

SOUTH DAKOTA BOARD OF PHARMACY MEETING

The Mission of the South Dakota Board of Pharmacy is to protect and promote the health and safety of the public by supporting pharmacists and pursuing the highest quality pharmaceutical care through education, communication, licensing, legislation, regulation, and enforcement.

DATE/TIME: April 8, 2021; 1:00PM - 5:00PM CDT

LOCATION: THIS IS A ZOOM MEETING DUE TO COVID-19 GATHERING RESTRICTIONS THERE IS NO LISTENING LOCATION

ZOOM MEETING: Join Zoom Meeting <https://zoom.us/j/8743756397> ; Meeting ID: 874 375 6397

Dial one of these phone numbers to join by phone.

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Meeting ID: 874 375 6397#

DRAFT MEETING AGENDA

- 1:00 PM A. Call to Order, Mission, Roll Call and Introductions – President Tom Nelson
- 1:05 PM B. Consent Agenda: *The consent agenda allows the board to approve all these items together without discussion or individual motions. Items may be removed from the consent agenda on the request of any one member. Items not removed may be adopted by general consent without debate. Removed items may be taken up either immediately after the consent agenda or placed later on the agenda at the discretion of the assembly.*¹
1. April 8, 2021 Agenda
 2. December 11, 2020 Board Meeting minutes
 3. New Licenses and Registrations – License Summary, Activity Report
 4. Approvals and Variances
- 1:10 PM C. Financial Report Financial Report - Revenue Report by Month, Remaining Authority Report
- 1:20 PM D. Staff Reports
1. Operations Report – Kari Shanard-Koenders, R.Ph., M.S.J., Executive Director
 2. Inspector Reports –Paula Stotz, R.Ph.; Carol Smith, R.Ph.; Tyler Laetsch, Pharm D
 3. PDMP Report – Melissa DeNoon, R.Ph., PDMP Director
- 1:50 PM E. Complaints, Investigations, Disciplinary Actions, Loss / Theft Report – Paula, Carol, Tyler
1. DEA Form 106—Avera McKennan
 2. DEA Form 106—Safeway Mt. Rushmore Rd, Rapid City
 3. DEA Form 106—Lewis Family Drug, Dell Rapids
 4. DEA Form 106—Lewis Family Drug, Beresford
 5. DEA Form 106—Sanford Health
 6. DEA Form 106—Quva, Loss in Transit to Winner Regional
 7. Complaint 2021-0001—Immunization issue
 8. DEA Form 106—CVS, Rapid City –resolved
 9. DEA Form 106—ANDA- Loss in Transit
 10. Complaint 2021-0002—Professional conduct by pharmacy staff
 11. DEA Form 106—Mylan- Loss in Transit
- 2:15 PM F. SD Pharmacists Association – Amanda Bacon, SDPHA; Dana Darger, R.Ph., SDPHA President
1. Activity Report
 2. Financial Report
- 2:30 PM G. Other Reports

1. SDSU College of Pharmacy – Interim Dean and Professor Dan Hansen, Pharm D.
2. SD Society of Health System Pharmacists (SDSHP) – Jeremy Daniel, Pharm D, BCPS, BCPP
3. SD Association of Pharmacy Technicians (SDAPT) – John Thorns, CPhT

2:40 PM H. Executive Session: per SDCL 1-25-2(3) to consult with legal counsel – Justin Williams, Esq.

2:45 PM Break

3:00 PM I. Old Business

1. NABP Information Sharing Network - Kari
2. FDA MOU with States on Compounding - Kari

3:30 PM J. New Business

1. Hy-Vee SD Technician Immunization Variance – Justin Manning, Pharm. D
2. MedifriendRx – Kevin Rew, Esq.
3. National Coalition for Drug Quality & Security - Denise Frank, R.Ph.
4. PharMerica E-kit Variance – Angela Bomgaars, Pharm D.

4:30 PM K. Other Business

1. Recent Meeting News
 - i. 2021 NABP Interactive Member Forum, January 27, 2021 – Cheri Kraemer, RPh
2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted
 - i. June 25, 2021, 8AM-12PM CDT (tentative)
 - ii. September 16, 2021 1PM-5PM MDT in coordination with 135th SDPHA Annual Meeting, Spearfish
 - iii. December 10, 2021 9AM-1PM CST
 - iv. April 2022 tbd SDSHP
 - v. June 2022, tbd
3. Upcoming Meetings
 - i. April 9-10, 2021, SDSHP 45th Annual Meeting Sioux Falls
 - i. 117th NABP Annual Meeting, May 13-15, 2021 Virtual **we need a voting delegate – fee waived**
 - ii. NABP/AACP 84th Annual District V Meeting, August 11-13, 2021 Winnipeg, Manitoba, CAN
 - iii. September 17-18, 2021 135th SDPHA Annual Meeting, Spearfish
 - iv. NABP/AACP 85th Annual District V Meeting, August 3-5, 2022, Custer State Park

4:40 PM L. Public Comment

5:00 PM M. Adjourn

Please note: The South Dakota State Board of Pharmacy may address items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency of the meeting.

Public comment is welcomed by the Board but will be heard only when that item on the agenda is reached and will be limited to five minutes per person. The Chairperson may allow additional time given to a speaker as time allows.

NOTE: This meeting is being held in a physically accessible place. Individuals needing assistance, pursuant to the Americans with Disabilities Act, should contact the Legislative Research Council (605/367-7781) in advance of the meeting to make any necessary arrangements.

¹ Adapted from http://www.wvcc.edu/CMS/fileadmin/PDF/Learning_Center/Consent_Agenda_FAQ.pdf

LICENSE SUMMARY**Period 12/1/20 – 02/28/21****PHARMACISTS**

2048 Current Total

10 New Licensees for period

License#	Last_Name	First_Name	City	State
R-6831	Blue	Coreliss	Bolingbrook	IL
R-6830	Benford	Micah	Louisville	KY
R-6829	Cherney	Mark	Carter Lake	IA
R-6827	Dowling	Franklin	Sioux Falls	SD
R-6826	Tran	Andre	Sioux Falls	SD
R-6825	Huynh	Uyen	Sioux Falls	SD
R-6823	Derboghossian	Ani	Fresno	CA
6828	Devine	Cassandra	Papillion	NE
6824	Patel	Brindalben	Sioux Falls	SD
6822	Jilek	Darcy	Sioux Falls	SD

FULL-TIME PHARMACY PERMITS

233 Current Total

0 New FT Permits for period

License#	Business	City	State	Type
100-0004	TURNER DRUG INC	Bowdle	SD	Change of Ownership
100-0946	SALEM DRUG INC	Salem	SD	Change of Ownership

PART-TIME PHARMACY PERMITS

67 Current Total

2 New PT Permits for period

License#	Business	City	State
200-1735	Avera McKennan	Lake Andes	SD
200-1736	Avera McKennan	Faulkton	SD

PHARMACY INTERNS

297 Current Total

3 New Registrations for period

TECHNICIAN REGISTRATIONS

1411 Current Total

82 New Registrations for period

NON-RESIDENT PERMITS

819 Current Total

27 New NR Permits for period

WHOLESALE PERMITS

1219 Current Total

34 New WH Permits for period

Activity Report	New	Renewal	Feb	Feb	YTD		
			2021	2020	This Year	Last Year	
Pharmacy Permits							
Full Time (SD)	0	0	0	0		3	4
Part Time (SD)	0	0	0	0		4	10
Non-Resident	3	3	6	6		147	124

Pharmacist Licenses

South Dakota	0	1	1	2		1305	1278
Non-Resident	3	0	3	4		757	755

Technician Registration	27	2	29	31		1408	1613
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Pharmacy Interns	2	1	3	8		333	330
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Wholesale Permits

South Dakota	0	1	1	1		47	62
Non-Resident	11	15	26	19		1211	1212

Inspections

Pharmacy Inspections			21	20		214	208
Wholesale Inspections			6	0		19	13
Other Pharmacy Visits/Meetings			78	41		500	260
Controlled Drug Destruction			0	2		0	2
PDMP Visits			11	16		131	143

Verifications:

Pharmacist						#VALUE!	0
Wholesalers						#VALUE!	0
Pharmacies						#VALUE!	0
Technicians / Interns						#VALUE!	0



**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 April 8, 2021 Board Meeting

Approvals

1. Remote Pick-Up Site in Waubay for Cornwell Drug in Webster
2. Remote Pick-Up Sites in Onida, Hoven, and Selby for Dakota Pharms, LLC dba Vilas Pharmacy in Gettysburg
3. AMDD MedDispense ADC to Omnicell ADC, Select Specialty Hospital, Sioux Falls

Variances/Waivers

1. Burke Community Pharmacy renewal of Telepharmacy Weekly Visit Waiver
2. Shane's Pharmacy Pierre renewal of Variance for E-Kit for Hughes County Jail
3. Correct Rx Non-Resident Pharmacy renewal of Variance for E-Kit for Pennington County Jail

New Pharmacies/Closed Pharmacies and New/Closed Wholesale Distributors

1. New SD Part-Time Pharmacy, Avera LTC AMDD in Lake Andes LTC, Lake Andes, # 200-1735
2. New SD Part-Time Pharmacy Avera LTC AMDD in Faulkton LTC, Faulkton, # 200-1736
3. New SD Part-Time Pharmacy Sioux Empire Triage Center dba The Link—Avera McKennan, Sioux Falls, #200-1737
4. New SD Wholesale License Sanford USD Medical Center, Sioux Falls, #600-3253

Remaining Authority by Object/Subobject

Expenditures current through 02/27/2021 12:50:31 PM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 34.0 %

09209 Board of Pharmacy - Info						PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL
EMPLOYEE SALARIES						
5101010 F-t Emp Sal & Wages	524,715	244,415	0	0	280,300	53.4
5101020 P-t/temp Emp Sal & Wages	166,415	84,327	0	0	82,088	49.3
5101030 Board & Comm Mbrs Fees	1,907	900	0	0	1,007	52.8
Subtotal	693,037	329,642	0	0	363,395	52.4
EMPLOYEE BENEFITS						
5102010 Oasi-employer's Share	51,776	23,949	0	0	27,827	53.7
5102020 Retirement-er Share	18,500	18,656	0	0	-156	0.0
5102060 Health Insurance-er Share	84,120	50,443	0	0	33,677	40.0
5102080 Worker's Compensation	1,000	394	0	0	606	60.6
5102090 Unemployment Compensation	300	329	0	0	-29	0.0
Subtotal	155,696	93,771	0	0	61,925	39.8
51 Personal Services						
Subtotal	848,733	423,413	0	0	425,320	50.1
TRAVEL						
5203010 Auto-state Owned-in State	7,229	617	0	0	6,612	91.5
5203020 Auto Priv (in-st.) L/rte	600	48	0	0	552	92.0
5203030 Auto-priv (in-st.) H/rte	6,000	884	0	0	5,116	85.3
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	1,773	0	0	47,566	96.4
CONTRACTUAL SERVICES						
5204010 Subscriptions	250	0	0	0	250	100.0
5204020 Dues & Membership Fees	500	202,400	0	0	-201,900	0.0
5204050 Computer Consultant	258,067	368,170	59,990	0	-170,093	0.0
5204080 Legal Consultant	4,278	0	0	0	4,278	100.0

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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	625	0	0	3,375	84.4
5204180	Computer Services-state	11,309	15,514	0	0	-4,205	0.0
5204181	Computer Services-state	3,919	0	0	0	3,919	100.0
5204200	Central Services	6,270	5,019	0	0	1,251	20.0
5204202	Central Services	103	34	0	0	69	67.0
5204203	Central Services	103	52	0	0	51	49.5
5204204	Central Services	418	297	0	0	121	28.9
5204207	Central Services	3,638	3,009	0	0	629	17.3
5204220	Equipment Serv & Maint	600	612	0	0	-12	0.0
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	450	0	0	650	59.1
5204490	Rents-private Owned Prop.	39,277	28,870	0	0	10,407	26.5
5204510	Rents-other	250	0	0	0	250	100.0
5204530	Telecommunications Srvc	5,200	2,794	0	0	2,406	46.3
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	47,446	0	0	359,582	88.3
Subtotal		967,518	693,292	59,990	0	214,236	22.1
SUPPLIES & MATERIALS							
5205020	Office Supplies	2,300	3,006	0	0	-706	0.0
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	56	0	0	344	86.0
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	4,433	0	0	4,617	51.0
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

Remaining Authority by Object/Subobject

Expenditures current through 02/27/2021 12:50:31 PM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 34.0 %

