

SD Board of Pharmacy Meeting Minutes
December 11, 2020 8:00 A.M. CST
South Dakota Board of Pharmacy Zoom Conference
4001 W. Valhalla Blvd Suite 202, Sioux Falls, SD 57106

Board Meeting was held via Zoom Conference

Board Members Present: President Lenny Petrik, Ashley Hansen, Tom Nelson, Cheri Kramer, and Dan Somsen

Board Staff Present: Executive Director Kari Shanard-Koenders, PDMP Director Melissa DeNoon, Inspectors Paula Stotz, Carol Smith and Tyler Laetsch, Secretary Rhea Kontos.

Attendees Present: Amanda Bacon, Joe Bergsmith, Lori Ollerich, Lorri Walmsley, Dana Darger, Melissa Goff, Christine Burg, Lauren Paul, Laura Stoebner, Dan Hansen, Jessica Adams, Tyler Aldren, Jessica Strobl, Bill Ladwig, Dan Feely, Mark Gerdes, Khia Warzecha, Gail Elliot, Amanda McNelly, and Melissa Gorecki.

A. Call to Order and Introductions

Meeting was called to order at 8:00 a.m. by President Petrik who read the Board of Pharmacy mission statement. Board Members, Board Staff, and meeting attendee introductions followed. Roll was called, and a quorum was in attendance.

B. Consent Agenda

The President reviewed the consent agenda noting any items could be removed for discussion. Dan Somsen made a motion to pull the financial report regarding the computer consultant fee, motion was seconded by Ashley Hansen. Kari Shanard-Koenders offered further explanation of the computer consultant fee at the next meeting. Dan Somsen made a motion to approve the consent agenda; motion was seconded by Tom Nelson. A voice vote was taken, and motion passed (4-0). Dan Somsen made a motion to approve the financial report; motion was seconded by Tom Nelson. A voice vote was taken, and motion passed (4-0).

C. Staff Reports

1. Staff Reports - Kari Shanard-Koenders, R.Ph., M.S.J., Executive Director

The Executive Director reported:

- Welcomed new board member, Ashley Hansen. Kari asked Ashley to introduce herself and shared that she is a SDSU '09 Pharmacy Graduate. Her residency was at Sanford and following that she was the pharmacy manager of the Aberdeen hospital. She has 9-year-old twins and a 5-year-old. She is on the advisory board of SDSU and SCHA.
- Covid-19 updates: 3000 Americans are dying a die from Covid. EAU has approved that Pfizer vaccine and 6800 doses should be arriving to SD soon. Moderna is close to EAU approval. The deployment efforts of moving the vaccine has been amazing to date. The administration of the vaccine will place a load on pharmacists. Some are bringing in extra staff. The EO, 2020-16, has not been officially extended but hopeful for an extension and if so, the extension will aid the state of SD for bringing in other pharmacists from other states can move onward. Kari will keep the board abreast of the fluid situation.

- Marijuana laws that were voted in need to be vetted in yet by legislation. One caveat is that if a pharmacy holds a DEA license, they cannot sell marijuana due to laws already in place restricting the sale of mood-altering drugs.
- With the Covid19 emergent need of qualified Immunizers, the SDSU college of pharmacy is offering a 20-hour class beginning on 1.6.21. Brittney Meyer is heading this up. The cost is \$175. Twelve hours of the class is online, and the remaining eight are in person.
- With the 2021 NABP Interactive Member Forum coming up on January 27, 21 via Zoom (11-4pm) an invitation is extended to any board member who is interested in attending. Cheri Kraemer attended last year.

2. Inspector Reports

a. Tyler Laetsch

- Mostly virtual inspections
- Pharmacies have been asking questions regarding Covid testing, Immunization protocols, marijuana effective dates and general CBD handling inquires.
- Some extensions have been granted for technicians to earn their certification due to testing issues
- CVS Rx birth control protocols
- A dental office where dispensing without proper recording

b. Paula Stotz, Inspector

Reported the following items:

- Most inspections were done virtually this quarter and 8 on-site inspections
- Three pharmacies had Med-drop boxes in place and in use without being properly installed – not bolted to the floor or wall, also no log
- A pharmacy, the Med-drop box properly installed, but the liner was overflowing and not maintained with a log or proper checking in place
- A pharmacy Med-drop box installed properly, but no log for date installed, liner #, liner size,
- A pharmacist leaving the pharmacy unattended for 1 hour for lunch due to COVID-19 – not a telepharmacy. A pharmacy cannot be open without the presence of a pharmacist, unless it is a telepharmacy
- A pharmacy operating as a telepharmacy with a Technician-in-training, without being a Certified technician without the proper training and required 2000 hours of experience.
- A pharmacy completed a controlled substance inventory in anticipation of a Board of Pharmacy inspection. Recommended an annual controlled substance for consistency.
- A pharmacy completed a controlled substance inventory in anticipation of a Board of Pharmacy inspection. Recommended an annual controlled substance for consistency.
- A pharmacy accepting digital signatures for faxed controlled substance prescriptions due to COVID-19 and providers now utilizing Telemedicine. The DEA has not changed this requirement due to COVID – a manual signature is required for paper, & faxed controlled substance prescriptions.

c. Carol Smith, Inspector

Reported the following observations/occurrences:

- Several pharmacies did not include the controlled substance prescriptions that were not picked up by patients in their biennial inventory.
- Refrigerator temperatures were not recorded
- Combat meth certificate was expired

- Counseling is not consistently performed on new prescriptions
- NIOSH list was not complete and specific to their pharmacy
- Controlled substance invoices did not have the quantity received verified and initialed

3. PDMP Report

Director Melissa DeNoon reported the following updates:

- PMPi Hub sharing set-up with TN (34 total).
- Statewide Gateway Integration Project: 11 HCEs 'Integration Request Received', 8 HCEs 'Credentials Sent', and 55 HCEs 'In Production' including 31/35 with Lewis locations:
- License Integration Project – Pharmacy, Nursing, Optometry, Podiatry, and Dentistry Boards are live. All users are going through daily. Medical board pending yet
- MedDrop Drug Take-Back Program: 83 receptacles in place; added HyVee's remaining 6 SD sites (all in Sioux Falls) to Trilogy's 'Automatic Reload' program.
- Presented at the SDPhA 134th annual convention
- PDMP presentation for the Sanford School of Medicine Pillar
- Elected as the new chair of the Membership committee for the NASCSA Executive Committee
- Upcoming in January: Opioid Abuse Committee meeting and the annual report to the SD Legislature
- As of October 2020, 11,758 pounds of Rx set for destruction were reported. DEA national day was successful once again.

D. Complaints, Investigations, Disciplinary Actions, Loss/Theft Reports

The following were reported by Paula Stotz, Carol Smith, and Tyler Laetsch and discussed.

1. DEA Form 106--- Monument Health
2. Complaint 2020-0005– Tech Diversion
3. DEA Form 106 – Avera McKennan Hospital
4. Complaint 2020-0006– Immunization issue
5. Complaint 2020-0007— Medication refill issue
6. DEA Form 106— Avera St. Mary's Hospital
7. Complaint 2020-0008--- privacy issues at pharmacies

E. SD Pharmacists Association – Amanda Bacon, SDPHA, Dana Darger, R.Ph., SDPHA President

1. Activity Report – the following items from the SDPhA report were highlighted by Ms. Bacon:
 - a. The 2021 SD Legislature will have more Republican lawmakers than last year. There will be 24 new members in 2021 and some of those new members have prior experience at the Capitol.
 - b. Constitutional Amendment A faces legal challenges. A lawsuit has been filed arguing that Amendment A was a constitutional revision - not an amendment. It also asserts that it violates the "one subject" rule, voters approved in 2016.
 - c. Operation Warp Speed is under way with 14,600 doses to be distributed amongst Avera, Monument Health and Sanford. The upcoming Modera vaccine is more pharmacy friendly due to storage requirements.
 - d. Facebook has been a good source of "news" reporting for the SDPHA.
 - e. The SDPhA Board Members/Executive Director will attend every fall district meet that schedules, if possible. This meeting has become an "optional" meeting, due to the close proximity to our annual meeting, and the fact that most of the "business" is now taken care of at the spring meetings.
 - f. The first virtual convention was a recent success. The SDPhA held its 134th annual meeting and convention virtually September 24-25. Great feedback was received post-convention.
 - g. SDPhA continues to monitor activity on a variety of fronts regarding potential legislation for the upcoming 2021 Legislative Session. The Board will discuss Legislative Days at the next board meeting and is working

with Interim Dean Dan Hansen and Dr. Teresa Seefeldt on what student involvement may look like. LLC has initiated some guidelines.

- h. Thank you to all that have contributed to the Commercial and Legislative Fund. Continued contributions are necessary to retain our Lobbyist, Bob Riter and Lindsey Riter-Rapp.
- i. As of 12.10.20 Arkansas is named the winner in the Rudledge vs. PCMA case. This opens up states to regulate PDMP's.
- j. The Pharmacy Technician University has 8 high school students in the DIAL Virtual Program.
- k. Work continues with the IA Pharmacists Association to promote the Midwest Pharmacy Expo. This year, the event will be virtual on Feb 1-7, 2021.

2. Financial Reports were not reviewed.

F. Other Reports

1. SDSU College of Pharmacy – Interim Dean and Professor Dan Hansen, Pharm D.
 - 2020 PharmD graduates exceeded the national average on the NAPLEX. Graduates who took the NAPLEX this summer, 98.65% passed on the first. The average score for SDSU graduates was 103.31 compared to 97.85 nationally.
 - A MS in Pharmaceutical Sciences is being proposed with a start date of fall 2021.
 - The Master of Public Health program had a successful accreditation site visit this fall. Anticipate hearing positive news about the accreditation of our MPH program later this spring
 - The Community Practice Innovation Center (CPIC) was approved by the South Dakota Board of Regents. The establishment of this Center will enable additional growth of practice-based research within the College.
 - Kim Hyland: Program Assistant in the Department of Pharmaceutical Sciences
 - Dr. Scout Forbes-Hurd: Experiential and Continuing Education
 - Current Search for: Dean, Research Associate, Instructor for Respiratory Care, Grant Support Specialist, Director of Clinical Education, Social & Administrative Sciences Faculty.
 - Dr. Komal Raina received a NIH sub-award titled "Skin Cancer Chemoprevention by Silibinin: Mechanisms and Efficacy". This is a sub-award to the National Cancer Institute-R01 grant partnered with the University of Colorado. The grant is focused on treatment of Basal cell carcinoma (BCC), a non-melanoma skin cancer type, which is a major health problem in the United States.
 - Dr. Jennifer Ball and members of the 2020 Special Committee on Substance Use and Pharmacy Education recently published a report with recommendations on core curricular content and delivery processes on substance misuse and substance use disorder (SUD) to the Association of Colleges of Pharmacy (ACCP).
 - Student pharmacists at SDSU were honored for their work to promote diabetes awareness through Operation Diabetes. The Student Collaboration for the Advancement and Promotion of Pharmacy won the Region 5 award for the Operation Diabetes competition sponsored by the American Pharmacist's Association Academy of Student Pharmacists.
2. SD Society of Health System Pharmacists (SDSHP) – Khia Warzecha, PharmD
 - SDSHP hosted a Virtual Dakota Night Winter Cocktail Party on 12/8. 31 attended (23 from SD and 8 from ND). SDSHP partnered with TeamBuilding.com to lead attendees through a "Winter Cocktail Party" event. During the event, a guest mixologist taught attendees how to create two festive cocktails and played some games. SDSHP thanks the SDSU COP&AHP and Coherus Biosciences for sponsoring this event.
 - Furthermore, SDSHP is planning on hosting the annual Resident CE seminars presented by various residents throughout the state through a virtual format in January-February 2021. More information on dates and registration will be emailed out to membership in the coming weeks. SDSHP is also working

on planning the upcoming Annual Meeting, currently scheduled for April 9-10th. Currently, the plan is for a live conference. However, there is a strong possibility of moving this to a virtual event depending on the outlook in the next coming weeks. The SDSHP Annual meeting committee is actively working on scheduling active and virtual meeting agendas to meet the needs of membership.

3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT
 - No report. No representation present at board meeting.
4. SD Health Professionals Assistance Program (SD HPAP) – Amanda McKnelly, MS, LAC, Maria Piacentino, MA, LPC-MH, QMHP, LAC
 - The SD HPAP was created in 1996 to monitor health professionals that have Rx addictions. Currently 8 are in the program in which 3 were mandated by the board. Case management is discussed with participants. Do not foresee any changes in the program at present. Kari Shanard-Koenders responded that the program is successful and has seen many positive outcomes. Many have said, “It has saved my life!”. A bill is heading to legislation in which the board of Nursing has spearheaded some changes. This will allow boards to create their own programs. Amanda has seen an uptick in calls from pharmacists that are struggling especially due to the complexities that Covid19 has brought this year.

Break

- Full Board meeting resumed at 9:50 a.m.

G. Old Business

1. Renewal for Aristada Variance – David Bain, Alchermes, Dan Feely represented
 - Update on the program: Three trainings are completed with two being done remotely. Up 30% in utilization due to Covid. Vivatrol has been added to the program. Kari noted that Pierre, Rapid City and Minnehaha have implemented Aristada beginning in 2016. Dan Feely shared that the program has benefitted 13 prisoners before moving back into the community. Kari informed that these are injectable products. Dan Somsen asked if follow-ups are done after jail release. Dan Feely answered that a medical representative is assigned to each one of the Rx. Affordability programs are also shared. Tom Nelson asked if the board has other variances that are handled administratively, and Kari answered “yes”. Kari suggested for this year to do a yearly approval. Cheri Kraemer made a motion to approve; motion was seconded by Tom Nelson. A voice vote was taken, and motion passed (5-0).
2. Renewal of E-Kit Variance for Avera Long Term Care – Mark Gerdes, R.Ph. & Josh Renberg
 - Avera Long Term Care is looking to up the quantity of E-Kits for each facility needs for another year. Kari mentioned to Mark that a letter requesting this has not been received by the board. Mark thought he had sent a letter. The new phone application, nexis system, looks to be promising and is in the transitional period. Kari said that the request will move forward but need document. The 2020-16 EO gives exemption through 12.31.2020 but if not extended a vote would be needed.
 - Board member Cheri Kraemer made a motion to extend another year and Tom Nelson seconded the motion. Voice call was taken; motion passed (5-0). Dan Somsen asked Mark Gerdes what language needs to be in the request and Mark said with the assistance of Josh Renberg he would forward to the board. Tom Nelson said that this needs to be voted on annually.
3. Education - Chris Sonnenschein, Pharm. D.
 - Chris shared his personal story of recovery stating that he is in alcoholic and he is creating a new life. It has been a tough journey that he felt inspired to share and this time was not to speak on the renewal of his license. He would like to bring the team together to help those in recovery create a new life and

look for opportunities. In the fall of 2018, he had a conversation with Kari which revealed he has a 4-year suspension even though his arrest was sealed. Chris sought employment in IA and was hired but shortly thereafter was let go due to the suspension. However, 48 hours later he received the letter he had been looking for. Other conversations were had with other board members, but it seems that the original 4-year suspension stands. He does not want to relapse and wanted this chance to speak about his experience and thanks the program for saving his life. He felt that he was speaking for the next person.

