

SD Board of Pharmacy Meeting Minutes
Friday, December 8 2017; 8:00 a.m. CST
South Dakota Board of Nursing Conference Room
4305 S. Louise Ave., Suite 201, Sioux Falls, South Dakota 57106

Board Members Present: President Diane Dady, Tom Nelson, Lenny Petrik, Lisa Rave, and Dan Somsen

Board Staff Present: Executive Director Kari Shanard-Koenders; PDMP Director Melissa DeNoon, Inspectors Gary Karel, Paula Stotz, Carol Smith; Secretary Beth Windschitl.

Attendees Present: Justin Manning, Brenda Jensen, Sue Schaefer, Amanda Bacon, Scott Setzepfandt, Cheri Kraemer, Jessica Harris, Amanda McKnelly, Joel Kurzman, Bill Ladwig, and Michael Burns

A. Call to Order and Introductions

The meeting was called to order by President Dady at 8:03 AM CST. Diane read the Board of Pharmacy mission statement, followed by introductions of Board Members, Board Staff and audience attendees. Roll call was taken; a quorum was present.

B. Consent Agenda

Executive Director Shanard-Koenders briefly reviewed the components of the consent agenda noting that any item could be removed from the consent agenda for discussion. Motion to approve consent agenda was made by Board Member Lisa Rave and seconded by Board Member Dan Somsen. Motion carried; Diane Dady-aye, Tom Nelson-aye, Lenny Petrik-aye, Lisa Rave-aye, and Dan Somsen-aye.

C. Staff Reports

1. Recognition / Staff Report

- I. Congratulations to Cheri Kraemer the first recipient of ACHC/PCAB Distinction in Hazardous Compounding
- II. Carol Smith completed the Critical Point Certificate in Sterile Compounding for Inspectors (CISCI)
- III. Secretary Jessica Neal has rescinded her resignation and will continue working for the Board of Pharmacy
- IV. Inspector Gary Karel will retire January 8, 2018. He has been an exemplary inspector sharing his vast knowledge and expertise with staff, peers, and industry personnel for over six years. He will be greatly missed. The position has been posted seeking an individual with both hospital and retail experience.

2. Inspector Reports

a. Gary Karel

Gary noted the following items in various pharmacies:

- PIC with professional license expired, a misdemeanor in the State of South Dakota; Executive Director sent a letter to pharmacist.
- Multiple places assessing USP 800 Guidelines and working on becoming compliant.
- Still have PIC's that have not taken any steps to inform staff about NIOSH 2016 document.
- Hood tested in a location and report stated "corrective action required". After discussion with PIC, a new hood was ordered.
- Documentation of cleaning records incomplete.
- Found SDV of medication that was punctured, not dated still in refrigerator.
- High Risk Policy should be updated annually

- Found bulk vial of antibiotic that was reconstituted and frozen in refrigerator. Temperature of refrigerator was 29 degrees.
- Multiple outdated antibiotics in refrigerator made in Accuflow devices and other outdates in other facilities.
- Multiple dose vials opened but not dated with 28-day dating.
- Hospital forgot to count all controlled substances in the entire facility. They only counted controlled substances in the Pharmacy Department.
- Acute Care facility sign agreement to review pharmacy orders after hours.
- IV Room that was built with windows in Hazardous Room, Anteroom and Non-Hazardous Room got contractor to fix (enclose) windows.
- Hospital pharmacy working on getting ceiling tiles caulked.

b. Carol Smith

Carol noted the following items during inspections:

- Attended four days at Critical Point; completed 33 modules of critical _____ and nine math modules.
- Is monitoring Tramadol when inspecting; seeing miscounts, however, one facility dispensed 38,000 tablets and were only 10 short after audit.
- Filling Suboxone – not being caught at fill and review point.
- Found a facility using refrigerator for medication and food storage.

c. Paula Stotz

Paula noted the following items:

- Controlled substance audits usually very close to exactly right on, several instances where the on hand amount is long – possibly due to nursing home billing cycles.
- Some pharmacies have implemented USP 800 already, several pharmacies are waiting for their corporate entity to come up with the policies and procedures. PICs can begin developing a list of drugs handled in their particular pharmacy, and identifying hazardous drugs to begin informing pharmacy staff of special handling requirements.
- One LTC pharmacy was not getting prescriptions, (drug, quantity, sig and any refills) but rather getting prescriptions from the LTC facility – no quantity, or refill information.
- Critical Access hospital installed new isolator and had the isolator certified but did not perform the required Gloved Fingertip Sample (GFS) or Media fills prior to using the isolator.
- A physician was using the NADEAN (Narcotics Addiction DEA Number) waiver and not intending to become a Narcotic treating provider.
- Discussed with PICs, Controlled substance prescriptions that are received via fax and appear with VOID or Invalid Rx – are not valid prescriptions, the pharmacist needs to call and verify the prescription as a telephone order, or are they to obtain the original prescription from the patient, was the prescription shredded or placed in the patient's medical record, document who they spoke to along with the date and their initials.

3. PDMP Report

Director Melissa DeNoon reported the following PDMP updates:

- Reviewed PDMP prescriber mandate registration statistics – enrollment levels are high (95% of required prescribers have access to PMP AWA RxE) and focus will now shift from registration to utilization and pharmacy submission compliance.
- AWA RxE has new reporting capabilities with the introduction of Tableau; platform offers expanded analytics providing prescriber and therapeutic drug class specific drilldown reporting opportunities.