52 Operating Subtotal	1,061,671	703,315	59,990	0	298,366	28.1
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Total	1,910,404	1,126,728	59,990	0	723,686	37.9
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Board of Pharmacy - Inspection Report		1st Qtr 2021		
Kari Shanard-Koenders				
Date	Destination	City	Purpose	PDMP / Narc Destruction, etc.
12/14/2020	COCA Vaccination Call	Sioux Falls	Webinar	
12/15/2020	OD2A Grant Call PDMP Data request	Sioux Falls	Webinar	
12/15/2020	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
12/16/2020	OD2A Grant Call ED Policy Toolkit	Sioux Falls	Webinar	
12/17/2020	DOH Covid 19 Call	Sioux Falls	Webinar	
12/21/2020	Rural OUD Advisory Meeting	Sioux Falls	Webinar	
12/22/2020	DOH All Staff Meeting	Sioux Falls	Webinar	
12/22/2020	One Rx Discussion with ND GPIN and NDSU	Sioux Falls	Webinar	
12/22/2020	Appriss Pandemic and Controlled Substance Prescribing	Sioux Falls	Webinar	
12/29/2020	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
12/30/2020	COCA Vaccination Call	Sioux Falls	Webinar	
01/05/2020	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
02/19/2020	Staff Evals Melissa, Paula, Rhea, Beth	Sioux Falls	Meeting	
01/04/2021	Covid Relief Webinar	Sioux Falls	Webinar	
01/06/2021	Opioid Abuse Advisory Committee	Sioux Falls	Webinar	
01/07/2021	Linda Young, Brittany Novotny - HPAP Bill Call	Sioux Falls	Legislative planning call	
01/07/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
01/11/2021	Inspection Review and Inspector Meeting	Sioux Falls	Webinar	
01/12/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
01/13/2021	PDMP Bi-Weekly Meeting	Sioux Falls	Webinar	
01/13/2021	DocuSign Meeting	Sioux Falls	Webinar	
01/14/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
01/14/2021	Jon Rosmann and IOWA Repository program	Sioux Falls	Webinar	
01/15/2021	J Manning and C Houdek Antibody testing	Sioux Falls	Webinar	
01/15/2021	DocuSign Demo	Sioux Falls	Webinar	
01/19/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
01/20/2021	NASCSA Education Committee	Sioux Falls	Webinar	
01/20/2021	Appriss Knowledge for Good Call	Sioux Falls	Webinar	
01/20/2021	License Recognition Bill Call	Sioux Falls	Webinar	
01/21/2021	iGov Drug Repository call	Sioux Falls	Webinar	
01/21/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
01/25/2021	Rural OUD Advisory Committee Call	Sioux Falls	Webinar	
01/26/2021	Appriss Call with Melissa and Lara Irvin	Sioux Falls	Webinar	
01/26/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
01/27/2021	FDB Conference Call	Sioux Falls	Webinar	
01/28/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
01/28/2021	NABP Integration with iGov (IA, AZ, SD)	Sioux Falls	Webinar	
01/29/2021	Monthly EO NABP Call	Sioux Falls	Webinar	
02/01/2021	Avera Addiction Center	Sioux Falls	Inspection	
02/02/2021	Legislative Days	Sioux Falls	Webinar	
02/02/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
02/03/2021	Igov Meeting Melanie	Sioux Falls	Meeting	
02/03/2021	Board Staff Meeting Website Updates	Sioux Falls	Teams Meeting	
02/04/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
02/08/2021	NCDQS for Drug Quality and security	Sioux Falls	Webinar	
02/09/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
02/10/2021	DocuSign Call - Brian	Sioux Falls	Webinar	
02/10/2021	NASCSA How Pharmacy and Physician uses PDMP	Sioux Falls	Webinar	
02/11/2021	NASCSA Audacity Call Alan McGill	Sioux Falls	Webinar	
02/11/2021	DOH Weekly COVID Call			
02/11/2021	211 Helpline Call		Webinar	
02/11/2021	SD Telepharmacy Discussion Justin Manning	Sioux Falls	Meeting	
02/12/2021	Tyler, Melissa, Kari Lucas SDSHP Slide Prep	Sioux Falls	Webinar	
02/12/2021	Review iGov items with Melanie	Sioux Falls	Meeting	
02/16/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
02/16/2021	NASCSA Education Committee	Sioux Falls	Webinar	
02/17/2021	APPRISS PDMP Funding Discussion	Sioux Falls	Webinar	

02/17/2021	SD Medicaid meeting Bill Snyder COVID - 19 Vaccine reimbursement	Sioux Falls	Webinar	
02/18/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
02/18/2021	I Gov Meeting and Eval Melanie	Sioux Falls	Meeting	
02/18/2021	BOP and DOH Education for Tyler, lintern	Sioux Falls	Meeting	
02/22/2021	Staff Evals Tyler, Carol	Sioux Falls	Meeting	
02/22/2021	Rural OUD Advisory Board Monthly Meeting	Sioux Falls	Webinar	
02/23/2021	FY22 Benefits Meeting	Sioux Falls	Webinar	
02/23/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
02/25/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
02/25/2021	NABP Monthly ED Call	Sioux Falls	Webinar	
03/02/2021	CDC COCA CALL	Sioux Falls	Webinar	
03/02/2021	PDMP Ongoing Funding Discussion	Sioux Falls	Webinar	
03/03/2021	LE Traing, Melissa, Erin Payne	Sioux Falls	Webinar	
03/03/2021	Bit Meeting Website Redirect Issues	Sioux Falls	Webinar	
03/04/2021	Online Supervisor Training Modules	Sioux Falls	Webinar	
03/04/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
03/11/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
03/11/2021	Legal Aspects Hiring and Sexual Harassment Training	Sioux Falls	Webinar	
03/11/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
03/11/2021	Avoiding Conflicts of Interest DOH Supervisor Training	Sioux Falls	Webinar	
03/15/2021	Rural OUD Advisory Board Monthly Meeting	Sioux Falls	Webinar	
03/16/2021	Scott Stolte Dean Interview	Sioux Falls	Webinar	
03/16/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
03/16/2021	Great Plains QIN LAN Event: Impact of Aging on Medication Use	Sioux Falls	Webinar	
03/17/2021	Wadsworth Dean Interview	Sioux Falls	Webinar	
03/17/2021	"Moving Targets: EPA's Impact on DEA Disposal in Healthcare"	Sioux Falls	Webinar	
03/18/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
03/19/2021	Dan Hansen Dean Interview	Sioux Falls	Webinar	
03/19/2021	Sarah Boblenz Telepharmacy conf call	Sioux Falls	Conference Call	
03/23/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
03/25/2021	DOH Weekly COVID Call	Sioux Falls	Webinar	
03/25/2021	USP COVID-19 Vaccine Handling Toolkit	Sioux Falls	Webinar	
03/29/2021	ASHP Accreditation Call for South East Tech	Sioux Falls	Webinar	
03/30/2021	St of SD Board of Pharmacy/Amex review	Sioux Falls	Webinar	
03/30/2021	SD DOH Mass Vaccination Call	Sioux Falls	Webinar	
03/30/2021	NASCSA Education Committee	Sioux Falls	Webinar	
04/01/2021	SD DOH COVID Call	Sioux Falls	Webinar	
04/08/2021	SD DOH COVID Call	Sioux Falls	Webinar	
04/08/2021	SD Board of Pharmacy Quarterly Meeting	Sioux Falls	Webinar	

Board of Pharmacy - Inspection Report		1st Qtr 2021		
Melissa DeNoon				
Date	Destination	City	Purpose	PDMP / NARC Destruction etc.
12/15/20	DOH Laura S and BOP/PDMP	Sioux Falls	Opioid RXs/Covid Impact Call	
12/15/20	NASCSA Membership Committee	Sioux Falls	Zoom Meeting	
12/16/20	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
12/17/20	DOH	Sioux Falls	Covid Zoom Call	
12/17/20	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
12/17/20	NABP PMPi Steering Committee	Sioux Falls	Zoom Meeting	
12/21/20	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
12/22/20	DOH All Staff	Sioux Falls	Zoom Meeting	
12/22/20	ONE RX & SD Opioid Workgroup	Sioux Falls	Zoom Meeting	
12/22/20	DOH	Sioux Falls	Covid Vaccine Zoom Call	
1/6/21	DOH Opioid Abuse Advisory Committee	Sioux Falls	Zoom Meeting	PDMP Presentation
1/7/21	DOH	Sioux Falls	Covid Zoom Call	
1/8/21	SD State Board of Dentistry	Sioux Falls	Board Meeting	PDMP Presentation
1/12/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
1/13/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
1/13/21	NASCSA Membership Committee	Sioux Falls	Zoom Meeting	
1/14/21	DOH	Sioux Falls	Covid Zoom Call	
1/14/21	RxCheck Governance Board	Sioux Falls	Zoom Meeting	
1/14/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
1/14/21	DOH - Laura Streich, Amanda Nelson	Sioux Falls	PDMP/Covid Impact Call	
1/19/21	SD Legislature House Health & Human Srvcs	Sioux Falls	Annual Opioid Report	PDMP Presentation
1/19/21	FDA	Sioux Falls	Webinar	
1/19/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
1/20/21	SD Legislature House Health & Human Srvcs	Sioux Falls	Annual Opioid Report	PDMP Presentation
1/20/21	Appriss Health	Sioux Falls	Webinar	
1/21/21	DOH	Sioux Falls	Covid Zoom Call	
1/21/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
1/21/21	TTAC PDMP Administrator Compliance Group	Sioux Falls	Zoom Meeting	
1/25/21	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
1/25/21	PMIX Standards Organization	Sioux Falls	Webinar	
1/26/21	Appriss Health & PDMP Staff	Sioux Falls	Ongoing Project Funding Call	
1/26/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
1/27/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
1/27/21	Appriss Health	Sioux Falls	Webinar	
1/28/21	DOH	Sioux Falls	Covid Zoom Call	
1/28/21	NABP PMPi Legislative & Policy Subcommittee	Sioux Falls	Zoom Meeting	
1/28/21	TTAC PDMP Administrator Town Hall	Sioux Falls	SUPPORT Act Zoom Call	
1/29/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	
2/3/21	SD BOP Staff	Sioux Falls	Website Meeting	
2/4/21	NASCSA Data Integrity Subcommittee	Sioux Falls	Zoom Meeting	
2/9/21	NASCSA - Kathy Keough	Sioux Falls	Mbrship Comm Zoom Call	
2/9/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
2/10/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
2/10/21	NASCSA	Sioux Falls	Webinar	
2/11/21	DOH	Sioux Falls	Covid Zoom Call	
2/11/21	211 Helpline Center	Sioux Falls	University Webinar	
2/12/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
2/12/21	SD BOP - Kari and Tyler	Sioux Falls	Discuss SDSHP Presentation	
2/16/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
2/17/21	NASCSA Data Integrity Subcommittee	Sioux Falls	Zoom Meeting	
2/17/21	SD BOP - Kari and DOH - Laura S, Kiley H	Sioux Falls	Funding Zoom Meeting	
2/17/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	

2/17/21	DOH-Laura S, Epis and USD Eval Team	Sioux Falls	Masked Data Extracts Meeting	
2/18/21	DOH	Sioux Falls	Covid Zoom Call	
2/18/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
2/18/21	Appriss Health	Sioux Falls	Webinar	
2/18/21	Appriss Health	Sioux Falls	Tableau Questions Meeting	
2/19/21	SD BOP - Kari	Sioux Falls	ACE Meeting	
2/19/21	JustGrants	Sioux Falls	Webinar	
2/22/21	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
2/22/21	NASCSA Membership Committee	Sioux Falls	Zoom Meeting	
2/23/21	CDC OD2A Peer-to-Peer	Sioux Falls	Webinar	
2/23/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
2/24/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
2/24/21	NADDI	Sioux Falls	Webinar	
2/24/21	Appriss Health	Sioux Falls	Webinar	
2/25/21	DOH	Sioux Falls	Covid Zoom Call	
2/25/21	Appriss Health	Sioux Falls	Tableau Questions Meeting	
2/25/21	TTAC	Sioux Falls	Webinar	
2/26/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	PDMP Presentation
2/26/21	USD Med School - Dr Lamfers, Dr Brown and DOH - Laura S	Sioux Falls	Medical Residents & PDMP Discussion	
3/2/21	BOP-Kari; Appriss-Lara I; DOH-Laura S, Kiley H	Sioux Falls	Funding Zoom Meeting	
3/3/21	DEA - Erin P and BOP - Kari	Sioux Falls	LEN Trning Class Zoom Mting	
3/3/21	NABP PMPi Steering Committee	Sioux Falls	Zoom Meeting	
3/4/21	DOH	Sioux Falls	Covid Zoom Call	
3/4/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
3/8/21	Monument Health and Appriss Health	Sioux Falls	Epic Integration Zoom Meeting	
3/9/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
3/10/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
3/15/21	USD Med School First Years	Sioux Falls	Annual PDMP Presentation	PDMP Presentation
3/15/21	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
3/15/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
3/16/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
3/17/21	NASCSA	Sioux Falls	Webinar	
3/18/21	DOH	Sioux Falls	Covid Zoom Call	
3/18/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
3/23/21	CDC OD2A Peer-to-Peer	Sioux Falls	Webinar	
3/23/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
3/24/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
3/25/21	DOH	Sioux Falls	Covid Zoom Call	
3/25/21	RxCheck Governance Board	Sioux Falls	Members-Only Call	
3/25/21	NASCSA Data Integrity Subcommittee	Sioux Falls	Zoom Meeting	
3/26/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	
4/1/21	DOH	Sioux Falls	Covid Zoom Call	
4/6/21	Maryland PDMP	Sioux Falls	Interstate Data Sharing Set-up	
4/6/21	DOH	Sioux Falls	Covid Vaccine Zoom Call	
4/7/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
4/7/21	NASCSA Membership Committee	Sioux Falls	Zoom Meeting	
4/8/21	DOH	Sioux Falls	Covid Zoom Call	
4/8/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
4/8/21	SD Board of Pharmacy	Sioux Falls	Quarterly Board Meeting	
4/9/21	SDSHP	Sioux Falls	Annual Conference	SD BOP/PDMP Presentation