4. FDA MOU with States on Compounding – Kari

- Kari reported that the board has one year to review the FDA MOU. The final copy is here. What is implied is that the board will have to report on anyone that ships over 5% compounding Rx. NABP has set up a program to report to. If the board does not sign, then it will affect businesses such as Cheri Kraemer's in such a way that it would limit the amount to <5% on shipments out of state. Previously physicians were compounders and the board does not have jurisdiction over physicians. Most other states have received the MOU as well and many have signed it. NABP already captures this data yearly. The board does not think that reporting will take a lot of time.
- Cheri Kraemer's comments: Al Carter of the APC board thinks NABP is in favor of all states signing. She feels under scrutiny by FDA because of compounding. Stated that they already report complaints to FDA. Shipping exceeds 5% because of the proximity to nearby states. Compounding of only human Rx not animal. Hormone specific formulations places over the 5%.
- Kari has sent the requested copy to the board's attorneys for their input. Cheri noted some clarifications have been made from earlier drafts such as the distribution and dispensing language as well as all human and not just sterile Rx. Dan asked about physician compounding and Kari responded that if an adverse reaction is known then are required to report.
- Kari suggested to vote or table it. Dan Somsen made a motion to table until legal advice has arrived; motion was seconded by Tom Nelson. A voice vote was taken, and motion passed (5-0).

H. New Business

1. Hy-Vee SD Technician Immunization Variance – Justin Manning, Pharm. D

- Move to next meeting. In summary Kari shared: This variance seeks permission for technicians to be able to administer all vaccinations. The pilot program in IA was successful. CE requirements would impact class offerings. Two technicians per store is the goal for training.

2. Election of Officers for 2021 – Lenny

- Currently Lenny is president with Tom Nelson as vice president. Any requests for changes was asked of the board. Kari asked if Tom was interested in switching to president and if Dan would like the vice president role. Both agreed. Effective beginning 2021.
- Board member Cheri Kraemer made a motion and Ashley Hansen seconded the motion. Voice call was taken; motion passed (5-0).

3. Board Policy Statement on Technicians Immunizing – 2020-11-19 – Kari

- Following guidance out of the PREP act not a lot has changed. On August 19, 2020, the U.S. Department of Health and Human Services (HHS) issued a declaration under the PREP Act authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer" certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. On September 9, 2020, HHS issued a declaration authorizing pharmacists "to order and administer," and a "supervised pharmacy intern acting under the supervision of [a] qualified

pharmacist” “to administer COVID-19 vaccines. On October 21, 2020, HHS issued another declaration under the PREP act authorizing “qualified pharmacy technicians” to administer ACIP-recommended vaccines to patients ages three (3) to eighteen (18) and FDA-approved COVID-19 vaccines to patients ages three (3) years of older under the supervision of a qualified pharmacist.

- Kari commented: That this policy decreases liability. The APHA is seeking to see if there is interest in their \$200 training program. Dan asked if technicians must go through the same program that pharmacists do. Kari replied, “no”, not the 20-hour course because technicians do not need as much training due to pharmacists doing all the legwork. HyVee in IA has set up a 5-hour program with a 6-hour ACPE in addition. Cheri noted that with HyVee and Justin Manning behind the effort gives the program credibility.
 - Kari interjected that the question is whether technicians will be able to administer Immunizations after Covid19. Amanda Bacon said that the push will come from the Federal level. Many other states have their technicians perform a broader level of responsibility than those of SD. Dan asked if certified technicians can work out of state. The HHS rules supersedes, and Amanda said that ‘yes’ they can. Ashley commented that it is odd that the “flu” shot is not included. Kari said the board will pull the old statement off the web site and use the list serve as a reminder.
 - Board member Ashley Hansen made a motion to approve new policy statement and Tom Nelson seconded the motion. Voice call was taken; motion passed (5-0)
4. CVS protocol for prescribing birth control – Kari
- Need to get papers on this. At present there are no pharmacists doing this yet. Lauren Paul of CVS apologized that the language on the form has been changed due to the interpretation of it. The protocol has changed, and she will send to the board.

I. Other Business

1. Recent Meeting News
 - i. FDA Intergovernmental Meeting on Compounding – October 20-21, Tyler and Kari attended with discussions surrounding the FDA MOU.
 - ii. NABP Task Force on Technician Duties December 1, 2020, Kari – Technician duties was the last topic that made changes for the scope of practice. Foresee more pushing on those issues
2. Future Board Meeting Dates - all held in Sioux Falls Board Room unless otherwise noted
 - i. April 8, 2021, 1PM-5PM, CDT in coordination with the SDSHP 45th Annual Meeting SF
 - ii. June 25, 2021, 8AM-12PM CDT (tentative)
 - iii. September 16, 2021 1PM-5PM in coordination with the 135th SDPHA Annual Meeting, Spearfish
 - iv. December 10, 2021 9AM-1PM CST
2. Upcoming Meeting
 - i. 2021 NABP Interactive Member Forum, January 27,2021 via Zoom
 - ii. 117th NABP Annual Meeting, May 13-15, 2021, Phoenix, AZ
 - iii. NABP/AACP 84th Annual District V Meeting, August 11-13, 2021 Winnipeg, Manitoba, CAN
 - iv. NABP/AACP 85th Annual District V Meeting, August 3-5, 2022, Custer State Park
 - v. 135th SDPHA Annual Meeting, Spearfish

L. Public Comment –

- Bill Ludwig spoke regarding technicians administrating Immunizations post pandemic. Recommended that board will need to continue to watch for proper immunization technique(s) along with being diligent and that all that seek to administer vaccines meet the standards that are set in place.

M. Adjourn

Tom Nelson made a motion to adjourn the meeting; Cheri Kraemer seconded the motion. Voice vote was taken, motion passed (5-0). Meeting adjourned at 11:40 a.m.

Meeting adjourned at 11:40 a.m. CST

PHARMACISTS

2036 Current Total

7 New Licensees for period

License#	Last Name	First Name	City	State
6821	Mendoza	Jenna	Lennox	SD
6820	Brunick	Colin	Sioux Falls	SD
6818	Lang	Jacob	Sioux Falls	SD
R-6819	Sison	Cesar	Chicago	IL
R-6817	Morrisson	Sara	Woodbury	MN
R-6815	Villarreal	Oswaldo	Mundelein	IL
R-6816	Kusnierz	Jonathan	Park Ridge	IL

FULL-TIME PHARMACY PERMITS

233 Current Total

0 New FT Permits for period

PART-TIME PHARMACY PERMITS

65 Current Total

0 New PT Permits for period

PHARMACY INTERNS

293 Current Total

67 New Registrations for period

TECHNICIAN REGISTRATIONS

1292 Current Total

71 New Registrations for period

NON-RESIDENT PERMITS

809 Current Total

35 New NR Permits for period

WHOLESALE PERMITS

1270 Current Total

23 New WH Permits for period



**South Dakota
Board of Pharmacy**

4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737
Fax: 605-362-2738

Approvals, Variances, and Pharmacy changes for December 11, 2020 Board Meeting

Approvals

1. None

Variances/Waivers

1. Renewal of MedVantx off Site Storage Variance.

New Pharmacies/Closed Pharmacies and New/Closed Wholesale Distributors

1. Change of Ownership, Turner Drug Inc, dba Turner Drug, Bowdle, #100-0004
2. Change of Ownership, Salem Drug Inc., dba Salem Community Drug, Salem, #100-0946
3. New Wholesale License - Avera Home Medical, Yankton, #600-3235
4. Closed- Spring Meds #100-2069
5. Closed – Ameripharm #2 #100-2061

Remaining Authority by Object/Subobject

Expenditures current through 12/05/2020 11:50:32 AM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 57.0%

09209 Board of Pharmacy - Info						PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL
EMPLOYEE SALARIES						
5101010 F-t Emp Sal & Wages	524,715	168,063	0	0	356,652	68.0
5101020 P-t/temp Emp Sal & Wages	166,415	57,797	0	0	108,618	65.3
5101030 Board & Comm Mbrs Fees	1,907	600	0	0	1,307	68.5
Subtotal	693,037	226,460	0	0	466,577	67.3
EMPLOYEE BENEFITS						
5102010 Oasi-employer's Share	51,776	16,457	0	0	35,319	68.2
5102020 Retirement-er Share	18,500	12,817	0	0	5,683	30.7
5102060 Health Insurance-er Share	84,120	34,679	0	0	49,441	58.8
5102080 Worker's Compensation	1,000	271	0	0	729	72.9
5102090 Unemployment Compensation	300	226	0	0	74	24.7
Subtotal	155,696	64,450	0	0	91,246	58.6
51 Personal Services						
Subtotal	848,733	290,910	0	0	557,823	65.7
TRAVEL						
5203010 Auto-state Owned-in State	7,229	612	0	0	6,617	91.5
5203020 Auto Priv (in-st.) L/rte	600	42	0	0	558	93.0
5203030 Auto-priv (in-st.) H/rte	6,000	868	0	0	5,132	85.5
5203040 Air-state Owned-in State	3,000	0	0	0	3,000	100.0
5203100 Lodging/in-state	9,479	0	0	0	9,479	100.0
5203140 Meals/taxable/in-state	1,679	224	0	0	1,455	86.7
5203150 Non-taxable Meals/in-st	2,000	0	0	0	2,000	100.0
5203220 Auto-priv.(out-state) L/r	200	0	0	0	200	100.0
5203230 Auto-priv.(out-state) H/r	1,600	0	0	0	1,600	100.0
5203260 Air-comm-out-of-state	10,000	0	0	0	10,000	100.0
5203280 Other-public-out-of-state	100	0	0	0	100	100.0
5203300 Lodging/out-state	6,400	0	0	0	6,400	100.0
5203320 Incidentals-out-of-state	152	0	0	0	152	100.0
5203350 Non-taxable Meals/out-st	900	0	0	0	900	100.0
Subtotal	49,339	1,746	0	0	47,593	96.5
CONTRACTUAL SERVICES						
5204010 Subscriptions	250	0	0	0	250	100.0
5204020 Dues & Membership Fees	500	0	0	0	500	100.0
5204050 Computer Consultant	258,067	345,880	82,280	0	-170,093	0.0
5204080 Legal Consultant	4,278	0	0	0	4,278	100.0

Remaining Authority by Object/Subobject

Expenditures current through 12/05/2020 11:50:32 AM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 57.0%

09209 Board of Pharmacy - Info							PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL	
5204140 Contract Pymts To St Agen	20,000	18,000	0	0	2,000	10.0	
5204160 Workshop Registration Fee	4,000	375	0	0	3,625	90.6	
5204180 Computer Services-state	11,309	9,143	0	0	2,166	19.2	
5204181 Computer Services-state	3,919	0	0	0	3,919	100.0	
5204200 Central Services	6,270	1,896	0	0	4,374	69.8	
5204202 Central Services	103	20	0	0	83	80.6	
5204203 Central Services	103	33	0	0	70	68.0	
5204204 Central Services	418	201	0	0	217	51.9	
5204207 Central Services	3,638	1,963	0	0	1,675	46.0	
5204220 Equipment Serv & Maint	600	577	0	0	23	3.8	
5204320 Audit Services-private	1,000	0	0	0	1,000	100.0	
5204360 Advertising-newspaper	1,000	0	0	0	1,000	100.0	
5204430 Publishing	1,000	0	0	0	1,000	100.0	
5204460 Equipment Rental	1,100	338	0	0	762	69.3	
5204490 Rents-private Owned Prop.	39,277	19,247	0	0	20,030	51.0	
5204510 Rents-other	250	0	0	0	250	100.0	
5204530 Telecommunications Srves	5,200	1,751	0	0	3,449	66.3	
5204550 Garbage & Sewer	50	0	0	0	50	100.0	
5204590 Ins Premiums & Surety Bds	1,450	0	0	0	1,450	100.0	
5204620 Taxes & License Fees	196,708	0	0	0	196,708	100.0	
5204960 Other Contractual Service	407,028	28,043	0	0	378,985	93.1	
Subtotal	967,518	427,467	82,280	0	457,771	47.3	
SUPPLIES & MATERIALS							
5205020 Office Supplies	2,300	2,290	0	0	10	0.4	
5205040 Educ & Instruc Supplies	300	0	0	0	300	100.0	
5205212	0	790	0	0	-790	0.0	
5205310 Printing-state	1,100	0	0	0	1,100	100.0	
5205320 Printing-commercial	400	0	0	0	400	100.0	
5205330 Supp. Public & Ref Mat	50	0	0	0	50	100.0	
5205350 Postage	4,900	581	0	0	4,319	88.1	
Subtotal	9,050	3,661	0	0	5,389	59.5	
CAPITAL OUTLAY							
5207901 Computer Hardware	5,764	3,522	0	0	2,242	38.9	
5207960 Computer Software	30,000	0	0	0	30,000	100.0	
5207961 Computer Software	0	295	0	0	-295	0.0	
Subtotal	35,764	3,817	0	0	31,947	89.3	

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Expenditures current through 12/05/2020 11:50:32 AM

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FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 57.0%

