

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: June 25, 2021; 8:00AM - 12:00AM CDT

LOCATION: In person - Hamlet Building, 4001 W. Valhalla Blvd., Suite 202, Sioux Falls, SD

Also via ZOOM MEETING option: 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#

MEETING AGENDA

- 8:00 AM A. Call to Order, Mission, Roll Call, and Introductions – Vice President Dan Somsen
- 8:05 AM B. Public Comment
- 8:15 AM C. 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. June 25, 2021 Agenda
 2. April 8, 2021 Board Meeting minutes
 3. New Licenses and Registrations – License Summary, Activity Report
 4. Approvals and Variances
 5. Financial Report
 6. Remaining Authority Report
- 8:20 AM 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
- 8:50 AM E. Complaints, Investigations, Disciplinary Actions, Loss / Theft Report – Paula, Carol, Tyler
1. DEA Form 106—Walgreens Spearfish
 2. DEA Form 106 – Costco Sioux Falls
 3. DEA Form 106 - Medvantx Sioux Falls
 4. DEA Form 106—Safeway Mount Rushmore Rd, Rapid City
 5. DEA Form 106—Safeway Mountain View Rd, Rapid City
 6. DEA Form 106—Hyvee Yankton
 7. DEA Form 106—CVS Rapid City
 8. Complaint #2021-0003
 9. DEA Form 106—Dakota Country Pharmacy, Phillip
 10. DEA Form 106—Anda loss in transit
 11. DEA Form 106—Wal-Mart, Watertown
 12. DEA Form 106—Brother's LTC, Brookings
- 9:15 AM F. SD Pharmacists Association – Amanda Bacon, SDPHA; Dana Darger, R.Ph., SDPHA President
1. Activity Report
 2. Financial Report

3. Finance Discussion per [SDCL 36-11-6](#) (see attachment)

- 9:30 AM G. Other Reports
1. SDSU College of Pharmacy – Dean 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
- 9:45 AM Break
- 10:00 AM H. Old Business
1. FDA MOU with States on Compounding – Kari
 2. Avera Drug Repository Variance Renewal and Report – Matt Toennis, Pharm D.
 3. Non substantive Policy Statement Review/update – Tyler, Kari
 4. Hy-Vee Telepharmacy – Hartford – Justin Manning, Pharm. D; Jim Mennen, BPharm, MS,MBA; Charles Hudek, R.Ph.
- 10:30 AM I. New Business
1. Walgreens Technician Immunization Variance Request – Lorri Walmsley, RPh
 2. Avera Hospital at Home, Glenn Voss, Pharm D and/ or Jeff DeRouchey, Pharm D.
 3. CVS New Virtual Verification Process – Lauren Paul, Pharm D, MS
 4. Amicus – GMP Consultants – Khristopher Le, Pharm D, Becca Mitchell, Pharm D
 5. Spring Meds – Mark Scott
- 11:30 AM J. Other Business
1. Recent Meeting News
 - i. 117th NABP Annual Meeting – Ashley Hansen, Pharm. D
 2. Future Board Meeting Dates – all held in Sioux Falls Board Room unless otherwise noted
 - i. September 16, 2021 1PM-5PM MDT in coordination with 135th SDPHA Annual Meeting, Spearfish
 - ii. December 10, 2021 9AM -1PM CST
 - iii. April 7, 2022 1PM-5PM MDT at The Lodge at Deadwood in coordination with SDSHP 46th Annual Conf
 - iv. June 24, 2022 8AM-12:00PM
 3. Upcoming Meetings
 - i. NABP/AACP 84th Annual District V Meeting, August 6, 2021 Virtual Meeting
 - ii. 135th SDPHA Annual Meeting September 17-18, 2021, Spearfish
 - iii. SDSHP 46th Annual Conference, April 8-9, 2022, Deadwood
 - iv. 118th NAPB Annual Meeting – May 19-21, 2022, Sheraton Wild Horse Pass, Phoenix
 - v. NABP/AACP 85th Annual District V Meeting, August 3-5, 2022, Custer State Park
- 12:00 AM K. 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 03/1/21 – 05/31/21****PHARMACISTS**

2055 Current Total

6 New Licensees for period

License#	Last Name	First Name	City	State
R-6837	Nicoski	Randy	Milwaukie	OR
R-6836	Harmon	Paige	Lombard	IL
R-6835	Harnois	James	Lockport	IL
R-6833	Pierson	Max	Worthington	MN
R-6834	Patel	Ami	Cedar Grove	NJ
R-6832	Salke	Brandon	Saint Charles	MO

FULL-TIME PHARMACY PERMITS

235 Current Total

3 New FT Permits for period

License#	Business	City	State
100-2073	Brown Pharmacy LLC	Watertown	SD
100-2072	Vytal Pharmacy	Sioux Falls	SD
100-2071	Hy-Vee, Inc.	Hartford	SD

PART-TIME PHARMACY PERMITS

68 Current Total

1 New PT Permits for period

License#	Business	City	State
200-1737	Sioux Empire Triage Center	Sioux Falls	SD

PHARMACY INTERNS

308 Current Total

8 New Registrations for period

TECHNICIAN REGISTRATIONS

1493 Current Total

71 New Registrations for period

NON-RESIDENT PERMITS

839 Current Total

23 New NR Permits for period

WHOLESALE PERMITS

1264 Current Total

51 New WH Permits for period

			May	May	YTD	YTD
Activity Reports	New	Renewal	2021	2020	This Year	Last Year
Pharmacy Permits						
Full Time (SD)	2	117	119	99	130	105
Part Time (SD)	0	22	22	31	27	42
Non-Resident	5	380	385	261	587	429

Pharmacist Licenses

South Dakota	0	0	0	0	1305	1279
Non-Resident	1	0	1	0	763	760

Technician Registration	32	2	34	20	1495	1703
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Pharmacy Interns	1	2	3	1	346	333
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Wholesale Permits

South Dakota	0	0	0	0	48	62
Non-Resident	22	2	24	11	1271	1242

Inspections

Pharmacy Inspections			26	24	281	243
Wholesale Inspections			1	0	26	13
Other Pharmacy Visits/Meetings			37	65	680	451
Controlled Drug Destruction			0	0	0	2
PDMP Visits			17	13	177	161



**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 June 25, 2021 Board Meeting

Approvals

1. Remote Pick Up site in Selby for Turner Drug in Bowdle

Variances/Waivers

1. Renewal of Automated Ekit Variance for PharMerica RxNow Machines in Avantara Mountain View; Avantara North; Avanatara Arrowhead; Fountain Springs; all of Rapid City and Avantara Pierre.

New Pharmacies/Closed Pharmacies and New/Closed Wholesale Distributors

1. CHOW SD Full-Time Pharmacy, Hy-Vee Pharmacy #3633, Hartford, #100-2071
2. New SD Full-Time Pharmacy, Vytal Pharmacy, Sioux Falls, #100-2072
3. New SD Full-Time Pharmacy, Brown Pharmacy LLC dba Downtown Drug, Watertown, #100-2073
4. CHOW SD Full-Time Pharmacy, Avera St. Luke's dba Avera State Street Pharmacy, Aberdeen, #100-2074

Remaining Authority by Object/Subobject

Expenditures current through 05/29/2021 03:50:49 PM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 9.0 %

09209 Board of Pharmacy - Info						PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL
EMPLOYEE SALARIES						
5101010 F-t Emp Sal & Wages	524,715	335,773	0	0	188,942	36.0
5101020 P-t/temp Emp Sal & Wages	166,415	115,683	0	0	50,732	30.5
5101030 Board & Comm Mbrs Fees	1,907	1,200	0	0	707	37.1
Subtotal	693,037	452,656	0	0	240,381	34.7
EMPLOYEE BENEFITS						
5102010 Oasi-employer's Share	51,776	32,868	0	0	18,908	36.5
5102020 Retirement-er Share	18,500	25,618	0	0	-7,118	0.0
5102060 Health Insurance-er Share	84,120	69,359	0	0	14,761	17.5
5102080 Worker's Compensation	1,000	542	0	0	458	45.8
5102090 Unemployment Compensation	300	451	0	0	-151	0.0
Subtotal	155,696	128,838	0	0	26,858	17.3
51 Personal Services						
Subtotal	848,733	581,494	0	0	267,239	31.5
TRAVEL						
5203010 Auto-state Owned-in State	7,229	1,256	0	0	5,973	82.6
5203020 Auto Priv (in-st.) L/rte	600	54	0	0	546	91.0
5203030 Auto-priv (in-st.) H/rte	6,000	1,067	0	0	4,933	82.2
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	434	0	0	1,245	74.2
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	2,811	0	0	46,528	94.3
CONTRACTUAL SERVICES						
5204010 Subscriptions	250	0	0	0	250	100.0
5204020 Dues & Membership Fees	500	405	0	0	95	19.0
5204050 Computer Consultant	258,067	500,210	1,020	0	-243,163	0.0
5204080 Legal Consultant	4,278	0	0	0	4,278	100.0

Remaining Authority by Object/Subobject

Expenditures current through 05/29/2021 03:50:49 PM

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FY Remaining: 9.0 %

09209 Board of Pharmacy - Info							PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL	
5204140 Contract Pymts To St Agen	20,000	18,000	0	0	2,000	10.0	
5204160 Workshop Registration Fee	4,000	909	0	0	3,091	77.3	
5204180 Computer Services-state	11,309	22,077	0	0	-10,768	0.0	
5204181 Computer Services-state	3,919	192	0	0	3,727	95.1	
5204200 Central Services	6,270	6,385	0	0	-115	0.0	
5204202 Central Services	103	34	0	0	69	67.0	
5204203 Central Services	103	52	0	0	51	49.5	
5204204 Central Services	418	393	0	0	25	6.0	
5204207 Central Services	3,638	4,299	0	0	-661	0.0	
5204220 Equipment Serv & Maint	600	3,452	0	0	-2,852	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	1,100	0	0	0	0.0	
5204490 Rents-private Owned Prop.	39,277	38,978	0	0	299	0.8	
5204510 Rents-other	250	0	0	0	250	100.0	
5204530 Telecommunications Srves	5,200	3,838	0	0	1,362	26.2	
5204550 Garbage & Sewer	50	57	0	0	-7	0.0	
5204590 Ins Premiums & Surety Bds	1,450	579	0	0	871	60.1	
5204620 Taxes & License Fees	196,708	202,400	0	0	-5,692	0.0	
5204960 Other Contractual Service	407,028	64,307	0	0	342,721	84.2	
Subtotal	967,518	867,667	1,020	0	98,831	10.2	
SUPPLIES & MATERIALS							
5205020 Office Supplies	2,300	3,481	0	0	-1,181	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	772	0	0	328	29.8	
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	1,003	0	0	3,897	79.5	
Subtotal	9,050	6,102	0	0	2,948	32.6	
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 05/29/2021 03:50:49 PM

HEALTH -- Summary

FY 2021 Version -- AS -- Budgeted and Informational

FY Remaining: 9.0 %

52 Operating Subtotal	1,061,671	880,397	1,020	0	180,254	17.0
Total	1,910,404	1,461,891	1,020	0	447,493	23.4

Board of Pharmacy - Inspection Report

2nd Quarter 2021

Kari Shanard-Koenders

Date	Destination	City	Purpose	PDMP/ Narc Destruction, etc.
04/09/2021	Presentation at SDSHP on BOP Update with Tyler and Melissa	Sioux Falls	Webinar	
04/09/2021	Monthly NABP Ex Off Meeting	Sioux Falls	Webinar	
04/10/2021	Attend SDSHP Meeting and CE	Sioux Falls	Webinar	
04/12/2021	Rural OUD Advisory Committee	Sioux Falls	Webinar	
04/15/2021	What to Expect if DEA comes	Sioux Falls	Webinar	
04/15/2021	Education Committee	Sioux Falls	Webinar	
04/15/2021	DOH Covid Call	Sioux Falls	Webinar	
04/15/2021	COCA Call J&J Vaccine	Sioux Falls	Webinar	
04/19/2021	P2 Guest Lecture Dr. Meyer Class	Sioux Falls	Webinar	
04/20/2021	Joint Press Conference Dr. Clayton and KMR	Sioux Falls	Webinar	
04/22/2021	DOH Covid Call	Sioux Falls	Webinar	
04/27/2021	COCA Call J&J Vaccine Thrombosis	Sioux Falls	Webinar	
04/27/2021	Consumer Protection Funds Meeting	Sioux Falls	Webinar	
04/29/2021	DOH Covid Call	Sioux Falls	Webinar	
04/30/2021	Sarah Jungers Meeting	Sioux Falls	Meeting	
05/03/2021	Surgery Out Three Weeks	Sioux Falls	Surgery	
05/12/2021	NABP Annual Meeting	Sioux Falls	Meeting	
05/13/2021	NABP Annual Meeting	Sioux Falls	Meeting	
05/14/2021	NABP Annual Meeting	Sioux Falls	Meeting	
05/21/2021	NASHP State Webinar	Sioux Falls	Meeting	
05/25/2021	Seton Hall MSJ Graduation	Sioux Falls	Meeting	
05/27/2021	NASCSA Education Committee	Sioux Falls	Meeting	
05/27/2021	DOH Covid Call	Sioux Falls	Meeting	
05/28/2021	The Link Initial Inspection Tyler, Nathan	Sioux Falls	Inspection	
06/02/2021	Security Training	Sioux Falls	Meeting	
06/02/2021	Staff Records Retention Meeting	Sioux Falls	Meeting	
06/02/2021	Tyler, Nathan, and Cardinal Health NUC Tele Disc	Sioux Falls	Meeting	
06/02/2021	Tyler, Nathan, and Amicus Group	Sioux Falls	Meeting	
06/04/2021	Tyler, Nathan, and Avera - Hospital at Home	Sioux Falls	Meeting	
06/05/2021	Completion NABP 2021 Resources and Responsibilities	Sioux Falls	Project	
06/09/2021	Staff Records Retention Meeting	Sioux Falls	Meeting	
06/10/2021	DOH Covid Call	Sioux Falls	Meeting	
06/17/2021	Susan Sporrer, Melissa, Kari Opioid/PDMP Discussion	Sioux Falls	Meeting	
06/24/2021	DOH Covid Call	Sioux Falls	Meeting	
06/25/2021	SD Board of Pharmacy Quarterly Meeting	Sioux Falls	Meeting	
06/25/2021	NABP Monthly EO	Sioux Falls	Meeting	