Board of Pharmacy - Inspection Repo 1st Qtr 2021				
Tyler Laetsch				
Date	Destination	City	Purpose	PDMP / Narc Destruction etc
12/14/20	Lewis Southgate	Sioux Falls	Virtual Inspection	PDMP
12/15/20	Cardinal Nuclear Pharmacy	Sioux Falls	NABP Blueprint Inspection	
12/15/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
12/16/20	Brookings Hospital	Brookings	Virtual Inspection	
12/16/20	Avera Grasslands	Mitchell	Virtual Inspection	PDMP
12/17/20	Lewis Family Drug	Lennox	Virtual inspection	PDMP
12/17/20	SDSU Practice Lab	Brookings	Virtual Inspection	
12/17/20	DOH COVID update	Sioux Falls	Virtual Meeting	
12/18/20	CareTrends Pharmacy	Sioux Falls	NABP Blueprint Inspection	PDMP
12/22/20	DOH all staff meeting	Sioux Falls	Virtual Meeting	
12/22/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
12/28/20	DOC Jamison Annex	Sioux Falls	Virtual Inspection	
12/28/20	DOC Hill	Sioux Falls	Virtual Inspection	
12/28/20	DOC Springfield	Springfield	Virtual Inspection	
12/28/20	DHS Yankton	Yankton	Virtual Inspection	
12/29/20	DOH COVID Vaccine Call	Sioux Falls	Virtual Meeting	
12/30/20	Salem Drug	Salem	Virtual Inspection	PDMP
12/30/20	COVID Vaccination Call	Sioux Falls	Virtual Meeting	
1/5/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
1/7/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
1/12/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
1/19/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
1/20/21	NABP CE Dietary Supplements	Sioux Falls	Virtual Meeting	
1/21/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
1/21/21	Lewis- Tea/Ellis Rd	Sioux Falls	Inspection	PDMP
1/25/21	Walgreen's Minn Ave	Sioux Falls	Inspection	PDMP
1/26/21	Sam's Club Pharmacy	Sioux Falls	Inspection	PDMP
1/26/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
1/27/21	Select Specialty Hospital	Sioux Falls	Inspection	
1/28/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
1/28/21	Concordance Health	Sioux Falls	Wholesale Inspection	
2/1/21	Avera Addiction Center	Sioux Falls	Inspection	PDMP
2/2/21	Lewis Dist Center	Sioux Falls	Wholesale Inspection	
2/2/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
2/3/21	Pharmerica	Sioux Falls	Inspection	PDMP
2/3/21	Office Meeting Website Update	Sioux Falls	Office Meeting	
2/4/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
2/8/21	Walgreens Sertoma Ave	Sioux Falls	Inspection	PDMP
2/9/21	DOH Covid Update	Sioux Falls	Virtual Meeting	
2/9/21	A-Ox Welding Supply	Sioux Falls	Wholesale Inspection	
2/10/21	Lewis Southwest	Sioux Falls	Inspection	PDMP
2/10/21	Avera Specialty Pharmacy	Sioux Falls	Inspection	PDMP
2/11/21	Lewis 5th St	Sioux Falls	Inspection	
2/11/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
2/16/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
2/17/21	Animal Health	Sioux Falls	Inspection	
2/17/21	Animal Health	Sioux Falls	Wholesale Inspection	
2/17/21	Lewis Phillips Ave	Sioux Falls	Inspection	PDMP
2/18/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
2/18/21	CVS in Target Highline	Sioux Falls	Inspection	PDMP
2/19/21	Scotland Pharmacy	Scotland	Inspection	PDMP
2/19/21	Landmann-Jungman Memorial Hospital	Scotland	Inspection	
2/23/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
2/25/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
2/26/21	MPJE Item Writing Workshop	Sioux Falls	Virtual Meeting	
3/2/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
3/2/21	COCA Janssen COVID Call	Sioux Falls	Virtual Meeting	

3/4/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
3/8/21	Walgreens Cliff Ave	Sioux Falls	Inspection	PDMP
3/9/21	Lewis MB2	Sioux Falls	Inspection	PDMP
3/9/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
3/9/21	DOH All Staff Meeting	Sioux Falls	Virtual Meeting	
3/10/21	Hyvee	Brookings	Inspection	PDMP
3/10/21	Medicap	Hartford	Inspection	PDMP
3/11/21	Lewis	Tea	Inspection	PDMP
3/11/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
3/12/21	Avera Dermatology Pharmacy	Sioux Falls	Inspection	PDMP
3/16/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
3/17/21	Bon Homme Pharmacy	Tyndall	Inspection	PDMP
3/17/21	Avera St. Michael's Hospital	Tyndall	Inspection	
3/22/21	Hyvee Cliff Ave	Sioux Falls	Inspection	PDMP
3/23/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
3/24/21	Sanford Canton Inwood Hospital	Canton	Inspection	
3/24/21	Haisch Pharmacy	Canton	Inspection	PDMP
3/25/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
3/29/21	Brandon Pharmacy	Brandon	Inspection	PDMP
3/29/21	Lewis Drug	Brandon	Inspection	PDMP
3/30/21	DOH COVID Vaccine call	Sioux Falls	Virtual Meeting	
3/31/21	Dan's Pharmacy	Sioux Falls	Inspection	PDMP
3/31/21	Avera 7th Ave	Sioux Falls	Inspection	PDMP
4/1/21	Parkston Drug	Parkston	Inspection	PDMP
4/1/21	Avera St. Benedict's	Parkston	Inspection	
4/6/21	Medvantx	Sioux Falls	Inspection	PDMP
4/6/21	Ameripharm	Sioux Falls	Inspection	
4/6/21	Medvantx Wholesale	Sioux Falls	Wholesale Inspection	PDMP
4/7/21	FDA MOU Call	Sioux Falls	Virtual Meeting	
4/8/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
4/8/21	Board Meeting	Sioux Falls	Virtual Meeting	
4/9/21	SDSHP Presentation	Sioux Falls	Virtual Meeting	

Board of Pharmacy - Inspection Report		1st Qtr 2021		
Paula Stotz				
Date	Destination	City	Purpose	PDMP / Narc Destruction etc
12/15/20	PharMerica - Avantha Fountain Springs	Rapid City	V-Inspection	
12/15/20	DOH Weekly COVID-19 Vaccine Call	Rapid City	Virtual Meeting	
12/16/20	Advances and Treatment of COVID-19	Rapid City	Webinar	
12/17/20	Fall River Hospital Pharmacy	Rapid City	V-Inspection	
12/17/20	DOH Weekly COVID-19 Udatde	Rapid City	Webinar	
12/22/20	DOH All Staff meeting	Rapid City	Virtual Meeting	
12/22/20	DOH COVID-19 Mass Vaccination	Rapid City	Webinar	
12/23/20	Monment Health Rapid City Hospital	Rapid City	V-Inspection	
1/5/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
1/7/21	DOH Weekly COVID Webinar	Rapid City	Webinar	
1/11/21	Board Inspection Question review	Rapid City	Virtual Meeting	
1/12/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
1/13/21	DOH Mass COVID Vaccine Plan call	Rapid City	Virtual Meeting	
1/14/21	FDA CDER Conference	Rapid City	Virtual Meeting	
1/16/21	SDSHP - Residents Seminar	Rapid City	Virtual Meeting	
1/19/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
1/19/21	PharMerica - Avantha Arrowhead	Rapid City	Virtual Inspection	
1/20/21	NABP Dietary Suppliment Regulation	Rapid City	Webinar	
1/21/21	DOH Weekly COVID Webinar	Rapid City	Webinar	
1/26/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
1/26/21	Walmart Pharmacy - Pierre	Rapid City	Virtual Inspection	PDMP
1/27/21	Lynns DakotMart Pharmacy - Pierre	Rapid City	Virtual Inspection	PDMP
1/28/21	DOH Weekly COVID Webinar	Rapid City	Virtual Meeting	
1/28/21	Monument Health Home + Specialty Pharmacy	Rapid City	Virtual Inspection	
2/2/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
2/2/21	Avera Campus Pharmacy - Pierre	Rapid City	Virtual Inspection	PDMP
2/4/21	Monument Health Behavioral Health Unit	Rapid City	Virtual Inspection	
2/4/21	DOH Weekly COVID Update	Rapid City	Virtual Meeting	
2/8/21	Avera Campus Pharmacy - Pierre	Rapid City	Virtual Inspection	PDMP
2/9/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
2/10/21	Critical Pont USP <71>	Rapid City	Training	
2/11/21	DOH Weekly COVID Webinar	Rapid City	Virtual Meeting	
2/11/21	Monument Health Dialysis Unit	Rapid City	Virtual Inspection	
2/16/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
2/17/21	Moderna Vaccine Training webinar	Rapid City	Virtual Meeting	
2/18/21	DOH Weekly COVID update	Rapid City	Virtual Meeting	
2/18/21	Monument Health Wholesale	Rapid City	Virtual Wholesale Inspection	
2/19/21	Airgas	Rapid City	Virtual Wholesale Inspection	
2/23/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
2/23/21	Pfizer Vaccine Training webinar	Rapid City	Training	
2/24/21	Monument Health Orthopedic & Spec Hospital	Rapid City	Virtual Inspection	
2/25/21	Concordance	Rapid City	Virtual Wholesale Inspection	
2/25/21	DOH Weekly COVID Update	Rapid City	Virtual Meeting	
3/1/21	Lincare	Rapid City	Virtual Wholesale Inspection	
3/15/21	MPJE Powerpoint training	Rapid City	Virtual training	
3/16/21	BHR - Customer Service, The 10¢ Decision,	Rapid City	Training	
3/16/21	MPJE Virtual training	Rapid City	Virtual training	
3/16/21	DOH Mass COVID Vaccine Call	Rapid City	webinar	
3/17/21	NASCA EPA's impact on CS Disposal in Healthcare	Rapid City	Webinar	
3/23/21	DOH Mass COVID Vaccine Call	Rapid City	Virtual Meeting	
3/24/21	Critical Point Best Practices Non-HD Nonsterile Cpding	Rapid City	Webinar	
3/25/21	NABP USP COVID-19 Vaccine Handling Toolkit	Rapid City	Webinar	
3/30/21	Critical Point			
3/30/21	DOH Mass COVID Vaccine Call			
4/1/21	DOH COVID-19 Weekly Update	Rapid City	Webniar	

Board of Pharmacy - Inspection Report		1st Qtr 2021		
Carol Smith				
Date	Destination	City	Purpose	PDMP/ Narc Destruction etc.
12/15/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
12/22/20	DOH Vaccine Zoom Meeting	Groton	Vaccine Update	
1/5/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
1/7/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
1/11/21	BOP Inspection Question Review	Groton	Virtual Meeting	
1/12/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
1/13/21	Inpatient Tx COVID & Immunomodulation	Groton	SDSHSP Virtual Mtg	
1/13/21	DOH COVID Vaccination Plan	Groton	Virtual Meeting	
1/14/21	FDA CDER Compliance Conference	Groton	Virtual Meeting	
1/19/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
1/20/21	Sanford Deuel County Medical Center	Groton	Inspection	
1/20/21	NABP Report ADV Events to FDA	Groton	Webinar	
1/21/21	ISMP 10 Top Med Errors Reported in 2020	Groton	Webinar	
1/21/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
1/22/21	Plaza Pharmacy	Aberdeen	Inspection	PDMP/Narc Destruction
1/28/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
1/28/21	Avera LTC AMDD #1	Aberdeen	Inspection	PDMP/Narc Destruction
1/28/21	Avera LTC AMDD #4 (Faulkton)	Aberdeen	Virtual Meeting	PDMP/Narc Destruction
1/29/21	Lewis Family Drug #43	Aberdeen	Inspection	PDMP/Narc Destruction
2/2/21	Genoa Healthcare LLC	Groton	Virtual Inspection	PDMP/Narc Destruction
2/2/21	DOH Weekly COVID Call	Groton	Virtual Inspection	
2/3/21	COVID-19 Monthly Updates: Top Ten Questions about mRNA Vaccines	Groton	Webinar	
2/4/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
2/8/21	Coteau des Prairies Hospital Pharmacy	Groton	Virtual Inspection	
2/9/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
2/10/21	Lewis Family Drug #38 Clear Lake	Groton	Virtual Inspection	PDMP/Narc Destruction
2/11/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
2/16/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
2/23/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
3/2/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
3/2/21	CDC COCA: What Clinicians Need to Know About J&J COVID Vaccine	Groton	Virtual Meeting	
3/4/21	Lori's Pharmacy	Groton	Inspection	PDMP/Narc Destruction
3/9/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
3/16/21	MPJE Power Point Review	Groton	Virtual Meeting	
3/16/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
3/18/21	Writing MPJE questions	Groton	Remote Working	
3/23/21	DOH Weekly Vaccine Call	Groton	Virtual Meeting	
3/23/21	Best Practices for Non-HD Nonsterile Cpd	Groton	Webinar	
3/24/21	Best Practices for Non-HD Nonsterile Cpd	Groton	Webinar	
3/25/21	NABP USP Covid-19 Vaccine Handling Toolkit	Groton	Webinar	
3/30/21	Lewis Family Drug #57	Clark	Inspection	PDMP/ Narc Destruction
3/31/21	Cornwell Drug	Webster	Inspection	PDMP/ Narc Destruction
4/1/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
4/8/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
4/8/21	Quarterly BOP Meetin	Groton	Virtual Meeting	



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SDPhA Update | Spring 2021

Submitted March 25, 2021

Legislative Session

The 2021 Legislative Session was one for the history books, and quite different than anything we've seen or dealt with before. Lobbying during a pandemic brought about some unique challenges and real-time learnings as we moved to carry on our work while keeping our lobby team safe. We were grateful to once again have retained the skillful services of long-time SDPhA lobbyist and general legal counsel Robert Riter, as well as Lindsey Riter-Rapp, who is in her second year as lobbyist for SDPhA. Things were quite active for the SDPhA Commercial and Legislative Branch even before the 96th Legislative Session began. As of the date of this report, the gavel has dropped on the main run of this year's session, however lawmakers will return to Pierre Mon., March 29 to consider any vetoes. Rumbblings remain of the possibility of a special session to deal with Initiated Measure 26 (IM26).