- Format of AWARxE platform changed on November 12, 2017.
- Sanford integration is on hold. Integration funding, from the 2016 Harold Rogers Grant, maybe reallocated to assist with Regional Health's EHR/ SD PDMP Integration.
- The Board sponsored MedDrop Drug Take-Back Program is underway with receptacles in two locations in the State, upcoming installation sites include Webster, Pierre, Martin, Sioux Falls, and DeSmet; and additional sites are being identified. Program goal was to place one receptacle in each county; however, some counties' dynamics made the objective unachievable.
- Current grant funding covers initial implementation costs for 15 sites (one receptacle and two collection bundles).
- The Harold Rogers 2016 Grant funding ends September 30, 2018. Identifying a dedicated, sustainable funding source for the Prescription Drug Monitoring Program is a Board priority. One way to increase funding is to raise licensing fees. Some States use controlled substance (CS) registrations fees to fund PDMP. In these States, CS registration is completed by the State's Board of Pharmacy.
- Reviewed upcoming PDMP related calendar events.

A. Complaints, Investigations, Disciplinary Actions, Loss/Theft Report

The following were reported by Gary Karel, Carol Smith, and Paula Stotz. Discussion followed.

1. Hy-Vee (Marion Road) in SF: DEA106
2. Walmart in Vermillion: Complaint
3. Hy-Vee (Sycamore) Forged Prescription
4. Flandreau Santee Sioux Tribe Clinic Pharmacy: DEA 106
5. Shopko Pharmacy in Sisseton: DEA 106
6. Sanford USD Medical Center: DEA 106

E. SD Pharmacists Association Update – Amanda Bacon, Executive Director

SDPhA Executive Director Amanda Bacon submitted the Activity and Financial written reports in the packet and briefly reviewed the following topics:

1. Newly elected Association Officers
2. 2017 Convention award winners
3. List of activities/events pharmacists might offer to celebrate American Pharmacists Month in October.
4. National legislative efforts
5. SDPhA Rebranding – website and social media
6. Pharmacy Technician University (PTU) – new contract with entity; Association serves as PTU program administrator (sets up logins and enrolls users); 12 individuals per group, cost to technician \$325.00. Fills a need for individuals who are not geographically near a State sponsored certification program.

F. Other Reports

1. SDSU College of Pharmacy – Dr. Jane Mort, Pharm D, Acting Dean

College of Pharmacy and Allied Health Professions Department Board Executive Director Shanard-Koenders reviewed the written report provided.

2. SD Health Professionals Assistance Program – Amanda McKnelly, MS, LAC

- No cost increases in 2018
- HPAP has implemented a survey of participants who successfully complete their program.
- The Board of Medicine did not renew their HPAP contract opting instead to launch an "internal monitoring" program.
- HPAP currently serves 135 participants throughout the state and recently added a new staff member to cover West River and Central South Dakota.
- Individuals now have immediate access to HPAP services; there is no longer a wait list.
- Provided HPAP utilization statistics for SD Board of Pharmacy participants and total participants.

3. SD Society of Health System Pharmacists – Jessica Harris, Pharm D, BCPS

- Live CE
- Dakota Night – total attendance 25,000

4. SD Association of Pharmacy Technicians – Jerrie Vedvei, CPhT - Invited

G. Old Business

1. USP <797> proposed revisions – Update – Gary

Briefly reviewed handout content noting:

- September/October, 2018 was the second public comment period for USP <797>.
- Want to avoid a third public comment period as new committee members will have been installed.
- Official rollout of both USP <797> and USP <800> is slated for December 1, 2019.
- Two sections of the Chapter documents (Segregated Compounding Area – SCA and Low Volume Hazardous Drug Compounding) conflict (question no.6 in handout). In this circumstance, the NABP has indicated they will defer to the Board's position on topic.

2. USP <800> and NIOSH 2016 – Paula

- USP <800> official date extended to 12/01/2019 to coincide with USP <797>.
- Pharmacies should not wait for the final document to begin implementation. Pharmacies should review current NIOSH 2016 hazardous drugs list; compile list of hazardous drugs the pharmacy receives, handles, stores, dispenses; perform an Assessment of Risk for hazardous drugs; use proper personal protective equipment, develop policies and procedures for hazardous drug (receiving to dispensing). USP 800 requires a four-step disinfecting process. Each hazardous drug may have a specific cleaning protocol to achieve tray decontamination/deactivation.
- Attended the NABP/FDA Interactive Compliance and Legal Forum held November, 2017. Day 1 topics included Federal requirements for compounding drugs, how the FDA conducts inspections of 503A and 503B facilities and current Good Manufacturing Practices (cGMP). Day 2 focused on outsourcing facility inspections, identifying insanitary conditions and key (cGMP) violations. Day 3 State Panel discussions on USP <797> and <800> inspecting up to standards

3. Office Software

- Continue to review Requests for Proposal (RFP)
- All vendors have similar project implementation timelines (seven to nine months) extending the proposed start date in Fall 2018

4. Hy-Vee Technician Product Verification (TPV) fka Tech-Check-Tech Program

The following was reported by Justin Manning as part of the quarterly update for Sioux Falls Store #4.

- Staff trained - 2 Technician and 1 Pharmacy intern. New full-time technician started in September, continues to train, and has performed no product verification
- Scripts verified by TPV totaled 164 (for September, October, and November).
- Quality verification entered on error to test; error was detected/caught by technician
- TPV is for new and refill prescriptions
- A handout highlighting MTM, immunization, and labor numbers was provided.

Justin Manning requested a new variance, identical to the variance approved by the Board for Hy-Vee Store #4, which allows a certified pharmacy technician/intern to complete final verification of a filled prescription or medication (new and refilled). The new variance would be for Hy-Vee Sioux Falls Store #3 at 3000 S Minnesota Ave and #5 at 3020 E. 10th St and be granted for a length of one year with an option to reapply to

continue the program. Three TPV store locations will provide an opportunity to garner best practices between the sites.

Lisa Rave a motion to approve the variance with a quarterly progress reporting requirement beginning June, 2018. 2nd –Tom Nelson. Motion carried; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik–aye, Lisa Rave–aye, and Dan Somsen–aye.

5. Report on Alchermes/Aristada Pilot Project Minnehaha County Jail – David Bain
Not in attendance

H. New Business

1. InstyMeds Medication Adherence System (IM-MAS), Michael Burns, R.Ph., InstyMeds VP Pharmacy Services
 - An informational presentation / overview of IM-MAS.
 - System is designed to address medication nonadherence as 24-31% of prescription orders written by *Providers* are not filled by patients.
 - Discussed the rationale for utilization in South Dakota hospitals, emergency rooms, urgent care, medical clinics and retail settings; technology can fill the need/gap in rural areas and after hours when pharmacies close.
 - InstyMeds is for first fill acute care only; machine would be located within the provider's facility at a monthly rental cost of \$1,500 - \$1,700.
 - Minnesota has 140 InstyMeds units in hospitals and urgent care sites.
 - South Dakota law allows Prescriber dispensing. South Dakota Board of Pharmacy would license the machine as a pharmacy.

2. Rapid City Regional Asteres Scriptcenter Request – Scott Peterson (not in attendance)
 - Formal request to allow Regional Health Home Plus Pharmacy to place *controlled substance prescriptions* in Asteres Scriptcenter remote pick-up/drop sites for retrieval by patients.
 - The Asteres Scriptcenter is a pick-up site not a dispensing location as all actions of dispensing occur at the pharmacy before the completed prescription is placed in the Scriptcenter.
 - Attendees discussed concerns regarding potential Scriptcenter locales – gas stations, café, etc.... Counter discussion focused on the huge service potential to rural patients and greater security vs. sending controlled substances through the mail.

Dan Somsen made a motion to revise the Board's current policy statement regarding pick-up/drop sites to allow for controlled substance prescription dispensing. 2nd –Lisa Rave. Motion carried; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik–aye, Lisa Rave–aye, and Dan Somsen–aye.

3. Proposed Licensure Compact Bill Discussion
 - In an effort to remove barriers so individuals who move the state can get to work quicker, Governor Daugaard is proposing a licensure compact for all license types in the State of South Dakota
 - Proposal would grant individuals an 18 month temporary license to practice
 - No profession is allowed to opt-out of the compact
 - The idea of a Licensure Compact that includes Pharmacists elicited great concern from attendees whose professional focus is patient safety.
4. Update of Prescribing Authority Document
 - Executive Director Shanard-Koenders briefly reviewed the Prescribers and Prescribing Authority document included in the Board Meeting packet. Document is also posted on the Board website.
5. Pharmacy Technician University and SDPhA – Amanda Bacon

- See Section E of Board Meeting Minutes
6. Proposed Biosimilar Legislation Discussion – Scott Setzepfandt, R. Ph., Genentech Company
- Review of biosimilar legislation being crafted for proposal and consideration during the 93rd legislative session.
 - Biosimilars are a new area not currently taught in pharmacy curriculum. They are biologic substitutions, are a different product and not identical to the original biologic.
 - The proposed legislation has been vetted by all interested parties and has passed in 39 states including Minnesota and Iowa.
 - The terms biologics and interchangeable biologics need to be defined in law.
 - Proposed legislation allows pharmacists to substitute biosimilar interchangeable injectable automatically without getting prescriber permission before substitution. Pharmacist meets the communication requirement threshold when they fill it and bill it.
 - Mr. Setzepfandt is asking pharmacists to provide feedback to the Department of Health regarding the proposed legislation.

J. Other Business Future Board Meeting Dates

1. Recent Meeting News

- i. 2017 FDA Intergovernmental Meeting on Compounding – September 25-27, 2017
 - Executive Director Shanard-Koenders briefly reviewed handout “What are information sharing /20.88 agreements”
 - FDA would like Boards of Pharmacy to provide a list of compounding pharmacies in their state; Advantage – if a critical / adverse event occurs, Board would have access to FDA’s information; Disadvantage – Board would have to provide any/all information requested by the DEA.
- ii. DEA Pharmacist Diversion Awareness Conference – October 1, 2017
- iii. NABP Interactive Executive Officer Forum – October 3-4, 2017
- iv. National Assn of State Controlled Substance Authorities – October 16-20, 2017
- v. Critical Point Boot Camp, October 24-27, 2017
- vi. NABP/FDA Interactive Compliance and Legal Officer Forum – November 28-30, 2017

2. Future Board Meeting Dates

- i. March 22, 2018 - Sioux Falls, in conjunction with SDSHP, Location TBD
- ii. June 8, 2018 – Sioux Falls, Location TBD
- iii. September 20, 2018, Sioux Falls, in conjunction with SDPHA, Location TBD
- iv. December 7th or 14th, 2018???? Location TBD

3. Future Meetings

- i. DEA Annual Diversion Conference, December 12-13, 2017, Dallas, TX
- ii. SDSHP 2018 Annual Meeting, March 23-24, 2018, Sioux Falls, BW Ramkota
- iii. NABP Annual Meeting, May 5-8, 2018, Hyatt Regency Denver

K. Executive Session: per SDCL 1-25-2; legal issues

- Tom Nelson motioned to move to go into Executive Session
- The Board members came out of Executive Session and went back into Regular Session

L. Adjourn

Adjourn at 1:10 PM MST – Motion to adjourn made by Board Member Lisa Rave, seconded by Board Member Lenny Petrik. Motion passed; Diane Dady–aye, Tom Nelson–aye, Lenny Petrik-aye, Lisa Rave-aye, and Dan Somsen–aye. Meeting adjourned.

LICENSE SUMMARY

Sept 1, 2107 – Nov 30, 2017

PHARMACISTS

2051 Current Total

19 New Licensees for period

License #	Prefix	Last Name	First Name	City	State
6543		BAHNSON	KAYLYN	GILLETTE	WY
6530		BALDWIN	ALI	BLOOMFIELD	NE
6531	R	BOMMERSBACH	LORI	GRAND FORKS	ND
6546	R	DEBUHR	DAVID	WEST FARGO	ND
6532		HANSON	STEPHANIE	SIOUX CITY	IA
6529	R	HARDY	KIMBERLY	GEORGETOWN	TX
6544		JORGENSEN	THOMAS	SIOUX FALLS	SD
6528		LARSON	KERRI	GARY	SD
6540	R	MAHMOOD	NABIHA	OAK BROOK	IL
6536	R	MEYER	SHELLEY	WHITEWOOD	SD
6537	R	MORELAND	DESIREE	MERRIMAN	NE
6541	R	PHAN	WILLIAM	TWENTYNINE PALMS	CA
6542	R	REJOUR	NANCY	ORLAND PARK	IL
6539	R	RICHTER	PAMELA	RAPID CITY	SD
6545	R	SEO	HUI	HIGHLAND	MD
6535	R	SIDDIQUE	SHAN	CHICAGO	IL
6533	R	TORRES	HELENA	SIOUX FALLS	SD
6538		VOS	ALEXANDER	MIDDLETON	WI
6534	R	WAGNER	STACEY	MITCHELL	SD

PHARMACY INTERNS

396 Current Total

86 New Registrations for period

FULL-TIME PHARMACY PERMITS

260 Current Total

0 New Pharmacy Permits for period

PART-TIME PHARMACY PERMITS

57 Current Total

0 New PT Pharmacy Permits for period

TECHNICIAN REGISTRATIONS

1679 Current Total

93 New Registrations for period

WHOLESALE PERMITS

1290 Current Total

21 New Permits for period

NON-RESIDENT PHARMACY PERMITS

773 Current Total

27 New Permits for period

Pharmacy Name	Address	City	State
A&K PHARMACY, LLC	7200 BROADWAY	NORTH BERGEN	NJ
BIOLOGICS INC	11800 WESTON PKWY	CARY	NC
BIOTEK REMEDYS	2 PENNS WAY, STE 404	NEW CASTLE	DE
BRILLIANT PHARMACY INC	15271 SOUTHWEST FREEWAY	SUGAR LAND	TX
CENTRO PEDIATRIC PHARMACY, LLC	7200 GLENVIEW DR STE 1	N RICHLAND HILLS	TX
CURERX	5060 W SUNSET BLVD STE C	LOS ANGELES	CA
EXPRESS VETERINARY PHARMACY	833 N COOPER RD STE 104	GILBERT	AZ
FOUNTAIN PLAZA PHARMACY	2825 W ANDREW JOHNSON HWY	MORRISTOWN	TN
GATEWAY HEALTH MART PHARAMCY MANDAN	500 BURLINGTON ST SE STE 2	MANDAN	ND
GATEWAY HEALTH MART PHARMACY NORTH	3101 N 11TH ST STE 2	BISMARCK	ND
GATEWAY HEALTH MART PHARMACY SOUTH	835 S WASHINGTON ST STE 2	BISMARCK	ND
GRASSO ENTERPRISES, LLC	31007 IH 10 WEST #108	BOERNE	TX
HCP PHARMACY, LLC	10694 JONES RD, STE 115	HOUSTON	TX
KNIPPERX INC	1250 PATROL RD	CHARLESTOWN	IN
L & M PHARMACY CARE	22 1ST ST NE STE A	LE MARS	IA
MCHUGH DRUGSTORE LLC	70 S MADISON ST	CARTHAGE	IL
MEDMINDER SYSTEMS INC	30 WEXFORD ST	NEEDHAM	MA

NEWSOM FAMILY PHARMACY LLC	9661 STRONG HWY	STRONG	AR
ONE WAY DRUG LLC	5835 S EASTERN AVE	LAS VEGAS	NV
ORPHAN PHARMACY SERVICES LLC	125 MICHAEL DR STE 106	SYOSSET	NY
OVER THE MOUNTAIN COMPOUNDING	4268 CAHABA HEIGHTS CT STE 103	BIRMINGHAM	AL
PHARMACY INNOVATIONS LLC	715 GARFIELD ST	TUPELO	MS
PRECISION COMPOUNDING PHARMACY INC	15722 W CENTER RD	OMAHA	NE
STERLING RX INC	1312 NORTHLAND DR	MENDOTA HEIGHTS	MN
THE NEBRASKA MEDICAL CENTER BELLEVUE PHARMACY	2510 BELLEVUE MEDICAL CENTER DR #100	BELLEVUE	NE
VANDERBILT UNIVERSITY MEDICAL CENTER	726 MELROSE AVE	NASHVILLE	TN
WALGREEN CO	2608 E COLFAX AVE	DENVER	CO

REVENUE REPORT BY MONTH

REVENUE REPORT BY MONTH													
	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	YTD FY17
Wholesale	1,000	6,200	1,200	0	38,800	140,600	45,400	15,000	7,200	5,400	1,800	0	262,600
FT Pharmacy	5,200	0	400	0	1,000	400	0	0	200	200	15,000	37,000	59,400
PT Pharmacy	160	480	0	480	480	0	0	0	0	320	2,400	5,600	9,920
Nonresident	18,200	8,200	2,200	600	3,800	0	1,200	7,800	3,200	400	68,600	62,200	176,400
Initial Certification	35	0	105	140	315	35	35	105	70	1,295	1,050	245	3,430
RPh Renewal	500	9,600	15,275	8,625	125	125	0	209,025	0	0	250	0	243,525
Interns	0	80	3,280	120	0	40	40	160	0	160	280	160	4,320
Reciprocity	0	600	600	900	900	150	450	450	600	1,200	450	750	7,050
Technicians	350	475	3,100	15,350	15,950	825	450	550	400	375	500	625	38,950
Miscellaneous	500	800	800	600	0	1,200	700	1,000	100	320	1,400	300	7,720
Other - Electronic Fees	0	0	0	0	0	0	0	0	0	0	0	0	0
Late Fee Penalties	25	25	0	125	0	0	0	375	50	0	300	0	900
Recovery Legal Fees	0	0	0	0	0	0	0	0	0	0	0	0	0
Fines, Forfeits & Penalties	0	0	0	0	0	0	0	0	0	0	0	0	0
Interest Revenue	0	0	0	0	0	0	0	0	0	0	0	0	0
Sub-Total	25,970	26,460	26,960	26,940	61,370	143,375	48,275	234,465	11,820	9,670	92,030	106,880	814,215
Federal Grant Program GY4	30126.36	12517.25	0.00	13348.97	0.00	0.00	17891.29	0.00	0.00	0.00	0.00	0.00	73,883.87
Federal Grant Program GY7											38465.14	0	38,465.14
CASH CENTER BALANCE	\$1,429,563.52												

Remaining Authority by Object/Subobject

Expenditures current through 12/02/2017 08:50:46 AM

HEALTH -- Summary

FY 2018 Version -- AS -- Budgeted and Informational

FY Remaining: 57.8%

09209 Board of Pharmacy - Info						PCT
Subobject	Operating	Expenditures	Encumbrances	Commitments	Remaining	AVL
EMPLOYEE SALARIES						
5101010 F-t Emp Sal & Wages	313,727	154,540	0	0	159,187	50.7
5101020 P-t/temp Emp Sal & Wages	102,646	52,298	0	0	50,348	49.1
5101030 Board & Comm Mbrs Fees	1,342	480	0	0	862	64.2
Subtotal	417,715	207,318	0	0	210,397	50.4
EMPLOYEE BENEFITS						
5102010 Oasi-employer's Share	29,062	15,004	0	0	14,058	48.4
5102020 Retirement-er Share	18,500	11,760	0	0	6,740	36.4
5102060 Health Insurance-er Share	42,516	27,175	0	0	15,341	36.1
5102080 Worker's Compensation	1,000	352	0	0	648	64.8
5102090 Unemployment Compensation	300	93	0	0	207	69.0
Subtotal	91,378	54,384	0	0	36,994	40.5
51 Personal Services						
Subtotal	509,093	261,702	0	0	247,391	48.6
TRAVEL						
5203010 Auto-state Owned-in State	6,600	2,791	0	0	3,809	57.7
5203020 Auto Priv (in-st.) L/rte	600	191	0	0	409	68.2
5203030 Auto-priv (in-st.) H/rte	6,000	2,436	0	0	3,564	59.4
5203040 Air-state Owned-in State	0	717	0	0	-717	0.0
5203100 Lodging/in-state	7,489	2,215	0	0	5,274	70.4
5203140 Meals/taxable/in-state	1,100	418	0	0	682	62.0
5203150 Non-taxable Meals/in-st	2,000	1,076	0	0	924	46.2
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	4,371	0	0	5,629	56.3
5203280 Other-public-out-of-state	100	126	0	0	-26	0.0
5203300 Lodging/out-state	6,400	4,983	0	0	1,417	22.1
5203320 Incidentals-out-of-state	152	271	0	0	-119	0.0
5203350 Non-taxable Meals/out-st	900	1,032	0	0	-132	0.0
Subtotal	43,141	20,627	0	0	22,514	52.2
CONTRACTUAL SERVICES						
5204010 Subscriptions	250	0	0	0	250	100.0
5204020 Dues & Membership Fees	500	50	0	0	450	90.0
5204050 Computer Consultant	298,567	30,000	114,000	0	154,567	51.8
5204140 Contract Pymts To St Agen	20,000	18,000	0	0	2,000	10.0

Remaining Authority by Object/Subobject

Expenditures current through 12/02/2017 08:50:46 AM

HEALTH -- Summary

FY 2018 Version -- AS -- Budgeted and Informational

FY Remaining: 57.8%

09209 Subobject	Board of Pharmacy - Info	Operating	Expenditures	Encumbrances	Commitments	Remaining	PCT AVL
5204160	Workshop Registration Fee	4,000	2,700	0	0	1,300	32.5
5204180	Computer Services-state	10,075	6,656	0	0	3,419	33.9
5204181	Computer Services-state	3,619	35	0	0	3,584	99.0
5204200	Central Services	5,985	1,199	0	0	4,786	80.0
5204202	Central Services	102	18	0	0	84	82.4
5204203	Central Services	102	52	0	0	50	49.0
5204204	Central Services	411	158	0	0	253	61.6
5204207	Central Services	3,579	1,710	0	0	1,869	52.2
5204220	Equipment Serv & Maint	600	823	0	0	-223	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
5204440	Newsletter Publishing	0	310	0	0	-310	0.0
5204460	Equipment Rental	1,100	686	0	0	414	37.6
5204490	Rents-private Owned Prop.	18,277	11,392	0	0	6,885	37.7
5204510	Rents-other	250	0	0	0	250	100.0
5204530	Telecommunications Svcs	5,200	1,445	0	0	3,755	72.2
5204550	Garbage & Sewer	50	27	0	0	23	46.0
5204590	Ins Premiums & Surety Bds	1,450	0	0	0	1,450	100.0
5204620	Taxes & License Fees	176,708	0	0	0	176,708	100.0
5204960	Other Contractual Service	7,528	4,121	0	0	3,407	45.3
Subtotal		561,353	79,382	114,000	0	367,971	65.6
SUPPLIES & MATERIALS							
5205020	Office Supplies	2,300	448	450	0	1,402	61.0
5205040	Educ & Instruc Supplies	300	0	0	0	300	100.0
5205210	Medical Supplies	0	4,650	0	0	-4,650	0.0
5205310	Printing-state	1,100	281	0	0	819	74.5
5205320	Printing-commercial	400	0	0	0	400	100.0
5205330	Supp. Public & Ref Mat	50	0	0	0	50	100.0
5205350	Postage	4,900	2,279	0	0	2,621	53.5
Subtotal		9,050	7,658	450	0	942	10.4
CAPITAL OUTLAY							
5207450	Office Furn & Fixtures	1,000	0	0	0	1,000	100.0
5207495		500	0	0	0	500	100.0
5207901	Computer Hardware	4,264	0	0	0	4,264	100.0
5207960	Computer Software	30,000	0	0	0	30,000	100.0

Remaining Authority by Object/Subobject

Expenditures current through 12/02/2017 08:50:46 AM

HEALTH -- Summary

FY 2018 Version -- AS -- Budgeted and Informational

FY Remaining: 57.8%

Subtotal	35,764	0	0	0	35,764	100.0
OTHER						
5208080 Refund Of Prior Yrs Rev	0	521	0	0	-521	0.0
Subtotal	0	521	0	0	-521	0.0
52 Operating Subtotal	649,308	108,188	114,450	0	426,670	65.7
Total	1,158,401	369,890	114,450	0	674,061	58.2

Activity Report			Nov	Nov	YTD	
	New	Renewal	2017	2016	This Year	Last Year

Pharmacy Permits

Full Time (SD)	0	0	0	7	0	10
Part Time (SD)	0	0	0	3	5	10
Non-Resident	25	8	33	19	103	102

Pharmacist Licenses

South Dakota	2	2	4	3	1245	1240
Non-Resident	6	5	11	4	727	708

Technician Registration

	19	35	54	100	1387	1301
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Pharmacy Interns

	2	1	3	0	331	326
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Wholesale Permits

South Dakota	0	23	23	18	26	21
Non-Resident	17	304	321	530	371	569

Inspections

Pharmacy Inspections			58	26	179	155
Wholesale Inspections			3	3	9	9
Other Pharmacy Visits/Meetings			11	26	160	141
Controlled Drug Destruction			0	0	0	3
PDMP Visits			21	7	95	66

Verifications:

Pharmacist			2	13	64	112
Wholesalers			22	51	167	214
Pharmacies			20	19	81	110
Technicians / Interns			0	4	26	28

Board of Pharmacy - Inspection Report

4th Quarter 2017

Kari Shanard-Koenders

Date	Destination	City	Purpose
10/1/17	DEA Pharmacy Awareness Diversion Conf	Sioux Falls	CE + Presentation
10/2/17	Sarah Boblenz - DEA	Sioux Falls	Visit
10/2/17	Big Picture/Albertson's Consulting licensure software	Sioux Falls	Demo of Software for office
10/3/17	NABP Executive Officer Forum	Chicago	NABP Meeting
10/4/17	NABP Executive Officer Forum	Chicago	NABP Meeting
10/5/17	Meeting with representatives from Amgen, Bio and Genentech regarding Biosimilar Legislation	Chicago	Meeting
10/10/17	Freb Gebhart Conference Call	Conference Call	Survey of Pharmacy Law
10/13/17	Sanford Hospice (Ava's House)	Sioux Falls	Inspection
10/17/17	Executive Directors Meeting	Pierre	Meeting
10/18/17	Avera Opioid Epidemic, A Wicked Problem of the Worst Kind	Sioux Falls	Meeting
10/25/17	Ad Hoc SDSMA Committee On Opioid Abuse	Sioux Falls	Meeting
11/1/17	CriticalPoint's 2017 USP <797> Study Results: Why Don't We Embrace Better Practice?	Sioux Falls	webinar
11/1/17	Accela Licensing Software Demo	Sioux Falls	Demo of Software for office
11/2/17	I Gov Licensing Software Demo	Sioux Falls	Demo of Software for office
11/6/17	Alix-Covington Care & Rehab Ctr	Sioux Falls	Inspection
11/7/17	LECC Healthcare Fraud Subcommittee	Sioux Falls	Meeting
11/7/17	SDPHA Sioux Falls District Meeting	Sioux Falls	Presentation
11/8/17	Staff Meeting	Sioux Falls	Staff Meeting
11/8/17	Sam's Pharmacy #10-8165	Sioux Falls	Construction Insp of Temp Pharm
12/1/17	HPAP Program Service Committee Biannual Meeting	Sioux Falls	Meeting
12/4/17	Governor Daugaard Licensure Compact Call	Conference Call	Meeting
12/4/17	Sioux Nation Ag Center	Sioux Falls	Wholesale Inspection
12/5/17	Meeting with Doug Barnett and Katie Mallery from AG office	Sioux Falls	Recap of Issues
12/7/17	Governor Daugaard Licensure Compact Call	Conference Call	Meeting
12/8/17	Board of Pharmacy Meeting	Sioux Falls	Quarterly Board meeting

Board of Pharmacy - Inspection Report

4th Quarter 2017

Date	Destination	City	Purpose	
<i>Gary Karel</i>				
10/1/17	DEA Pharmacy Awareness Diversion Conf	Sioux Falls	CE + Presentation	
10/2/17	Sarah Boblenz -DEA	Sioux Falls	Visit	
10/2/17	Sanford Oncology	Sioux Falls	Gary & Sarah met with Joe determine how to handle CS involved with research studies	
10/2/17	Big Picture/Albertson's Consulting	Sioux Falls	Demo of Software for office	
10/4/17	Lewis Drugs Southgate #1	Sioux Falls	Inspection	PDMP
10/4/17	Avera Med Grp Family HC Emergency Dept	Sioux Falls	Inspection	PDMP
10/5/17	Brother's Pharmacy	Brookings	Inspection	PDMP
10/5/17	SDSU College of Rx Practice Lab	Brookings	Inspection	
10/5/17	Jackrabbitt Pharmacy	Brookings	Temp Relocate Const Insp	
10/5/17	Rambo LTC, Inc	Brookings	Inspection	
10/7/17	SDAPT Fall Conference	Sioux Falls	Law Presentation w/MJD	
10/9/17	Prairie Pharmacy	Corsica	Relocate Rx-Const Insp	
10/11/17	Lewis Family Drug #58	Viborg	Inspection	PDMP
10/11/17	Norm's Thrifty White Pharmacy	Freeman	Inspection	PDMP
10/12/17	Platte Community Memorial Hospital	Platte	Inspection	
10/12/17	Hoffman Drug	Platte	Inspection	PDMP
10/13/17	Sioux Falls Specialty Hospital	Sioux Falls	Inspection	
10/13/17	Sanford Hospice (Ava's House)	Sioux Falls	Inspection	
10/17/17	Walmart Pharmacy 10-4865 (North)	Sioux Falls	Inspection	PDMP
10/19/17	Walmart Pharmacy 10-3237 (East)	Sioux Falls	Inspection	PDMP
10/24/17	Winner Regional HC Center Pharmacy	Winner	Inspection	
10/25/17	Community Mem Hospital Pharmacy	Burke	Inspection	
10/26/17	Lewis Family Drug #68	DeSmet	New Construction Inspection	
10/26/17	Avera DeSmet Memorial Hospital	DeSmet	New Construction Inspection	
10/26/17	Salem Community Drug	Salem	Inspection	PDMP
11/1/17	Lewis Drug #12	Brookings	Inspection	PDMP
11/1/17	Walmart Pharmacy 10-1538	Brookings	Inspection	PDMP
11/6/17	Allxa-Covington Care & Rehab Ctr	Sioux Falls	Inspection	
11/7/17	Law Enforcement Coordinating Committee Conv	Sioux Falls	Health Care Fraud	
11/8/17	Sam's Pharmacy #10-8165	Sioux Falls	Construction Insp of Temp Pharm	
11/9/17	Hy-Vee Pharmacy #1820	Vermillion	Inspection	PDMP
11/10/17	Avera Gregory Healthcard Center	Gregory	Inspection	PDMP
11/14/17	Lewis Family Drug #65 (S. Minn)	Sioux Falls	Inspection	PDMP

11/15/17	Brookings Hospital Pharmacy	Brookings	Inspection	
11/15/17	Flandreau Santee Sioux Tribe Clinic Pharmacy	Flandreau	Inspection	PDMP
11/16/17	Omnicare of South Dakota	Sioux Falls	Inspection	
11/21/17	Freeman Regional Health Services (Hospital)	Freeman	Inspection	
11/21/17	Parker Pharmacy	Parker	Inspection	PDMP
11/28/17	Sanford Chamberlain Med Ctr Pharmacy	Chamberlain	Inspection	
11/29/17	Wagner Community Memorial Hospital	Wagner	Inspection	
11/30/17	Costco Pharmacy #1159	Sioux Falls	Inspection	PDMP
12/4/17	Sioux Nation Ag Center	Sioux Falls	Wholesale Inspection	

Board of Pharmacy - Inspection Report

4th Quarter 2017

Melissa DeNoon

Date	Destination	City	Purpose	
10/1/17	DEA PDAC	Sioux Falls	Presentation & CE	PDMP
10/2/17	Sarah Boblenz - DEA	Sioux Falls	Meeting	
10/2/17	Albertson's Big Picture E-Lic.	Sioux Falls	E-Lic. Software Demo	
10/3/17	Courthey Earl - e.Republic	Sioux Falls	Opiate Tech. Interview	
10/7/17	SDAPT Fall Conference	Sioux Falls	Law Presentation w/GK	PDMP
10/16/17	NASCOSA	San Antonio, TX	Annual Conference	
10/17/17	NASCOSA	San Antonio, TX	Annual Conference	
10/18/17	NASCOSA	San Antonio, TX	Annual Conference	
10/19/17	NASCOSA	San Antonio, TX	Annual Conference	
10/20/17	NASCOSA	San Antonio, TX	Annual Conference	
10/23/17	OA Team	Sioux Falls	Monthly CC	
10/26/17	HHS Region VIII	Sioux Falls	Qtrly CC	
11/1/17	Appriss Health	Sioux Falls	Bimonthly Tech CC	
11/1/17	Byrne/Accela E-Licensing	Sioux Falls	E-Lic. Software Demo	
11/2/17	Rachel Oelmann - DSS	Sioux Falls	STR Grant CC	
11/2/17	iGov - E-Licensing	Sioux Falls	E-Lic. Software Demo	
11/7/17	LECC	Sioux Falls	Conference	
11/7/17	Great Plains QIN	Sioux Falls	Webinar Practice Run	
11/8/17	SD BOP Staff	Sioux Falls	Meeting	
11/14/17	Great Plains QIN	Sioux Falls	Webinar - presenter	PDMP
11/14/17	NABP PMPI Steering Comm.	Sioux Falls	Conference Call	
11/15/17	Appriss Health	Sioux Falls	Bimonthly Tech CC	
11/20/17	OA Team	Sioux Falls	Monthly CC	
11/27/17	TTAC	Sioux Falls	Webinar	
11/28/17	Great Plains QIN	Sioux Falls	Webinar - presenter	PDMP
11/29/17	Appriss Health	Sioux Falls	Bimonthly Tech CC	
12/4/17	Puneet Neolia - Appriss Health	Sioux Falls	Tableau CC	
12/5/17	Puneet Neolia - Appriss Health	Sioux Falls	Tableau CC	
12/6/17	Coteau des Prairies HC System	Sioux Falls	Webinar Host on SD PDMP	PDMP
12/7/17	TTAC	Sioux Falls	Webinar	
12/7/17	TTAC, WA, MI PDMP Directors	Sioux Falls	Conference Call	
12/8/17	SD Board of Pharmacy	Sioux Falls	Quarterly Board Meeting	

Board of Pharmacy - Inspection Report

4th Quarter 2017

<i>Paula Stoltz</i>									
Date	Destination		City	Purpose					
10/1/17	DEA Pharmacy Diversion Awareness Conference		Sioux Falls	CE + Presentation					
10/1/17	Dakota County Pharmacy		Phillip	E- Inspection		PDMP			
10/1/17	Phillip Health Services		Phillip	E- Inspection					
10/12/17	Avera Campus Pharmacy		Pierre	E- Inspection		PDMP			
10/18/17	Boyd's Drug Mart Pharmacy W		Rapid City	E- Inspection		PDMP			
10/19/17	Lynn's Dakotamart Pharmacy		Belle Fourche	E- Inspection		PDMP			
10/19/17	Shopko Hometown Pharmacy		Belle Fourche	E- Inspection		PDMP			
10/19/17	Regional Home + Pharmacy		Spearfish	E- Inspection		PDMP			
10/25/17	Walmart Pharmacy		Spearfish	E- Inspection		PDMP			
10/26/17	Community Health Center of the Black Hills Pharmacy		Rapid City	E- Inspection					
10/26/17	Medicine Shoppe- Advanced Care Pharmacy		Rapid City	E- Inspection					
10/27/17	Walgreens W. Pharma cy		Rapid City	E- Inspection		PDMP			
10/30/17	Custer Regional Senior Care		Rapid City	E- Inspection		PDMP			
11/1/17	Lynn's Dakotamart Pharmacy		Custer	E- Inspection		PDMP			
11/2/17	Fail River Health Services		Hot Springs	E- Inspection		PDMP			
11/2/17	SD States Vets Home Pharmacy		Hot Springs	E- Inspection		PDMP			
11/3/17	Walmart Pharmacy #1604		Hot Springs	E- Inspection		PDMP			
11/6/17	Vilas Telepharmacy		Rapid City	E- Inspection		PDMP			
11/7/17	Carson Drug		Lead	E- Inspection		PDMP			
11/9/17	Boyd's Express Pharmacy		Custer	E- Inspection		PDMP			
11/9/17	Sam's Club Pharmacy		Rapid City	E- Inspection		PDMP			
11/15/17	CVS Pharmacy dba Target Pharmacy		Rapid City	E- Inspection		PDMP			
11/16/17	Custer Regional Hospital Pharmacy		Rapid City	E- Inspection		PDMP			
11/16/17	Shopko Hometown Pharmacy		Custer	E- Inspection		PDMP			
11/17/17	Walgreens Pharmacy Mt Rushmore Rd		Hot Springs	E- Inspection		PDMP			
11/21/17	Regional Home + Pharmacy #1		Rapid City	E- Inspection		PDMP			
11/27/17	Regional Health Rehab		Rapid City	E- