxycodone HCL/Acetaminophen	3,937	261,295	50,698	66

***VA reporting began in Dec 2014**

VA Impact is interesting as their data provides a significant impact with a high number of Rxs, Quantity, Days Supply and Quantity/Rx.

Approved for On-Line Access		% Of
Pharmacists	809	73%
Physicians	644	23%
Physician Assistants	213	45%
Nurse Practitioners	177	38%
Dentists	84	19%
Other	12	
Designated Agents	175	

- Three PDMP presentations were provided to clinics in the last month.

- A research project with SDSU is being conducted regarding the impact of Hydrocodone moving to Schedule II.
- Integration activities are proceeding

2. Board Meeting Dates for 2015

- i. June 12th – Sioux Falls
- ii. September 17th (coincide with SDPhA in Deadwood)
(may consider alternative date/location)
- iii. December 4th – Sioux Falls

L. Other Meetings

1. SDSHP Annual Meeting; Sioux Falls, April 17-18
2. NABP Annual Meeting, New Orleans, May 16 – 19
3. SDPhA Annual Meeting, September 18 – 19 Deadwood

Diane Dady motioned to adjourn. Motion seconded by Lenny Petrik. Motion carried.
Adjourned @ 1:25 p.m.

Lisa Rave, President

Date

Randy L. Jones – Executive Director

Date