A few key bills from the 96th Legislative Session:

- **HB 1046** - SDPhA supported this legislation designed to limit liability for certain exposures to COVID-19. The basic premise of the bill was to protect healthcare workers and others from frivolous lawsuits against those serving others throughout the pandemic. The cause had strong support from more than 40 organizations representing mostly healthcare and business. Gov. Kristi Noem signed the bill Feb. 18.
- **HB 1097** – This hotly debated bill provided for philosophical exceptions to required vaccinations. It seems we see a similar bill nearly every year of late, and they always elicit long and emotional debate. SDPhA opposed this bill, and testified against this legislation. HB 1097 died in committee. A very close vote of 7-6 sent it to the 41st legislative day.
- **HB 1159** – This bill also died in committee after somewhat contentious testimony and debate. We also opposed HB 1159 which would have prohibited employers (including healthcare) from instituting immunization policies for employees. The House Health and Human Service Committee sent it to the 41st Legislative day on a 9-3 vote.
- **HB 1247** – An act to provide for the protection of the consciences of medical professionals. SDPhA was among the coalition strongly opposed to this legislation. The extremely broad language in bill was of chief concern. It essentially allowed for any employee to refuse any task for nearly any reason. After passing out of the House Affairs committee, HB 1247 died on the House floor. Currently, SDCL 36-11-70 addresses dispensing and matters of conscience for pharmacists.

A few other key bills we monitored extremely closely, but on which we ultimately chose not to take a formal position:

- **HB 1077** - Provides for licensure by endorsement for certain licensed professionals and occupations. This bill makes permanent some of the flexibilities granted during the pandemic. The key difference between this bill

and the reciprocity bill we rigorously opposed the last year of the Daugaard Administration – this bill does not replace a licensing board's current process. Gov. Kristi Noem signed this into law Feb. 23.

- **HB 1014** - This bill creates uniform complaint and declaratory ruling procedures for agencies regulating certain professions and occupations, including pharmacy. While we and other had some concern about this legislation – it was clearly on the fast-track. It moved through both chambers swiftly, and was signed by Gov. Noem Feb. 22.
- **SB 4** - Revises certain provisions of the health professionals assistance program. Current law requires the health professions to operate a joint program. This legislation allows each board to select their own. Gov. Noem signed this bill March 9.
- **HB 1263** – Is the Governor's effort to provide price transparency for healthcare costs. SDPhA did not take a position on this bill, and while there's still not a lot of clarity around how this will work in practical application, the legislation sped through both chambers with essentially no opposition and was delivered to the Governor March 9. She has not yet signed it, but it can also go into law without her signature.

Several other several other key pieces of legislation on which SDPhA kept a close watch: controlled substance scheduling, telemedicine and telehealth, open meeting requirements, and various bills which addressed government authority during a pandemic. In addition, the issue of exactly how to implement IM 26 (medical marijuana) dominated the legislature, and ultimately ended with the state in the same position it was when Session began – with IM 26 set to become law as currently written July 1, 2021.

You can see the full scope of the bills we followed this session [online with the SDPhA's new bill tracker](#). An exported list is also supplied at the end of this report document for your convenience.

Legislative Flu Shot Clinic

The Legislative Research Council had previously asked SDPhA to once again assist lawmakers by providing influenza immunizations. However, due to the pandemic and an unexpected supply of influenza vaccine at the Department of Health, it was later decided that this year, DOH would provide vaccinations to interested lawmakers in Pierre for the State of the State address. We look forward to providing the clinic again next year. It's a fantastic way to have a lot of great conversations about the importance of immunizations, and other pharmacy related topics.

Legislative Days

Like so many other events of the past year, Legislative Days also pivoted to a virtual event. Feb. 2, we held an online, townhall style opportunity for pharmacists, pharmacy technicians and pharmacy students to learn about our work thus far in the legislative session. Robert Riter and Lindsey Riter-Rapp, SDPhA lobbyists, and Amanda Bacon, SDPhA executive director discussed the various bills and legislation SDPhA was working on your behalf. The group also heard updates from Kari Shanard-Koenders, Executive Director, Board of Pharmacy, and Interim Dean Dan Hansen from the SDSU College of Pharmacy and Allied Health Professions. We look forward to 2022 and the opportunity to again hold this event in-person. Save the date for Jan. 25-26, 2022! We plan a dinner and legislative update at Red Rossa, as well as wellness checks at the Capitol the morning of Jan. 26, courtesy of the SDSU student pharmacists. This is a fantastic opportunity to show a much broader range of the great work you all do each day. It's also a unique chance for students to hone their skills by providing wellness checks, while also having the option to sit-in on various committees that morning, and venture onto the House and Senate floors to meet their lawmakers. There's nothing like learning the legislative process first-hand! Practicing pharmacists, we strongly encourage you to join us next year – your involvement further showcases, for students and lawmakers alike, the importance of having a strong presence at the table during legislative session.

Legislative Process 101

In the absence of our typical opportunity to show students the legislative process in-person this year, we were delighted virtually join the classroom of Dr. Erin Miller Tues., Feb. 4. Executive Director Amanda Bacon provided students with a walk-through of the legislative process, and used real-time examples from the current legislative session to explain many of the issues, challenges and pitfalls bill can face on the way from becoming an idea to a law, as well as the politics often in play behind the scenes. The students had fantastic questions, and we had great dialogue about how the process works, and how the results impact them each day in their professions. Our thanks to Dr. Miller for having us – we thoroughly enjoyed the opportunity.

Coronavirus (COVID-19)

Vaccination Distribution / Pandemic Response

As millions of Americans receive the COVID-19 vaccine, including more than 220,000 to date in South Dakota, pharmacists continue to play a key part in vaccine rollout across the state. Hospital pharmacists have been vital in meeting the initial challenges of vaccine distribution, handling, storage, standing up vaccination clinics, and finally, getting shots in arms. Community retail pharmacists across the state also answered the call to prepare to vaccinate the state's general population. While the Federal Pharmacy Program now has vaccine in the stores of some of the state's larger chains, distribution to independent and smaller community pharmacies has yet to roll out. Challenges in storage, transportation and minimum orders have complicated this process, and we continue to participate in conversations weekly with the South Dakota Department of Health (SD DOH) on opportunities to further engage our pharmacists who are ready, willing, and able to provide vaccinations to those in their communities. Presumably these challenges will lessen with greater availability of the Janssen / Johnson and Johnson vaccine which has much less stringent storage, handling, and ordering requirements.

Communication

We encourage everyone to continue to closely watch your email, the [SDPhA Facebook Group](#) page and the [SDPhA website](#) for updates and important pandemic and vaccine-related information. 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 make weekly updates to 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 ongoing 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.

Advocacy and Engagement

While the initial frenzied pace of the pandemic response has slowed, 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 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.

RUTLEDGE V. PCMA

In timing that came as a bit of a surprise to nearly everyone, The Supreme Court ruled on this case in late Fall 2020. While the unanimous ruling in favor of Rutledge was exactly the outcome we had hoped for (and cheered loudly upon its release) no one really anticipated a ruling until Spring 2021. As you may remember, SDPhA worked diligently to secure the support of the South Dakota Attorney General in this case, and we remain very appreciative of their signing on to the amicus brief from the National Association of Attorneys General. SDPhA signed on to a similar brief submitted to the court on behalf of state and national pharmacy associations.

While the ruling does not end DIR fees or unfair reimbursement, the Court held that the Employee Retirement Income Securities Act of 1974 (ERISA) does NOT prevent states from regulating the pricing or rates that Pharmacy Benefit Mangers (PBMs) pay pharmacies for dispensing prescriptions to beneficiaries on ERISA plans (plans that are sponsored by a private employer or union). In other words, it means state laws that address pricing and rates apply to ERISA plans, which PBMs had claimed were exempt from the state laws. Provisions such as reimbursements to pharmacies, MAC transparency, and the ability to decline to dispense prescriptions in the face of negative reimbursements all fall within the state's authority to regulate ERISA plans. Additionally, ERISA plans should be subject to reimbursement floors and prohibitions on retroactive claim reductions.

In another case of consequence we are closely watching - the U.S. Supreme Court vacated a ruling by the U.S. Circuit Court of Appeals for the 8th Circuit in *Wilke v. PCMA*. The case struck down North Dakota PBM regulations due to ERISA preemption issues. The Supreme Court determined that the 8th Circuit's ruling cannot stand in light of the ruling in *Rutledge v. PCMA*. Although not a reversal of the 8th Circuit's decision, the Supreme Court's order will require the circuit court to reevaluate North Dakota's law under the *Rutledge* decision.

South Dakota, Like Arkansas and North Dakota is in the 8th circuit, so what happens with these cases sets a precedent for how we move forward addressing PBMs in our state. This is no small undertaking, and SDPhA is diligently working on the path forward for relief for South Dakota pharmacists. You're going to hear much more about this at our Spring Meetings and the SDPhA Annual Convention in September.

SPRING DISTRICT MEETINGS

Due to continued COVID-19 protocols, Spring District meetings will again take place via Zoom. Please watch your emails, the website and social media for dates and connection instructions. This spring meeting is the most important district meeting of the year, as the fall meeting is now optional. Many important items need to be addressed, including the election or re-election of district officers; nominations for the state association board of directors; and the recognition and nomination of worthy pharmacists, reps and technicians to be considered by the Executive Board for the awards presented at our annual meeting. We look forward to restoring these to in-person functions in 2022.

SOUTH DAKOTA PHARMACISTS ASSOCIATION ANNUAL MEETING

Typically, we would report here that early bird registration has begun for the annual meeting, but this Spring, we are evaluating the best path forward for the annual event. The board's preference is to gather as planned Sept. 17-18 in Spearfish, SD, if at all possible. But in addition to the obvious considerations of health and safety, we also have to consider whether holding an in-person event this year is financially feasible. We are in the process of surveying exhibitors regarding their ability to travel and participate with us. We know several companies have no-travel orders through the end of 2021, and simply put, without enough exhibitors, we cannot feasibly hold the event in person. The board will issue a decision on an in-person, virtual, or hybrid convention option by early May, so stay tuned!

APHA ANNUAL MEETING | MARCH 12-15

With the APhA Annual meeting being held virtually this year, Executive Director Amanda Bacon and SDPhA Board President Dana Darger had no need to travel to attend or participate in the House of Delegates. Both were online events, as was the National Alliance of State Pharmacy Association (NASPA) annual conference. Even online, these continue to be valuable resources for members. The 2022 meeting is scheduled in San Antonio, and it is our hope that we are again able to travel and take our SDSU SCAPP students and faculty out for a dinner/activity.

NCPA Congressional Pharmacy Fly-In | April 19-21

For the second year in a row, SDPhA will participate in the NCPA fly-in without leaving the office! This year NCPA is arranging virtual visits between associations, members and congressional delegations. This is a very welcome opportunity to meet with our South Dakota Congressional Delegation to secure support for various federal pieces of legislation affecting pharmacy, as well as bring them up to speed on pharmacy issues here at home.

DEA TAKE-BACK EVENT | APRIL 24

Please visit https://www.deadiversion.usdoj.gov/drug_disposal/takeback/ to view information provided by the DEA. We continue to work to encourage pharmacist participation in these locally-held events. We also continue to work with pharmacists and the BOP to promote the year-round pharmaceutical disposal receptacles. If you have a story you'd like to share about either to aid in that promotion, please contact our office.

NATIONAL BILLS

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 most recent major bills currently related to the aforementioned issues.

S. 298 | Pharmacy Benefit Manager Accountability Study Act of 2021

This bill requires the Government Accountability Office to study the role pharmaceutical benefit managers play in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes. It currently has one cosponsor. This bill was referred to the Committee on Health, Education, Labor and Pensions 2/8/2021

S. 920 | To Amend the Federal Food, Drug, and Cosmetic Act to Allow for the importation of affordable and safe drugs by wholesale distributors, pharmacies, and individuals.

The full text of this bill is not yet available online. It was introduced just two days before the filing of this report. It does have 21 cosponsors. It was referred to the committee on Health, Education, Labor and Pensions Subcommittee on Primary Health and Retirement Security 3/23/2021. There is a similar bill in the House – H.R. 2181.