Board of Pharmacy - Inspection Report

2nd Quarter 2021

Melissa DeNoon

Date	Destination	City	Purpose	PDMP/NARC Destruction etc.
4/9/21	SDSHP	Sioux Falls	Annual Conference	BOP/PDMP Presentation
4/12/21	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
4/14/21	NADDI	Sioux Falls	Webinar	
4/14/21	NASCSA	Sioux Falls	Webinar	
4/15/21	DOH	Sioux Falls	Covid Zoom Call	
4/15/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
4/21/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
4/22/21	SDSU COP P2 Law Class	Brookings	Annual PDMP Presentation	PDMP Presentation
4/23/21	TTAC/NASCSA Veterinary Best Practices Workgroup	Sioux Falls	Zoom Meeting	
4/23/21	DOH RFP Review Team	Sioux Falls	Zoom Meeting	
4/27/21	USD Sanford School of Medicine QI Boot Camp	Sioux Falls	PDMP Presentation	PDMP Presentation
4/27/21	SD Consumer Protection Division	Sioux Falls	Zoom Mtg Funding Disc.	
4/29/21	DOH	Sioux Falls	Covid Zoom Call	
4/29/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
4/30/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	
5/5/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
5/6/21	DOH	Sioux Falls	Covid Zoom Call	
5/13/21	DOH	Sioux Falls	Covid Zoom Call	
5/13/21	RxCheck Governance Board	Sioux Falls	Zoom Meeting	
5/13/21	SD Dental Association	Sioux Falls	Annual Conference	BOP/PDMP Presentation
5/14/21	State of AK Office of Substance Misuse & Addiction Prevention	Sioux Falls	Trilogy MedWaste MedDrop Program Discussion	
5/19/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
5/20/21	DOH	Sioux Falls	Covid Zoom Call	
5/20/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
5/20/21	PMPi Legislative & Policy Subcommittee	Sioux Falls	Zoom Meeting	
5/20/21	TTAC PDMP Admin Compliance Group	Sioux Falls	Zoom Meeting	
5/21/21	MI PDMP - Haley Winans	Sioux Falls	Zoom Meeting	
5/21/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
5/24/21	Rural OUD Advisory Board	Sioux Falls	Zoom Meeting	
5/25/21	NADDI	Sioux Falls	Webinar	
5/25/21	NASCSA Data Integrity Subcommittee	Sioux Falls	Zoom Meeting	
5/25/21	DOH	Sioux Falls	Data Extract Zoom Mting	
5/26/21	TTAC/NASCSA Veterinary Best Practices Workgroup	Sioux Falls	Zoom Meeting	
5/27/21	DOH	Sioux Falls	Covid Zoom Call	
5/27/21	TTAC	Sioux Falls	Webinar	
6/1/21	FDA	Sioux Falls	Webinar	
6/2/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
6/2/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	
6/7/21	NASCSA Membership Committee	Sioux Falls	Zoom Meeting	
6/10/21	DOH	Sioux Falls	Covid Zoom Call	
6/10/21	RxCheck Governance Board	Sioux Falls	Zoom Meeting	
6/11/21	NASCSA Executive Committee	Sioux Falls	Zoom Meeting	
6/15/21	NABP 2021 Program Review and Training	Sioux Falls	Zoom Meeting	
6/16/21	Appriss Health & PDMP Staff	Sioux Falls	Bimonthly CRM & SGI CC	
6/17/21	NASCSA PMP Committee	Sioux Falls	Zoom Meeting	
6/17/21	Opioid/PDMP/HIE Leaders and DOH	Sioux Falls	Programs' Discussion	
6/21/21	Residents	Sioux Falls	PDMP Presentation	PDMP Presentation
6/22/21	NASCSA Data Integrity Subcommittee	Sioux Falls	Zoom Meeting	
6/24/21	TTAC	Sioux Falls	Webinar	
6/25/21	SD Board of Pharmacy	Sioux Falls	Quarterly Board Meeting	
6/25/21	DOH CDC OD2A Team	Sioux Falls	Zoom Meeting	

Board of Pharmacy - Inspection Report 2nd Quarter 2021

Tyler Laetsch

Date	Destination	City	Purpose	PDMP/ Narc Destruction etc
4/9/21	SDSHP Presentation	Sioux Falls	Virtual Meeting	
4/12/21	Walgreen's Kiwanis	Sioux Falls	Inspection	PDMP
4/13/21	Siouxland Surgical Center #1	Dakota Dunes	Inspection	
4/13/21	Siouxland Surgical Center #2	Dakota Dunes	Inspection	
4/14/21	NABP DEA Update Presentation	Sioux Falls	Virtual Meeting	
4/15/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
4/19/21	SDSU P2 Regulatory Talk	Sioux Falls	Virtual Meeting	
4/20/21	Lewis Family Drug	De Smet	Inspection	PDMP
4/20/21	Avera De Smet Memorial Hospital	De Smet	Inspection	
4/22/21	Apria	Sioux Falls	Wholesale Inspection	
4/22/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
4/22/21	Lewis Long Term Care	Sioux Falls	Inspection	PDMP
4/26/21	Walmart	Mitchell	Inspection	PDMP
4/26/21	Animal Health	Mitchell	Wholesale Inspection	
4/27/21	Lewis Family Drug-County Fair	Mitchell	Inspection	PDMP
4/27/21	Walgreens	Mitchell	Inspection	PDMP
4/29/21	Davis Pharmacy	Vermillion	Inspection	PDMP
4/29/21	Sanford Vermillion Hospital	Vermillion	Inspection	
5/6/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
5/7/21	Animal Health VAWD Virtual Call	Sioux Falls	Virtual Meeting	
5/11/21	Animal Health VAWD on site	Sioux Falls	VAWD Inspection	
5/12/21	Encompass Health	Sioux Falls	Inspection	
5/13/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
5/13/21	Sanford Oncology Clinic Pharmacy	Sioux Falls	Inspection	PDMP
5/18/21	Walmart Minn. Ave	Sioux Falls	Inspection	PDMP
5/18/21	Hyvee #5	Sioux Falls	Inspection	PDMP
5/19/21	Lewis Family Drug	Wessington Springs	Inspection	PDMP
5/19/21	Weskota Memorial Hospital	Wessington Springs	Inspection	
5/20/21	Northside	Huron	Inspection	PDMP
5/20/21	Coburn's	Huron	Inspection	PDMP
5/26/21	Roger's Pharmacy	Yankton	Inspection	PDMP
5/26/21	Yankton Medical Clinic Pharmacy	Yankton	Inspection	PDMP
5/27/21	DOH COVID Update	Sioux Falls	Virtual Meeting	
5/28/21	Sioux Empire Triage Center	Sioux Falls	Opening Inspeccion	
6/1/21	FDA Drug Topics Webinar	Sioux Falls	Virtual Meeting	
6/1/21	AMICUS call	Sioux Falls	Virtual Meeting	
6/2/21	Staff Meeting	Sioux Falls	Meeting	
6/3/21	Cardinal Nuclear Pharmacy Call	Sioux Falls	Virtual Meeting	
6/3/21	Hyvee Louise Ave	Sioux Falls	Inspection	PDMP
6/4/21	Hyvee	Yankton	Inspection	PDMP
6/4/21	Walgreens	Yankton	Inspection	PDMP
6/7/21	Lincare	North Sioux City	Wholesale Inspection	
6/7/21	Lewis Family Pharmacy	Elk Point	Inspection	PDMP
6/9/21	Staff Meeting	Sioux Falls	Meeting	
6/9/21	HyVee W 10th St	Sioux Falls	Inspection	PDMP
6/10/21	Huron Medical Center	Huron	Inspection	
6/10/21	Lewis	Mitchell	Inspection	PDMP
6/14/21	Avera LTC	Sioux Falls	Inspection	PDMP
6/14/21	Lifescape	Sioux Falls	Inspection	
6/15/21	NAPB Training	Sioux Falls	Virtual Meeting	
6/16/21	Walmart Louise Ave	Sioux Falls	Inspection	PDMP
6/17/21	Avera Flandreau	Flandreau	Inspection	
6/17/21	Lewis Family Pharmacy	Flandreau	Inspection	PDMP
6/21/21	Lewis Westgate	Sioux Falls	Inspection	PDMP
6/21/21	Avel eCare	Sioux Falls	Inspection	
6/22/21	Praxair	Sioux Falls	Wholesale Inspection	
6/22/21	Walgreens- Louise Ave	Sioux Falls	Inspection	PDMP
6/23/21	Hyvee Sycamore Ave	Sioux Falls	Inspection	PDMP
6/23/21	Avera Campus Pharmacy	Sioux Falls	Inspection	PDMP

6/25/21	Quarterly Board Meeting	Sioux Falls	Meeting	
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Board of Pharmacy - Inspection Report

2nd Quarter 2021

Paula Stotz

Date	Destination	City	Purpose	PDMP/ Narc Destruction etc
4/14/21	What to Expect When the DEA Visits Your Hospital or Healthcare Facility	Rapid City	Webinar	
4/14/21	Plastic Surgery Center of Rapid City	Rapid City	Inspection	
4/15/21	HDA 2021 Traceability Reaching 2023	Rapid City	Webinar	
4/15/21	DOH COVID-19 Weekly Update	Rapid City	Webinar	
4/21/21	DOH Joint Press Conference	Rapid City	Webinar	
4/22/21	EPA Hazardous Waste	Rapid City	Webinar	
4/22/21	DOH COVID-19 Weekly Update	Rapid City	Webinar	
4/28/21	Legal Issues Facing Pharmacy	Rapid City	Webinar	
4/29/21	HDA Webinar series	Rapid City	Webinar	
4/29/21	DOH COVID-19 Weekly Update	Rapid City	Webinar	
4/29/21	Black Hills Surgical Hospital	Rapid City	Inspection	
5/4/21	Vilas Pharmacy	Faith	Inspection	PDMP
5/4/21	Vilas Pharmacy	Eagle Butte	Inspection	PDMP
5/5/21	Smith's Pharmacy	Lemmon	Inspection	PDMP
5/12/21	HAD Webinar Series	Rapid City	Webinar	
5/13/21	NABP Virtual Convention	Rapid City	Convention	
5/14/21	NABP Virtual Convention	Rapid City	Convention	
5/18/21	White River Community Pharmacy	White River	Telepharmacy Inspection	PDMP
5/18/21	The Winner Pharmacy	Winner	Inspection	PDMP
5/19/21	Winner Family Drug	Winner	Inspection	PDMP
5/19/21	Winner Regional Healthcare Center	Winner	Inspection	
5/20/21	Burke Community Pharmacy	Burke	Inspection	PDMP
5/20/21	Community Memorial Hospital	Burke	Inspection	
5/26/21	Thrifty White Drug	Deadwood	Inspection	PDMP
5/26/21	Monument Health Lead Deadwood Hospital	Deadwood	Telepharmacy Inspection	
5/27/21	DOH COVID-19 Weekly Update	Rapid City	Webinar	
6/9/21	Uptown Market - Remote Pick Up Site	Selby	Pick Up Site Visit	
6/9/21	Bowdle Hospital	Bowdle	Inspection	
6/9/21	Turner Drug	Bowdle	Inspection	PDMP
6/10/21	Avera Gettysburg Hospital	Gettysburg	Inspection	
6/10/21	Vilas Pharmacy	Gettysburg	Inspection	PDMP
6/15/21	BHR Managing Conflict	Rapid City	Training	
6/15/21	CVS Pharmacy in Target	Rapid City	Site Visit	
6/16/21	ACHC - State Board Inspections	Rapid City	Webinar	
6/23/21	Presho Community Pharmacy	Presho	Telepharmacy Inspection	PDMP
6/24/21	Office Day	Sioux Falls	Meeting	
6/24/21	DOH COVID-19 Weekly Update	Sioux Falls	Webinar	
6/25/21	Board of Pharmacy Quarterly meeting	Sioux Falls	Meeting	

Board of Pharmacy - Inspection Report

2nd Quarter 2021

Carol Smith

Date	Destination	City	Purpose	PDMP/ Narc Destruction etc.
4/14/21	What to Expect When the DEA Visits Your Hospital or Healthcare Facility	Groton	Webinar	
4/15/21	DOH Weekly COVID Call	Aberdeen	Virtual Meeting	
5/6/21	DOH Weekly COVID Call	Groton	Virtual Meeting	
5/11/21	EPA Subpart P-What You Need to Know	Groton	Webinar	
5/18/21	Marshall County Hospital	Britton	Inspection	
5/25/21	Dosch Family Pharmacy	Eureka	Inspection	PDMP
5/25/21	Eureka Community Health Services Avera	Eureka	Inspection	
6/14/21	Walmart 10-1500	Watertown	Inspection	PDMP
6/16/21	Walgreens 10007	Watertown	Inspection	PDMP
6/16/21	Airgas	Watertown	Inspection	
6/16/21	Pharmerica	Watertown	Inspection	
6/17/21	Avera St. Luke's Hospital	Aberdeen	Inspection	
6/17/21	Dakota Plains Surgical	Aberdeen	Inspection	
6/22/21	HyVvee 1871	Watertown	Inspection	PDMP
6/23/21	Avera McKennan Campus Pharmacy	Sioux Falls	Inspection	PDMP
6/24/21	Board of Pharmacy Office	Sioux Falls	Meeting	
6/24/21	Department of Health Bi-monthly COVID Call	Sioux Falls	Virtual Meeting	
6/25/21	Quarterly BOP Meeting	Sioux Falls	Meeting	

South Dakota Prescription Drug Monitoring Program Update

June 25, 2021

What's New at the SD PDMP?

- RxCheck Hub sharing set up with NE – currently share with 36 other PDMPs
- Statewide Gateway Integration Project 'In Production'
 - Avera Health, Sanford Health, and Monument Health
 - SD Health Link
 - 4 Hospitals
 - 10 Clinics
 - 76 Pharmacies
 - Appriss' Communication Campaign led to 22 Integration Requests
- License Integration Project Status
 - Pharmacy Board, Nursing Board, Optometry Board, Podiatry Board, and Dentistry Board are live with auto reverification and auto-approval of new accounts
 - Medical Board – participation still pending

MedDrop Program Update

- Receptacles in SD Retail Pharmacies and Hospitals
 - 2017 – 2 in place
 - 2018 – 12 in place
 - 2019 – 38 in place
 - 2020 – 83 in place (added 6 HyVee locations to “Automatic Reload”)
 - 2021 – 84 in place – Davis Pharmacy new site as of May
 - 90 sites serviced by the BOP's program
- Pounds Returned for Destruction
 - 2017 – 35 lbs.
 - 2018 – 1,496 lbs.
 - 2019 – 4,287 lbs.
 - 2020 – 7,302 lbs.
 - Total Since Inception – 17,309 lbs.

Virtual Presentations Given/Events Attended

- SDSHP Annual Conference BOP/PDMP Presentation
- SDSU College of Pharmacy P2 Class PDMP Presentation
- USD Sanford School of Medicine Resident Quality and Safety Boot Camp PDMP Presentation
- SD Dental Association BOP/PDMP Presentation

- Sanford Resident Orientation PDMP Presentation

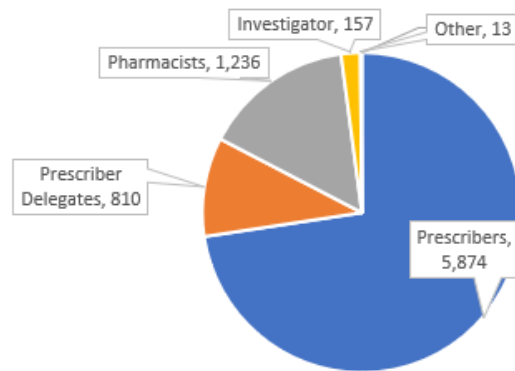
Upcoming Events

- KS BOP/CDC OD2A Peer to Peer Learning Collaborative – August 2021 in Kansas City, MO

Year 2020 Top Ten Controlled Substances (CS) to SD Patients	RXs	Quantity	Days of Supply	Avg Quant/Rx	2019 Rank	2018 Rank
HYDROCODONE BITARTRATE/ACETAMINOPHEN	145,862	8,163,653	1,903,727	56	1	1
TRAMADOL HCL	117,316	7,462,916	2,028,465	64	2	2
DEXTRAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE SULF-ASPARTATE	84,146	3,850,061	2,515,776	46	4	6
LORAZEPAM	83,383	3,624,931	1,822,438	43	3	3
CLONAZEPAM	74,180	4,044,728	2,177,195	55	5	5
ZOLPIDEM TARTRATE	72,381	2,494,954	2,494,698	34	6	4
METHYLPHENIDATE HCL	59,198	2,558,605	1,776,849	43	7	7
ALPRAZOLAM	51,106	2,730,626	1,335,811	53	8	8
OXYCODONE HCL	48,042	2,726,177	675,526	57	9	9
LISDEXAMFETAMINE DIMESYLATE	40,550	1,232,607	1,219,092	30	10	10

Clinical Alerts Measures	Total Alerts for All Prescribers	Total Prescribers Received Alerts	Prescriber/Dispenser Alerts	Daily Active MME Threshold Alerts	Opioid & Benzo Threshold Alerts
2018 Totals	90,879	13,029	515	34,592	55,772
2019 Totals	72,963	12,350	407	25,949	46,607
2020 Totals	66,931	11,579	229	22,389	44,313

SD PMP AWARe Users as of Q1 2021





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SDPhA Update | Summer 2021

Submitted June 16, 2021

SPRING DISTRICT MEETINGS

Due to continued COVID-19 protocols, Spring District meetings again took place via Zoom. This Spring meeting is the most important district meeting of the year, as the Fall meeting is now optional. Districts addressed many important items, 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 district meetings to in-person functions in 2022.

SDPhA BOARD RETREAT | JUNE 4-5

After more than a year of meeting only via Zoom due to the pandemic, the SDPhA board was able to meet in person for the Annual retreat. The board always uses this time together to tackle some of the association's biggest tasks, such as strategic planning and legislative goals for the coming year, continuing education opportunities and agenda items for the annual meeting and convention, setting the budget, and selection of annual award winners. After so many months of meeting only via Zoom, it was great to collaborate and fellowship physically together in the same room.

SOUTH DAKOTA PHARMACISTS ASSOCIATION ANNUAL MEETING

As previously announced, SDPhA will move forward with the 135th annual meeting in person Sept. 17-18 in Spearfish, SD. After carefully evaluating the needs survey sent to nearly 100 potential sponsors and exhibitors, the board decided to move forward with an in-person event. In order to best meet the needs of those vendors who are able to travel, SDPhA will follow the CDC guidelines for large gatherings, whatever they may be, at the time of the event. Online registration will launch with the launch of the new website, and vendor packets are underway. We look forward to bringing our pharmacists, technicians, students and industry partners back together again, and celebrating the pharmacy superheroes who stood (and continue stand) on the front line of the COVID-19 pandemic.

MARIJUANA INTERIM LEGISLATIVE STUDY

With IM 26 (medical marijuana) set to go into effect July 1, and everyone awaiting the South Dakota State Supreme Court decision on Amendment A (recreational or adult use marijuana) the legislature is working through a summer study tackling both issues. SDPhA has been actively engaged in this process. The first interim study committee meeting took place May 26-27. At the request of the chairman, SDPhA provided testimony from the pharmacy perspective. Jeremy Daniel, PharmD, BCPS, BCPP, provided committee members with exceptional insight into the clinical facts around medical marijuana, its actual effectiveness on certain disease states, and how it interacts with medications. SDPhA has not taken a position on this issue, but has worked hard to position pharmacists as the medication experts and a trusted resource. Throughout testimony, there was a repeated call, particularly from law enforcement, that since IM 26 labels marijuana as medicine, it should be treated as such, and handled through the same distribution channels. We've had

numerous conversations and calls with lawmakers and law officers explaining that, to the Drug Enforcement Agency (DEA), marijuana remains a Schedule I drug. That means the consequences to a pharmacist/pharmacy could be devastating. These conversations are ongoing, as is the interim study, and we will continue to participate in the process. Secretary Kim Malsam-Rysdon has said she anticipates the Department of Health will start issuing certification cards to patients and caregivers by mid-November.

IM 26 OVERSIGHT COMMITTEE

Initiated Measure 26 requires the creation of an oversight committee, and South Dakota pharmacists will have a seat at the table. On June 2, Eric Grocott, a past president of SDPhA, was appointed to the 14-member oversight committee by the executive board of the Legislative Research Council. The committee's role is to review and advise on medical marijuana in South Dakota.

DEA TAKE-BACK EVENT | APRIL 24

Please visit <https://takebackday.dea.gov/sites/default/files/NTBI20%20Totals.pdf> to view full take-back event totals and information. We continue to help spread the word about these opportunities and 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 located throughout the state. If you have a story you'd like to share about either to aid in that promotion, please contact our office.

PBM REFORM WORKGROUP

The Supreme Court's unanimous ruling in the Rutledge case set off a flurry of legislative activity in many states, including South Dakota. 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 Managers (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.

SDPhA has worked diligently for many years to educate lawmakers on the complexities of PBMs. The intricacies of the process are not always easily understood, but in general, our lawmakers have always known that when SDPhA comes to talk to them about something – it's because there's a great need. Gag clause laws, clawbacks, DIR fees, and the 340B program have all been addressed through legislation in recent legislative sessions. But, as always, the PBMs continue to find workarounds. Now, the Rutledge ruling gives us more backing to strengthen our laws. SDPhA is working together with other stakeholders to establish the best path forward to tackling this issue in the 2022 legislative session. Workgroup meetings are already underway, and SDPhA has also met with representatives of the state to gauge their interest and support. It seems quite evident that it will take a concentrated effort from all parties to garner the needed support. We anticipated this challenge, and know our pharmacists will rise with us to meet it. We look forward to sharing more details on these efforts at the annual meeting in Spearfish.

WILKE V. PCMA

On a similar note, SDPhA has signed on to participate as Amicus Curiae in PCMA vs. Wilke (8th Cir.). In 2017, the State of North Dakota enacted comprehensive legislation to regulate many practices of pharmacy benefit managers (PBMs) that the State perceived as abusive to patients and pharmacies. Among other things, North Dakota regulates the disclosure of the fees that PBMs charge pharmacies and the use by PBMs of esoteric accreditation and certification standards that

restrict pharmacy access. In addition, North Dakota limits arbitrary and costly restrictions in PBM contracts designed to steer patients to PBM-affiliated pharmacies, and it has prohibited copay claw-backs and the use of gag clauses to prevent pharmacists from disclosing drug price information to patients.

Before North Dakota's law went into effect, the Pharmaceutical Care Management Association (PCMA), the lobbying arm of the PBM industry, sued to prevent the State from enforcing its PBM law. PCMA's lawsuit claimed that two federal laws, the Employee Retirement Income Security Act of 1974 (ERISA) and Medicare Part D, prevent North Dakota from regulating PBMs. The U.S. Court of Appeals for the Eighth Circuit agreed, invalidating North Dakota's PBM law in its entirety. However, in light of the Rutledge case decision, the Supreme Court issued an order granting North Dakota's petition for review, vacated the Eighth Circuit's decision, and sent the case back to the Eighth Circuit for further consideration.

According to PCMA, Rutledge is limited to State laws that regulate the rates at which PBMs reimburse pharmacies. PCMA argues that ERISA and Medicare Part D preempt any other State law regulating PBMs. An adverse decision in Wilke could severely limit the States' ability to regulate PBMs.

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.

COMMERCIAL AND LEGISLATIVE (C & L) FUND

All of this legislative work leads us here – to the very important role the Commercial and Legislative Fund plays in our ability to move forward with PBM reform, and other legislative priorities. 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 C & L 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, and mount an effort to strengthen our state PBM laws, you will see more focus on sustaining this essential fund. We will highlight the work we do with it, how you can contribute, and frankly, why it's more important now than ever to do so. We need support to continue to ensure our 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 WEBSITE REBUILD

The final details are nearly complete, and after a lot of work to establish a new payment gateway and credit card processor, we are thrilled to share that SDPhA will launch a completely new, updated, and much more user-friendly website! The new website features 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, to 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. The launch of the new website will coincide with the opening of convention registration, and we are thrilled about both!

SCAPP | SDSU APhA – ASP CHAPTER

We continue to work closely with SDSU and the student pharmacists, and we are thrilled to welcome a new student liaison to the SDPhA board. Kaylee Ayers will join Katelynn Jackson in that role. The student liaisons have done an amazing job keeping us apprised of activities, and the SDPhA board remains committed to supporting the students in every way possible. We look forward to getting back to in-person activities with the SCAPP members such as convention attendance (free of charge), rooms for convention and Legislative Days, and support for the Back-to-School Picnic, Pharmacy Days, and American Pharmacists Month activities.

CORONAVIRUS (COVID-19)

Vaccination Distribution / Pandemic Response

As millions of Americans receive the COVID-19 vaccine, including more than 361,000 (as of the date of this report) 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. The DOH website has a [complete list of Federal Pharmacy Program locations](#). Distribution to independent and smaller community pharmacies continues to present challenges. 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.

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. Even as the pandemic wanes, communication and offering assistance to our pharmacists and pharmacies 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. The new website will continue to house [COVID-19 Resources](#). 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 the all the rapidly moving parts on Capitol Hill. Advocacy efforts now focus on maintaining the flexibilities extended to pharmacists by the federal government, while continuing to advocate for change that allows pharmacists to practice to the full scope of their expertise. This has included not only work on emergency provider status, but on immunizations, testing, payment, compounding and funding programs as well. The National Alliance of

State Pharmacy Associations (NASPA) also continues to work on our behalf with many of our national partners on matters of concern and importance to pharmacists.

NCPA CONGRESSIONAL PHARMACY FLY-IN | APRIL 19-21

For the second year in a row, SDPhA participated in the NCPA fly-in without leaving the office! This year NCPA arranged 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. Jessica Strobl, SDPhA Treasurer joined Amanda Bacon in representing the association in these conversations.

NASPA LEADERSHIP RETREAT | APRIL 19-21

Going virtual does have some advantages – typically budget and time constraints would preclude SDPhA from participating in the National Alliance of State Pharmacy Associations (NASPA) leadership retreat for executives and presidents-elect. However, this year the event was held virtually, allowing Kristen Carter, SDPhA President-Elect and Amanda Bacon, Executive Director, to participate in the two-day event. This was truly a great opportunity for collaboration among attendees from all the states. It was also a chance for our presidents-elect to learn more about the nuts-and-bolts of the day-to-day work in association management, especially as it relates to finances in the non-profit sector. We hope some sort of virtual option remains available for this event in the future.

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, dispensing requirements, improvements to Medicare, prescription drug misuse and abuse, compounding guidance and provider status. The list that follows are the most recent major bills currently related to the aforementioned issues.

[NEW! H.R. 3554/S. 1909 | To amend title XVIII of the Social Security Act to reform requirements with respect to direct and indirect remuneration under Medicare part D, and for other purposes, or the Pharmacy DIR Reform to Reduce Senior Drug Costs Act](#)

The Congressional Research Service has not yet developed a summary for this bill. The bill aims to create requirements for Part D plans to address DIR fees by: Requiring pharmacy negotiated price concessions, payment, and fees to be included at the point of sale for Medicare Part D prescriptions; Requiring disclosure to the pharmacy of price concessions and incentive payments; and establishing standardized pharmacy performance metrics. This bill was introduced 5/25/2021, and currently has 16 co-sponsors. It was referred to the Committee on Energy and Commerce in addition to the Committee on Ways and Means.

[NEW! H.R. 2608 | Ensuring Seniors Access to Local Pharmacies Act](#)

This bill establishes several requirements for prescription drug plans under the Medicare prescription drug benefit. Specifically, the bill requires prescription drug plans to allow any pharmacy located in a health professional shortage area, a medically underserved area, or a rural area to be included as an in-network pharmacy if the plan already has other in-network pharmacies in the same area. The bill also establishes certain standards for prescription drug plans regarding pharmacy reimbursements and related disclosures. Among other things, the bill prohibits prescription drug plans from reimbursing a pharmacy in an amount that is less than the amount the pharmacy benefits manager (PBM) reimburses an affiliated pharmacy (i.e., a pharmacy that has a shared ownership interest with the PBM) for the same services. This bill was introduced 4/15/2021 and has 15 co-sponsors. It was referred to the Committee on Energy and Commerce in addition to the Committee on Ways and Means.

[NEW! H.R. 2759/S. 1362 | Pharmacy and Medically Underserved Areas Enhancement Act](#)

A summary is in progress on this bill which aims to enable Medicare beneficiaries access to pharmacist-provided services under Medicare Part B by amending section 1861(s)(2) of the Social Security Act to recognize pharmacists as providers. Pharmacist-provided services would be reimbursable under Medicare Part B only if provided in areas of the country that HRSA defines as medically underserved areas (MUAs), medically underserved populations (MUPs), or health professional shortage areas (HPSAs). The legislation does not expand services beyond each state's already existing scope of practice. Pharmacist services would be reimbursed at 85% of the physician fee schedule. This bill was introduced 4/22/2021 and was referred to the Committee on Energy and Commerce in addition to the Committee on Ways and Means. It currently has 31 co-sponsors.

[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;

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

- 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 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 72 co-sponsors and was referred to the House Committee on Energy and Commerce 5/1/2020.

PHARMACY TECHNICIAN UNIVERSITY (PTU)

Technicians – finding them, training them, and keeping them is becoming an even more pressing issue now than perhaps maybe ever before. PTU is helping us help our pharmacies answer that call, and our slate of trainings and tools continues to grow. 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 106 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 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 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. During the 2020-2021 school year, we had 8 students from various South Dakota High Schools enrolled. We already have 4 on the list for this Fall. 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 (HPAP)

The passage of SB4 in 2021 means changes to some of the requirements for HPAP program administration. We continue to appreciate the open communication with the Board of Pharmacy on what this may mean for the future of the program. Our association continues to support HPAP, and saw no changes in the billing for FY 20201-2022. A pharmacist may access the program by self-referral, board referral, or referral from another person or agency, employer, coworker or family member.

THE SOUTH DAKOTA PHARMACIST

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

SOCIAL MEDIA / EMAIL BLASTS

We continue to work on our social media footprint. This is something we consider vital to our work of representing the pharmacy profession through advancing patient care, enhancing the public awareness and serving in the best interest of public health and pharmacy. It's also sometimes a challenge with a one-man office. There are a lot of things to tackle in a day, and sometimes the social media posts fall victim to the more urgent issues of any given day. That being said, the board is committed to this communication, as we know it's effective – so expect to see more posts from them on our platforms, too.

Here's what's important to know about each of our social spaces:

- Our Facebook and Instagram (Instagram remains a work in progress) are primarily consumer-driven health messages. These posts are intended to give you easy access to content you can in turn share on your social channels to help engage your patients and the general public.
- The SDPhA Member News and Announcements Facebook Group page is where you will now find industry news, SDPhA event and meeting information, and legislative updates as warranted.

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

- LinkedIn gives us an additional forum to gather and share news impacting the pharmacy profession. The page is established. Look for increased messaging there soon.

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

ASSOCIATION MANAGEMENT ROTATION

SDPhA is pleased to welcome Benjamin Ostebee for an APPE in Association Management late this summer. Ostebee is scheduled to begin work with Amanda Bacon and the SDPhA Board of Directors Aug. 23, and will conclude her rotation Sept. 24. We are thrilled to work with student pharmacists who want to take a deeper dive into this unique field of management, learning the day-to-day operations, the complexities of running an association, and the many management aspects unique to associations and legislative work. We look forward to the opportunity to work with more students in the future.

SDPHA OFFICE UPDATE

There hasn’t been the typical moment to catch our breath coming out of legislative session this year. Continued work regarding the pandemic, national advocacy work, the legislative Interim committee, and laying the groundwork for enhanced PBM efforts, as well as now planning for a live convention in September – have meant an extremely busy start to the “off-season” for the SDPhA office. I appreciate the opportunity to share our recent work with you, and continue to greatly appreciate the spirit of collaboration I have received from the BOP. It will take all of us standing together in the coming months as we work through the many issues that lie ahead.