52 Operating Subtotal	1,061,671	436,691	82,280	0	542,700	51.1
<hr/>						
Total	1,910,404	727,601	82,280	0	1,100,523	57.6
<hr/>						

Activity Report			Nov	Nov	YTD	YTD
	New	Renewal	2020	2019	This Year	Last Year
Pharmacy Permits						
Full Time (SD)	0	0	0	0	1	1
Part Time (SD)	0	0	0	0	2	9
Non-Resident	5	4	9	11	109	104
Pharmacist Licenses						
South Dakota	3	0	3	2	1300	1273
Non-Resident	1	1	2	7	748	746
Technician Registrations	16	25	41	36	1332	1535
Pharmacy Interns	1	4	5	2	293	316
Wholesale Permits						
South Dakota	1	21	22	18	25	23
Non-Resident	2	452	454	337	550	399
Inspections						
Pharmacy Inspections			19	35	152	150
Wholesale Inspections			0	1	11	11
Other Pharmacy Visits/Meetings			64	35	271	157
Controlled Drug Destruction			0	0	0	0
PDMP Visits			15	24	97	94

Board of Pharmacy - Inspection Report

4th Quarter 2020

Kari Shanard-Koenders					
Date	Destination		City	Purpose	PDMP/ Narc Destruction, etc.
09/24/2020	SDPHA speaker and attend meeting		Sioux Falls	Zoom Meeting	
09/25/2020	SDPHA speaker and attend meeting		Sioux Falls	Zoom Meeting	
09/30/2020	NABP Interactive Executive Officer Forum		Sioux Falls	Zoom Meeting	
10/01/2020	SD-DOH COVID-19 webinar		Sioux Falls	Webinar - Zoom	
10/01/2020	NASCSA Town hall Meeting		Sioux Falls	Zoom Meeting	
10/02/2020	COVID Vaccination Planning/Implementation Meeting		Sioux Falls	Zoom Meeting	
10/02/2020	South East Technical Advisory Council		Sioux Falls	Meeting	
10/06/2020	Standing Order Review		Sioux Falls	Zoom Meeting	
10/07/2020	Board of Pharmacy Staff Meeting		Sioux Falls	Teams Meeting	
10/08/2020	SD-DOH COVID-19 webinar		Sioux Falls	Webinar - Zoom	
10/08/2020	Farukhi, Abdul (USATXS), Tyler, David McVey meeting on Houston Pharmacies being investigated		Sioux Falls	Conference Call	
10/09/2020	Pharmacists COVID Vaccination Planning/Implementation Meeting		Sioux Falls	Zoom Meeting	
10/09/2020	Walgreens Front End Pharmacy Training		Sioux Falls	Conference Call	
10/15/2020	SD-DOH COVID-19 webinar		Sioux Falls	Webinar	
10/19/2020	Board of Pharmacy Staff Meeting		Sioux Falls	Teams Meeting	
10/22/2020	SD DOH All Staff Meeting		Sioux Falls	Webinar	
10/23/2020	Justin Manning Meeting Technicians		Sioux Falls	Conference Call	
10/26/2020	Rural OUD Advisory Meeting		Sioux Falls	Webinar	
10/27/2020	50 State FDA IGA Meeting		Sioux Falls	Webinar	
10/28/2020	50 State FDA IGA Meeting		Sioux Falls	Webinar	
10/29/2020	SD-DOH COVID-19 webinar		Sioux Falls	Webinar	
10/29/2020	Appriss Health Marketing Meeting		Sioux Falls	Webinar	
10/30/2020	Monthly NABP Exec Officer Calls		Sioux Falls	Webinar	
11/02/2020	NASCSA Education Committee		Sioux Falls	Conference Call	
11/03/2020	Security Training		Sioux Falls	Videos	
11/03/2020	DOH Mass Vaccination Call		Sioux Falls	Webinar	
11/05/2020	American Society for Pharmacy Law Conference		Sioux Falls	Webinar	
11/06/2020	American Society for Pharmacy Law Conference		Sioux Falls	Webinar	
11/07/2020	American Society for Pharmacy Law Conference		Sioux Falls	Webinar	
11/08/2020	American Society for Pharmacy Law Conference		Sioux Falls	Webinar	
11/10/2020	DOH All Staff Meeting		Sioux Falls	Webinar	
11/17/2020	DOH Mass Vaccination Call		Sioux Falls	Webinar	
11/18/2020	ISMP Medication Safety Meeting		Sioux Falls	Webinar	
11/18/2020	ED Policy Toolkit: Education Work Group OD2A		Sioux Falls	Webinar	
11/18/2020	ED Policy Toolkit Treatment and Naloxone Work Group OD2A		Sioux Falls	Webinar	
11/20/2020	HPAP Legislation Work Group Meeting		Sioux Falls	Webinar	
11/23/2020	Rural OUD Advisory Meeting		Sioux Falls	Webinar	
11/23/2020	DOH Mass Vaccination Call		Sioux Falls	Webinar	
11/30/2020	Office Weekly Staff Meeting		Sioux Falls	Webinar	
12/01/2020	Law Enforcement Coordinating Committee		Sioux Falls	Webinar	
12/01/2020	NABP Task Force on Technician Education, Practice Responsibilities, and Competence Assessment		Sioux Falls	Webinar	
12/02/2020	Tyler, Justin Manning, HyVee Technician Immunization Program		Sioux Falls	Webinar	
12/08/2020	DOH Mass Vaccination Call		Sioux Falls	Webinar	
12/08/2020	NASCSA Education Committee		Sioux Falls	Webinar	
12/08/2020	ED Policy Toolkit: Education Work Group OD2A		Sioux Falls	Webinar	
12/09/2020	ED Policy Toolkit: Treatment and Naloxone Work Group OD2A		Sioux Falls	Webinar	
12/11/2020	SD Board of Pharmacy Quarterly Meeting		Sioux Falls	Webinar	

Board of Pharmacy - Inspection Report

4th Quarter 2020

Tyler Laetsch				
Date	Destination	City	Purpose	PDMP/ Narc Destruction etc
9/25/20	SDPhA presentation and meeting	Sioux Falls	Virtual Meeting	
9/28/20	Lewis Family Drug	Chamberlain	Virtual Inspection	PDMP
9/28/20	G&G Global	Lennox	Virtual Wholesale Inspection	
9/29/20	Wal-Mart	Vermillion	Virtual Inspection	PDMP
10/1/20	Wal-Mart	Brookings	Virtual Inspection	PDMP
10/5/20	Avera Med Group-Emergency Dept	Sioux Falls	Virtual Inspection	
10/6/20	Lewis	Brookings	Virtual Inspection	PDMP
10/7/20	True Care Pharmacy	Sioux Falls	Virtual Inspection	PDMP
10/7/20	Sanford Chamberlain Med Ctr Pharmacy	Chamberlain	Virtual Inspection	
10/13/20	Lewis #11	Sioux Falls	Inspection	PDMP
10/15/20	Brother's Pharmacy	Brookings	Virtual Inspection	PDMP
10/15/20	Rambo Pharmacy	Brookings	Virtual Inspection	PDMP
10/15/20	Omnicare	Sioux Falls	Inspection	PDMP
10/19/20	Norm's Thrifty White	Freeman	Virtual Inspection	PDMP
10/21/20	MAT Webex	Sioux Falls	Virtual Meeting	
10/26/20	Wal-Mart Arrowhead	Sioux Falls	Virtual Inspection	PDMP
10/26/20	Avera on Louise Inpatient	Sioux Falls	Virtual Inspecticon	PDMP
10/27/20	DOH all staff meeting	Sioux Falls	Virtual Meeting	
10/27/20	FDA Intergovernmental Compounding Meeting	Sioux Falls	Virtual Meeting	
10/27/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
10/28/20	FDA Intergovernmental Compounding Meeting	Sioux Falls	Virtual Meeting	
10/29/20	Gregory Drug	Gregory	Virtual Inspection	PDMP
10/29/20	Meeting with Attorney to train on iGov	Sioux Falls	Virtual Meeting	
10/30/20	CE Avera Grandrounds	Sioux Falls	Virtual Meeting	
11/2/20	Office meeting	Sioux Falls	Virtual Meeting	
11/2/20	SDSMA Opioid White Paper Meeting	Sioux Falls	Virtual Meeting	
11/3/20	Costco	Sioux Falls	Virtual Inspection	PDMP
11/3/20	SD DOH Weekly COVID Vaccine Meeting	Sioux Falls	Virtual Meeting	
11/4/20	CVS in Target Louise Ave	Sioux Falls	Virtual Inspection	PDMP
11/5/20	Lewis	Canton	Virtual Inspection	PDMP
11/6/20	Gregory Hospital	Gregory	Virtual Inspection	
11/6/20	Avera Behavior Health Hospital	Sioux Falls	Virtual Inspection	PDMP
11/10/20	Avera on Louise Retail	Sioux Falls	Virtual Inspection	PDMP
11/10/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
11/10/20	DOH all staff meeting	Sioux Falls	Virtual Meeting	
11/12/20	Parker Pharmacy	Parker	Virtual Inspection	PDMP
11/12/20	Lewis Drug Eastgate	Sioux Falls	Virtual Inspection	PDMP
11/17/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
11/30/20	Office meeting	Sioux Falls	Virtual Meeting	
12/1/20	LECC Healthcare Fraud Forum	Sioux Falls	Virtual Meeting	
12/1/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
12/2/20	Hy-Vee Tech Immunization call	Sioux Falls	Virtual Meeting	
12/3/20	Avera Queen of Peace	Mitchell	Virtual Inspection	
12/8/20	Freeman Hospital	Freeman	Virtual Inspection	
12/8/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
12/10/20	Staff Meeting for Board Meeting	Sioux Falls	Virtual Meeting	
12/11/20	Board Meeting	Sioux Falls	Virtual Board Meeting	

Board of Pharmacy - Inspection Report

4th Quarter 2020

Melissa DeNoon					
Date	Destination		City	Purpose	PDMP/NARC Destruction etc.
9/24/20	SDPhA 134th Annual Convention 2020		Sioux Falls	Virtual Conference	
9/25/20	SDPhA 134th Annual Convention 2020 - BOP Update and PDMP Presentation - KSK, TL		Sioux Falls	Virtual Conference & Presentation	PDMP Presentation
9/28/20	Rural OUD Advisory Bd		Sioux Falls	Meeting CC	
9/28/20	Appriss Health License Integration Project		Sioux Falls	Project Discussion CC	
9/30/20	Appriss Health Prescriber Report		Sioux Falls	Webinar	
10/1/20	NASCSA Town Hall		Sioux Falls	Zoom Meeting	
10/6/20	Naloxone Standing Order Review		Sioux Falls	Zoom Meeting	
10/7/20	Appriss Health & PDMP Staff		Sioux Falls	Bimonthly CRM & SGI CC	
10/7/20	BOP Staff		Sioux Falls	Weekly Teams Call	
10/9/20	Substance Abuse Presentation USD Yr 3 Med Students		Sioux Falls	Teaching Webinar	PDMP Presentation
10/19/20	BOP Staff		Sioux Falls	Weekly Teams Call	
10/21/20	NABP		Sioux Falls	MAT Webinar	
10/21/20	Appriss Health & PDMP Staff		Sioux Falls	License Integration Project CC	
10/22/20	NASCSA PMP Committee		Sioux Falls	Zoom Meeting	
10/22/20	NASCSA Data Integrity Subcommittee		Sioux Falls	Zoom Meeting	
10/26/20	Rural OUD Advisory Board		Sioux Falls	Zoom Meeting	
10/26/20	BOP Staff		Sioux Falls	Weekly Teams Call	
10/27/20	NASCSA 2020 Annual Conference		Sioux Falls	Zoom Conference	
10/29/20	ONDPCP		Sioux Falls	DTB Webinar	
10/29/20	Appriss Health & PDMP Staff		Sioux Falls	Project Discussion CC	
10/29/20	Kari and PDMP Staff		Sioux Falls	Appriss Marketing Discussion	
10/29/20	TTAC		Sioux Falls	Webinar	
10/30/20	DOH CDC OD2A Grant Teams		Sioux Falls	Monthly Teams Meeting	
10/30/20	SD Bd of Dentistry's Vendor, Big Picture & PDMP Staff		Sioux Falls	License Integration Project CC	
11/2/20	BOP Staff		Sioux Falls	Weekly Teams Call	
11/4/20	Appriss Health & PDMP Staff		Sioux Falls	Bimonthly CRM & SGI CC	
11/4/20	DOH CDC OD2A Grant ED Policy Toolkit PDMP Wkgrp		Sioux Falls	Zoom Meeting	
11/5/20	Appriss Health		Sioux Falls	Webinar	
11/5/20	NASCSA Executive Committee		Sioux Falls	Zoom Meeting	
11/5/20	Appriss Health & PDMP Staff		Sioux Falls	License Integration Project CC	
11/5/20	TTAC		Sioux Falls	Webinar	
11/6/20	NASCSA Membership Committee		Sioux Falls	Zoom Meeting	
11/10/20	DOH All Staff		Sioux Falls	Zoom Meeting	
11/10/20	DOH Covid IMZ		Sioux Falls	Zoom Meeting	
11/12/20	RxCheck Governance Board		Sioux Falls	Zoom Meeting	
11/12/20	NASCSA Kathy Keough		Sioux Falls	Zoom Meeting	
11/17/20	DOH Covid IMZ		Sioux Falls	Zoom Meeting	
11/17/20	NASCSA Data Integrity Subcommittee		Sioux Falls	Zoom Meeting	
11/18/20	Appriss Health & PDMP Staff		Sioux Falls	Bimonthly CRM & SGI CC	
11/18/20	DOH CDC OD2A Grant ED Policy Toolkit Edu Wkgrp		Sioux Falls	Zoom Meeting	
11/18/20	TN PDMP Staff		Sioux Falls	PMPi Set Up CC	
11/19/20	NASCSA PMP Committee		Sioux Falls	Zoom Meeting	
11/19/20	TTAC PDMP Compliance Group		Sioux Falls	Zoom Meeting	
11/20/20	DOH CDC OD2A Grant Teams		Sioux Falls	Monthly Teams Meeting	
11/23/20	Rural OUD Advisory Board		Sioux Falls	Zoom Meeting	
11/30/20	BOP Staff		Sioux Falls	Weekly Teams Call	
12/1/20	LECC Healthcare Fraud Forum		Sioux Falls	Zoom Meeting	
12/1/20	NASCSA		Sioux Falls	Webinar	
12/2/20	Appriss Health & PDMP Staff		Sioux Falls	Bimonthly CRM & SGI CC	
12/2/20	DOH CDC OD2A Grant ED Policy Toolkit PDMP Wkgrp		Sioux Falls	Zoom Meeting	
12/3/20	DOH		Sioux Falls	Covid Zoom Call	
12/3/20	NASCSA		Sioux Falls	Webinar	
12/8/20	DOH		Sioux Falls	Covid Vaccine Zoom Call	
12/9/20	DOH CDC OD2A Grant ED Policy Toolkit Edu Wkgrp		Sioux Falls	Zoom Meeting	
12/10/20	Appriss Health		Sioux Falls	Admin Config Settings Webinar	
12/10/20	BOP Staff		Sioux Falls	Weekly Teams Call	
12/11/20	SD BOP		Sioux Falls	Quarterly Virtual Board Meeting	
12/11/20	NASCSA Executive Committee		Sioux Falls	Zoom Meeting	

Board of Pharmacy - Inspection Report

4th Quarter 2020

Date	Destination	City	Purpose	PDMP/ Narc Destruction etc
9/25/20	SDPhA Annual Meeting	Rapid City	Virtual Meeting	
9/29/20	Safeway Pharmacy - Mt Rushmore Rd	Rapid City	Inspection	PDMP
9/30/20	Medicine Shoppe	Rapid City	Inspection	PDMP
10/1/20	Boyd's Express Pharmacy	Rapid City	Inspection	PDMP
10/6/20	Lynn's Dakotamart Pharmacy	Belle Fourche	Inspection	PDMP
10/6/20	Prairie Hills Pharmacy	Belle Fourche	Inspection	PDMP
10/7/20	Monument Health Spearfish Hospital Pharmacy	Rapid City	V-Inspection	
10/7/20	Monument Health Spearfish Surgery Center	Rapid City	V-Inspection	
10/8/20	SD Minimum Security Prison	Rapid City	V-Inspection	
10/13/20	Monument Health Home Plus Pharmacy - Spearfish	Spearfish	Inspection	PDMP
10/14/20	Monument Health Lead/Deadwood Hospital	Rapid City	V-Inspection	
10/15/20	Community Health Center of the Black Hills	Rapid City	V-Inspection	
10/15/20	Boyd's Eastside Pharmacy	Rapid City	Inspection	PDMP
10/16/20	Bennett County Hospital Pharmacy	Rapid City	V-Inspection	
10/27/20	DOH All staff meeting	Rapid City	Virtual Meeting	
10/27/20	DOH Weekly COVID-19 Vaccine Webinar	Rapid City	Meeting	
10/28/20	Walmart Pharmacy - Lacrosse St	Rapid City	V-Inspection	PDMP
10/28/20	Boyd's Drug	Rapid City	Inspection	PDMP
10/29/20	Monument Health Same Day Surgery	Rapid City	V-Inspection	
10/29/20	Monument Health - Rehab	Rapid City	V-Inspection	
10/29/20	Monument Health - Custer Hospital	Rapid City	V-Inspection	
10/30/20	Vilas LTC Pharmacy	Rapid City	V-Inspection	
11/2/20	Weekly Board Office staff call	Rapid City	Virtual Meeting	
11/2/20	BIT Security training	Rapid City	Training	
11/3/20	Monument Health Rapid City Hospital - DEA investigation	Rapid City	Meeting	
11/5/20	Monument Health Home + Pharmacy #1	Rapid City	V-Inspection	PDMP
11/5/20	Winner HealthMart Pharmacy	Rapid City	V-Inspection	PDMP
11/6/20	Burke Community Pharmacy	Rapid City	V-Inspection	PDMP
11/10/20	DOH All staff Zoom meeting	Rapid City	Virtual Meeting	
11/10/20	Monument Health Sturgis Hospital	Rapid City	V-Inspection	
11/11/20	DOH Weekly COVID-19 Vaccine Call	Rapid City	Virtual Meeting	
11/12/20	Tablet to BIT office - scanning issues	Rapid City	Updates	
11/12/20	Family Pharmacy -DowntownMobridge	Rapid City	V-Inspection	PDMP
11/13/20	Dakota Country Pharmacy	Rapid City	V-Inspection	PDMP
11/16/20	FDA CDER- Orange Book FAQ	Rapid City	Webinar	
11/17/20	DOH Weekly COVID-19 Vaccine Call	Rapid City	Virtual Meeting	
11/17/20	Walgreens Pharmacy - Pierre	Rapid City	V-Inspection	PDMP
11/18/20	Smith's Drug - Lemmon	Rapid City	V-Inspection	PDMP
11/19/20	COVID-19 Antibody Testing Webinar	Rapid City	Webinar	
11/19/20	Monument Health Home + Home Infusion	Rapid City	V-Inspection	
11/24/20	SD State Veterans Home Pharmacy - Hot Springs	Rapid City	V-Inspection	
11/25/20	Lynns DakotaMart Pharmacy - Hot Springs	Rapid City	V-Inspection	PDMP
11/30/20	Weekly Board Office staff call	Rapid City	Virtual Meeting	
12/1/20	Rushmore Compounding	Rapid City	V-Inspection	PDMP
12/1/20	DOH Weekly COVID-19 Vaccine Call	Rapid City	Virtual Meeting	
12/2/20	Wall Drug	Rapid City	V-Inspection	PDMP
12/3/20	Carson Drug	Rapid City	V-Inspection	PDMP
12/3/20	Philip Health Services	Rapid City	V-Inspection	
12/4/20	Winner Family Pharmacy	Rapid City	V-Inspection	PDMP
12/7/20	Weekly Board Office staff call	Rapid City	Virtual Meeting	
12/9/20	Medicine Shoppe Advanced Care Pharmacy	Rapid City	V-Inspection	
12/10/20	Staff meeting - Board meeting review	Rapid City	Virtual Meeting	
12/11/20	Quarterly Board of Pharmacy meeting	Rapid City	Virtual Meeting	

Board of Pharmacy - Inspection Report

4th Quarter 2020

<i>Carol Smith</i>				
Date	Destination	City	Purpose	PDMP/ Narc Destruction etc.
10/5/20	Walmart	Aberdeen	Inspection	PDMP
10/7/20	BOP Staff Meeting	Groton	TEAMS Meeting	
10/12/20	i-Surgery Aberdeen	Groton	Virtual Inspection	
10/14/20	DT Pharmacy	Aberdeen	Inspection	
10/19/20	BOP Staff Meeting	Groton	TEAMS Meeting	
10/20/20	Prairie Lakes Campus Pharmacy - Watertown	Groton	Virtual Inspection	PDMP
10/20/20	Mallard Pointe - Watertown	Groton	Virtual Inspection	
10/20/20	Prairie Lakes HealthCare System - Watertown	Groton	Virtual Wholesale Inspection	
10/26/20	Aberdeen Medical Center (United Clinic) Pharm	Aberdeen	Inspection	PDMP
10/27/20	BIT Security Education	Groton	Technology Education	
10/27/20	DOH Zoom Meeting	Groton	DOH Zoom Update	
10/27/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
10/29/20	Kesslers Inc dba Jones Drug	Aberdeen	Virtual Inspection	PDMP
10/29/20	Kesslers Pharmacy	Aberdeen	Virtual Inspection	PDMP
10/30/20	Aberdeen Medical Ctr dba State Street Pharmacy	Aberdeen	Inspection/NABP Cpd	PDMP
11/2/20	BOP Staff Meeting	Groton	TEAMS Meeting	
11/3/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
11/10/20	DOH Zoom Meeting	Groton	DOH Surgeon General	
11/10/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
11/17/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
11/18/20	Pharm & Patient Safety: ISMP Med Error Report	Groton	NABP CE	
11/19/20	Tablet to BIT	Aberdeen	Software Update - Password	
11/23/20	Maximizing Vaccination Opportunities in COVID-19 for Pharmacists	Groton	Webinar	
11/24/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
11/30/20	BOP Staff Meeting	Groton	TEAMS Meeting	
12/1/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
12/8/20	DOH Vaccine Zoom Meeting	Groton	TEAMS Meeting	
12/10/10	Prairie Lakes HealthCare System - Watertown	Groton	Virtual Inspection	
12/10/20	BOP Staff Meeting	Groton	TEAMS Meeting	
12/11/20	BOP Quarterly Meeting	Groton	Virtual Board Meeting	

South Dakota Prescription Drug Monitoring Program Update

December 11, 2020

What's New at the SD PDMP?

- PMPi Hub sharing set up with TN (34 total)
- VHA Mission Act PDMP Integration Project National Rollout began on November 9 and all VHA facilities are to be live with the integration by the end of 2020 – Sioux Falls VA Health Care System and VA Black Hills Health Care System live on December 8
- Statewide Gateway Integration Project
 - Integration Request Received – 11
 - Credentials Sent – 8 (includes remaining 5 Lewis locations)
 - In Production – 55 (reported 20 at last Board meeting; 31/35 Lewis locations plus Orthopedic Institute in SF, Haisch Pharmacy in Canton, Brown Clinic in Watertown, and The Medicine Shoppe Pharmacy in Rapid City)
- License Integration Project Status
 - Pharmacy Board, Nursing Board, Optometry Board, Podiatry Board, and Dentistry Board are live with auto reverification and auto-approval of new accounts
 - Medical Board – participation still pending

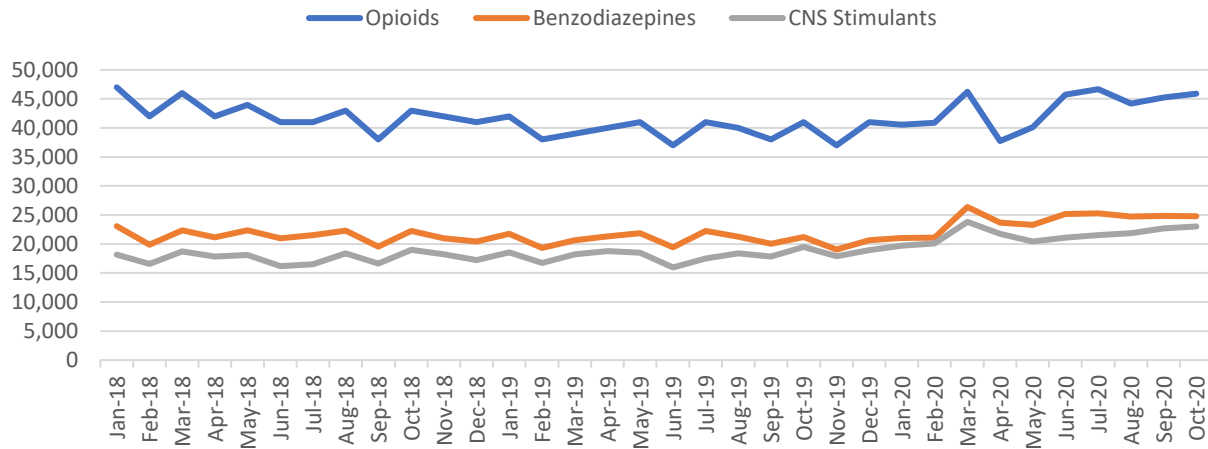
Virtual Presentations Given/Events Attended

- SDPhA 134th Annual Convention BOP/PDMP Presentation
- PDMP presentation for the Sanford School of Medicine Pillar 2 Friday Academy on 'Substance Abuse'
- 2020 NASCSA Conference – elected to the NASCSA Executive Committee and new Chair of the Membership Committee; also, a member of the PMP Committee and 3 of its subcommittees

Upcoming Events

- Opioid Abuse Advisory Committee Meeting/PDMP Update – January 2021
- SD PDMP Annual Report to SD Legislature – January 2021

SD Patients Trending Prescriptions



Bundle Report Month	Total # Bundles Returned	Total Weight Returned	Total Aggregate Weight Returned
Oct-17	1	35	35
Feb-18	3	95	130
Mar-18	2	64	194
Apr-18	2	54	248
May-18	5	179	427
Jun-18	5	128	555
Jul-18	2	79	634
Aug-18	7	197	831
Sep-18	6	204	1,035
Oct-18	4	135	1,170
Nov-18	6	192	1,362
Dec-18	5	169	1,531
Jan-19	9	303	1,834
Feb-19	5	159	1,993
Mar-19	6	209	2,202
Apr-19	10	377	2,579
May-19	10	374	2,953
Jun-19	8	274	3,227
Jul-19	10	314	3,541
Aug-19	12	381	3,922
Sep-19	13	373	4,295
Oct-19	16	500	4,795
Nov-19	16	575	5,370
Dec-19	15	448	5,818
Jan-20	18	601	6,419
Feb-20	22	736	7,155
Mar-20	15	473	7,628
Apr-20	14	392	8,020
May-20	17	512	8,532
Jun-20	16	510	9,042
Jul-20	21	640	9,682
Aug-20	18	554	10,236
Sep-20	22	701	10,937
Oct-20	29	821	11,758



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SDPHA Written Report

Submitted Dec. 3, 2020

General Election

Presidential Election

After several legal challenges and recounts, the transition to a Joe Biden (D) administration is now formally underway in Washington D.C. President-elect Biden will take the oath of office Wed., Jan. 20, 2021. We continue to watch closely for what this transition may mean for several key issues of interest and importance to the pharmacy profession, including Operation Warp Speed, the effort to get a COVID-19 vaccine out to the general population.

South Dakota – Statewide Races

Sen. Mike Rounds (R-SD) and Rep. Dusty Johnson (R-SD) both handily won their reelection bids and will return to Washington D.C. to represent South Dakota for another term.

Legislative Races

The 2021 South Dakota Legislature will have even more Republican lawmakers than last year. Only 11 Democrats will hold seats – that’s down from 16 last year. Several lawmakers switched houses after being termed in their current chamber, and there will be 24 new members of the legislature in 2021. Some of those “new” members actually have prior experience at the Capitol, and are making a comeback after some time away. The party ratio: 94 Republicans, 11 Democrats, 0 Independents.

Statewide Ballot Questions

There were three ballot questions, below we highlight the two of greatest interest to the profession.

Constitutional Amendment A: An Amendment to the South Dakota Constitution to legalize, regulate and tax marijuana; and to require the legislature to pass laws regarding hemp as well as laws ensuring access to marijuana for medical use. While it passed 54% to 46%, it faces legal challenges. Pennington County Sheriff Kevin Thom and the Superintendent of the South Dakota Highway Patrol Col. Rick Miller have filed a lawsuit that ask a judge to void the recreational marijuana amendment. The lawsuit argues Amendment A was actually constitutional revision – not an amendment - that should have required a constitutional convention and a special election. It also asserts Amendment A violates the “one-subject” rule, voters approved in 2016.

Initiated Measure 26: Initiated Measure to legalize marijuana for medical use. *Passed 70% to 30%*

Next Steps: We expect the 2021 Legislative Session will bring several bills to adjust the language of IM 26. Then look for administrative rules to help manage it. It will then be up to local governments to decide whether they want to allow marijuana shops in their communities, and what the parameters of those allowances would be, such as: where they can

be located, the number of them allowed, hours of operation, etc. Regulatory authority for medical marijuana currently falls under the Department of Health.

Coronavirus (COVID-19)

Vaccination Planning / Operation Warp Speed

As the nation prepares for the approval of a COVID-19 vaccine, we continue to work to ensure pharmacists are allowed to provide the vaccine to patients without unnecessary barriers. SDPhA is working closely with the South Dakota Department of Health Immunization Program. Make sure you closely watch your email, the [SDPhA Facebook Group](#) page and the [SDPhA website](#) for updates and important information

Key takeaways as of Dec. 2, 2020:

- Currently state officials have been told to expect the first allocation (approximately 7800 doses) of Pfizer vaccine in mid-December.
- This allocation will be distributed to Avera, Monument Health, and Sanford.
- State officials expect the first allocation of the Moderna vaccine shortly after the Pfizer vaccine. They expect South Dakota to receive a smaller allocation of the Moderna vaccine.
- You can view the current [state vaccination plan here](#). The link is also on the SDPhA webpage.
- ACIP approved [recommendations in an emergency meeting](#) Dec. 1. These recommendations will help shape the balance of the DOH priority population plan, which is forthcoming.
- If you can vaccinate, and want to, you need to sign up via a [provider enrollment form](#) which was sent out to PICs 11.5.2020.
- If you plan to vaccinate, you also need to sign up on the [Vaccine Finder](#) website.
- The DOH is holding weekly calls for immunizers on Tuesdays. The call-in information is sent out via a listserv. Please contact the SDPhA office if you are not on the list, but would like to be.
- SDPhA is sending out recaps of these calls via email, as well as posting them to the SDPhA Facebook Group page.
- The latest information on HHS's current guidance for pharmacists and pharmacy technicians regarding all immunizations can be found on the [SDPhA COVID-19 Resource Webpage](#).

Important Note: The deadline is has passed (Nov. 6, 2020) for long term care facilities to choose their provider of choice for a vaccination program. If your LTC partner did not register and choose you as their provider of choice, the provider will default to a CVS or Walgreens which has coverage in their area. If there is no CVS or Walgreens within 75 miles of a particular facility, the state will work with others in the area to provide that service. We previously sent an email with more details. [You can access that here](#).

Communication

Communication and offering assistance to our pharmacists and pharmacies anywhere and everywhere we can during this pandemic continues to be a top priority for SDPhA. Pharmacies and pharmacists are critical to the well-being of the citizens of South Dakota, not only in dealing with COVID-19, but also in our residents' ongoing care. We continue to update the [COVID-19 Resource Page](#) on our website which was established early-on in the pandemic. It houses links and resources which address many of the concerns and questions we have received here in the office. We post "news" related information on our Facebook Group page. That includes pertinent updates from CMS, HHS, the FDA, DSS, etc. We continue to send out emails to all as appropriate. We greatly appreciate the strong and open channels of communication with several state agencies, our congressional delegation and the South Dakota Board of Pharmacy on items of concern to pharmacists as well as the public health and safety.

Key Safety Communications

For the safety of pharmacists and staff we continue to communicate several key messages which include:

- Heed CDC guidelines as much as possible
- Encourage drive up or delivery
- Frequently clean and disinfect counters, waiting areas and other spaces where public interaction occurs with and EPA-approved disinfectant
- Monitor all staff for sickness regularly. Take temperatures once per shift and send them home if they have symptoms of a respiratory infection
- If you or a staff member have symptoms and require a test, it's imperative your health provider knows you are a pharmacist or pharmacy staff to obtain high priority for testing purposes
- You can find more information regarding pharmacy team exposure on our Covid-19 resource page

Advocacy and Engagement

While the initial frenzied pace of the pandemic response has slowed somewhat, we continue to engage with the BOP, South Dakota Department of Health, and other state partners on behalf of pharmacists where appropriate.

Meantime at the federal level, we remain in close communication with our Congressional delegation, and continue to keep apprised of, and engaged where suitable, in the all the rapidly moving parts on Capitol Hill. Advocacy efforts now focus on maintaining the flexibilities extended to pharmacists by the federal government, while continuing to advocate for change that allows pharmacists to practice to the full scope of their expertise. This has included not only work on emergency provider status, but on immunizations, testing, payment, compounding and funding programs as well. The National Alliance of State Pharmacy Associations (NASPA) also continues to work on our behalf with many of our national partners on matters of concern and importance to pharmacists.

National Efforts

SDPhA remains engaged in a variety of ways in various national efforts on key topics directly impacting our pharmacists such as: COVID-19 related bills, DIR fee relief, PBM reform, pricing transparency, improvements to Medicare, prescription drug misuse and abuse, compounding guidance and provider status. There were many efforts to include some of these topics in Coronavirus legislation, including: DIR fee relief, dispensing requirements, compounding requirements, provider status and scope of practice. The list that follows are the major bills currently related to the aforementioned issues.

[H.R 6201 | Families First Coronavirus Response Act](#)

This bill responds to the COVID-19 outbreak by providing paid sick leave, tax credits, free COVID-19 testing; expanding food assistance and unemployment benefits; and increasing Medicaid funding. There are several sections of the bill which impact Medicare, COVID-19 testing and funding therefor. This bill has 20 related bills. South Dakota's entire Congressional Delegation supported this bill. The Families First Coronavirus Response Act became Public Law No: 116-127 3/18/2020

[H.R 748 | CARES Act](#)

This bill responds to the COVID-19 outbreak and its impact on the economy, public health, state and local governments, individuals and businesses. In terms of healthcare, the act addresses medical supply and emergency drug shortages, access to healthcare for COVID-19 patients, testing and preventative services, support for healthcare providers and

many other matters of personal and professional consequence to pharmacists. South Dakota's entire Congressional Delegation supported this bill. This bill has 48 related bills. The CARES Act became Public Law No: 116-136 3/27/2020

[H.R 6800 | HEROES Act](#)

This bill responds to the COVID-19 outbreak and its impact on the economy, public health, state and local governments, individuals and businesses. In terms of healthcare, it establishes a fund to award grants to provide pandemic premium pay for essential workers, modifies and expands the Paycheck Protection Program (which provides loans and grants to small businesses and nonprofit organizations), provides funding and establishes requirements for COVID-19 testing and contract tracing, eliminates cost-sharing for COVID-19 treatments. It also expands several programs and policies including those regarding Medicare and Medicaid, health insurance. This bill narrowly passed the House 5/15/2020. Rep. Dusty Johnson R-SD did not support the legislation. Hearings were held on this bill in the Senate Committee on Small Business and Entrepreneurship 7/23/2020.

[H.R 6666 | COVID-19 Testing, Reaching and Contacting Everyone Act](#)

This bill authorizes the Centers for Disease Control and Prevention (CDC) to award grants for testing, contact tracing, monitoring, and other activities to address COVID-19 (i.e., coronavirus disease 2019). Entities such as federally qualified health centers, nonprofit organizations, and certain hospitals and schools are eligible to receive such grants. In awarding the grants, the CDC shall prioritize applicants that (1) operate in hot spots and medically underserved communities, and (2) agree to hire individuals from the communities where grant activities occur. This bill has 64 co-sponsors and was referred to the House Committee on Energy and Commerce 5/1/2020.

[H.R. 19 | Lower Costs, More Cures Act of 2019](#)

This bill provides for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Food and Drug Administration and for other purposes. The bill aims to end the so-called "pay-for-delay" tactic regarding generic drugs, place a cap on seniors' out-of-pocket drug expenses, and increase drug price transparency. There are 25 other bills related to this one. H.R. 19 was referred to the Subcommittee on Antitrust, Commercial, and Administrative Law 12/19/2019. The bill has 146 co-sponsors, including Rep. Dusty Johnson.

[S. 640/H.R. 1034 | Phair Pricing Act of 2019 \(Identical Bills\)](#)

This bill requires that certain negotiated prices for covered drugs under the Medicare prescription drug benefit be disclosed at the point-of-sale. Specifically, negotiated prices offered under a prescription drug plan (PDP) must be disclosed at the point-of-sale; the disclosed price must include specified adjustments, payments, and fees that are negotiated with the pharmacy (e.g., dispensing fees) by the PDP sponsor or pharmacy benefit manager. Additionally, the Centers for Medicare & Medicaid Services must establish certain quality measures for PDP sponsors to use when determining incentive payments and adjustments (e.g., performance payments) to pharmacies. The Senate bill currently has 14 cosponsors and was referred to the Committee on Finance 3/4/2019. The House version has 75 cosponsors and was referred to the Subcommittee on Health 2/7/2019

[S. 2723 | Mitigating Emergency Drug Shortages Act](#)

This bill aims to increase authority for the U.S. Food and Drug Administration (FDA) regarding enhanced manufacturing reporting requirements and new market-based incentives to encourage drugs in shortage or at risk of shortage. We know this legislation is of particular importance to SDSHP, and SDPhA is committed to working with SDSHP on these issues. This legislation has been introduced, and referred to the Committee on Health, Labor, and Pensions. 10/29/2019. The bill has four cosponsors.

[H.R. 789/H.R. 803/S. 988 \(Identical Bills\) | Improving Transparency and Accuracy in Medicare Part D Spending Act](#)

This bill prohibits Medicare prescription drug plan sponsors from retroactively reducing payment on clean claims submitted by pharmacies. S. 988 has been referred to the Committee on Finance. Identical House bill H.R. 803 was referred to Subcommittee on Health 3/1/2019. The bill has 27 cosponsors.

[H.R. 1332 | Fair Care Act of 2019](#)

This bill is intended to address the high costs of health care services, prescription drugs, and health insurance coverage in the United States and for other purposes. This is a companion bill to H.R. 803/H.R. 789. The bill was referred to the Subcommittee on Health 2/26/2019.

[H.R. 1035 | Prescription Drug Price Transparency Act](#)

This bill would codify Medicare transparency provisions concerning maximum allowable costs for generics and apply them to the Federal Employee Health Benefits Program. It would also establish a MAC appeals process and prohibit PBM requirement to use a PBM-owned pharmacy. Referred to the Committee on Energy and Commerce, Ways and Means, Oversight and Reform 2/7/2019. The bill has 38 cosponsors.

[H.R. 3528 | Every Prescription Conveyed Securely Act – 115th Congress](#)

This bill generally requires, with specified exceptions, electronic prescribing under the Medicare prescription drug benefit with respect to covered drugs that are controlled substances. The bill was placed on the Union Calendar 6/12/2018. The bill has 51 cosponsors.

[H.R. 4275 | Empowering Pharmacists in the Fight Against Opioid Abuse Act – 115th Congress](#)

This bill requires the Department of Health and Human Services (HHS) to develop and disseminate training programs and materials on: (1) the circumstances under which a pharmacist may refuse to fill a controlled substance prescription suspected to be fraudulent, forged, or indicative of abuse or diversion; and (2) federal requirements related to such refusal. HHS must seek input from relevant stakeholders. This bill passed the House 6/12/2018, and was received in the Senate, and referred to the Committee on Health, Education, Labor and Pensions 6/13/2018.

[S. 2553 | Know the Lowest Price Act of 2018 – 115th Congress](#)

This bill prohibits a prescription drug plan under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee of any difference between the price, copayment, or coinsurance of a drug under the plan and a lower price of the drug without health-insurance coverage. This bill became public law 115-262 on 10/10/2018. Senators Thune and Rounds supported the bill.

[S. 2554 | Patient Right to Know Drug Prices Act – 115th Congress](#)

This legislation would prohibit gag clauses in Health Insurance Marketplace plans as well as Employee Retirement and Income Security Act (ERISA) plans—employee benefit plans offered by private sector employers. This bill became public law 115-263 on 10/10/2018. Senators Thune and Rounds supported the bill.

H.R. 592/S. 109 | Pharmacy and Medically Underserved Areas Enhancement Act – 115th Congress

Amends Title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services. Referred to the Subcommittee on Health. 2/1/2017. Senators Thune and Rounds have graciously agreed to co-sponsor this important legislation. The House version has 296 cosponsors. The Senate version has 55.

H.R. 1038 / S. 413 | Improving Transparency and Accuracy in Part D Drug Spending Act – 115th Congress

Similar/Companion bills dealing with DIR fees. Introduced in the Subcommittee on Health 3/9/2017. Senators Thune and Rounds have agreed to co-sponsor this legislation.

2020/2021 Influenza Immunization Resources

CDC Campaign/Resources

Given the ongoing COVID-19 pandemic, flu shots are of the utmost importance this year. The CDC kicked off its annual campaign at the end of September, and has excellent resources available at [cdc.gov/flu/](https://www.cdc.gov/flu/). This website has a great deal of information for Health Professionals and patients alike. We will add flu resources and information our website and social media as it becomes available. The South Dakota Department of Health's website is <http://doh.sd.gov/diseases/infectious/flu/>.

Recommendations by the Advisory Committee on Immunization Practices (ACIP) for the use of influenza vaccine are now updated for 2020: <https://www.cdc.gov/vaccines/acip/recommendations.html>

In addition to the important role that health care providers play in recommending influenza vaccination for their patients, influenza vaccination of health care personnel is important to protect themselves, their patients, their family, and the community from influenza. The FDA urges health care organizations to encourage their members to get vaccinated.

National Influenza Vaccination Week

National Influenza Vaccination Week (NIVW) is a national observance that was established to highlight the importance of continuing influenza vaccination, as well as fostering greater use of flu vaccine after the holiday season into January and beyond. NIVW is scheduled for December 6-12, 2020. For more information, visit <https://www.cdc.gov/flu/resource-center/nivw/index.htm>.

Fall District Meetings

The SDPhA Board Members/Executive Director will attend every fall district meeting that schedules, if possible. This meeting has become an "optional" meeting, due to the close proximity to our annual meeting, and the fact that most of the "business" is now taken care of at the spring meetings. For a list of all our scheduled meetings, please visit our website at www.sdpha.org and look under the calendar on the right-hand side. You'll also find a list in the Events section on our Facebook page.

2020 Annual Convention Highlights

First Virtual Convention a Success

The meeting place was unlike anything in its 134-year history, but the tradition of the South Dakota Pharmacists Association (SDPhA) annual convention and meeting lives on. SDPhA held its 134th annual meeting and convention virtually September 24-25. The event was highlighted by a wide variety of continuing education opportunities, installing new officers and honoring colleagues with awards for excellence and community service.

Newly Elected Association Officers

President: Dana Darger, Regional Health, Rapid City

President-Elect: Kristen Carter, Lynn's Dakotamart

Vice President: Melissa Gorecki, South Dakota Developmental Center, Warner

Treasurer: Jessica Strobl, Lewis Drug, Dell Rapids

At Large Board Member: Bernie Hendricks, SDSU, Brookings

At Large Board Member: Andy Tonneson, Pharmacy Specialties, Inc. Sioux Falls

Immediate Past President: Lori Ollerich, Pharmacy Specialties, Inc., Sioux Falls

2020 Convention Award Winners

Bowl of Hygeia – Doug Johnson, Tyndall, SD

Hustead Award – Lori Ollerich, Sioux Falls, SD

Distinguished Young Pharmacists Award – Josh Ohrtman, Rapid City, SD

Outgoing Presidents Award (Gavel Award) – Lori Ollerich, Sioux Falls, SD

Technician of the Year Award - Brenda Jensen, Sioux Falls, SD

Salesperson of the Year Award – Tim Arnold, Lake Quivirea, Kansas

Fifty Years in Pharmacy

Richard Amundson – Watertown, SD

Doug Johnson – Tyndall, SD

Dennis Jones – Sioux Falls, SD

Robert Lewis – Sioux Falls, SD

SDPhA By-Laws Amendment

SDPhA board brought forward and amended to the Association by-laws to deal with correcting an error of omission in which "Vice President" is missing in the listing of officers in Article XI – Commercial and Legislative Section 2. In accordance with our by-laws, these revisions were distributed to the membership for consideration at least 15 days before the annual meeting, as well as printed in the annual convention booklet. SDPhA board members, executive director, and general legal counsel were unanimous in their support of the amendment, which added "Vice President" back into the aforementioned section. This was presented at the first business meeting and, adopted following a unanimous vote at the second business meeting. If you have any questions, please contact the SDPhA office or any SDPhA board member.

2021 Legislative Session and Legislative Days 2021

Legislative Efforts

SDPhA continues to monitor activity on a variety of fronts regarding potential legislation for the upcoming 2021 Legislative Session. We don't really expect it will be, "business-as-usual" this session, but we don't yet have a firm handle or guidance on how the typical business, or events during session will proceed. There is a planning document which has been circulating at the Capitol, and also found its way to the media which indicates some of the changes under consideration. This document references still allowing for food and beverages in the President and Speaker's lobbies which would help facilitate our typical Legislative Days event at the Capitol, but there are no direct references to groups or events. While we currently still have our Legislative Days event on the schedule Jan. 26-27, 2021, the health and safety of all will of course be the most important and determining factor. The SDPhA Board will discuss Legislative Days at the next board meeting, and is working with Interim Dean Dan Hansen and Dr. Teresa Seefeldt on what student involvement may look like. Please stay tuned for more information.

Commercial and Legislative Fund

The pandemic has given us a very unique opportunity to showcase the key role pharmacists play in the health and well-being of our communities, and is opening key doors for the profession. We work hard daily to position ourselves at the table that allows us access to opportunities as they arise. That is why the Commercial and Legislative Fund is so very important. The C&L Fund is separate from the SDPhA general accounts. It is used to support the legislative work we do, and relies nearly exclusively on contributions. Lobbying is an expensive, but necessary function, so the importance of this fund cannot be overstated. It is critical, and assists SDPhA in the protection and promotion of the profession during the Legislative Session. Expect to see more from us regarding this fund, and the work we do with it in the coming days. It's imperative that you know we are at a pivotal point with the C&L fund, and that we need your support to continue to ensure we have a seat at the table in Pierre. You can expect to see reminders in your email and on social media to contribute. You can easily contribute at sdpha.org, or send a check to SDPhA, P.O. Box 518, Pierre, SD 57501. We need to have the financial resources available to fully swing into action on bills and policy that affect pharmacists in South Dakota. During 2019/2020, we expended around \$11,000 to fund lobbying activities. This year contributions were again well short of the needed funds to continue to support a lobbyist. Simply put, we can't retain our Lobbyist, Bob Riter and his partner Lindsey Riter-Rapp without this support. ***Thank you to all those who have, and continue to support our efforts!***

Rutledge v. PCMA

The Supreme Court heard oral arguments on this case on Oct. 6. If Arkansas wins this case, it does not end DIR fees or unfair reimbursement, but it could give states the authority to determine whether these practices are detrimental - saying whether states indeed have the right to regulate PBMs. We expect a decision in Spring 2021. Previously, we met with Jason Ravnsborg, Attorney General for South Dakota, to urge his support of the amicus brief from the National Association of Attorneys General in this case, and were pleased to secure that support. SDPhA signed on to a similar brief submitted to the court on behalf of state and national pharmacy associations.

SDPhA has begun to lay the groundwork for what needs to happen next in South Dakota should we obtain a favorable ruling, as well as what routes we need to pursue if we don't, or if the Court Splits on the matter.

American Pharmacists Month

October has come and gone, but it is a time when we recognize all our pharmacists contribute to the world of healthcare in our communities! Our public Facebook page, featured several posts showcasing the many components of your vital role as a member of the health care team and provider of patient services. In addition to the social media pieces, SDPhA was pleased to once again partner with SCAPP/APhA-ASP on an American Pharmacists Month campaign through assistance in placing billboards within the state. Finally, pharmacistsforhealthierlives.org has some fantastic videos, articles and information which you can share anytime to promote a the role of a pharmacist on the healthcare team. Throughout this pandemic, pharmacists have remained the most accessible member of the health care team. Just a small social media share can start some great conversation about your role as medication experts.

Additional Ideas for your facility:

Schedule Special Health Events (when and where appropriate in accordance with current CDC COVID guidelines)

- Promote vaccinations
- Offer various general health screenings – cholesterol, diabetes, osteoporosis
- Offer blood pressure screenings – talk to patients about the signs of heart attack and stroke

Offer Medication Check ups

- Invite patients to bring medications (prescription and nonprescription) so pharmacists can examine them for expiration dates, potential interactions and other medication related problems

OTC Tours

- Geared toward the needs of specific groups – parents, athletes, older adults
 - Help each group understand how to select appropriate products for conditions most likely to affect them. Emphasize label reading, active ingredients, and consulting with a pharmacist when there are questions.

Geriatrics and Their Medications

- Brown Bag Event
- Encourage influenza & pneumococcal immunizations

Don't Be Shy!

- Invite your local newspaper or TV reporter to one of your events. If you'd like some help with news releases or talking points for media interviews, contact Amanda at the SDPhA office.

Recognize Pharmacy Technicians

- National Pharmacy Technician Day Oct. 15, 2019

Education, Communication, Public Affairs and Professional Relations

Continuing Education

The Association continues to focus on providing quality continuing education for practitioners. SDPhA continues to work with the SDSU College of Pharmacy to bring you interesting continuing education opportunities at the annual convention and throughout the year. We have also been engaged from time-to-time to assist pharmaceutical companies in getting the word out on local opportunities for informative programs.

Reaching Out

The Association prepares and delivers Legislative and Association Updates, CE and pharmacy-related information at fall and spring district meetings, in addition to delivering a variety of educational programs at each Annual Convention. The Association continues to work with student pharmacists on the American Pharmacists Month campaign, which helps bring awareness to the state about all pharmacists can do, and how patient care is improved with a pharmacist engaged. SDPhA previously provided SDSU students a grant for, and continues to assist with, pieces related to the, “More Than a Count” campaign. This campaign showcases the profession and SDPhA utilizing traditional and social media platforms to engage both pharmacists throughout the state as well as members of the general public.

The South Dakota Pharmacist

Communicating with our members quickly and effectively is extremely critical to the success of the Association. The South Dakota Pharmacist continues a quarterly electronic distribution. You can also find it posted with past issues on our website. It always offers 1.5 hours of CE, and provides a source of communication for the association on rules, legislative issues and education that affect pharmacy practice.

Website/Social Media/Email Blasts

The SDPhA website (sdpha.org) continues to be updated and improved. A mass e-mail system is typically utilized when important information needs to be shared.

This legislative session we will also utilize a new communications platform called Voter’s Voice. This tool will allow us to communicate with you via different methods of your choosing, including an opt-in for text messages, something many have asked us for. These messages will contain ready-made tools for you to quickly communicate with both state legislators and our congressional delegation when it matters most. We’ll roll out this new platform shortly after convention, so keep a close eye on our social media and your email.

We continue to utilize and expand our social media footprint. This growing presence is something we consider vital to our work of representing the pharmacy profession through advancing patient care, enhancing the public awareness, and serving in the best interest of public health and pharmacy. You’ll now find us increasing our use of LinkedIn and Instagram, in addition to the Facebook pages many of you already follow.

Here’s what’s important to know about each platform:

- Our Facebook and Instagram are primarily consumer-driven health messages. These posts are intended to give you easy access to content you can in turn share on your social channels to help engage your patients and the general public.
- The SDPhA Member News and Announcements Facebook Group page is where we share industry news, SDPhA event and meeting information, and legislative updates as warranted.
- LinkedIn gives us an additional forum to gather and share news impacting the pharmacy profession. The page is established. Look for increased messaging there soon.

Please like, follow, share, and engage with us – that’s what makes these tools effective.

Pharmacists for Healthier Lives

Pharmacists for Healthier Lives is a campaign to reach patients and the public at large with information about what pharmacy is really all about. It showcases pharmacists as frontline members of the healthcare team, and details how pharmacists ensure better patient outcomes. Through the National Alliance of State Pharmacy Associations (NASPA), all state associations have had a unique opportunity to contribute to the campaign, and weigh in on the content, tone and

direction. You'll find we often link to it on our SDPhA Facebook page – it has some great resources your pharmacy can share online too. pharmacistsforhealthierlives.org/

SDSU SCAPP/APhA- ASP Chapter

We continue to work closely with SDSU, and the student pharmacists. The student liaisons have done an amazing job keeping us apprised of activities, and the SDPhA board remains committed to supporting the students in every way possible. This includes activities such as convention attendance (free of charge), rooms for convention and Legislative Days, and support for the Back-to-School Picnic, Pharmacy Days, and American Pharmacists Month activities. We commend them on continuing the successful messaging created as part of the “More Than a Count” campaign, and will continue to work with them on messaging and communication. We believe these activities are an incredible investment in your association’s future. The student pharmacists have worked hard to assist us with this virtual meeting as well, which is greatly appreciated! We also remain a resource for faculty whenever needed, and collaborate on projects whenever possible.

Pharmacy Technician University (PTU)

SDPhA is pleased to continue to offer low-cost access to this online training module. SDPhA has now enrolled more than 90 participants. We are one of the first Associations in the nation to work with Therapeutic Research Center (TRC) and PTU in this manner, and are now working with them, and other state Associations to help set up their programs as well.

We are also thrilled to report 8 student participants from the DIAL Virtual program offered in various South Dakota High schools are enrolled in the course for the 2020-2021 school year. We appreciate the pharmacists who have stepped up in communities across the state to work with the DIAL program and these students. This is an exceptional opportunity to introduce the profession into the school systems, and we are grateful for everyone working together who makes it happen.

Beginning Jan. 1, 2020, completion of a PTCB-recognized education/training program or equivalent work experience became required of all new CPhT applicants. To be considered eligible for the Pharmacy Technician Certification Exam (PTCE) under these new requirements, a candidate must attest to completion of a PTCB-recognized education/training program, or equivalent work experience as a pharmacy technician (min. 500 hours). We are extremely pleased to report the Therapeutic Research Center - PTU 101 module we administer qualifies as a PTCB-Recognized Education/Training Program of the CPhT program. In addition to PTU 101, we now offer two additional training modules as well through TRC – PTU Elite: Compounded Sterile Preparation Technician Program, and PTU Elite: Soft Skills Program. We have entered a new contract, which did slightly increase our rates, but the program remains very cost effective. For more details and enrollment information, contact Amanda Bacon at amanda@sdpha.org or (605) 224-2338.

Antibiotic Stewardship Workgroup

This workgroup was established by the Health Department and South Dakota pharmacists are playing a very large role. The work continues with meetings.

Prescription Drug Abuse/Awareness

The Association continues its work to bring awareness to the proper disposal of medications. As the number of Drug Take-Back Sites continues to increase across the state, we are thrilled to help promote them and they are some of the most responded to and shared posts on our social media. In addition, we continue to support and promote the DEA

President – Dana Darger | President Elect – Kristen Carter | Vice President – Melissa Gorecki | Treasurer – Jessica Strobl | Board Member -- Bernie Hendricks | Board Member – Andy Tonneson | Executive Director -- Amanda Bacon

Drug Take-Back events. The fall event was held Oct. 24. Visit https://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html for more information.

Prescription Drug Monitoring Program

The Prescription Drug Monitoring Program (PDMP) continues to grow and be an excellent resource for practitioners. South Dakota state law mandates PDMP registration for everyone who has a SD Controlled Substance Registration (SD CSR). While the Board of Pharmacy is the entity managing the program, an advisory board was established under the law which consists of at least twelve (12) designees. Dave Mentele and Jim Bregel serve on the advisory board. The group continues to make recommendations to the Board of Pharmacy as to how to best use the program to improve patient care and reduce the misuse, abuse or diversion of controlled substances. The advisory council also makes recommendations to the Board regarding safeguards for release of information to only persons who are entitled to access in order to maintain the confidentiality of program information.

Healthcare Fraud Forum

SDPhA was pleased to participate in this virtual meeting Dec. 1 hosted by the U.S. Attorney's Office. This forum typically takes place at the Law Enforcement Coordinating Committee meeting held annually in November, but was cancelled due to the pandemic. We always look forward to this opportunity to learn from and visit with our law enforcement partners and others, so were pleased to participate virtually to learn more on bogus EFT schemes, healthcare fraud complaints and the state's COVID-19 response. We appreciate their work to find a way to continue to bring us together and provide key updates.

South Dakota Opioid Abuse Advisory Committee

A survey recently released by the Centers for Disease Control and Prevention finds 13% of respondents (in June) said they had started or increased substance abuse to deal with stress or other emotions related to COVID-19. Nationwide, pharmacists continue to engage in the work to prevent prescription drug abuse with the knowledge that real solutions must balance the need for patient access to medications for legitimate medical purposes with the need to prevent diversion and abuse. Pharmacists are in a unique position to combat this epidemic due to their expertise and accessibility. SDPhA Vice President Kristen Carter represents SDPhA on the South Dakota Opioid Abuse Advisory Committee. This committee meets twice a year.

SDSMA Ad Hoc Committee on Prescription Drug Diversion and Abuse

Form SDPhA President Bukovich continues to participate in the South Dakota State Medical Association (SDSMA) Ad Hoc Committee on Prescription Drug Diversion and Abuse. The committee comprised of members from numerous South Dakota healthcare professional organizations was formed in early 2019 by the SDSMA with the goal of developing evidence-based guidelines for acute pain prescribing and treatment. The committee collaboratively finalized the whitepaper, Effective Management of Acute Pain, which SDPhA also formally supported in June 2019. SDPhA remains committed to continuing to work closely with all stakeholders on this issue which is aligned closely with our mission and purpose.

Health Professional Assistance Program

Our association continues to support the HPAP program. The SDPhA Board was pleased to welcome Amanda McKnelly and Maria Piacentino of Midwest Health Management Services, which operates the HPAP program, to a recent board

meeting. McKnelly and Piacentino spoke to the finer points of the HPAP program's role and function, including associated costs to SDPhA, and pharmacist participant numbers. Program costs to SDPhA have doubled since 2018. SDPhA does continue to support the HPAP program, and encourage its use. A pharmacist may access the program by self-referral, board referral, or referral from another person or agency, employer, coworker or family member.

Midwest Pharmacy Expo – PharmaCE Expo

We continue our work with the Iowa Pharmacists Association to promote the Midwest Pharmacy Expo, which is a comprehensive event offering a great deal of excellent CE for pharmacists and technicians. This year, the event is virtual – billed as the PharmaCE Expo. The online event now extends from Feb. 1-7, 2021. South Dakota pharmacists have the opportunity to access at a great rate to attend. The event has become more regional, with a significant number of states engaged. Go to midwestpharmacyexpo.com for details.

Other Office Information

- Converted SDPhA Annual Convention to virtual platform and developed virtual showcase for vendors
- Developed and enhanced promotional materials on the importance of SD Pharmacists
- Provided outreach and shared information with new lawmakers regarding pharmacy
- Provided guidance on pertinent legislation, working with state lawmakers
- Updated educational materials to share with interested groups
- Acted in advisory and liaison capacities to other agencies, departments, associations
- Worked with SD BOP on rules revisions
- Subcommittee members representing Pharmacy on the PDMP working group
- Increased awareness, especially with lawmakers, regarding immunization activities available from pharmacies
- Developed documents for utilization of pharmacy, students, and technicians for Legislative Session, District Meetings, and other applications
- Worked with pharmacy students to share information and enhance networking opportunities
- Lobby our Congressional delegation to move national pharmacy legislation forward and share information on national issues that involve pharmacy
- Updated various policy materials

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1 through December 2, 2020

	Jul 1 - Dec 2, 20	Budget	% of Budget
Ordinary Income/Expense			
Income			
Membership			
SD Board of Pharmacy Transfer	0.00	199,000.00	0.0%
Associate Member	0.00	200.00	0.0%
District Dues			
District 9 - Yankton	15.00	0.00	100.0%
District 8 - Watertown	60.00	0.00	100.0%
District 7 - Sioux Falls	100.00	0.00	100.0%
District 2 - Black Hills	120.00	0.00	100.0%
District 1 - Aberdeen	100.00	0.00	100.0%
Total District Dues	395.00	0.00	100.0%
Student Membership	0.00	1,100.00	0.0%
Total Membership	395.00	200,300.00	0.2%
Corp Endorsements			
NASPA-PQC Endorsement	300.00	300.00	100.0%
PAAS Endorsement	60.00	275.00	21.8%
PMG Endorsement	2,945.00	10,000.00	29.5%
Total Corp Endorsements	3,305.00	10,575.00	31.3%
Interest/Dividends	165.16	3,000.00	5.5%
Convention Income			
PhRMA Education Grant	5,000.00	5,000.00	100.0%
Convention Sponsor	500.00	0.00	100.0%
Exhibitors	3,500.00	7,500.00	46.7%
Registrations	10,725.00	9,375.00	114.4%
Student Sponsorship	50.00	0.00	100.0%
Total Convention Income	19,775.00	21,875.00	90.4%
Total Income	23,640.16	235,750.00	10.0%
Gross Profit	23,640.16	235,750.00	10.0%
Expense			
American Pharmacists Month	765.00	1,850.00	41.4%
Accounting/Tax Prep	2,683.83	4,800.00	55.9%
Salary & Benefits			
Payroll Taxes	2,072.04	4,972.50	41.7%
Payroll Expense	14.77	50.00	29.5%
Executive Director	27,083.30	65,000.00	41.7%
Insurance	5,404.50	10,809.00	50.0%
Retirement	1,625.00	3,900.00	41.7%
Total Salary & Benefits	36,199.61	84,731.50	42.7%
Advertising	0.00	3,000.00	0.0%
Dues/Subscriptions	0.00	3,300.00	0.0%
Technology/Net/Software	7,134.64	11,000.00	64.9%
Furniture/Copier/Assets	706.15	2,300.00	30.7%
Hlth Professionals Assist Prog	20,000.00	20,000.00	100.0%
Insurance (D&O, Office)	0.00	3,600.00	0.0%
Legal/Professional	1,231.56	5,000.00	24.6%
Merchant Card Fees	1,405.67	2,300.00	61.1%
Phone/Internet	2,274.73	4,500.00	50.5%
Postage	25.40	150.00	16.9%
Office Supplies	614.34	1,500.00	41.0%
Publications & Printing (Exp)			
Journal	1,312.00	3,200.00	41.0%
Total Publications & Printing (Exp)	1,312.00	3,200.00	41.0%
Scholarships	0.00	1,000.00	0.0%
Rent	0.00	4,700.00	0.0%
Board Travel & Meetings	1,354.94	20,000.00	6.8%

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1 through December 2, 2020

	Jul 1 - Dec 2, 20	Budget	% of Budget
Staff Travel			
In-State	0.00	5,000.00	0.0%
Out-of-State	0.00	6,000.00	0.0%
Total Staff Travel	0.00	11,000.00	0.0%
Convention Expense	2,712.93	10,000.00	27.1%
Misc Expense	-38.00	500.00	-7.6%
Total Expense	78,382.80	198,431.50	39.5%
Net Ordinary Income	-54,742.64	37,318.50	-146.7%
Other Income/Expense			
Other Income			
PTU Pass Thru Income	5,575.00	0.00	100.0%
C/L Contributions Pass Thru			
Corporation/Business C/L Contr.	600.00	0.00	100.0%
Individual C/L Contr.	2,415.00	0.00	100.0%
Total C/L Contributions Pass Thru	3,015.00	0.00	100.0%
Total Other Income	8,590.00	0.00	100.0%
Other Expense			
PTU Pass Thru Exp	4,395.00	6,500.00	67.6%
Total Other Expense	4,395.00	6,500.00	67.6%
Net Other Income	4,195.00	-6,500.00	-64.5%
Net Income	-50,547.64	30,818.50	-164.0%

**SD Pharmacists Association C & L
Revenue & Expenses Budget vs. Actual
July 1 through December 2, 2020**

	<u>Jul 1 - Dec 2, 20</u>	<u>Budget</u>	<u>% of Budget</u>
Income			
C & L Income	0.00	5,500.00	0.0%
Interest	0.21	0.00	100.0%
Total Income	0.21	5,500.00	0.0%
Expense			
Legislative Exp	0.00	12,450.00	0.0%
Total Expense	0.00	12,450.00	0.0%
Net Income	0.21	-6,950.00	-0.0%

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN
DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS
BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER
APPROPRIATE STATE AGENCY] AND
THE U.S. FOOD AND DRUG ADMINISTRATION

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0800 (expires 10/31/2023).

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate¹ and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.² This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

- a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:
 1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

¹ For purposes of this MOU, see the definitions of “inordinate amounts” and “distribution of compounded human drug products interstate” (also referred to as “distributed interstate”) in Appendix A.

² As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and
 3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).
- b. To qualify for these exemptions, a compounded human drug product must, among other things,³ meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:
1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or
 2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).
- c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

- a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State
 1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues⁴ relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

³ To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.

⁴ For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.
3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.
4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network⁵ or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).⁶

⁵ For purposes of this MOU, see the definitions of “serious adverse drug experience,” “serious product quality issue,” and “Information Sharing Network” in Appendix A.

⁶ The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),⁷ the results of the investigation as permitted by State law.
 7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.
- b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate⁸
1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:
 - (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus
 - (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the

⁷ The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

⁸ The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

facility in which they were compounded during that same calendar year.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If X is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.
3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
 - a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
 - b. the names of States in which the pharmacy is licensed;
 - c. the names of States into which the pharmacy distributed compounded human drug products; and
 - d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.
4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information

1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

a. Complaints:

- i. Name and contact information of the complainant, if available;
- ii. Name and address of the pharmacy that is the subject of the complaint;
- iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;
- iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and
- v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

b. Inordinate Amounts:

- i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;
 - ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;
 - iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;
 - iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;
 - v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;
 - vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and
 - vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.
2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.
 - a. Name and contact information of the complainant or notifier;
 - b. Name and address of the physician that is the subject of the complaint or notification; and

- c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.
3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:
 - Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));
 - Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or
 - Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

- a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

- b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only “in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed” by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience:** Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).
- **Distribution of compounded human drug products interstate:** Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.
- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.
- **Inordinate Amounts:** A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.⁹
- **Product Quality Issue:** Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.
- **Serious Adverse Drug Experience:** Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

⁹ The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue:** Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

December 11, 2020

South Dakota Board of Pharmacy
Kari Shanard-Koenders, Executive Director
4001 W. Valhalla Blvd., Suite 106
Sioux Falls, SD 57106

Re: Hy-Vee, Inc. Variance for Technician-Administered Immunizations

Dear Members of the Board of Pharmacy:

Community pharmacies have become an important access point for immunizations that can prevent serious long-term illness and death. Hy-Vee would like to increase the number of South Dakota residents who receive immunizations and are thus protected from preventable diseases and infections by expanding access to immunizations by utilizing properly trained and supervised pharmacist technicians to administer immunizations. Therefore, Hy-Vee respectfully submits the below information requesting a variance to 20:51:28:02.01, 20:51:29:20, & 20:51:29:21(6) to allow for Technician-Administered Immunizations. This innovative program would achieve the important public health benefit of increasing access to immunizations, while ensuring through proper training, supervision, reporting, and that public safety is maintained.

We ask that the variance be considered at the December 11th, 2020 Board of Pharmacy meeting and for a time period of 1 year.

Please let me know if you require further information or if you have any questions about the variance request. Thank you for your consideration.

Sincerely,

Justin Manning
Pharmacy Supervisor NW Region
Hy-Vee, Inc.
jmanning@hy-vee.com
(515) 559-2486

Technician-Administered Immunization Program Summary

I. Introduction

Community pharmacies have become an important access point for immunizations. As the volume of immunizations has added to other work in community pharmacies, the workload has increased the wait time for getting an immunization administered in some pharmacies. Immunizations are of critical importance to the residents of South Dakota. Immunization-preventable diseases cause long-term illness and hospitalization and account for the deaths of approximately 42,000 people in the country annually. Although the Centers for Disease Control and Prevention has set a goal of 70% of the population receiving the influenza vaccination, only 45.6% of people in the country receive this immunization each year.

Several states have recognized the need to increase access to immunizations. One method of achieving this goal is to allow properly trained and supervised pharmacy technicians to administer immunizations. Our proposed program would implement a technician-administered immunization program at Hy-Vee, Inc. This program would achieve the important public health benefit of increasing access to immunizations, while ensuring through proper training, supervision, reporting, and that public safety is maintained.

II. Program Goals and Objectives

A. Goals

The goals of this program are: (1) increase the number of persons protected from preventable diseases and infections by expanding pharmaceutical immunization services; (2) provide enhanced patient care when administering vaccines in pharmacies; and (3) increase pharmacy staff satisfaction.

B. Objectives

The program will achieve the stated goals by executing the following objectives:

1. Train certified pharmacy technicians in proper immunization storage, patient evaluation, administration and safety techniques, emergency procedures, and record keeping.
2. Operate a program of pharmacy technician-administered immunizations in the 11 South Dakota pharmacy locations under the direct supervision of a pharmacist.

III. Program Details

A. Program Overview

If the South Dakota Board of Pharmacy provides a variance to Hy-Vee to conduct this program, participating certified pharmacy technicians will be trained in proper immunization techniques and immunization safety through an ACPE accredited training program from CEImpact (<https://learn.ceimpact.com/library/course/2253>). This training will satisfy the requirements of 20:51:28:02.01. In addition, all certified pharmacy technicians will be certified in cardiopulmonary

resuscitation. The pharmacies will chose certified technicians who are interested in expanding their scope of work and express desire to participate in the program. All technicians selected for participation will be both registered with the South Dakota Board of Pharmacy and nationally certified by having successfully completed a NCCA-accredited pharmacy technician certification program.

We believe that this pilot program would expand access to immunizations for all of our communities served, both urban and rural, while ensuring public safety through rigorous training, supervision, reporting, and evaluation. Additionally, we believe that this program will improve staff satisfaction by both easing the workload of our pharmacists while allowing technicians the opportunity to become more involved in the care of patients.

B. Procedures Ensuring Public Health and Safety

Numerous procedures will be used during the program to ensure the public health and safety is not compromised. As described above, all technicians will complete rigorous training prior to participating in immunization administration and will be directly supervised by a pharmacist. Additionally, all immunizations will be ordered and administered in compliance with the current recommendations of the Advisory Committee on Immunization Practices (ACIP), and our current SD pharmacy immunization protocol. A summary of key safety procedures is provided below.

1. Verification

Prior to the ordering and administration of an immunization, the pharmacist will consult and review the statewide immunization registry or health information network and our pharmacy immunization protocol. The pharmacist shall assess the patient and verify the appropriateness and safety of the immunization for the patient.

2. Contraindications and Precautions

Each patient will be screened for contraindications and precautions. If a patient has one or more of the contraindications or precautions present, the patient's primary care provider will be consulted before the immunization is administered. If the patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

3. Informed Consent

Hy-Vee will be responsible for identifying patients willing to partake in the program and will obtain proper informed consent. Written informed consent will be obtained from patients prior to immunization administration by pharmacy technicians.

4. Vaccines that May Be Administered

Vaccines and immunizations that may be ordered and administered are outlined in our SD pharmacy immunization protocol and follow the recommendations of the ACIP. A technician may also administer any vaccine pursuant to a prescription or medication order for an individual patient, provided the pharmacist conducts and documents the final verification for the accuracy, validity,

completeness, and appropriateness of the patient's prescription or medication order prior to administration.

5. Documentation

All vaccines administered must be properly documented.

a. Individual Records

An individual record of administration must be created for each patient and the record must be maintained in accordance with state and federal regulations. The record shall be readily retrievable and must include all information as required by our immunization protocol.

b. Vaccine Information Statement

Prior to administration, the current Vaccine Information Statement (VIS) for each vaccine to be administered must be discussed and provided to each patient (or if the patient is a minor, the patient's parent or legal guardian).

6. Immunization Safety

Each technician administering vaccines must follow appropriate infection control and sterilization technique precautions to minimize the risk for spread of disease. To prevent inadvertent needle-stick injury or reuse, needles and syringes must be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices will be used in all possible circumstances to reduce the risk for injury.

7. Management of Adverse Events

All allergic, anaphylactic, or other emergency conditions following vaccine administration must be managed according to the emergency process included in our immunization protocol. Any serious complications must be reported to the Vaccine Adverse Event Reporting System (VAERS) within twenty-four (24) hours. The pharmacist must complete a Hy-Vee Incident Report in the event of any reported serious adverse reaction and documentation of this report will be filed and maintained in the pharmacy policy and procedure manual. If a vaccine is administered pursuant to a prescription or medication order, the prescriber must also be notified within twenty-four (24) hours of a serious complication.

IV. Rule Variance Request

Hy-Vee respectfully requests that the Board provide a variance 20:51:28:02.01, 20:51:29:20, & 20:51:29:21(6) to allow for Technician-Administered Immunizations. These rules provides that only an authorized pharmacist may administer immunizations. We are requesting that properly trained and supervised pharmacy technicians are permitted to administer immunizations at the identified Hy-Vee locations in accordance with this summary.

As described in this project summary, significant percentages of the population are unprotected from fully preventable diseases and illnesses. Long wait times, a shortage of primary

care providers in rural areas, and other barriers prevent thousands from accessing immunization services. Community pharmacies like Hy-Vee have become an important access point for immunizations, but the volume of immunizations has added to other work within the pharmacies. By implementing this program and utilizing pharmacy technicians to administer immunizations, Hy-Vee can increase the availability and accessibility of immunizations and provide enhanced patient care.

V. Supporting Information

Programs similar to Hy-Vee's proposed program have demonstrated the public health benefits of allowing pharmacy technicians to administer immunizations. For example, in 2016 and 2017, a technician-administered immunization pilot program was conducted in Idaho by Washington State University's College of Pharmacy and Albertsons Companies. The program successfully trained twenty-five pharmacy technicians to administer immunizations through a combination of home study and live training. The technicians went on to administer 953 immunizations in a six-month period, with zero adverse events reported.

The study authors concluded that including pharmacy technicians in the immunization process resulted in a great public health benefit, as more patients were able to be immunized due to "the decreased workflow burden on pharmacists and the increased interest in immunizations among the immunization-trained technicians." Allowing pharmacy technicians to administer immunizations allowed pharmacists to focus more time on providing other clinical services while increasing access to vaccinations. Attached are articles describing this program, the study methodology and results, information on the pharmacy technician training, and the status of technician-administered vaccines in other states.

Hy-Vee launched a pilot program with the Iowa Board of Pharmacy in August, 2020 across 12 pharmacy locations. Certified technicians were trained in a same manner listed above and are providing vaccinations according to our Iowa Pharmacy Protocol. These roughly 30 pharmacy technicians have provided over 6633 immunizations since starting in August thru November 1st, accounting for over 40% of the vaccinations given in these locations. Feedback from the pharmacy staff (technicians and pharmacist) has been excellent. The technicians have enjoyed being able to provide vaccinations and expand their scope of practice, while the pharmacists appreciate the extra assistance with workflow and ability to provide other clinical services to their patients.

Attachments

A	Kimberly C. McKeirnan, et al., <i>Training Pharmacy Technicians to Administer Immunizations</i> , 58 J. AM. PHARM. ASS'N 174 (2018).
B	Washington State University College of Pharmacy & Albertsons, <i>WSU, Albertsons Create First U.S. Program Allowing Pharmacy Technicians to Administer Immunizations</i> , WSU INSIDER (April 18, 2017), https://news.wsu.edu/2017/04/18/pharmacy-technicians-to-immunize/ .
C	Washington State University College of Pharmacy, <i>Pharmacy Technician Immunization Training</i> , WASH. ST. U., https://pharmacy.wsu.edu/pharmacy-technician-immunization-training/#accreditation .
D	Kimberly C. McKeirnan, <i>An Update on Technicians as Immunizers</i> , PHARM. TIMES (March 19, 2019), https://www.pharmacytimes.com/publications/supplements/2019/march2019/an-update-on-technicians-as-immunizers .

Pharmacy Locations:

Pharmacy Name	Address	City	State	Zip
Hy-Vee Pharmacy (1039)	790 22nd Avenue South	Brookings	SD	57006
Hy-Vee Pharmacy #5 (1637)	3020 East 10th Street	Sioux Falls	SD	57103
Hy-Vee Pharmacy #6 (1638)	1231 E. 57th Street	Sioux Falls	SD	57108
Hy-Vee Pharmacy #7 (1639)	2700 W. 10th Street	Sioux Falls	SD	57104
Hy-Vee Pharmacy #1 (1624)	1601 S. Sycamore Avenue	Sioux Falls	SD	57103
Hy-Vee Pharmacy #2 (1631)	4101 South Louise Avenue	Sioux Falls	SD	57106
Hy-Vee Pharmacy #3 (1632)	3000 S. Minnesota	Sioux Falls	SD	57105
Hy-Vee Pharmacy #4 (1633)	1900 South Marion Road	Sioux Falls	SD	57106
Hy-Vee Pharmacy (1820)	525 West Cherry Street	Vermillion	SD	57069
Hy-Vee Pharmacy (1871)	1320 9th Avenue SE	Watertown	SD	57201
Hy-Vee Pharmacy (1899)	2100 N. Broadway	Yankton	SD	57078



**South Dakota
Board of Pharmacy**

4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737
Fax: 605-362-2738

DATE: November 11, 2020

WHAT: **DRAFT** Board Policy Statement Number 20-12-11

WHY: UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING QUALIFIED PHARMACY TECHNICIANS TO ADMINISTER ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) RECOMMENDED VACCINES TO PEDIATRIC PATIENTS AGES THREE YEARS TO EIGHTEEN YEARS AND FDA-APPROVED COVID-19 VACCINES TO PATIENTS DURING THE PUBLIC HEALTH EMERGENCY

On August 19, 2020, the U.S. Department of Health and Human Services (HHS) issued a declaration under the PREP Act authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer" certain vaccines to patients ages three (3) to eighteen (18) during the federally-declared COVID-19 public health emergency. The purpose of this declaration was to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies." ***This is a new authorization for pharmacists in South Dakota which allows for ordering and administering certain vaccines without a prescription or protocol. The declaration includes the pharmacist obligations to complete this activity including training and reporting requirements.***

On September 9, 2020, HHS issued a declaration authorizing pharmacists "to order and administer," and a "supervised pharmacy intern acting under the supervision of [a] qualified pharmacist" "to administer" FDA-approved COVID-19 vaccines, when available, to patients ages three (3) years or older during the federally-declared public health emergency. ***This is a new authorization for a pharmacist to be able to order a COVID-19 vaccine without a prescriber order or protocol and includes similar training and reporting requirements.***

On October 21, 2020, HHS issued another declaration under the PREP Act authorizing "qualified pharmacy technicians" to administer ACIP-recommended vaccines to patients ages three (3) to eighteen (18) and FDA-approved COVID-19 vaccines to patients ages three (3) years or older under the supervision of a qualified pharmacist (<https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>). Note: This declaration also clarified the ability of qualified pharmacy interns to administer such vaccines. ***This is a new authorization for South Dakota Pharmacy Technicians as they have not previously been allowed to immunize.***

HHS defines a "qualified pharmacy technician" as a technician "licensed and/or registered in accordance with state requirements." ***Under South Dakota rules, registered pharmacy technicians do not have authority to administer vaccines (or any other drug). The HHS authorization, however, "preempts any state and local law that prohibits or effectively prohibits [qualified pharmacy] technicians from administering COVID-19 or routine childhood vaccines" as outlined in the declaration.***

In addition to being registered, the pharmacy technician must comply with the following requirements to be eligible to administer vaccines pursuant to this declaration:

- The pharmacy technician must be registered with the Board of Pharmacy. In SD, technicians are required to become Certified. We strongly encourage Certified and Grandfathered technicians train as immunizers.
- The vaccination must be ordered by the supervising qualified pharmacist (or a prescriber).

- The supervising qualified pharmacist must be readily and immediately available to the qualified pharmacy technicians administering vaccines.
- The vaccine must be FDA-authorized or FDA-licensed.
- In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).
- In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The qualified pharmacy technician or state-authorized pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. **Note: Because pharmacy technicians in South Dakota had no prior authority to administer vaccines, few, if any, are likely to have completed this type of training program. This training must be completed and documented prior to a technician administering any vaccine. The Pharmacists-in-Charge in each pharmacy are responsible for ensuring that any pharmacy technician administering vaccines has received the required training and it is documented.**
- The qualified pharmacy technician or state-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. **Note: This training must be completed and documented prior to administration of any vaccine. The Pharmacists-in-Charge in each pharmacy are responsible for ensuring that any pharmacy technician or administering vaccines has obtained basic CPR certification.**
- The qualified pharmacy technician must complete a minimum of two hours of ACPE- approved, immunization-related continuing pharmacy education during the relevant State licensing period(s). **Note: South Dakota law does not require pharmacy technicians to obtain continuing education for registration. Certified technicians are required by their certifying entity -- PTCB or NHA – to obtain continuing education to renew their certification with those entities. The Pharmacists-in-Charge are responsible for ensuring that any pharmacy technician administering vaccines under this declaration obtains the required immunization-related CE during the 2021 registration year.**
- The supervising qualified pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction where vaccines are administered, including informing the patient's primary care provider when appropriate/available and submitting the required immunization information to the state or local immunization information system (vaccine registry).
- The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events.
- The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or state-authorized pharmacy intern.
- The qualified pharmacy technician and state-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate and that **vaccination administrations should not be viewed as a substitute for a well-child visit with a pediatrician or other licensed primary care provider.**
- The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) and ensure compliance from any immunizer under his or her supervision as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

A South Dakota immunizing pharmacist, who orders vaccines, and qualified pharmacists, pharmacy interns, and pharmacy technicians who administer vaccines in compliance with DHHS declarations during the federally-declared COVID-19 public health emergency shall not be deemed by the Board of Pharmacy to be in violation of the South Dakota Pharmacy Practice Act, SDCL 36-11, or rules in ARSD 20:51.



 **INTERACTIVE MEMBER FORUM** January 27, 2021

Please Select a Board Member to Join Us for an Interactive, Virtual Discussion on Current Issues Facing Boards of Pharmacy

We are asking for your assistance in identifying **one board member** to attend the virtual NABP Interactive Member Forum to collaborate with their colleagues on best practices and advances in regulating for the protection of public health. The forum will take place on **January 27, 2021**, and will provide attendees with unique ways to virtually interact and network. Attendees will discuss current topics with their peers and share what has worked for their board in hopes of helping others.

Once you have identified who will be attending, please send his or her name and email address to Sharon Stryczek, NABP meeting services manager, at NABPMeetings@nabp.pharmacy, no later than **November 5, 2020**. If you already submitted the name of your selected attendee via your Interactive Executive Officer Forum registration, those names have been added to the invitee list – thank you.

By mid-November, official invitations to register for the forum will be sent to all selected members. Attendees are being asked to indicate what issues they would like to discuss as part of the registration process.

Thank you for your assistance!

fPast Interactive Forum Participants Share Their Experiences

“Loved the format” and “Included an excellent range of topics.”

“Great meeting. Great dialogue. Well organized and informative.”

“The group discussions are very beneficial because you get to share one-on-one with other boards.”