S. 259 | Safe and Affordable Drugs from Canada Act of 2021

This bill requires the Food and Drug Administration (FDA) to allow for the personal importation of prescription drugs from Canada in certain instances. Such a drug must (1) be purchased from an approved Canadian pharmacy and dispensed by a pharmacist licensed in Canada; (2) be purchased by an individual for personal use only and in quantities not to exceed a 90-day supply; (3) be filled using a valid prescription from a physician licensed in a U.S. state; and (4) have the same active ingredients, route of administration, dosage form, and strength as an FDA-approved drug. Certain types of drugs may not be imported under this program, such as controlled substances, biological products, or

intravenously injected drugs. An approved pharmacy under this program must be located and licensed in Canada and meet additional requirements, such as participation in ongoing and comprehensive quality assurance programs. The bill has 12 cosponsors. It was referred to the Committee on Health, Education, Labor, and Pensions 2/4/2021. H.R. 832 is the related House Bill.

[H.R. 1319 | American Rescue Plan Act of 2021](#)

This bill provides additional relief to address the continued impact of COVID-19 (i.e., coronavirus disease 2019) on the economy, public health, state and local governments, individuals, and businesses.

Specifically, the bill provides funding for

- agriculture and nutrition programs, including the Supplemental Nutrition Assistance Program (SNAP, formerly known as the food stamp program);
- schools and institutions of higher education;
- child care and programs for older Americans and their families;
- COVID-19 vaccinations, testing, treatment, and prevention;
- mental health and substance-use disorder services;
- emergency rental assistance, homeowner assistance, and other housing programs;
- payments to state, local, tribal, and territorial governments for economic relief;
- multiemployer pension plans;
- small business assistance, including specific programs for restaurants and live venues;
- programs for health care workers, transportation workers, federal employees, veterans, and other targeted populations;
- international and humanitarian responses;
- tribal government services;
- scientific research and development;
- state, territorial, and tribal capital projects that enable work, education, and health monitoring in response to COVID-19; and
- health care providers in rural areas.

The bill also includes provisions that

- extend unemployment benefits and related services;
- make up to \$10,200 of 2020 unemployment compensation tax-free;
- make student loan forgiveness tax-free through 2025;
- provide a maximum recovery rebate of \$1,400 per eligible individual;
- expand and otherwise modify certain tax credits, including the child tax credit and the earned income tax credit;
- provide premium assistance for certain health insurance coverage; and
- require coverage, without cost-sharing, of COVID-19 vaccines and treatment under Medicaid and the Children's Health Insurance Program (CHIP).

This bill has 18 related bills. South Dakota's entire Congressional Delegation voted against this bill. The American Rescue Plan Act became Public Law No: 117-2 3/11/2021

[H.R 6201 | Families First Coronavirus Response Act – 116th Congress](#)

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 – 116th Congress

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 – 116th Congress

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 – 116th Congress

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.

SDPHA WEBSITE REBUILD

We are thrilled to share that within the next several weeks, SDPhA will launch a completely new website! While we did redesign the site roughly three years ago to make it more user-friendly, the website platform or back end remained the same. Fast-forward three years, and that functionality is simply out-of-date. It led to some issues in the convention registration process for some, and makes for a cumbersome process for paying district dues and contributions for the C&L Fund.

The new website will feature a completely mobile-responsive and modern design, and a fully upgraded and intuitive user experience – from convention registration to contacting us and everything in between. The new website will feature a forms library which will play a key role in streamlining conventions and eliminating the use of so much paper moving forward. Another key feature is an area we call the Action Center. That's where you'll find all the issues we're working on at the federal and state level. It'll also house the new bill tracker we launched this legislative session, and it will even allow for you to opt in to text alerts about key issues, and let you know when to contact your legislators on an issue of importance to the profession. The Action Center will be a vital piece of our communications on legislative issues, and we are excited for you to see it, and put it into action yourself.

Pharmacy Technician University (PTU)

Technicians – finding them, training them, and keeping them is becoming an even more pressing issue in light of the pandemic. PTU is helping us help our pharmacies answer that call, and our slate of trainings and tools continues to grow. Now more than ever we are pleased to continue to offer low-cost access to this online training module, and to further enhance the programs we offer through it. To date SDPhA has enrolled more than 105 participants. Not only were we one of the first Associations in the nation to work with Therapeutic Research Center (TRC) and PTU in this manner, we

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

are now working on a partnership with them that will make us one of four state associations in the nation to provide an enhanced array of services nationwide. We're excited to share more about that in the near future

We are also enhancing our partnership with the DIAL Virtual program by working with them to elevate the promotion of the pharmacy technician program they offer in the schools (which uses our PTU platform). Working together with school principals and administrators we hope to identify more students interested in the field, and increase access to the program. For the 2020-2021 school year, we have 8 students from various South Dakota High Schools enrolled. We greatly 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.

Just a reminder, the Therapeutic Research Center - PTU 101 module we administer qualifies as a PTCB-Recognized Education/Training Program of the CPhT program, and upon completion, allows participants to sit for the certification exam. In addition to PTU 101, we now offer four additional training modules through TRC:

- PTU Elite: Immunizations
- PTU Elite: Math Mastery – Community Pharmacy
- PTU Elite: Compounded Sterile Preparation Technician Program
- PTU Elite: Soft Skills Program.

For more details and enrollment information, contact Amanda Bacon at amanda@sdpha.org or (605) 224-2338.

HEALTH PROFESSIONAL ASSISTANCE PROGRAM

Our association continues to support the HPAP program. A pharmacist may access the program by self-referral, board referral, or referral from another person or agency, employer, coworker or family member. As referenced earlier in our report, SB4 changed some of the requirements for program administration. We have, and continue to appreciate the open communication with the Board of Pharmacy on what this may mean for the program, and SDPhA moving forward.

C&L FUND

The pandemic has given us a very unique opportunity to showcase the vital 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. Unfortunately, the C&L fund is reaching a critically low level. As we roll out the new website, expect to see more focus on sustaining this essential fund. We will highlight the work we do with it, how people can you can contribute, and frankly, why it's more important now than ever to do so. We need 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 2020/2021, we expended around \$12,000 to fund lobbying activities. Fund contributions again fell well short of the amount needed 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!***

SDPHA OFFICE UPDATE

COVID-19 and everything it encompasses continues to dominate most of the work. We encourage pharmacists to continue to reach out and let us know what they need, and we continue to work to facilitate resolution to issues in any way we can. Our other priority is moving forward the work to enhance PBM compliance with current South Dakota laws, and strengthening statute where needed. Add in convention, in whatever form it takes, and I anticipate a very busy Spring and Summer season.

I continue to greatly appreciate the spirit of collaboration I have received from the BOP, and I look forward with the knowledge that together we can navigate the challenges that lie ahead.

Kind Regards,

Amanda

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1, 2020 through March 2, 2021

	Jul 1, '20 - Mar 2, 21	Budget	% of Budget
Ordinary Income/Expense			
Income			
Membership			
SD Board of Pharmacy Transfer	202,400.00	199,000.00	101.7%
Associate Member	400.00	200.00	200.0%
District Dues			
District 9 - Yankton	15.00	0.00	100.0%
District 8 - Watertown	80.00	0.00	100.0%
District 7 - Sioux Falls	120.00	0.00	100.0%
District 2 - Black Hills	160.00	0.00	100.0%
District 1 - Aberdeen	140.00	0.00	100.0%
Total District Dues	515.00	0.00	100.0%
Student Membership	1,540.00	1,100.00	140.0%
Total Membership	204,855.00	200,300.00	102.3%
Corp Endorsements			
NASPA-PQC Endorsement	300.00	300.00	100.0%
PAAS Endorsement	210.00	275.00	76.4%
PMG Endorsement	6,464.00	10,000.00	64.6%
Total Corp Endorsements	6,974.00	10,575.00	65.9%
Interest/Dividends	231.60	3,000.00	7.7%
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	231,835.60	235,750.00	98.3%
Gross Profit	231,835.60	235,750.00	98.3%
Expense			
Legislative	240.00	0.00	100.0%
American Pharmacists Month	1,830.00	1,850.00	98.9%
Accounting/Tax Prep	3,851.26	4,800.00	80.2%
Salary & Benefits			
Payroll Taxes	3,315.17	4,972.50	66.7%
Payroll Expense	30.38	50.00	60.8%
Executive Director	43,333.28	65,000.00	66.7%
Insurance	8,106.75	10,809.00	75.0%
Retirement	2,600.00	3,900.00	66.7%
Total Salary & Benefits	57,385.58	84,731.50	67.7%
Advertising	0.00	3,000.00	0.0%
Dues/Subscriptions	150.00	3,300.00	4.5%
Technology/Net/Software	7,986.36	11,000.00	72.6%
Furniture/Copier/Assets	1,124.59	2,300.00	48.9%
Hlth Professionals Assist Prog	20,000.00	20,000.00	100.0%
Insurance (D&O, Office)	3,329.00	3,600.00	92.5%
Legal/Professional	1,527.10	5,000.00	30.5%
Merchant Card Fees	1,914.07	2,300.00	83.2%
Phone/Internet	4,090.27	4,500.00	90.9%
Postage	33.15	150.00	22.1%
Office Supplies	738.36	1,500.00	49.2%
Publications & Printing (Exp)			
Journal	2,731.11	3,200.00	85.3%
Total Publications & Printing (Exp)	2,731.11	3,200.00	85.3%
Scholarships	0.00	1,000.00	0.0%
Rent	0.00	4,700.00	0.0%

SD Pharmacists Association
Profit & Loss Budget vs. Actual

July 1, 2020 through March 2, 2021

	Jul 1, '20 - Mar 2, 21	Budget	% of Budget
Board Travel & Meetings	1,528.49	20,000.00	7.6%
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	3,669.93	10,000.00	36.7%
Misc Expense	42.79	500.00	8.6%
Total Expense	112,172.06	198,431.50	56.5%
Net Ordinary Income	119,663.54	37,318.50	320.7%
Other Income/Expense			
Other Income			
PTU Pass Thru Income	8,375.00	0.00	100.0%
C/L Contributions Pass Thru			
Individual C/L Contr.	150.00	0.00	100.0%
Total C/L Contributions Pass Thru	150.00	0.00	100.0%
Total Other Income	8,525.00	0.00	100.0%
Other Expense			
PTU Pass Thru Exp	7,830.00	6,500.00	120.5%
Total Other Expense	7,830.00	6,500.00	120.5%
Net Other Income	695.00	-6,500.00	-10.7%
Net Income	120,358.54	30,818.50	390.5%

**SD Pharmacists Association C & L
Profit & Loss Budget vs. Actual
July 1, 2020 through March 2, 2021**

	<u>Jul 1, '20 - Mar 2, 21</u>	<u>Budget</u>	<u>% of Budget</u>
Income			
C & L Income	3,390.00	5,500.00	61.6%
Interest	672.34	0.00	100.0%
Total Income	4,062.34	5,500.00	73.9%
Expense			
Legislative Exp	4,792.50	12,450.00	38.5%
Total Expense	4,792.50	12,450.00	38.5%
Net Income	-730.16	-6,950.00	10.5%



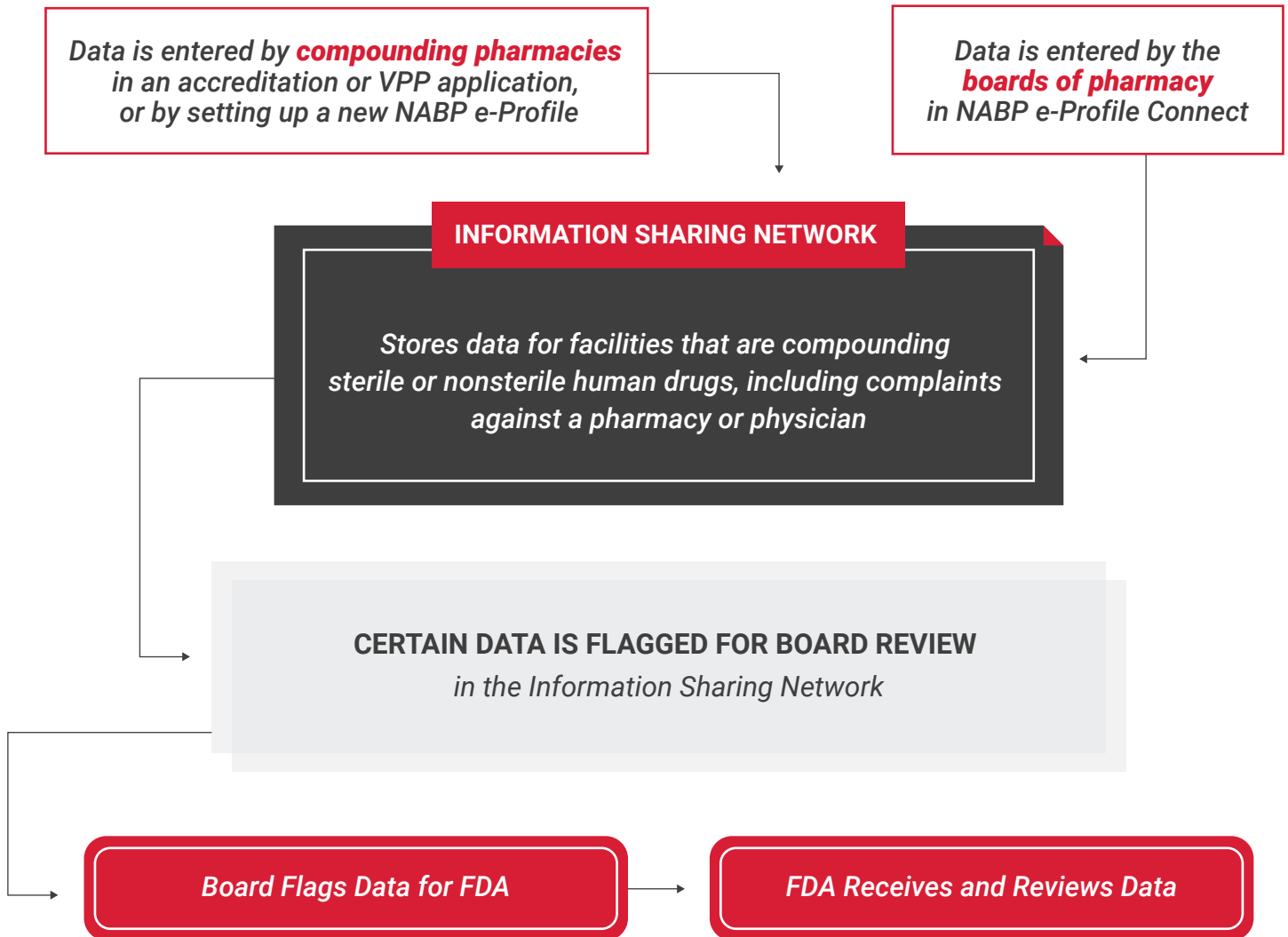
Collect and Share Compounding Data With NABP's Information Sharing Network

NABP's Information Sharing Network helps state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA). Access to the network is free and allows your board to meet the obligations outlined in the memorandum of understanding (MOU) on compounded human drug products.