Kind Regards,

Amanda Bacon

Executive Director

South Dakota Pharmacists Association

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1, 2020 through May 18, 2021

	Jul 1, '20 - May 18, 21	Budget	% of Budget
Ordinary Income/Expense			
Income			
Membership			
SD Board of Pharmacy Transfer	202,400.00	199,000.00	101.7%
Associate Member	500.00	200.00	250.0%
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	204,955.00	200,300.00	102.3%
Corp Endorsements			
NASPA-PQC Endorsement	300.00	300.00	100.0%
Career Center Endorsement	274.50	0.00	100.0%
PAAS Endorsement	306.00	275.00	111.3%
PMG Endorsement	13,549.00	10,000.00	135.5%
Total Corp Endorsements	14,429.50	10,575.00	136.4%
Interest/Dividends	292.67	3,000.00	9.8%
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	239,452.17	235,750.00	101.6%
Gross Profit	239,452.17	235,750.00	101.6%
Expense			
Legislative	240.00	0.00	100.0%
American Pharmacists Month	1,830.00	1,850.00	98.9%
Accounting/Tax Prep	4,361.84	4,800.00	90.9%
Salary & Benefits			
Payroll Taxes	4,354.11	4,972.50	87.6%
Payroll Expense	38.65	50.00	77.3%
Executive Director	56,874.93	65,000.00	87.5%
Insurance	9,908.25	10,809.00	91.7%
Retirement	3,412.50	3,900.00	87.5%
Total Salary & Benefits	74,588.44	84,731.50	88.0%
Advertising	0.00	3,000.00	0.0%
Dues/Subscriptions	2,150.00	3,300.00	65.2%
Technology/Net/Software	19,663.72	11,000.00	178.8%
Furniture/Copier/Assets	1,580.91	2,300.00	68.7%
Hlth Professionals Assist Prog	20,000.00	20,000.00	100.0%
Insurance (D&O, Office)	3,455.00	3,600.00	96.0%
Legal/Professional	1,527.10	5,000.00	30.5%
Merchant Card Fees	2,210.69	2,300.00	96.1%
Phone/Internet	5,327.60	4,500.00	118.4%
Postage	33.15	150.00	22.1%
Office Supplies	738.36	1,500.00	49.2%
Publications & Printing (Exp)			
Journal	3,641.04	3,200.00	113.8%
Total Publications & Printing (Exp)	3,641.04	3,200.00	113.8%
Scholarships	0.00	1,000.00	0.0%

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1, 2020 through May 18, 2021

	Jul 1, '20 - May 18, 21	Budget	% of Budget
Rent	2,328.00	4,700.00	49.5%
Board Travel & Meetings	1,688.14	20,000.00	8.4%
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	193.24	500.00	38.6%
Total Expense	149,227.16	198,431.50	75.2%
Net Ordinary Income	90,225.01	37,318.50	241.8%
Other Income/Expense			
Other Income			
PTU Pass Thru Income	9,775.00	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	9,925.00	0.00	100.0%
Other Expense			
PTU Pass Thru Exp	9,090.00	6,500.00	139.8%
Total Other Expense	9,090.00	6,500.00	139.8%
Net Other Income	835.00	-6,500.00	-12.8%
Net Income	91,060.01	30,818.50	295.5%

SD Pharmacists Association C & L
Revenue & Expenses Budget vs. Actual
July 1, 2020 through May 18, 2021

	<u>Jul 1, '20 - May 18, 21</u>	<u>Budget</u>	<u>% of Budget</u>
Income			
C & L Income	3,390.00	5,500.00	61.6%
Interest	672.44	0.00	100.0%
Total Income	4,062.44	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	-730.06	-6,950.00	10.5%

36-11-6. Use of funds by Pharmacists Association--Approval of expenditures--Filing statement.

The board may, upon receipt, pay to the South Dakota Pharmacists Association eighty percent of all fees the board receives for renewals of certificates of registration as a pharmacist. The association shall use the funds for the following association activities to benefit the public and the profession: continuing education, matters related to registration standards for pharmacists, professional service standards, and general operating expenses related to the activities enumerated in this section. The association shall also use funds received to pay any legislated assessment to support a diversion program for chemically impaired pharmacists. Expenditures of funds shall be approved by the president and treasurer of the association. The association shall annually file in the office of the board an itemized statement of the receipts of the association and disbursements from the receipts.

Source: SDC 1939, § 27.1004; SL 1967, ch 102, § 5; SL 1996, ch 230, § 2; SL 2005, ch 199, § 33.

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).

Pharmacist Impact on Reducing Medication Costs for Patients and Decreasing Medication Waste: Implementation and Expansion of the South Dakota Drug Repository Pilot Program

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**Pharmacist Impact on Reducing Medication Costs for Patients and
Decreasing Medication Waste:
Implementation and Expansion of the South Dakota Drug Repository
Pilot Program**

ABSTRACT

Purpose

Data published in 2019 found 37 states had laws allowing unused medications to be donated and re-dispensed to patients through drug repository programs (DRPs). In South Dakota, this is prohibited based on rule, ARSD20:51.13:02, summarized as pharmacies are prohibited to accept unused medications from patients. A pilot program was implemented with the objective to provide evidence demonstrating the impact provided to patients.

Methods

This retrospective, chart-reviewed study analyzed patient data from the DRP and a matched cohort from July 1, 2019 to February 28, 2021. Primary objectives were to track the number of prescriptions filled and average wholesale price of each prescription dispensed through the DRP. The secondary outcome was to compare the time for patients to receive prescriptions, from time of prescribing to insurance approval.

Results

Since implementation, over \$2.4 million in prescription drugs have been donated. Prescriptions have been dispensed to 135 patients, totaling over \$1.3 million based on average wholesale price. In comparing the DRP to matched cohort, DRP patients waited on average 13.5 days for insurance approval while matched cohort patients waited on average two days for insurance approval. The results showed DRP patients were able to pick up their prescription on average 14.5 days prior to insurance approval – meaning they were able to start therapy with a new medication over two weeks ahead of time.

Conclusion

The DRP pilot program showed improved access to medications, decreased costs for patients, and lessened prescription drug waste. Pharmacists are critical to the success of programs by ensuring the safety and viability of donated medications. Additionally, this program promotes pharmacists optimizing overall medication access and care.

Keywords: drug repository, specialty pharmacy, pharmacist, medication access, waste reduction

BACKGROUND

In the United States, state boards of pharmacy are responsible for establishing rules that dictate how patients can safely and legally access medications. As of 2019, 37 states had laws allowing unused medications to be donated and redispensed to patients through drug repository programs.^{1,2} Drug repository programs are driven by patient needs that have been identified by healthcare providers including patient advocates, pharmacists, nurses, and physicians, along with patient desires to give back in order to decrease the financial burden of medication for others. In January 2020, the American Society of Clinical Oncology issued a position statement on state drug repository programs, outlining their support, in that widespread use of such programs could lower costs for patients and payers and improve access to treatment for people who are unable to afford high-cost cancer drugs—all while reducing the amount of unused medications in the outpatient setting.¹ Redispensing of unused medication may assist patients in need, offering timely and affordable access to medications prescribed while also lessening waste of healthcare dollars on such things as hazardous medication disposal. Drug repository programs can also provide a bridge for those patients awaiting access to medication assistance programs or prior authorizations, allowing them to start therapy immediately.

In South Dakota, returning unused medications is prohibited based on the following rule, ARSD20:51.13:02 Return of unused drugs, summarized as pharmacists and pharmacies are prohibited to accept unused drugs or prescribed medications from patients or their proxy. Noticing the need for a drug repository program in South Dakota, especially with several nearby states having functioning programs in place^{3,4,5}, oncology clinic pharmacists and specialty

pharmacists within Avera McKennan worked with the South Dakota Board of Pharmacy (SDBOP) to propose the development of a drug repository pilot program at the Avera Specialty Pharmacy (ASP). ASP was originally granted a one-year variance for ARSD20:51.13:02 to allow the pharmacy to accept the return of unused drugs and redispense the drugs under the following stipulations:

1. Only legend drugs in the original, unopened, sealed or tamper-evident container which includes lot number(s) and expiration date(s) are eligible for donation
2. Drugs packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened however the single unit-dose package is unopened

The variance was granted starting July 1, 2019 and extended for an additional year through June 30, 2021. Policies and procedures were created for accepting, storing, dispensing, and documenting donated legend drugs. The creation of patient donation and receipt forms helped to ensure transparent communication and adequate documentation of all program transactions. The policies dictated what medications would not be accepted, including controlled substances, drugs with REMS requirements, and drugs with temperature sensitive storage requirements.

The pilot program initially focused on oncology specialty medications due to the expensive nature of those medications and frequent therapy changes. During the second year of operation, the goal was to increase the specialty medication scope through increased awareness and education to employees across the rural Avera footprint, focusing on specialty disease states of rheumatology, infectious disease, and transplant/hepatology, along with greater advertisement to patients through flyers, webpage information, and television

broadcasts. Working to engage the health system outside of the Sioux Falls region to ensure patients could participate anywhere across the state, the program received a grant from the South Dakota Society of Health-System Pharmacists to assist with shipping costs of repository donations and dispensations to and from ASP.

METHODS & MATERIALS

The objective of this study was to demonstrate the impact this program aims to provide to the community in South Dakota by increasing patient access to medication.

Endpoints

The primary objective was to track the number of prescriptions filled and the average wholesale price of each prescription for patients who received medication through the drug repository program. Secondary objectives included comparing the amount of time it takes for a patient to start a medication, from time of prescribing to insurance approval, between drug repository dispensations and a matched cohort group, and to identify potential cost to pharmacies that participate in such a program including time spent counseling patients, maintaining inventory, and providing community awareness of the program.

Inclusion/Exclusion Criteria

The study population inclusion criteria for the drug repository program patient group included dispensations from the ASP drug repository; the inclusion criteria for the matched cohort group included dispensations filled outside of ASP drug repository program, a new prescription for the same medication as the drug repository program patient, and the medication being dispensed within a 12 month period around the drug repository program

dispensation. The only exclusion criteria was prescriptions filled outside of the study timeframe of July 1, 2019 to February 28, 2021.

Study Design

This retrospective, chart-reviewed study analyzed patients from the DRP and a matched cohort patient group from July 1, 2019 to February 28, 2021 to compare the time for patients to receive prescriptions. Electronic medical records, including MOSAIQ, Meditech, EnterpriseRx, and Dromos, were utilized in order to collect the patient information listed:

- Patient name
- Prescription number
- Medication prescribed
- Quantity prescribed
- Prescription benefit coverage
- Prescription benefit utilized (for matched cohort patients only)
- Date prescription written
- Date prescription filled
- Date of drug receipt by patient (pickup or mailed date)
- Date of insurance approval (if applicable)
- Cost of prescription filled based on AWP (for drug repository patients only)

With the secondary endpoint of potential cost to pharmacies, self-reported data was collected regarding time spent:

- Writing policies, protocols, and creating forms
- Training staff

- Counseling patients about utilizing the drug repository program
- Maintaining donation inventory
- Developing community outreach and awareness of the program
- Coordinating and creating internal webpage with all inventory data

RESULTS

Since implementation of the program through mid-June 2021, 141 prescriptions have been dispensed from the repository totaling \$1,397,955.64 based on average wholesale price. The average cost of each prescription dispensed amounts to around \$10,000. During this time, \$2,514,571.54 in medications have been donated to the repository program. Some of the most commonly donated and dispensed medications can be found in Table 1.

Regarding the secondary endpoint of comparing the amount of time it takes for a patient to start a medication, from time of prescribing to insurance approval, between drug repository dispensations and a matched cohort group, 68 dispensations in the drug repository group were able to be matched to 55 dispensations in the cohort patient group. For the drug repository group, 13 dispensations were excluded as the date of insurance approval was before the written date of the prescription, meaning it was not the first time the patient had received the medication. Of the 55 dispensations reviewed for inclusion criteria, 28 of them had an insurance approval date after the prescription written date, with the average difference in wait time for insurance approval around 13.5 days. For 16 of those 28 dispensations, the patient picked up or was mailed medication from the drug repository program on average 14.5 days prior to their insurance approval – meaning they were able to start therapy with a new

medication over two weeks ahead of time. For the additional 27 dispensations included, insurance approval was not necessarily a factor in why they received medication from the repository. It was due to other reasons including a lapse in coverage, a delay in the ability for the patient to obtain their medication or supply, or the prescription being a medication not routinely covered by insurance, meaning it saved the patient an out-of-pocket expense.

When comparing to the matched cohort group of patients, of the 55 dispensations, eight of them were excluded as insurance approval was before the written date of the prescription, meaning it was not the first fill by the patient. Forty-seven dispensations met inclusion criteria where the insurance approval was after the prescription written date, with the average difference in wait time for insurance approval around two days. While this time was much shorter than our average wait time for the repository program patients, it means we are identifying those patients who would benefit most from the repository, rather than those patients with less concern over coverage or paying for medication.

The additional secondary endpoint was focused on potential program cost. Initially, the time to set up the program including writing policies, protocols, and creating forms, training staff and the creation of an internal inventory webpage amounted to 15 hours of pharmacist time. The overall maintenance of the program after two years amounts to one and a half to two hours of pharmacist time per week.

DISCUSSION

Strengths

The program has been able to demonstrate significant cost savings through repurposing of medication that would have otherwise been destroyed. The strengths of this study were the ability to show the drug repository pilot program can provide medication to patients over two weeks ahead of time, while waiting for insurance and/or prior authorization approval, and provided data highlighting the help provided to patients for lapses in coverage and delays in obtaining medications or supplies – a huge part of the mission of the Avera Health organization.

Limitations

The limitations of this study included a small patient sample for the repository and matched cohort comparison, and with data requiring manual chart review making it challenging to uncover insurance information and coverage dates at times.

CONCLUSION

Drug repository programs have been shown to improve access to medications, decrease costs for patients, and lessen prescription drug waste. Pharmacists are critical to the success of programs by ensuring the safety and viability of donated medications, along with dispensing and counseling of patients on their medications. For patients waiting on insurance approval, based on our study results, they were able to receive medication from the repository program on average over 14 days ahead of time. Current time spent maintaining program donations and dispensations amounts to around one and a half to two hours per week. This drug repository pilot program not only helps to assist patients in South Dakota, it promotes pharmacists optimizing overall medication access and care.

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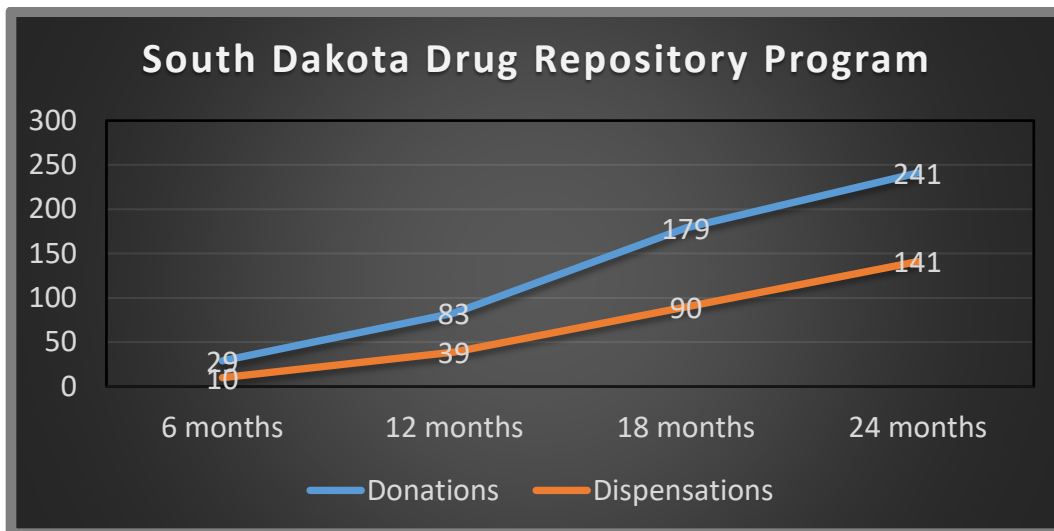
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TABLES AND FIGURES

Table 1. Medications Most Commonly Donated and Dispensed

Medications Most Commonly Donated and Dispensed
Abemaciclib 100 mg & 150 mg tablets
Abiraterone 250 mg tablet
Alpelisib 300 mg (2x150 mg) dose
Apixaban 5 mg tablet
Dasatinib 100 mg tablet
Enoxaparin 100 mg/1ml syringe
Everolimus 5 mg tablet
Heparin Lock Flush (100 units/mL) 3 mL
Ibrutinib 560 mg tablet
Olaparib 150 mg tablet
Upadacitinib 15 mg tablet

Figure 1. Number of Donations and Dispensations





**South Dakota
Board of Pharmacy**
4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737 Fax: 605-362-2738
PharmacyBoard@state.sd.us

DATE: June 5, 2020, Revised 9/24/2020, Revised June 25, 2021
WHAT: Board Policy Statement Number 20-06-05
WHY: April 8, 2020 PREP Act Authorizing Pharmacist and Technician Testing for COVID-19

~~BOARD POLICY STATEMENT COVID-19 TESTING BY PHARMACISTS~~

The South Dakota Board of Pharmacy acknowledges that the United States Department of Health and Human Services (HHS) published guidance on April 8, 2020 regarding the fact that the Public Readiness and Emergency Preparedness (PREP) Act passed, authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, and that the Food and Drug Administration (FDA) has authorized¹ through its Emergency Use Authorization (EUA).² Further the HHS Office of General Counsel has issued an advisory opinion that says licensed pharmacists may order and administer COVID-19 tests regardless of state or local restrictions.³

Further, the Coronavirus Aid, Relief, and Economic Security (CARES) Act allows patients who are uninsured to be billed by pharmacists to HRSA for COVID-19 testing services.⁴ Additionally, the SD Medicaid program will pay pharmacists as well.⁵

It is the Board's policy that during the COVID-19 Federal Emergency, pharmacists may order, perform, and report COVID-19 tests without a separate provider order or collaborative practice agreement if the requirements listed below are met. Currently, most of the tests are Clinical Laboratory Improvement Amendments (CLIA) waived tests per the Centers for Disease Control (CDC) and supported by the Food and Drug Administration (FDA) and therefore will require a CLIA waiver to perform these tests.^{5,6} When the emergency declaration has ended, the pharmacist may only perform these tests by physician order. This policy statement is to further clarify and allow pharmacists to order and perform COVID-19 testing for their patients.

This policy is in effect ~~for the duration of the State of South Dakota declared emergency or the~~ until the PREP Act, ~~whichever expires soonest~~ for countermeasures against COVID-19 concludes.

Before a pharmacist may begin testing, the following must be completed:

1. The pharmacy notifies the Board before testing commences and provides the Board with the policy and procedures written for testing which includes the type of FDA authorized test, staff training, the location of testing, i.e., parking lot of pharmacy, planned personal protective equipment (PPE) use, documentation, informing the provider of the test results.
2. A pharmacist conducting COVID-19 testing must be dedicated to testing only and may not be working in a dispensing role while performing testing. Pharmacy interns and technicians may assist in the COVID-19 testing if the actual testing is performed by a patient or a pharmacist.
3. For testing that is completed by the patient, pharmacy staff may provide the patient with supplies and education. Pharmacy technicians and interns may witness the patient performing self-testing and proper placement of the test medium into proper containers, if applicable.

4. The pharmacy must obtain a Clinical Laboratories Improvement Act (CLIA) waiver to perform tests, if they will be using a device to process the tests in house. If sending to a commercial laboratory, the CLIA waiver is not required.
5. The pharmacy must assure that all staff performing and assisting with these tests have consented to performing the assigned tasks, have accessible the appropriate PPE to protect themselves and any staff from aerosolization, and have received proper training to perform the assigned tasks involved in the testing process.
6. The pharmacist may perform testing in a location which is not a licensed location, if the pharmacist is conducting the testing is licensed with the Board.
7. The pharmacist or testing vendor must report test results to the South Dakota Health Department at **sd.gov/diseasereport**
8. The pharmacy must receive an approval from the board allowing the pharmacy to begin testing before any type of testing is done in the pharmacy or by pharmacy staff.
9. For PREP Act Immunization Guidance, see Policy Statement 20-12-11

References:

1. US HHS Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>
2. FDA Emergency Use Authorization for therapeutic and medical devices to diagnose and respond to public health emergencies: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
3. HHS Office of General Counsel Advisory Opinion, found at <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>
4. HRSA Uninsured CARES Act: [COVID-19 Uninsured Program Portal](https://www.hrsa.gov/covid-19/uninsured)
5. Medicaid Provider Bulletin & FAQ: https://dss.sd.gov/docs/medicaid/providers/ProviderBulletins/2020/COVID19_FAQ_Providers%205.1.20.pdf
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Passed by the South Dakota Board of Pharmacy on June 5,2020.

Revised and Passed by the South Dakota Board of Pharmacy on September 24, 2020

Revised and Passed by the South Dakota Board of Pharmacy on June 25, 2021



**South Dakota
Board of Pharmacy**

4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106

Phone: 605-362-2737 Fax: 605-362-2738
PharmacyBoard@state.sd.us

DATE: December 3, 2010, Revised June 25, 2021

WHAT: Board Policy Statement Number 10-12-01

**WHY: GUIDELINES FOR APPROVAL OF PHARMACISTS OR OTHER PHARMACY
EMPLOYEES WORKING AT HOME**

INTRODUCTION

The Board requires pharmacies that allow pharmacists and other employees to perform routine pharmacy functions from home to have policies and procedures in place that ensure compliance with good practice standards. This is necessary to ensure that patient safety and security of the patient's health information is maintained at the same level as if those functions were performed within the pharmacy.

GUIDELINES

A copy of the policies and procedures for working at home must be readily available at the pharmacy for review by the Board of Pharmacy Inspector. Home based workers shall also have a copy at their home work site.

The Policies and Procedures shall include the following:

- ~~1. Home based workers must be assigned a Virtual Personal Network (VPN) and secure ID to log in to remote systems.~~ a secure log in to the system via a Virtual Personal Network (VPN) or terminal server with two-factor identification.
- ~~2. Home based workers must maintain a business telephone line.~~
- ~~1. Home based workers must maintain a separate designated area at home for work. This includes a locking desk or file cabinet.~~
2. Home based workers must take precautions to protect information from theft.
3. Home based workers must collect, use, and disclose information only for the purpose associated with their job role and function.
4. Home based workers must have access to clinical resources as designated by the board.
5. Home based workers must have a means of disposal of protected health information (PHI) that will not risk the security of that information.

6. All pharmacy technicians and interns working remotely must have direct communication access to a pharmacist and the pharmacist is able to supervise the technician and interns electronically.

Passed by the South Dakota Board of Pharmacy on 12/03/2010

Revised and Passed by the South Dakota Board of Pharmacy June 25, 2021



Lorri Walmsley, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington D-105
Phoenix, AZ 85034
p: 602-214-6618
Lorri.Walmsley@walgreens.com

May 21, 2021

Via Email

South Dakota State Board of Pharmacy
Attention: Kari Shanard-Koenders
Executive Director
4001 W. Valhalla Blvd., Suite 106
Sioux Falls, SD 57106
Email: kari.shanard-koenders@state.sd.us

Dear Executive Director Shanard-Koenders and South Dakota Board of Pharmacy Members,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state South Dakota, I am writing to request appearance at your June 25, 2021 meeting to discuss our pilot project expanding the role of technician immunization administration to all ACIP approved vaccines.

Community pharmacy-based immunizations have been one of the most significant achievements in public health in recent years. Various studies have demonstrated that pharmacists increase vaccination rates against influenza, pneumonia, and herpes zoster. Patients have shown high acceptance of pharmacy-based immunizations, with 97% of vaccinated patients' surveyed reporting satisfaction with their experience in the pharmacy. One-third of all influenza vaccines given during the 2013-2014 flu season were provided in a community pharmacy. In addition, studies have demonstrated that pharmacy-based immunizations are more cost-effective than those provided in other settings, including physician offices.¹

Community pharmacies have further demonstrated their value in public health through partnerships with the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services to deliver COVID-19 testing and vaccinations to optimize supply and equity during the pandemic. Further, HHS has taken steps to ensure that pharmacies and pharmacists are optimized to their fullest capacity through the technician vaccine administration allowances in the PREP Act.² Most recently, the CDC and ACIP issued interim clinical considerations and recommendations for the co-administration of other routine vaccinations with the COVID-19 vaccine to expand vaccination rates further.³ While the U.S. Department of Health and Human Services Healthy People goals for 2030 include increasing vaccination rates for the flu vaccine and Tdap during pregnancy, neither of these vaccines are covered within the scope and authority within the PREP Act.⁴ Our proposed pilot program would address the need for co-administration of vaccines outside of the scope of the PREP act to increase the vaccination rates for other routine vaccines for South Dakotans. Enabling trained and supervised technicians to administer all ACIP recommended vaccines allows the Pharmacist to focus their time and efforts on the clinical evaluation of gaps in care and consultation to improve vaccination rates safely and efficiently

We are requesting approval of the pilot for one year with a six-month check in on results.

If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley, R.Ph.

Enclosure: Walgreens South Dakota Technician-Administered Immunization Program Pilot



Walgreens South Dakota Technician-Administered Immunization Program Pilot

Introduction

Community pharmacy-based immunizations have been one of the most significant achievements in public health in recent years. Various studies have demonstrated that pharmacists increase vaccination rates against influenza, pneumonia, and herpes zoster. Patients have shown high acceptance of pharmacy-based immunizations, with 97% of vaccinated patients surveyed reporting satisfaction with their experience in the pharmacy. One-third of all influenza vaccines given during the 2013-2014 flu season were provided in a community pharmacy. In addition, studies have demonstrated that pharmacy-based immunizations are more cost-effective than those provided in other settings, including physician offices.¹

Community pharmacies have further demonstrated their value in public health through partnerships with the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services to deliver COVID-19 testing and vaccinations to optimize supply and equity during the pandemic. Further, HHS has taken steps to ensure that pharmacies and pharmacists are optimized to their fullest capacity through the technician vaccine administration allowances in the PREP Act.² Most recently, the CDC and ACIP issued interim clinical considerations and recommendations for the co-administration of other routine vaccinations with the COVID-19 vaccine to expand vaccination rates further.³ While the U.S. Department of Health and Human Services Healthy People goals for 2030 include increasing vaccination rates for the flu vaccine and Tdap during pregnancy, neither of these vaccines are covered within the scope and authority within the PREP Act.⁴ Our proposed pilot program would address the need for co-administration of vaccines outside of the scope of the PREP act to increase the vaccination rates for other routine vaccines for South Dakotans. Enabling trained and supervised technicians to administer all ACIP recommended vaccines allows the Pharmacist to focus their time and efforts on the clinical evaluation of gaps in care and consultation to improve vaccination rates safely and efficiently.

Goals

The goals of our program are threefold, first and foremost, to safely improve vaccination rates for all ACIP recommended vaccines for South Dakotans. Second, enhance pharmacy workflow and patient experience by offering a seamless experience for patients who wish to receive multiple vaccinations recommended by ACIP and the CDC. And lastly, to improve pharmacy team member satisfaction and engagement through expanded roles and optimization of workflow.

Objectives

The program will achieve its goals by allowing Certified Immunization Trained Technicians to perform all ACIP recommended vaccines for patients in our 14 South Dakota-based locations. All participating technicians will be supervised by an Immunization Trained Pharmacist and will opt into vaccination after receiving the training as outlined in the program details below and demonstrated proficiency. Immunization Trained technicians will only participate in the non-clinical portions of the vaccine administration, and vaccines will only be given after the clinical assessment and counseling on potential risks and side effects on all immunization is performed by the Immunization Trained Pharmacist.



Walgreens South Dakota Technician-Administered Immunization Program Pilot

Program Details

Employee Selection:

South Dakota Licensed and Certified Pharmacy Technicians that have opted into participation, have completed immunization administration training, and have demonstrated proficiency.

Training:

Select Certified Pharmacy Technicians will complete training as outlined below:

Activity	Description
APhA Pharmacy-Based Immunization Administration by Pharmacy Technicians Training Program	Self-Study Learning -2 hours self-study with assessment Live Training Seminar -4 hours <i>Learning objectives of both sessions⁵</i>
Adult & Child CPR for Healthcare Providers [Cardio Partners only] OR Adult, Child, and Infant First Aid/CPR/AED Online	Blended Online and Live training OR Online training
OSHA Bloodborne Pathogen Training (BBP)	Online Training in LTMP Final Assessment –Completed Annually
Immunization Administration Training	Overview and acknowledgment of vaccine preparation and administration procedures for all immunizations
Training & Authorization Form	Training with the pharmacy manager to demonstrate mastery of administration

Documentation of training activities will be maintained by employee in file #17 in the pharmacy and the Walgreens Learning and Talent Management Portal (LTMP.)

Description of Immunization Pharmacy Technician Functions:

1. Enter the Vaccine into the Immunization Selection Tool and Intercom Plus
2. Technician chooses the appropriate vaccine administration record (VAR); flu, non-flu, offsite clinic
3. Gather immunization, emergency supplies, and prepare the vaccine.
 - Sharps Container, Emergency Supply Kit, gloves, alcohol pads, bandages, and cotton balls
 - Reconstitute vaccine if applicable and prepare the appropriate dose for administration



Walgreens South Dakota Technician-Administered Immunization Program Pilot

4. Administer Vaccine:
 - Inside the immunization area/consultation room, to area technician will question and confirm with the patient:
 - i. Full Name
 - ii. Date of Birth
 - iii. Vaccination
 - Complete immunization using good hand hygiene and appropriate immunization technique.
 - Complete the chart in Section F
 - Instruct the patient to remain in the area for approximately 15 minutes for observation to monitor the patient for post-immunization adverse reactions
5. Pharmacist and Technician will complete post-immunization requirements.
 - Technician will clearly print name and Pharmacist clearly print and sign Section F of the VAR
 - Technician will scan the VAR into the patient profile in Intercom Plus

The Pharmacist will be responsible for the clinical assessment and counseling on the vaccination, including potential risks and side effects on all immunizations.

Procedures for Ensuring Public Health and Safety

Immunization-trained Pharmacy Technicians will only participate in the non-clinical functions of vaccine administration. The Pharmacist will be responsible for the clinical assessment and counseling on the vaccination, including potential risks and side effects on all immunizations.

1. Clinical Review

Upon entry of the vaccination into Intercom Plus, the Immunization Trained Pharmacist will perform the clinical review to assess the appropriateness of therapy, review the statewide immunization registry, screen for contraindications/precautions, and perform vaccine verification. If a contraindication or precaution is present, the patient's primary healthcare provider will be consulted, or a referral to care will be advised.

2. Consultation

Before vaccine administration, the patient will be counseled regarding the potential risks, side effects of all immunizations and a discussion about potential gaps in care to include recommendations for other vaccinations. The VIS will be provided and reviewed before administration with the patient or the patient's parent/legal guardian.

3. Informed Consent

The Pharmacist will screen patients for receipt of the vaccine based upon ACIP Guidelines. No qualified patient shall receive a Vaccine who fails to meet the stated criteria, has a medical contraindication to the vaccine, an allergy to



Walgreens South Dakota Technician-Administered Immunization Program Pilot

components of the vaccine, or severe prior reaction to a Vaccine. Each Pharmacist will inform the Vaccine recipient of the potential benefits and risks of the vaccine. This disclosure must be documented by the execution of informed consent by each qualified individual/patient (or the qualified individual/patient's parent or legal guardian in the event the qualified individual/patient is less than eighteen (18) years of age) receiving a Vaccine.

4. Vaccines

All vaccines indicated in our South Dakota Standing Order Protocol are recommended and follow current published CDC and ACIP recommendation guidelines and recommended schedules and COVID-19 vaccines as recommended and approved by ACIP.

5. Post Administration

Following administration of a Vaccine, a Pharmacy Provider will recommend qualified individuals/patients remain under observation for at least fifteen (15) minutes, following state and local regulations, to monitor for adverse events. A Pharmacy Provider will instruct the qualified individual/patient to report any adverse events to the Pharmacy Provider after receiving the vaccine.

6. Waste Disposal.

Sharps and syringes will be disposed of in an approved impenetrable sharps container using universal precautions. All full sharps containers must be disposed of according to state regulations.

7. Patient Record.

Each vaccine will be documented in Intercom Plus and an electronic record of each patient for five (5) years or required Law. Such record shall include: the name, address, and date of birth of the patient; the date of administration and site of injections; the name, dose, manufacturer's lot number, and expiration date of the vaccine; name and address of the patient's primary health care provider ("PCP"), as identified by the patient; the name of the Pharmacist administering the immunization; a record of any consultation or other professional information provided to the patient; and the name and date of the Vaccine Information Sheet provided to the patient. A personal immunization record card will be given to each qualified individual/patient with a record of the date of vaccination and the name/location/telephone number of the administering pharmacy.

8. Adverse Reaction Reporting.

All adverse reactions to the vaccine shall be submitted to the FDA and the CDC via the Vaccine Adverse Events Reporting System ("VAERS") form with a copy of each such report provided to the qualified individual/patient's primary care physician.

9. Emergency Treatment Procedures

In an anaphylactic reaction, the Pharmacist will follow the Walgreens Standard Operating Procedures and Emergency Procedures outlined in our South Dakota Standing Order Protocol.



Walgreens South Dakota Technician-Administered Immunization Program Pilot

10. Workplace Safety

All immunization Trained employees complete training on bloodborne pathogens and needlestick prevention annually. Additionally, all employees will review the Walgreens Immunization Safety playbook that provides the latest information on safety guidelines and best practices for infection control. Current safety measures include CDC immunization guidance, patient screening tools, temperature checks, facemasks and shields, hand-hygiene and cleaning procedures, and patient safety guidelines.

11. State Registry Reporting.

All vaccines will be reported to the South Dakota Department of Health's Vaccine Registry as required by state law.

Rule Variance Request

Walgreens is requesting that the South Dakota Board of Pharmacy provide a one-year variance to 20:51:28:02.01, 20:51:29:20, and 20:51:29:21(6) to allow Certified Immunization-Trained Pharmacy Technicians under the supervision of an Immunization Trained Pharmacist to administer all ACIP recommended vaccines, including COVID-19 vaccines.

Pharmacies play an integral role in the vaccination of the public that was further heightened by the COVID-19 pandemic. Properly trained and supervised Pharmacy Technicians are well suited to assist pharmacists and pharmacies with the non-clinical portions of vaccine administration, allowing pharmacists more time to identify gaps in care, counsel patients, and improve patient outcomes.

Additional Supporting Information

Idaho was the first adopter of this concept in 2016-17; since then, Colorado, Illinois, Indiana, Nevada, Rhode Island, Utah, and Washington have taken steps to allow this activity with several additional states discussion. Between August 1, 2019, and April 20, 2020, technicians have provided an estimated 27,000 immunizations at Walgreens pharmacies in Idaho and 19,000 immunizations in Rhode Island. The Idaho Board of Pharmacy estimated that Pharmacy Technicians gave 25,000 vaccines in the first year after adopting the rule with no adverse event or errors reported to the Board of Pharmacy⁶.

Internal surveys have provided positive feedback on Technicians administered immunizations by pharmacists, technicians, and patients. The ability to delegate this administrative task to trained technicians allows for increased pharmacist capacity for engaging in additional clinical and patient care services.

Technician Immunization Program Feedback and Benefits⁷:

- Pharmacists in the study felt that their immunizing technicians were properly trained to administer immunizations, capable of giving immunizations, and empowered by their new role within the pharmacy.
- Findings also included a pharmacist-perceived increase in vaccination rates and recommendation for other technicians to be trained to administer immunizations.
- Pharmacists' opinions revealed that working with newly trained immunizing pharmacy technicians has not only positively affected the morale of their team, but can help to increase the number of vaccinations given by the pharmacy.
- There was no risk to pharmacist employment position as the Pharmacist must complete clinical review prior to technician administration to confirm vaccine eligibility and is responsible to confirm correct product and dosage is being provide by Technician.



Walgreens South Dakota Technician-Administered Immunization Program Pilot

- Providing technician the ability to complete the non-clinical task of immunization administration provides the pharmacist additional capacity to practice at the top of their licensure to engage patients in additional activities such as medication therapy management services, adherence monitoring, prescriptive authority, etc.

The American Pharmacist Association (APhA) House of Delegates, representing over 60,000 pharmacists nationwide supports this concept. Most recently a policy was introduced and adopted as a policy statement regarding Pharmacy Technicians Role in Immunization Administration at the 2020 Annual Meeting.⁸

1. *APhA urges state boards of pharmacy and state legislative bodies to authorize immunization administration by qualified pharmacy technicians as a technical function that may be delegated by immunizing pharmacists.*
2. *APhA supports the development of standardized training in immunization administration and continuing education opportunities for immunizing pharmacy technicians.*
3. *APhA supports pharmacists individual discretion in delegating immunization administration to qualified pharmacy technicians with the requisite education, training, and experience.*
4. *APhA supports voluntary participation by pharmacy technicians in the training and provision of immunization administration*
5. *APhA supports the role of pharmacists as the healthcare professional providing clinical patient assessment, decision making, and patient counseling for all immunizations administered by a pharmacy technician.*

References:

1. Dylan Atkinson, Alex Adams, and David Bright. "Should pharmacy technicians administer immunizations?." INNOVATIONS in pharmacy 8.3 (2017): 16-16.
2. U.S. Department of Health and Human Services. Third Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and the Republication of the Declaration. October 2020 <https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf> (Accessed Online May 2021)
3. Centers for Disease Control and Prevention. Interim Clinical Considerations Co-administration with other vaccines May 2021 <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration> (Accessed Online May 2021)
4. U.S. Department of Health and Human Services and Office of Disease Prevention and Health Promotion. Healthy People 2030 Vaccination Goals <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration> (Accessed Online May 2021)
5. American Pharmacists Association. Pharmacy-Based Immunization Administration by Pharmacy Technicians <https://www.pharmacist.com/Education/Certificate-Training-Programs/Technician-Immunizations> (Accessed Online May 2021)
6. Alex Adams, Shane Desselle, and Kimberly McKeirnan. "Pharmacy technician-administered vaccines: on perceptions and practice reality." Pharmacy 6.4 (2018): 124. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6306786/>



Walgreens South Dakota Technician-Administered Immunization Program Pilot

7. [Bertsch TG, McKeirnan KC, Frazier K, VanVoorhis L, Shin S, Le K.](https://www.ncbi.nlm.nih.gov/pubmed/31036525) July 2019. Supervising pharmacists' opinions about pharmacy technicians as immunizers. *J Am Pharm Assoc.* Volume 59, Issue 4, Pages 527-532. <https://www.ncbi.nlm.nih.gov/pubmed/31036525>
8. American Pharmacist Association. APhA House of Delegates Policy and Procedure Manual. 2019. Available from: https://media.pharmacist.com/HOD/18512+-+HOD+Policy+and+Procedures+Manual+2020_online.pdf (Accessed Online May 2021).

Pharmacy Locations

Location #	Address	City	County	State	Zip	License Number
1975	1720 S SYCAMORE AVE	SIOUX FALLS	MINNEHAHA	SD	57110	100-1863
5242	4900 S CLIFF AVE	SIOUX FALLS	LINCOLN	SD	57108	100-1802
5243	2605 W 12TH ST	SIOUX FALLS	MINNEHAHA	SD	57104	100-1803
5514	1806 S MINNESOTA AVE	SIOUX FALLS	MINNEHAHA	SD	57105	100-1846
5643	540 MOUNTAIN VIEW RD	RAPID CITY	PENNINGTON	SD	57702	100-1813
5745	3620 W 41ST ST	SIOUX FALLS	MINNEHAHA	SD	57106	100-1810
9512	1125 N LACROSSE ST	RAPID CITY	PENNINGTON	SD	57701	100-1918
9806	2020 BROADWAY AVE	YANKTON	YANKTON	SD	57078	100-1898
10007	421 9TH AVE SE	WATERTOWN	CODINGTON	SD	57201	100-1895
10347	901 S BURR ST	MITCHELL	DAVISON	SD	57301	100-1911
10572	100 E SIOUX AVE	PIERRE	HUGHES	SD	57501	100-1920
10656	1902 MOUNT RUSHMORE RD	RAPID CITY	PENNINGTON	SD	57701	100-1927
10729	7120 W 41ST ST	SIOUX FALLS	MINNEHAHA	SD	57106	100-1925
12906	1430 NORTH AVE	SPEARFISH	LAWRENCE	SD	57783	100-1942



Virtual Verification

Lauren Paul, PharmD, MS
Senior Director, Pharmacy Regulatory Affairs

June 25, 2021



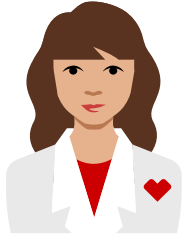
What is Virtual Verification?

Virtual Verification is a process developed by CVS Health to streamline the process of filling prescriptions.

Through the Virtual Verification process, the pharmacist verifies the prescription through photographic images of the prescription taken by the licensed pharmacy technician in lieu of physically handling the prescription.

All other aspects of the prescription-filling process remain unchanged.

What are the benefits of Virtual Verification?



Elevates the role of the registered pharmacist.

Improves patient satisfaction.



Increases accountability and quality



Elevating the role of pharmacists

Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.¹

To further enhance and optimize patient care services delivered at community pharmacies, leveraging trained pharmacy technicians to take on roles that have proven to not require the professional judgment of a pharmacist should be considered. Paramount and centric to all rules, including pharmacy technician roles and responsibilities, is patient safety.

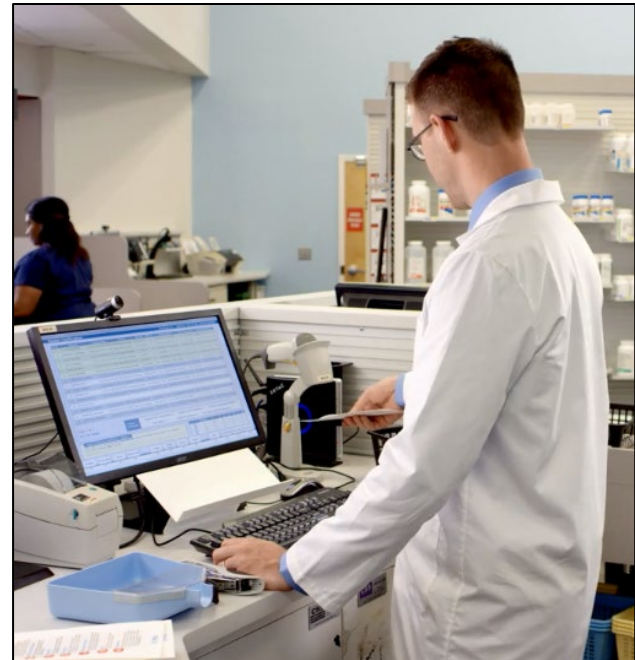
Increasing the scope of pharmacy technician practice to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.²

¹Gaither CA, et al. Final report of the 2014 National Sample Survey of the Pharmacist Workforce to determine contemporary demographic, practice characteristics and quality of work-life. 2014. Available from: <https://www.aacp.org/sites/default/files/finalreportofthenationalpharmacistworkforcestudy2014.pdf> (Accessed October 15, 2019).

²Zellmer WA, et al. Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference. Am J Health Syst Pharm. 2017;74(17):1321-1332.

In today's workflow, physical handling consumes a majority of the pharmacist's time during Product Verification

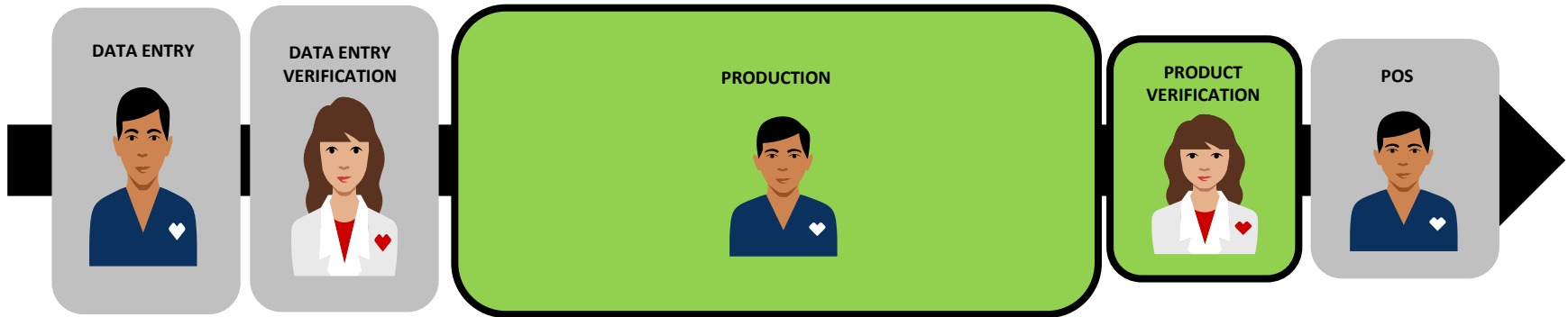
1. Retrieve basket
 2. Remove label and product from basket
 3. Scan label
 4. Scan product label
 5. Open vial
 6. Pour contents into Visual Verification Tray
 7. **Inspect product compared to stock image**
 8. Pour contents back into vial
 9. Close vial
 10. Retrieve empty prescription bag
 11. Place contents into bag
 12. Affix label to bag
 13. Staple label to bag
 14. Place bag into holding area
- } Small % of total process



Roughly 90% of the Product Verification process is spent physically handling the product and performing manual tasks

Virtual Verification brings physical workstation changes

Workflow:



Hard Copy

Data Entry Verification WS-CHAIN - Mon, 23 Oct 2017 11:55:25 AM

FILL 01

patient: Wallace, William
 dob 01/01/1928
 age 88 years, 9 months
 male

drug metformin hcl 1,000 mg tablet
 strength 1,000 MG dose 0 1 TABLET

sig Take 1 tablet by mouth twice daily

prescribed 60 EA date written 07/19/2017
 dispensed 60 EA num refills 05 1 TABLET
 days supply 30

quality alert
CAUTION
 Look Alike Sound Alike
 metFORMIN (glucophage)
 metFORMIN ER (glucophage XR)
 metronIDAZOLE (flagyl)

prescriber Evans, Lily
 presc. phone (703) 212-3443
 dea AS9432042

Lily Evans, MD
 1 Crystal Drive
 Arlington, VA 22202
 (703) 212-3443

Name: William Wallace Date: 7/19/2017
 Address: 2 CVS Drive, Woonsocket, RI DOB: 1/1/1928

Glucophage 1,000 mg
i po bid

City #60 Refills: 5

DEA A59432042 NPI 1071096417

Select a function and press <Enter>
 Info: Sig Lang (L) | Zoom (Z) | Profile (ES) Notes: Add/View DUR Comments (AC)/(DC) | Patient Notes (N) | Fill Notes (FN) Actions: Dose Schedule (D) | Delete (DE) | Prescriber Request (PR) | Exit (X) | Continue Verification (Enter)

eRX

Data Entry Verification

	Approved eRx	PRESCRIBED	DATA ENTERED	Rx: 0103018	FILL 00
Patient	William, Hank	William, Hank	William, Hank	Age: 39 years, 1 month	
DOB / Gender	06/02/1980 / M	06/02/1980 / M	06/02/1980 / M	Form: Tablet	
Address	34 Empire Ct Harrisville, ME	34 Empire Ct Harrisville, ME	34 Empire Ct Harrisville, ME	Pkg size: 1000 EA	
Drug	ibuprofen 600 MG Tablet	ibuprofen 600 MG Tablet	ibuprofen 600 MG Tablet	Mfg: amneal pharmace	
DAW	0	0	0	1 TABLET	
SIG	Take 1 tablet (600 mg total) by mouth 3 (three) times a day	Take 1 tablet by mouth 3 times daily	Take 1 tablet by mouth 3 times daily		
Quantity	Prescribed QTY: 90 Dispensed QTY: — Days Supply: 30	90 EA 90 EA 30	90 EA 90 EA 30		
Refills	2	2	2		
Prescriber	Doe, Bob 140 Bourne Ave Rumford, RI Phone #: (631) 444-2613 NPI #: 1122334455 DEA #: BD1597535 State Licensure: 534486500	Doe, Bob 140 Bourne Ave Rumford, RI Phone #: (631) 444-2613 NPI #: 1122334455 DEA #: BD1597535	Doe, Bob 140 Bourne Ave Rumford, RI Phone #: (631) 444-2613 NPI #: 1122334455 DEA #: BD1597535		
Sup.	Evans, Lily Phone #: (703) 212-3443 DEA #: BE9432042	Evans, Lily Phone #: (703) 212-3443 DEA #: BE9432042	Evans, Lily Phone #: (703) 212-3443 DEA #: BE9432042		
Date	Date Written: 05/09/2019 Do Not Fill Before:	05/09/2019	05/09/2019		

Select a function and press <Enter> Comments Populate Here Data Entry - Last Updated By: S. Smit

Info: Sig Lang (L) | Actions: Dose Schedule (D) | Force Counseling (F) | Delete (DE) | Reject (R) | Prescriber Request (PR) | Exit (X) | Complete Verification (Enter)

More Options (M)

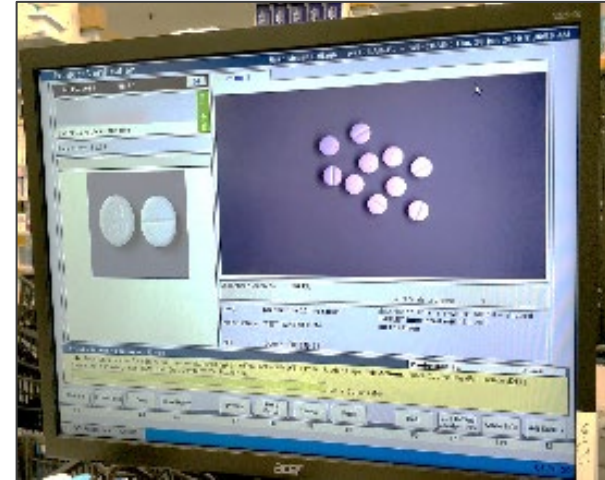
WHAT'S CHANGING?

At Production



- Technicians will take pictures of the product at production
- Technicians will bag prescriptions
- Each Production workstation will be re-arranged to accommodate the Rx Imager and newly designed counting and imaging tray, prescription bags and staplers

At Product Verification



- Pharmacists will initiate product verification from the queue instead of by label scan
- Pharmacists will perform product verification from the image captured at production from anywhere
- Pharmacists will no longer bag prescriptions

So how does it work?



RxImager Device and Counting Tray

- Take pictures of medications only.
- Take a picture of the entire dispensed quantity. The Pharmacist will need to inspect all the pills/each product, like they do during manual verification.
- Ensure the following before taking a picture:
 - The imaging tray is fully inserted into the Rx Imager
 - Pills are not overlapping or stacked on top of one another
 - The product and/or camera is not moving
 - The front door is closed
- Use the external camera to take pictures of liquids or products that do not easily fit under the internal camera.

Processing a Prescription

The technician must fulfill a Nexium prescription for Jonathon Smith

Workflow Steps:

1. Access Production Queue
2. Print Label and retrieve from inventory just as you currently do
3. Scan NDC to initiate three-step Accuracy Scan
 - ❖ Keep only one script at the production station at a time

Accuracy Scan User: Taillang Lin wks04:Alt-F1 - FUCHSIA_A_R1: Tue, 10 Mar 2020 10:29:54

SMITH, JONATHON
DOB 10/05/1971 Age 48 Years Gender Male Address 25 MAIN ST WOODSOCKET, RI 02895 Phone Number (401) 555-8989 Rx Number 0102504

1 **Manufacturer Barcode**
Scan each package

2 **Capture Product Image**

3 **Scan Bag Rx**

drug nexium 24hr 20 mg capsule
manufacturer PFIZER CONS.HLT
ndc 00573-2450-42
package size 42 EA
dispensed quantity 28 EA
expiration date 03/10/2021

Patient Prefers Amber Vial NON - SAFETY CAP Required

Select a function and press <Enter> Comment: CALL PT WHEN READY
Scan NDC or Continue (Enter), Exit (X)

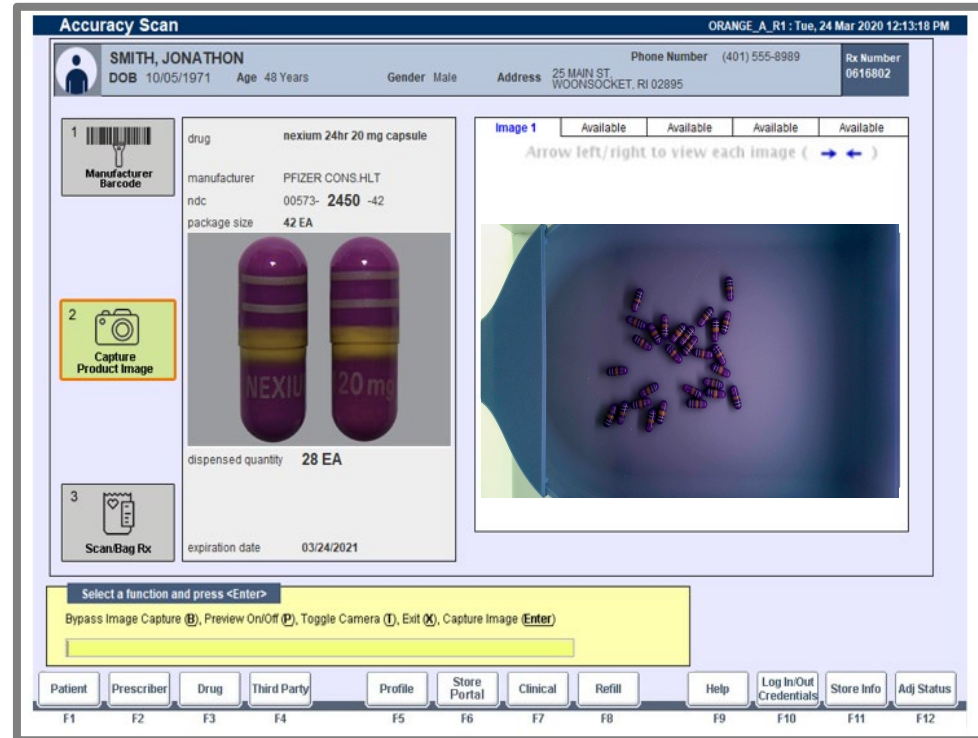
Patient Prescriber Drug Third Party Profile Store Portal Clinical Refill Help Log In/Out Credentials Store Info Adj Status
F1 F2 F3 F4 F5 F6 F7 F8 F9 F10 F11 F12

Processing a Prescription

Arrow left/right to view each image (→ ←)

Workflow Steps:

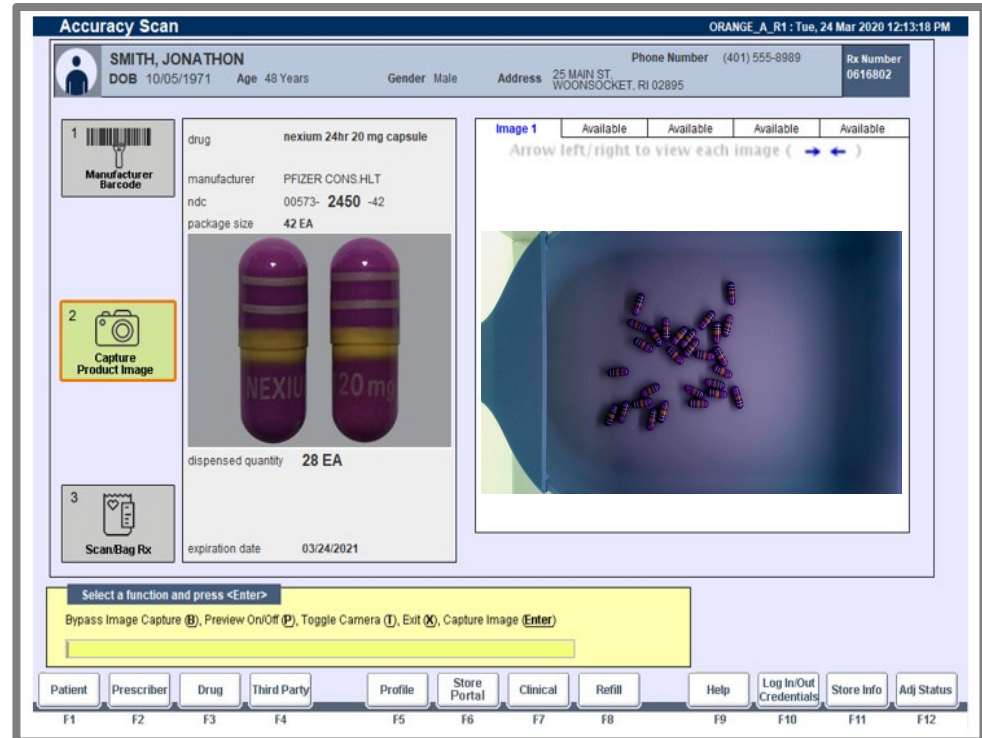
1. Pour pills on the elevated side of the tray
2. Count amount and slide pills to lower half of tray
3. Slide tray into the device
4. Press [Enter] once
 - ❖ Be careful not to hit [Enter] multiple times unless you want to take multiple images
 - ❖ In the case of multiple vials, take one image of each vial separately



Processing a Prescription

Workflow Steps:

1. The Technician reviews the image on the screen ensuring its accuracy.
2. Select a function and press [C] + [Enter] to continue processing the prescription.
3. Put the product in the vial and wrap the label around the vial.



Processing a Prescription

Workflow Steps:

1. Review the dialog box on the right hand side of the screen for Bagging Activities
2. Scan vial(s)
 - ❖ In the case of multiple vials/product, scan each one at a time, NOT one multiple times
3. Scan any additional documents
4. Places each item in the prescription bag
5. Attach the label to the bag along with any other required documents

The screenshot displays the 'Accuracy Scan' interface. At the top, it shows the user 'Tailing Lin' and the date 'Tue, 10 Mar 2020 10:38:28'. The patient information for 'SMITH, JONATHON' includes DOB 10/05/1971, Age 48 Years, Gender Male, Address 25 MAIN ST, WOONSOCKET, RI 02895, and Phone Number (401) 555-8989. The Rx Number is 0102504. The drug is 'nexium 24hr 20 mg capsule' by 'PFIZER, CONS. HLT' with NDC 00573-2450-42 and a package size of 42 EA. The dispensed quantity is 28 EA and the expiration date is 03/10/2021. The interface includes a 'BAGGING ACTIVITIES (2)' section with 'Rx Label' checked and 'Rx Vial' set to 0 scanned. A yellow callout box instructs to 'Scan each vial and place directly in prescription bag'. At the bottom, there are buttons for 'Patient', 'Prescriber', 'Drug', 'Third Party', 'Profile', 'Store Portal', 'Clinical', 'Refill', 'Help', 'Log In/Out Credentials', 'Store Info', and 'Adj Status'. A comment field contains 'CALL PT WHEN READY'.

Processing a Prescription

Workflow Steps:

1. RPH verifies prescription on-screen
2. Complete Verification [Enter]

Product Verification ORANGE_A_R1 : Tue, 24 Mar 2020 3:55:13 PM

Rx: 0616802 Fill 00 N/A

Smith, Jonathon patient
10/05/1971 48 years, 5 months

Patient Pay \$25.84





Image 1



Dispensed quantity 28 EA # of Vials scanned 1

drug	nexium 24hr 20 mg capsule	description This is an amethyst, oblong - shaped CAPSULE, DELAYED RELEASE(DR/EC) imprinted with NEXIUM 20 mg on one side
manufacturer	PFIZER CONS.HLT	
NDC	00573- 2450 -42	

Select a function and press <Enter> Production By: T. Lin

Info: Zoom (Z) | Review Data Entry (V) | Review Warnings (W) | Verified By Details (VB) | Immunization Gaps (IM) Actions: Force Counseling (F) | Delete (DE) | Reject (R) | Exit (X) | Complete Verification (Enter)

More Options (M)

Patient Prescriber Drug Third Party Profile Store Portal Clinical Refill Help Log In/Out Credentials Store Info Adj Status

F1 F2 F3 F4 F5 F6 F7 F8 F9 F10 F11 F12

How liquids are Imaged for Verification



- Image each amber bottle standing up to show medication/water fill line
- Image each stock bottle used to fill amber bottles, including:
 - NDC
 - Drug name and strength
 - Lot number & expiration date



Workflow and Recordkeeping

Workflow

- The colleague at Production can choose to bypass the new workflow if needed (in case of hardware malfunctions, or a quantity too great to image). This bypass requires the pharmacist to perform the product check manually
- Pharmacists have the option to Reject a prescription processed through this workflow and either a) send it back to Production for re-processing or b) pull the bag and perform the product check manually
- The primary products excluded from this workflow are: Schedule 2 (C2) products, immunizations, compounded medications and products too large/cumbersome to image (bowel prep, diapers, enemas, etc.)
 - We monitor for products that the majority of stores end up bypassing the majority of time to evaluate if products should be excluded.
 - Any product could be excluded by NDC, if needed.
 - Example of excluded product is Nitrolycerin tablets due to special packaging and lack of ability to image the tablets

Records

- Images captured during the workflow process (and ultimately verified by the pharmacist) are stored for 2 years
 - If an image is captured and the Pharmacist chooses to verify it the 'old way' (see: bullet 2 above) we do not store the image. This is because we want to maintain a clear trail of what the pharmacist saw and used to verify the prescription.
 - These are accessible centrally and from the Rx Image Retrieval Tool at the store
- Virtual Verification does not change our existing credentialing process or records keeping process

Virtual Verification declutters production and verification workspaces

Today



Baskets are stacked and organized to keep prescriptions in time order while awaiting Product Verification

Physical obstructions can make it difficult for Pharmacists to oversee workflow

With Virtual Verification



Prescriptions are bagged at Production and put into the Waiting Bin in batches, alleviating the clutter and anxiety that come with basket stacks

Increasing patient satisfaction

Virtual Verification simplifies the “expedite” process, resulting in an improved patient experience

Today’s process, when a patient arrives to pick up Rx waiting for RPh verification

1 Patient presents at POS or Drive Thru



2 Technician expedites Rx and notifies RPh



- 3 Pharmacist searches baskets to find Rx
- 4 Scans label and vial to start QV2
- 5 Verifies accuracy of product manually
- 6 Bags Rx and moves to Green Zone
- 7 Notifies tech / patient that Rx is ready



8 Technician retrieves Rx from Green Zone

9 Completes sale



With Virtual Verification

1 Patient presents at POS or Drive Thru

2 Technician expedites Rx and notifies RPh

3 Pharmacist verifies accuracy of product digitally



4 Technician retrieves Rx from Waiting Bin

5 Completes sale

**Increasing accountability and
quality**

Virtual Verification workflow has been designed with patient safety and quality as the number one priority and extensively studied to make sure this enhancement meets that objective. This workflow delivers multiple benefits to quality and safety to our pharmacies, including:

In workflow benefits:



Bagging Safety Scans: In an effort to advance our quality assurance processes, additional safety scans have been added. If a technician fails to perform all safety scans during bagging, the pharmacist is required to perform manual verification.



Image Review: Images enable pharmacists to easily review all loose pills in Visual Verification Tray and information on each dispensed product (e.g., expiration date, lot #).

Out of workflow benefits:






Patient Inquiry Resolution: Easy to confirm quantity dispensed with a simple image retrieval tool search (e.g., 30 vs 90, 1 box vs 3 boxes).



Potential Error Investigation Support: investigation supported through the image retrieval tool to confirm what was dispensed to the patient

In Closing: There are many sources of value of Virtual Verification

SOURCE OF VALUE		BENEFIT / IMPACT
<p>Elevate the role of the registered pharmacist</p> 	<ul style="list-style-type: none"> • Pharmacists can be closer to patients by removing the physical handling of product it frees them up to eventually spend their time giving immunizations, counseling and performing other patient care activities • Pharmacist can focus on the product verification without interruption • Improve pharmacist satisfaction and allow them to participate in a more patient centered health care model 	
<p>Increase patient satisfaction</p> 	<ul style="list-style-type: none"> • Simplifies the expedite process for a more seamless patient experience • Also provides a cleaner look to the pharmacy production area by removing the stacks of baskets 	
<p>Increase accountability and quality</p> 	<ul style="list-style-type: none"> • Additional bagging scans that must be performed to ensure accuracy • We are already working on AI capabilities that will use the captured image to detect potential errors like co-mingling and quantity discrepancies 	

May 26, 2021

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd., Suite 106
Sioux Falls, SD 57106

Re: Consideration of AMICUS to Perform 503B Inspections

Dear Ms. Shanard-Koenders,

On behalf of AMICUS GMP Consultants, LLC ("AMICUS"), we respectfully request consideration by the South Dakota Board of Pharmacy ("Board") to recognize and approve AMICUS as a qualified contractor to perform inspections of 503B outsourcing facilities applying for licensure as a (resident or non-resident) Outsourcing Facility Distributor with the Board. The contractual and financial relationship for such inspections will transpire specifically between AMICUS and the license applicant. The Board will hold no contractual or financial obligation within this inspection process. This letter and accompanying documents serve to provide detailed information regarding AMICUS ownership, qualifications of inspectors, and the inspection approach utilized. AMICUS welcomes the opportunity to answer questions from the Licensing Committee and/or the Board at upcoming meetings.

My name is Becca Mitchell and I am the Director of Quality and Regulatory for AMICUS. Kristopher Le, the CEO and Principal Consultant for AMICUS, is a 2010 Doctor of Pharmacy graduate of The University of Florida College of Pharmacy. Dr. Le co-owns AMICUS, along with Jun Fabella, Russel Odegard, and Michael Pruett who are silent partners. Originally a division of Dynalabs, AMICUS is now an independently owned, private company that provides full-service consulting services in the 503B outsourcing and pharmaceutical manufacturing industries. We perform compliance audits, assist with compliance remediation, and provide validation services to FDA-registered entities across the country. The AMICUS team works with state boards of pharmacy nationwide and with FDA, including drafting and implementing Compliance Master Plans submitted to FDA for remediation of firms under consent decree. AMICUS also provides on-site auditing services of drug substance (API) manufacturers and analytical testing laboratories for clients.

All AMICUS inspections of drug product compounding or manufacturing facilities are performed by not less than two AMICUS employees, at least one of whom is a pharmacist. The three principal consultants are Dr. Kristopher

Le, Don Carter, and myself. A brief synopsis of the qualifications for each is provided below, and CVs are attached for a more thorough review.

- **Kristopher Le, PharmD; CEO & Principal Consultant** – Experienced executive with over 10 years in the pharmaceutical compounding and manufacturing industries; was the Director of 503B Operations and Pharmacist-in-Charge for Nephron Pharmaceuticals and responsible for the first 503B inspection by FDA that yielded zero Form 483 observations. Dr. Le is currently a licensed pharmacist in nine states.
- **Don Carter, Director of Validation** – For almost 15 years, Mr. Carter has worked in engineering, validation, and formulation development with GMP-compliant firms. He has a degree in Science and Chemical Technology and brings a wealth of hands-on experience and technical expertise to the AMICUS team. Mr. Carter focuses on equipment and facility design and qualification, process validation, and drug product development strategies.
- **Becca Mitchell, PharmD; Director of Quality and Regulatory** – a 2008 graduate of the University of Arkansas for Medical Sciences College of Pharmacy, Dr. Mitchell has over a decade of experience in 503A and 503B compounding and is currently an appointed member of the Arkansas State Board of Pharmacy. During her tenure as Pharmacy Director and then VP of Quality and Regulatory for US Compounding, Inc., Dr. Mitchell hosted over 40 audits from state boards of pharmacy, FDA, DEA, and PCAB/ACHC. Dr. Mitchell is currently a licensed pharmacist in 17 states.

AMICUS employs a six-systems approach very similar to the inspection methodology outlined in FDA's Drug Manufacturing Inspection Compliance Program. Firms are inspected for effective, compliant quality systems that include adequate description of management responsibility, appropriate resources, control of production operations, and continuous improvement evaluation. Audits are conducted on-site, generally over not less than two (2) days. The audit team tours the facility, including visual observation of material receipt & storage, sterile and non-sterile manufacturing, visual inspection, labeling, packaging, and distribution. A thorough review of the firm's Quality Systems is performed to ensure the firm's training program, document control, vendor oversight, batch review and disposition, product complaints, environmental monitoring, and other quality assurance functions are compliant with industry standards. Production controls including contamination control, gowning, personnel and aseptic process qualification, and equipment qualifications and calibrations are evaluated. Written policies and procedures are compared to executed documents for assessment of compliance.

At the conclusion of each inspection, the audited firm is provided with a written report of findings, including assessment of severity and references to specific industry guidance or statutory requirements. When conducted

on behalf of a client as part of due diligence, AMICUS provides a comprehensive audit report that summarizes the company operations, details the audit observations, and assesses the overall compliance of the firm to the stated expectations applicable to the audit. Because of its varied experience with both traditional drug manufacturing and 503B outsourcing facilities, AMICUS is well-suited to provide effective, meaningful inspections of drug manufacturer permit applicants that balance the necessity of compliance with preserving patient access and prioritizing patient safety.

The following documents* are provided along with this letter for Committee consideration:

- AMICUS Ownership Disclosure*
- Consultant CVs
- Sample Audit Agenda*
- Sample Audit Report (redacted)*
- Sample Audit Checklist (Auditor Use Only, redacted)*

**These documents contain confidential & proprietary information; please do not share to the general public.*

In closing, AMICUS has the experience, expertise, and availability to conduct audits that can be submitted to the Committee for review when an applicant has not timely received an FDA inspection, to provide the Committee with a mechanism to assess candidates for licensure or licensure renewal. It would be a sincere honor to collaborate with the Committee and its current inspection staff in this capacity. We appreciate your consideration of AMICUS and look forward to answering any questions Board staff, Committee members, or Board members have during an upcoming meeting.

Respectfully,



Becca Mitchell, PharmD, FAPC
Director of Quality and Regulatory

Cc Kristopher Le, PharmD
AMICUS CEO & Principal Consultant

Enclosures



amicus.

GMP Consultants

Audit Agenda

cGMP 6 Systems

cGMP 6 Systems Audit

Site Name	[Site Name]
Site Address	[Site Address]
Audit Dates	[DD-DD Month YYYY] 0900 – 1630 (Day 1), 0900 – 1630 (Day 2), 0900 – 1630 (Day 3)
Auditors	Kristopher Le, PharmD. <i>AMICUS CEO & Principal Consultant – Lead Auditor</i> Becca Mitchell, PharmD. <i>AMICUS Director of Quality & Regulatory – Co-auditor</i>
Site Host(s)	[Host Name], [Host Title]
Products/Services Provided	GMP sterile drug product compounding/repackaging, packaging, labeling, storage, testing, release, and distribution.

PURPOSE & SCOPE

The purpose of this audit is to perform a review of the procedures, process and systems in place at the [Site Name] facility located at [Site Address] and evaluate compliance with current Good Manufacturing Practice and company internal procedures as applicable to FDA Registered 503B Outsourcing Facilities. The audit focuses on the aseptic production of sterile compounded drug products, facility and equipment controls for compounding/repackaging, release and stability testing, receipt, storage, labeling and packaging, distribution and the quality systems supporting these processes, including:

- Management Controls
- Quality Systems and Compliance
- Oversight of Laboratory Controls
- Material Management

The audit will be conducted to the standards of cGMP as per the following:

- 21 CFR Parts 11, 210, 211, and 820
- ICH Q10 Pharmaceutical Quality System
- Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry (Draft, December 2018)
- [Site Name] Internal Policies and Procedures

Audit Agenda - Day 1

Item #	Description	Leader (Time)
1	Welcome and Introduction <ul style="list-style-type: none"> • Introductions • Review of agenda • Opening Presentation including Facility Layout and Organizational charts - [503B] 	All (30 min)
2	Facility Tour <ul style="list-style-type: none"> • Warehouse • Production Areas • Labeling/Packaging 	[Site Name] (~ 2 h)
Break for lunch – may be a working lunch		60 min
Review SOPs, Policies, Guidelines, Work Instructions – Specific list of documents will be provided the morning of the audit (if an SOP Table of Contents is provided in advance); however, please include the following: <ul style="list-style-type: none"> • Master Equipment Validation Plan (Please have available) • Cleaning Validation (Please have available) • Environmental Monitoring (Please have trending and reports available) • Pest Control (Please have reports available) • Quality and Supplier Agreements (Please have available) 		
4	Production Controls <ul style="list-style-type: none"> • Warehousing <ul style="list-style-type: none"> • Receiving and Sampling • Storage Facilities, including Document, Stability and Retain/Reserve • General facility control <ul style="list-style-type: none"> • Back-up generators • Water System(s) • Contamination control • Area/line clearance • Labelling controls & operations 	Becca Mitchell, PharmD.
5	Validation Controls <ul style="list-style-type: none"> • Validation policy & procedure(s) <ul style="list-style-type: none"> • Qualification/validation master plan for [Site Name] facility, computer, equipment, process and cleaning • Cleaning Validation 	Kristopher Le, PharmD.
6	Equipment & Facility Controls – Production & Lab <ul style="list-style-type: none"> • Cleaning & use logs • Preventive maintenance • Calibration and qualification • Cleaning verification process and calculations • Temperature Mapping 	Becca Mitchell, PharmD.
8	Quality Release <ul style="list-style-type: none"> • QC release system including COA • QC data review • Specifications 	Kristopher Le, PharmD.
9	End of Day 1	All

Audit Agenda - Day 2

Item #	Description	Leader (Time)
1	<p>Observation</p> <ul style="list-style-type: none"> • Gowning • Aseptic Manufacturing / Compound Process <ul style="list-style-type: none"> ○ Formulation, Sterilization, Primary Packaging ○ Environmental and Personnel Monitoring <p>Environmental Monitoring (EM)</p> <ul style="list-style-type: none"> • EM-Performance Qualification (PQ) • EM Data Collection and Trending • Review of EM results, sampling techniques, incubation, enumeration, training, etc. • QC Release of EM Materials 	Kristopher Le, PharmD. (2-3 hours)
2	<p>Quality Systems</p> <ul style="list-style-type: none"> • Internal audit • Evaluation of compounding and laboratory changes, deviations, and trends • Review of equipment maintenance investigations, and related manufacturing investigations. • Review of process validation and associated changes • Equipment maintenance, calibration, and equipment performance • Sampling, testing, and evaluation of components (including APIs), in-process materials, for release. 	Becca Mitchell, PharmD. (2-3 hours)
Break for lunch – may be a working lunch		60 min
3	<p>Observation</p> <ul style="list-style-type: none"> • Gowning • Aseptic Manufacturing / Compound Process <ul style="list-style-type: none"> ○ Formulation, Sterilization, Primary Packaging 	Becca Mitchell, PharmD. (2-3 hours)
4	<p>Quality Systems</p> <ul style="list-style-type: none"> • Method validation (Identification tests; Quantitative tests for impurities' content; Limit tests for the control of impurities) • OOS • Evaluation of specification and BUDs • Production records and documentation (review of data integrity) 	Kristopher Le, PharmD. (2-3 hours)
5	End of Day 2	All

Audit Agenda - Day 3

Item #	Description	Leader (Time)
1	Observation <ul style="list-style-type: none"> Gowning Compounding Aseptic Packaging	Kristopher (2-3 hours)
2	Quality Systems <ul style="list-style-type: none"> Internal audit Evaluation of compounding and laboratory changes, deviations, and trends Review of equipment maintenance investigations, and related manufacturing investigations. Review of process validation and associated changes Equipment maintenance, calibration and equipment performance Sampling, testing, and evaluation of components (including APIs), in-process materials, for release.	Becca (2-3 hours)
Break for lunch – may be a working lunch		60 min
3	Observation <ul style="list-style-type: none"> Gowning Compounding Aseptic Packaging	Becca (2-3 hours)
4	Quality Systems <ul style="list-style-type: none"> Method validation (Identification tests; Quantitative tests for impurities' content; Limit tests for the control of impurities) OOS Evaluation of specification and BUDs Records and documentation (review of data integrity)	Kristopher (2-3 hours)
5	End of Day 2	All

Please provide, (if not already provided) the provision of the following items to further enhance our understanding of your systems and procedures currently in place.

- Copy of the organizational chart
- List of all policies and SOPs (Table of Contents format is acceptable)
- Facility floor plan (including all areas as applicable: material receiving and storage, material preparation and cleaning areas, compounding, aseptic fill finish/packaging, visual inspection, labeling)
- Copy of your Quality Manual (if available) and Site Master File (SMF)
- Copies of any licenses (if not already included in the SMF)
- Pest Control reports
- List of audits from Health Authorities in the US, dates and any audit observations and conclusions

Have prepared the following:

- SOP binders
- Environmental monitoring reports including utilities monitoring for the previous 4 quarters
- Batch production records for product including all prior steps
- Maintenance records for process equipment used in drug product compounding
- List of deviations and OOS (including other non-product related such as not following the SOP, equipment maintenance issue, utilities or environmental monitoring alerts/action limits exceeded).

Spring Meds Inc.

Springmeds Inc. operates a website Springmeds.com that displays prices for all its products.

Patients go on to the Springmeds.com website and place their order for either a prescription medication or an OTC product. These orders are filled by one of two pharmacies. Currently Healthwarehouse in Florence, Kentucky fills most of the orders. The other pharmacy is HRX Pharmacy in Holladay, Utah. Healthwarehouse is licensed or authorized to ship to all fifty U.S. states. HRX pharmacy is only licensed in 20 states. If an order comes in for a prescription product on Springmeds.com, Healthwarehouse will contact the patient's doctor or their pharmacy then fill and ship the order. The dispensing pharmacy will then provide Springmeds.com with a tracking number. Springmeds.com will bill the patient and send the patient their tracking number. If the patient orders an OTC product we will send some of those orders to HRX to ship out, but most will be shipped from Healthwarehouse.

We are planning on opening a pharmacy in Sioux Falls that will provide service for Springmeds.com. The website www.springmeds.com is a separate business from the Sioux Falls pharmacy. We are looking to open the pharmacy in September 2021. We would hire a pharmacist and a technician and have them work an eight hour shift, 9-5 Monday to Friday. The Sioux Falls pharmacy would manage the orders placed on the Springmeds.com website. They would confirm the order with the patient and acquire the prescription. This would be done by contacting the patient's doctor for a new prescription or the patient's pharmacy for a prescription transfer. Alternatively, the patient could mail in their original prescription or if appropriate we would refer them to a telemedicine provider. Once a valid prescription is received, Sioux Falls Pharmacy would defer the prescription. The dispensing pharmacy would be selected based upon if that pharmacy is licensed in the patient's state and the level of service the pharmacy is able to provide for that order. The prescription would then be transferred to that pharmacy with detailed order instructions. The dispensing pharmacy would send notification to Springmeds.com that the order has been shipped along with the tracking number. Springmeds.com would then bill the order and send a confirmation email to the patient informing them that their order has been shipped and provide them with that tracking number.

The Sioux Falls pharmacy would over time get licensed in all states and dispense all medications from Sioux Falls for Springmeds.com.