PATHWAYS FOR DATA ENTRY

& the flow of data through NABP e-Profile Connect

Developed as an expansion of NABP e-Profile Connect, the Information Sharing Network will be available for boards of pharmacy to begin entering data in early 2021.



Visit www.nabp.pharmacy/Compounding-Project for more information on how the Information Sharing Network works or to access the FDA MOU.

Data Collected

The Information Sharing Network collects the following pharmacy and complaint data.

General Pharmacy Information – Entered by the Pharmacy or the Board

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
 - Human drug compounding – sterile or nonsterile
 - Patient-specific or non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, additional data is collected related to licensing, prescription orders, and distribution numbers

Complaint Information – Entered by the Board

Complaints of adverse drug experiences or product quality issues relating to human drug products that are compounded by a physician and distributed interstate are also entered by the board. Data collected includes:

- Name and contact information of the complainant or notifier
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

Complaints of adverse drug experiences, product quality issues, or distribution of human drug products that are compounded by a physician are also entered by the board.

For a complete list of data collected in the Information Sharing Network, visit www.nabp.pharmacy/Compounding-Project.

Data for Board Review

The Information Sharing Network flags data for the boards of pharmacy to review based on certain criteria.

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate.
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate.

By logging in to e-Profile Connect, the boards can review and submit the information to FDA with the click of a button.

Sending Data to FDA

Boards must submit the required information to FDA in accordance with the timelines outlined in the MOU, which can be as little as five days depending on the type of complaint.

A list of the data transmitted to FDA and the associated timelines can be found at www.nabp.pharmacy/Compounding-Project.

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).

April 8, 2021

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 April 8th, 2021 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, PharmD
Health and Wellness Innovation
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

From: Max Iantorno <miantorno@medifriendrx.com>

Subject: Re: [EXT] South Dakota BOP Meeting on 4/8 @ 1pm CDT

Beth,

Thank you for taking our inquiry. We have kiosks to be deployed in Arizona, Texas, and Florida in the next few months attaching to the local licensed pharmacies. The kiosks are designed to fit into a treatment zone without disrupting work flow. The kiosks are stocked with medications in unit of use containers. The formulary is of course determined by the pharmacy but should be tailored to the needs of the patient population. The kiosk limits access to authorized personnel and can be affixed to a wall for additional security.

The kiosk has a loading compartment that does not permit access to medications already stocked inside. New medications are loaded into the tray and when that compartment is shut, the kiosk begins to stock itself, taking the containers from the tray, scanning and photographing each, and assigning a slot. A record of what has been stocked, including the bar code scans and photographs, is sent to the pharmacy so the pharmacy knows that everything sent was in fact placed inside.

Prescriptions are sent to the pharmacy and can be marked for dispensing at the kiosk. The intention is that the prescription provider can give the patient the option of picking up their medication immediately, and has the benefit of knowing that the patient has retrieved the medication.

The experience for the patient is much like going to a pharmacy window. The patient identifies himself at the kiosk, and the kiosk informs the patient what prescriptions it has received and gives the patient the choice to obtain them. (If the medication is not in stock, the patient can be given the option of delivery by the pharmacy, pickup at the pharmacy, or transfer of the prescription.) Assuming that the patient wishes to receive the in-stock medication, the steps are:

1. The pharmacist causes the kiosk to pull medication, which is scanned and photographed for pharmacist verification.
2. Upon verification, the pharmacist causes the kiosk to label the container, which is again scanned and photographed for pharmacist verification.
3. Consultation is offered to the patient via the audio-visual capabilities of the kiosk. There is a camera and screen so the patient and pharmacist can see one another and a handset so they hear one another.
4. After completing the adjudication and other steps of dispensing, the pharmacist causes the kiosk to release the medication to the patient.

Each step of the dispensing process is controlled by the pharmacist, and the use of unit of use containers eliminates human error.

I wanted to share our initial information by the 3/25 for the 4/8 @1pm CDT meeting. Let me know if you need anything else from our end.



PROVIDING THE FIRST RX
AT THE POINT OF CARE

Innovative Technology to Bring Full Pharmacy Services to the Point of Care

MedifriendRx® is a healthcare technology company that simplifies the prescription delivery and pick-up process by bringing full pharmacy services to the point of care.

Our state-of-the-art kiosk is designed to fit easily into the treatment zones of medical clinics and doctors' offices without disrupting workflow.

Patients have the convenience of leaving their doctor's office with their prescription in hand, and doctors are able to provide better outcomes-based care because they know that their patients have picked up their prescription.

6 FEET TALL X 3 FEET WIDE X 18 INCHES DEEP



Designed by a pharmacist

MedifriendRx is founded by Pat Iantorno, PharmD. Over his career, Pat has installed more than 200 pharmacies, primarily in medical settings such as community clinics and medical office buildings occupied by clusters of professionals. His focus has always been to bring pharmacy services to the patient at their doctor's office, strengthening the "Triangle of Care" formed by the physician, patient and pharmacist.

Putting pharmacies into these settings so greatly improved the ease of prescription pick-up for the patient that medication non-adherence rates dropped from 31% of prescriptions to about 1.5%.

The MedifriendRx kiosk continues that mission, bringing access to pharmacy services and dispensing to the patient at the point of care.

WORKFLOW PROCESS



Doctor patient visit

At this time the Doctor prescribes the Rx to the patient. The order is then electronically transmitted to the Pharmacy



Pharmacist processes order

The Pharmacist will then process the Rx order in the Pharmacy. The order then gets pushed to the MedifriendRx.



Pharmacist approves RX, releases to patient and gives consultation



Medical Staff is on hand (optional) or a patient interfaces the kiosk independently

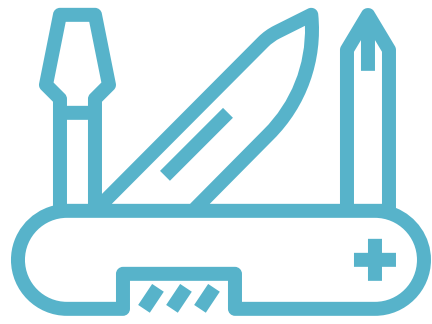


Our Model

- The MedifriendRx kiosk is attached to the license of a pharmacy and placed in a medical setting, such as hospital, physician's office, or clinic.
- It serves as a pharmacy window, conveniently placed in the medical setting.
- The prescriber is able to offer the patient the ability to pick up the prescription onsite.
- The kiosk is stocked with medications in unit of use containers. The formulary is customized to the needs of the patient population at the medical office.
- At the kiosk, the patient identifies herself, just as at a pharmacy window. The patient can access the kiosk herself, or with the assistance of medical center staff.
- The pharmacist operates the kiosk remotely:
 - When the e-Rx is sent to kiosk, the kiosk labels and captures images of the Rx container for pharmacist approval.
 - The pharmacist reviews the labelled container and prescription on the MedifriendRx web portal, approving it.
 - The pharmacist is able to offer consultation directly through integrated audio-visual devices or by a call to the patient's own phone.

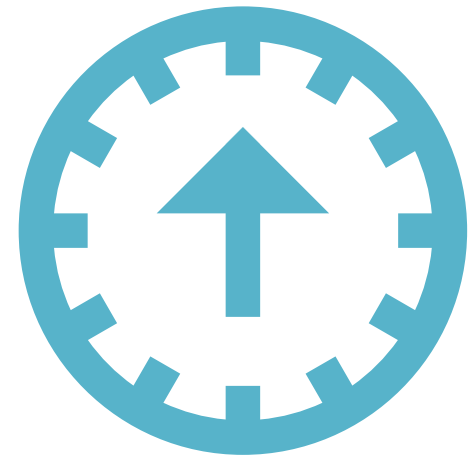
WHY WE STAND OUT

Why It's Better



SIZE

SMALL ENOUGH
TO FIT IN A
TREATMENT
ZONE



SPEED

PRESCRIPTION
PROCESSING UNDER 2
MINUTES



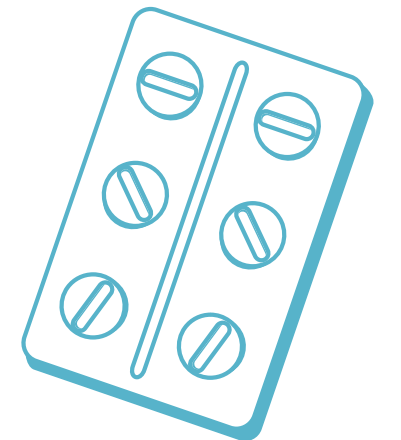
SELF-STOCKING

THE MACHINE SELF-
STOCKS WHOLESALER
ORDERS FOR
INVENTORY
COMPLETION



LABELING

LABELS BOTH
BOTTLES & BOXES
IN A VARIETY OF
SIZES



INVENTORY

CUSTOMIZED
DRUG INVENTORY
& HOLDS 350-400
DRUGS

ADDITIONAL BENEFITS



PHARMACIST CONSULTATION

Real-time consultation is offered to patients through our video monitor and our telephone handset, or by a call to the patient's own phone



100% ACCOUNTABILITY

We keep track of everything that goes into the machine and everything that goes out, assuring drug security



GREATER ACCESS

Allows access to medications in locations that are without pharmacy access



IMPROVED COMPLIANCE

medifriendRx allows the patient to leave their appointment with medication in-hand



CARD READERS

Card readers are integrated in the kiosk to conveniently accept patient payments



SANITARY

The kiosk's surfaces are easily sanitized and drug inventory is sealed off from airborne pathogens

DRUG CAPACITY

STORES 350-400 DRUGS/ NDCs



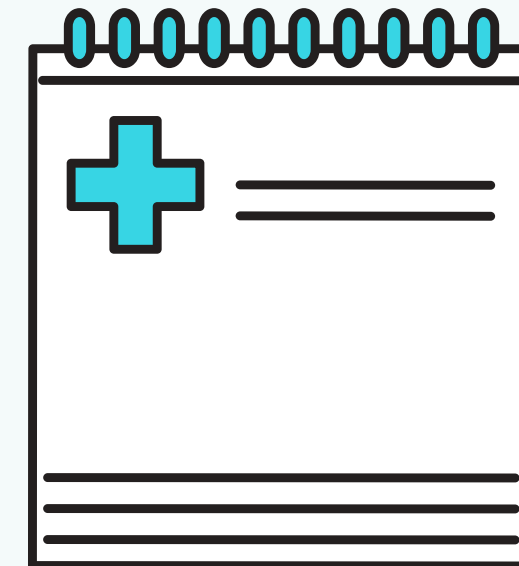
BOTTLES & BOXES

MEDIFRIENDRX
STORES BOTH
BOXES AND
BOTTLES BASED ON
PRESCRIBER HABITS



UNIT OF USE CONTAINERS

DRUGS ARE DISPENSED
IN ORIGINAL
MANUFACTURERS
CONTAINERS, NEGATING
THE NEED FOR
MEDICATION COUNTING
& INCREASES SAFETY



SCHEDULE II-V DRUGS

BASED ON STATE
REGULATIONS & CLIENT
NEEDS, WE ARE
CAPABLE OF
DISPENSING SCHEDULE
II-V DRUGS

INVENTORY



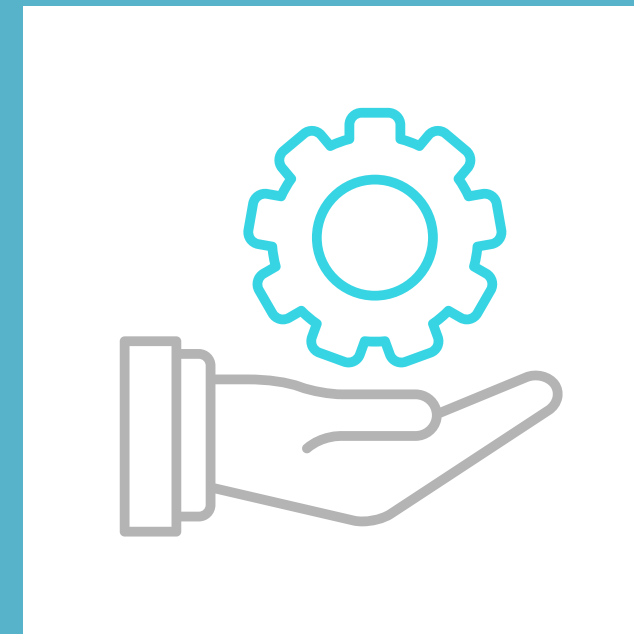
CUSTOMIZED

MEDIFRIENDRX TAILORS THE INVENTORY TO MEET PRESCRIBER NEEDS & FORMULARY REQUIREMENTS (I.E. HIV, PEDIATRICS, ETC.)



SECURITY

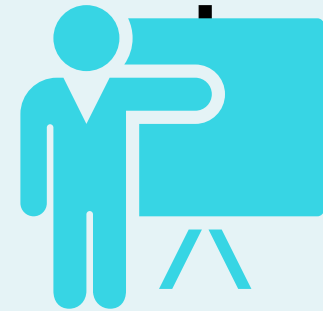
DRUGS ARE LOCKED AND SECURE, ONLY AUTHORIZED PERSONNEL CAN ACCESS THE DRUGS



DISPENSING OPTIONS

- 1) DISPENSED DIRECTLY FROM MEDIFRIENDRX
- 2) MAILED DIRECTLY TO PATIENT
- 3) TRANSFERRED TO A PHARMACY OF PATIENT CHOICE

OUR GREAT SERVICES



TRAINING

We have qualified pharmacist-trainers available to offer on-site training sessions to your staff



INVENTORY CONTROL

We track all inventory in and out to assure compliance and safety



MAINTENANCE & OPERATIONS

We provide services and repairs rapidly, most resolved within 24 hours



TECHNICAL SUPPORT

Our highly qualified technical team is immediately available by phone to help alleviate any issues

Technology for the New Paradigm of Caution

The COVID-19 pandemic has brought the concept of social distancing to the forefront. With a second wave of COVID-19 expected, and other respiratory ailments certain to follow, we know the importance of keeping sick people out of public spaces, including stores, where they can infect others.

The presence of the MedifriendRx kiosk throughout hospital system increases the likeliness that the patient can pick up their prescription without exposing others to illness, or being exposed to someone else's illness at a public retail pharmacy.

Pick Up
Prescription
Here



For Customer Service Call
800-352-5573
Made in the USA

medifriendRx



Max Iantorno, VP
858-692-8731

hello@medifriendRx.com

www.medifriendRx.com

Designed & built in the U.S.A.



March 16, 2021

Dear Ms. Kari Shanard-Koenders and the South Dakota Board of Pharmacy,

My name is Denise Frank, and I am the Accreditation and Inspection Services Director for the National Coalition for Drug Quality & Security. We launched our Quality and Security (QAS) Accreditation Program and QAS Inspection Program for Wholesale Drug Distributors in 2019.

Iowa was the first state to take a deep look into our programs, sending compliance officers to observe on accreditation site surveys. Iowa approved waivers from wholesale drug distributors that had achieved the NCDQS QAS Accreditation to accept our accreditation for licensure in Iowa in lieu of NABP accreditation. The Board subsequently revised the rule, and to be licensed in Iowa as a resident or nonresident wholesale drug distributor, the facility must be accredited by either NCDQS QAS Accreditation or NABP DDA (fka VAWD).

Many additional states now recognize our accreditation, and will accept NCDQS QAS accreditation and/or QAS inspection for licensure including Nebraska, Vermont, Maryland, Mississippi and New Hampshire. Kansas also accepts our inspections. Minnesota will accept our inspections during the pandemic emergency. We have several other states pending.

Our inspections cover much more than the areas listed in *SDLRC Rule 20:67:06:01. Regular inspections required.* Our accreditation standards are even more in-depth.

We are asking that NCDQS QAS Accreditation be recognized by the Board, and that NCDQS be approved by the Board as an inspection agency to accept either our accreditation or our inspections for licensure.

Thank you,

Denise M. Frank, RPh
Accreditation and Inspection Services Director
denise@ncdqs.org
612-860-1705



National Coalition for Drug Quality & Security

Denise Frank, Director of Accreditation and Inspections



History and Programs

- Unmet need for accreditation of small, independent, secondary and specialty wholesale distributors
- Unmet need for inspection services for wholesalers in a state that does not perform inspections regularly
- Launched the Quality and Security (QAS) wholesale drug distributor accreditation program and inspection program in September 2019.
- Provides Board of Pharmacy compliance officer training on the inspection of distributors including common items of noncompliance.
- Provides Consultant training in accreditation standards.



QAS Accreditation and Inspection

- Iowa recognized NCDQS QAS accreditation for licensure by waiver in 2019 until the rule was revised in late 2020 to require either NCDQS or NABP accreditation for licensure.
- Accreditation recognized and inspections accepted by Nebraska, Maryland, Vermont, Mississippi and New Hampshire.
- Inspections also accepted by Kansas and by Minnesota (limited).
- Working with other states for recognition of the NCDQS QAS accreditation and acceptance of NCDQS QAS inspections for licensure.



QAS Programs

- What's the difference between an **accreditation** and an **inspection**?
- **We are educational rather than punitive in approach.** Our goal is to promote the quality and security of the pharmaceutical supply chain.
- **We support the smaller, independent and specialty wholesale distributors** that do not have the resources to maintain a regulatory compliance team. We are clear and transparent with the information needed to become compliant with the standards.



Conflict of Interest

- The advisory board is not involved in the accreditation decisions and does not have access to applicant materials.
- Staff involved in accreditation, and contract reviewers, surveyors and inspectors do not have interest in, or management of, any drug manufacturing or distribution facilities.
- We do not provide any paid (for profit) consulting services.



Accreditation Standards

1. Business Information
2. Administration
3. Safety and Crisis Operations
4. Environment
5. Security
6. Human Resources
7. Vendors
8. Product Receipt
9. Product Storage
10. Quarantine
11. Customers
12. Customer Orders
13. Quality Program



Accreditation Process

- Application and Submission
- Document Review
- Site Survey
- Remediation
- Accreditation
 - Standard three-year accreditation
 - One-year conditional for new businesses
- Year 2 and Year 3 reviews



Inspections

- Inspections are performed only by licensed pharmacists to be accepted by boards of pharmacy that require all inspections to be performed by licensed pharmacists.
- Pictures may be taken and incorporated into the report, as appropriate.
- Inspections range from 2.5 to 6 hours in total, depending on the type and size of the facility, and the number and range of products carried.



Inspection Includes

- Cover page
- Summary page that includes items of noncompliance and a response or plan from the facility to remediate any issues
- The detailed inspection report



Inspection Sections

- Facility Information
- Administration
- Crisis Operations
- Facility Environment and Security
- Human Resources
- Product Flow
- Quality Program



Inspection Report Example

IV. FACILITY ENVIRONMENT AND SECURITY

1. Outside perimeter of the building is well lit.	Compliant
2. All doors locked from outside	Compliant
3. Visitors (non-employees) ID checked, sign in, accompanied ID checked if the person is unknown or unexpected.	Compliant
4. Doors cannot be opened from the inside undetected to prevent diversion Fire doors can be opened from the inside without a sound.	Non-compliant
5. Drug storage and handling areas are restricted access to only authorized personnel.	Compliant
6. Does the facility carry controlled substances schedule III-V ?	Yes
a. Cage is kept locked Cage door was standing open when staff was inside working.	Unknown or Partially Compliant
b. Access to cage restricted to authorized personnel, list posted on cage No list of authorized persons posted.	Non-compliant
c. Cage entry is part of the alarm system	Compliant
d. Cage is covered by security camera	Compliant
e. Sign-in log to document non-authorized persons accessing cage No sign-in log or other documentation of persons accessing cage who are not on the authorized person list.	Non-compliant

Observations are color-coded for easy identification of items requiring attention.

Notes from the inspector are also included.

If pictures were taken to address a particular item, they would also appear with the item in the report.



Questions?

Please send questions and comments to:

NCDQS info@ncdqs.org

Denise Frank denise@ncdqs.org



Thank you!



Standards

V1.1 10/10/2019

Business Information

1. The business is appropriately registered or incorporated and carries general and product liability insurance.
2. The business has a defined organizational structure and clear lines of authority (management and supervision).
3. The facility has and maintains appropriate current, valid federal licensure, permits and/or registrations
4. The facility has and maintains appropriate current, valid state licensure, permits and/or registrations in its home state and in any state into which products are distributed. This includes any state-issued controlled substance license/registration/permit.
5. There is a process for ensuring compliance and keeping up-to-date with state and federal laws, rules and regulations, including all states into which products are distributed.
6. There is a process for keeping informed and up-to-date with industry best practices and compliance with accreditation requirements and standards.
7. There is a process to complete appropriate reporting to federal and state agencies and accreditation organizations; and to complete and keep on file self-inspections or reports where required.
8. The business has a finance department or uses a CPA, develops an annual budget or plan and reviews periodic financial reports of performance to the budget.
9. Co-located businesses, if any, have appropriate physical and electronic segregation of products and operations.



10. The business has a designated representative for the facility who has appropriate education, training and experience and is actively involved in the day-to-day operations of a single facility.

Administration

1. There is a document control policy and procedure that describes how policies and procedures are developed, reviewed, revised, approved, and archived.
2. There is a document retention policy that includes where documents are stored, how documents are kept secure, how documents are accessed and by whom, and how documents are destroyed at the end of the required storage time.

Safety and Crisis Operations

1. A safety and crisis plan is developed and a hard copy of the safety and crisis plan is kept on the premises and with key personnel.
2. Contact lists are maintained for emergency services and for repair vendors (such as electric company, HVAC repair, etc.). A list of employee contact information is maintained.
3. Maps are posted indicating exits, location of fire extinguishers and first aid kits, and safe areas to congregate for weather emergencies (tornado, etc.) as appropriate.
4. Plans address people safety, business continuity, product security and disposition, and paper and electronic data security and disposition.

Environment

1. Neat, clean, free from pests and of adequate size for the volume of business.
2. Products are stored off the floor.



3. Appropriate storage areas for controlled substances, listed chemicals, and EPA hazardous products.
4. All areas where products are stored (including quarantine areas, refrigerators and freezers) are continuously monitored for temperature. Probes are placed based on temperature mapping when appropriate and replaced or calibrated annually.
5. Products are stored within conditions indicated on the packaging or labeling for the products. If there is no indication of storage conditions, product will be stored at USP defined controlled room temperature.
6. General product storage and quarantine areas are also monitored for humidity.
7. Temperature and humidity excursions are communicated to appropriate staff in real time and there is an action plan that includes the quarantine of product that has experienced an excursion.

Security

1. An alarm system is present and operational, and includes appropriate alarm contacts at entry points and additional monitoring such as glass break, motion detectors, etc. as appropriate. There is a procedure for responding to alarms.
2. Doors are kept locked from the outside.
3. Authorized staff have unique alarm codes, alarm system arming and disarming reports are reviewed to monitor after-hours access.
4. Access to drug storage areas is restricted.
5. Visitors (all non-employees) are required to provide current, valid ID and sign in and out of the facility on a log sheet or book, and are accompanied when in drug storage and handling areas.



6. Cameras are in use with appropriate placement, there is a process to secure the recorded data from alteration or deletion, and recordings are kept for the length of time to be useful in investigating inventory discrepancies or other issues. There is a procedure for the appropriate use and review of recordings.
7. Controlled substance cages and vaults are locked, part of the alarm system and included in the camera monitoring system.
8. Access to the controlled substance cage/vault limited to authorized personnel with a list of authorized personnel posted, a log kept of non-authorized person's access, and a procedure to ensure non-authorized persons are accompanied when in the cage/vault.
9. Computer systems
 - a. Unique ID and passwords. Passwords are required to be updated at least every 90 days unless using biometrics.
 - b. Access level is restricted and dependent on position.
 - c. Remote access is through a VPN or other secure, encrypted process.

Human Resources

1. Hiring process includes verification of education and work history, criminal background checks and drug screening. Financial background checks for select personnel.
2. Training process developed that includes initial training, training on new or revised policies and procedures, and ongoing annual training that includes how training is tracked and documented.
3. Content of training includes orientation, review of job description, policies and procedures, crisis plans, safety training, and training specific to the position and any equipment to be used.



4. There is an employee performance and competency review process that includes how reviews are documented.
5. Routine, random and for-cause criminal and financial background checks and drug screening process for all employees is in place and documented including the process for handling results.
6. Stepped disciplinary process including a procedure for reporting, if appropriate
7. Process to deal with termination or resignation of employees that includes immediate deactivation of alarm codes and computer access.

Vendors

1. Vendors for prescription products procure products directly from manufacturers or repackagers, or from wholesale distributors that purchase directly from manufacturers or repackagers. If the product has additional transactions, transactions are only between manufacturers, repackagers and wholesale distributors. There are no transactions showing the product was purchased from a pharmacy, dispenser, or other healthcare provider or facility.
2. Vendors for OTC products procure products directly from manufacturers or repackagers, or from wholesale distributors that purchase directly from manufacturers or repackagers. If the product has additional transactions, transactions are only between manufacturers, repackagers and wholesale distributors. There are no transactions showing the product was purchased from a pharmacy, dispenser, or other healthcare provider or facility. Transactions can be traced directly back to the manufacturer.
3. Initial verification and authentication of vendors, including licensure verification directly with licensing agencies (state and federal), any disciplinary actions, verification of wholesaler and 3PL reporting to FDA, and verification of vendors sources of products (including OTC vendors).



4. Process for when unable to authenticate and verify a vendor, including reporting.
5. Process for authentication of vendor licensing when license expires.
6. Process for authentication of vendors at least annually (in addition to the time of license expiration).

Product receipt

1. Process for receiving products from vendors including verification against the purchase order, review of transaction data, and physical inspection of outer containers or boxes and inner packs and units.
2. Process for quarantine of products that are damaged or exposed to temperature excursions during transit that may affect product integrity.
3. Process for quarantine of products when a discrepancy is detected (does not match purchase order, transaction data, etc.).
4. Process for quarantine of product that may be suspicious or illegitimate.
5. Process for handling controlled substances and refrigerated/frozen products.
6. Process for quarantine of product returns received from customers.

Product storage

1. Process to detect and prevent diversion, theft and loss of product within the facility.
2. Process for defacing, shredding or destruction of labels, containers, product boxes and cases to prevent their use in counterfeiting.
3. Inventories
 - a. Full physical inventory of all products process.



- b. Cycle count processes including frequency of controlled substance and listed chemical inventories.
- c. Inventory discrepancy procedure for documentation, investigation and reporting.
- d. Process for short-dated and expired products, and for products that have been damaged or whose integrity is questionable (temperature excursions, etc.).
- e. Process for investigation, documentation and reporting of suspected theft or significant loss.
- f. Process for handling products that are recalled or withdrawn from the market.
- g. Procedure for handling requests for information or notifications regarding suspicious or illegitimate product from trading partners, state agencies, DEA and FDA.
- h. Process to segregate product (physically or electronically) that is 340B, limited distribution or specific contract product to prevent distribution to unauthorized customers.

Quarantine

1. Separate, distinct and secure areas for quarantined product (general, refrigerated, frozen, controlled substance).
2. Separation and labeling of products or areas for different types of products in quarantine.
3. Quarantined product is part of the physical inventory processes.
4. Process to handle recalls and withdrawals disposition and documentation.
5. Process to evaluate customer-returned product and documentation.



6. Process to evaluate products that have experienced a temperature excursion or other condition that may affect product integrity and documentation.
7. Process to investigate product quarantined due to other discrepancies including appropriate notifications and reporting to FDA, DEA, state regulatory agencies and trading partners as appropriate, such as:
 - a. Orders received damaged.
 - b. Issues matching product received to purchase orders.
 - c. Transaction data missing, incomplete, or other discrepancies.
 - d. Suspicious product procedure.
 - e. Illegitimate product procedure.
8. Process to handle and document disposition of quarantined product including:
 - a. Product returns to manufacturer or distributor.
 - b. Sending products to a reverse distributor for credit or destruction including receiving confirmation of destruction.
 - c. In-house destruction of products.

Customers

1. Prior to distribution of products, initial verification and authentication of customers that includes the process to review ARCOS data (for controlled substances), licensure information verified directly with the state or federal licensing agency (including any disciplinary actions noted), confirming “ship to” address is legitimate.
2. Process to follow if unable to authenticate and verify a customer including reporting.
3. Process for authentication of customer licensing when license expires.
4. Process for authentication of customers at least annually (in addition to the time of license expiration).



Customer orders

1. Process for suspicious order detection, investigation and reporting.
2. Process to prevent distribution to customers whose license has expired, or when there is an issue, discrepancy, or active investigation of a suspicious order.
3. Process to prevent distribution to a different address than the licensed or authorized address on file.
4. Process to ensure accuracy in picking products.
5. Packing orders process that includes:
 - a. Visual inspection of products for damage and accuracy of picked order verified prior to packing.
 - b. Confirming appropriate materials are used in packing orders to ensure the integrity of temperature sensitive products, protection from heat and protection from products being frozen.
 - c. If using temperature indicators, provision of instructions to customers.
 - d. Proper handling and packing of hazardous product including an indication to the customer that a product is hazardous.
6. Shipping orders
 - a. Process to provide transaction data to customers at or before the time the customer receives products.
 - b. Process to ensure security and storage conditions of packed shipments as appropriate prior to carrier pick up.
 - c. Verification and authentication of common carriers used, that includes verification of their driver security training, background checks and drug testing of drivers.
 - d. Process to track orders.



Quality Program

1. There is a quality committee, meetings are held quarterly (or more often), and are documented.
2. There is a process to gather data, investigate, review and analyze data, trend data over time, create improvements and evaluate effectiveness (CAPA).
3. The process includes (but is not limited to) a review of:
 - a. Vendors: failed authentication or verification, supply issues.
 - b. Customers: comments and complaints, failed authentication or verification, suspicious orders.
 - c. Carriers: delivery/damage issues, theft/loss.
 - d. Inventory: failed product receipt, inventory adjustment records, theft/loss, temperature and humidity records, suspicious or illegitimate product investigations and requests/notifications from trading partners or regulatory agencies.
 - e. HR: performance, disciplinary actions, background checks and drug testing results.
 - f. Internal audits, external audits, inspections or survey results.

Update History:

V1.1 10/1/19 approved 10/10/19

Vendors. Added additional clarification to items (1.) and (2.) to indicate products may have multiple transactions in the history, and that no transactions are allowed where the product was obtained from a dispenser, pharmacy, or other healthcare provider.



Phone: 800-547-7296
Fax: 800-547-7304
Sioux Falls SD 57105

February 17, 2021

South Dakota Board of Pharmacy

I am proposing a variance to the emergency kit drug quantities currently allowed to be kept in a nursing facility for emergency use.

No more than 60 non-controlled substances (excluding antibiotics) and no more than 12 controlled substances, constituting no more than 6-doses of any one controlled substance, would be accessible to designated nursing staff at any given moment.

We would be bound to follow, with great diligence, the strict guidelines as outlined in the South Dakota Department of Health Laws and Rule ARSD 20:51:15 and 44:73.

I appreciate your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Angela Bomgaars', is written in a cursive style.

Angela Bomgaars, PharmD.
PharMerica | Pharmacy Director
1507 W 51st Street - Sioux Falls, SD 57105
Phone: 605-338-7007 | Fax: 800-547-7304 | Angela.Bomgaars@pharmerica.com

PharMerica Emergency Kit List of Drugs

Max 12 controls, max 6 doses each

*Morphine 20mg/1ml oral Soln. (Roxanol) 0.5ml oral syringes
*Morphine INJECTION
*Hydrocodone/APAP 5/325mg Tabs
*Oxycodone/APAP 5/325mg Tabs
*Oxycodone 5mg Tabs
*Lorazepam 0.5mg Tabs
*Lorazepam 2mg/1ml Inj.
*Lorazepam intensol
*Tramadol 50mg Tabs
*Hydromorphone 2mg Tabs
*Fentanyl 12.5mcg patch

Max 60 non controls

Naloxone 0.4mg/1ml injection (Narcan)
Needle/Carpject (use with Naloxone)
Methylprednisolone Dose Pack
Enoxaparin 100mg/1ml injection (Lovenox)
Enoxaparin 40mg/0.4ml injection (Lovenox)
Heparin injection
Glucose 15g gel (Glucose)
Glucagen injection
SPS (Kayexalate)
Atropine drops
Glycopyrrolate (Robinul) injection
Lidocaine 1% injection (Xylocaine)
Methylprednisolone 125mg/2ml injection (Solu-Medrol)
Ondansetron 2mg/1ml injection (Zofran)
Ondansetron 4mg tablet (Zofran)
Hydralazine 25mg tablets
Amlodipine 10mg tablets
Epinephrine 1:1000 (1mg/1ml) injection
Filter Needle (Use with Epinephrine)
Furosemide 20mg tablet (Lasix)
Furosemide 10mg/1ml injection (Lasix)
Haloperidol 5mg/1ml injection (Haldol)
Nitroglycerin 0.4mg SL tablet (Nitrostat)
Mephyton 5mg tablet (Vitamin K)
Prednisone 5mg tablet
Prednisone 2.5mg tablet
Dexamethasone 4mg tablets
Fluconazole 100mg tablet (Diflucan)
Warfarin 1mg tablet (Coumadin)
Warfarin 5mg tablet (Coumadin)
Diphenhydramine Tabs
Albuterol 0.083% 3ml inhalation vials (Proventil)

Ipratropium 0.02% 2.5ml inhalation vials (Atrovent)
DuoNeb vials
LANTUS
NOVOLOG
NOVOIN R
NOVOLIN N
LEVEMIR
NOVOLOG 70/30
CathFlo (Alteplase)
NS 1L
NS minibag plus 100ml
NS flushes
Heparin flushes
D5W 1L
D5 ½NS 1L
LR 1L

ABX

Amoxicillin 250mg capsule (Amoxil)
Amox/Clav 875mg tablet (Augmentin)
Azithromycin 250mg tablet (Zithromax)
Cefuroxime 250mg tablet (Ceftin)
Cephalexin 250mg capsule (Keflex)
Ciprofloxacin 250mg tablet (Cipro)
Cefdinir 300mg capsules (Omnicef)
Doxycycline 100mg tablet (Vibramycin)
Metronidazole 500mg tablet (Flagyl)
Levofloxacin 250mg tab (Levaquin)
Nitrofurantoin mono-mcr 100mg capsules (Macrobid)
Sulfameth/Trimeth DS tab (Bactrim DS)
Ceftriaxone 1g injection (Rocephin)
Cefazolin 2 gram in Dextrose 50ml Duplex

PharMerica Emergency Kit List of Drugs

Max 12 controls, max 6 doses each

*Morphine 20mg/1ml oral Soln. (Roxanol) 0.5ml oral syringes (6 x 0.5ml syringes)
*Morphine INJECTION (6 vials)
*Hydrocodone/APAP 5/325mg Tabs (6)
*Oxycodone/APAP 5/325mg Tabs (6)
*Oxycodone 5mg Tabs (6)
*Lorazepam 0.5mg Tabs (6)
*Lorazepam 2mg/1ml Inj. (6)
*Lorazepam intensol (1 bottle)
*Tramadol 50mg Tabs (6)
*Hydromorphone 2mg Tabs (6)
*Fentanyl 12.5mcg patch (6)

Max 60 non controls

Naloxone 0.4mg/1ml injection (Narcan) (1)
Needle/Carpuject (use with Naloxone) (1)
Methylprednisolone Dose Pack (1)
Enoxaparin 100mg/1ml injection (Lovenox) (1)
Enoxaparin 40mg/0.4ml injection (Lovenox) (1)
Heparin injection (1)
Glucose 15g gel (Glucose) (1)
Glucagen injection (1)
SPS (Kayexalate) (3)
Atropine drops (1)
Glycopyrrolate (Robinul) injection (1)
Lidocaine 1% injection (Xylocaine) (4)
Methylprednisolone 125mg/2ml injection (Solu-Medrol)(1)
Ondansetron 2mg/1ml injection (Zofran) (2)
Ondansetron 4mg tablet (Zofran) (4)
Hydralazine 25mg tablets (4)
Amlodipine 10mg tablets (4)
Epinephrine 1:1000 (1mg/1ml) injection (2)
Filter Needle (Use with Epinephrine) (2)
Furosemide 20mg tablet (Lasix) (10)
Furosemide 10mg/1ml injection (Lasix) (4)
Haloperidol 5mg/1ml injection (Haldol) (2)
Nitroglycerin 0.4mg SL tablet (Nitrostat)(1)
Mephyton 5mg tablet (Vitamin K) (2)
Prednisone 5mg tablet (20)
Prednisone 2.5mg tablet (10)
Dexamethasone 4mg tablets (10)
Fluconazole 100mg tablet (Diflucan) (3)
Warfarin 1mg tablet (Coumadin) (10)
Warfarin 5mg tablet (Coumadin) (2)
Diphenhydramine Tabs (2)
Albuterol 0.083% 3ml inhalation vials (Proventil) (5)
Ipratropium 0.02% 2.5ml inhalation vials (Atrovent) (5)
DuoNeb vials (5)
LANTUS (1)
NOVOLOG (1)
NOVOIN R (1)
NOVOLIN N (1)

LEVEMIR (1)
NOVOLOG 70/30 (1)
CathFlo (Alteplase) (1)
NS 1L (6)
NS minibag plus 100ml (4)
NS flushes (10)
Heparin flushes (10)
D5W 1L (1)
D5 ½NS 1L (1)
LR 1L (1)

ABX

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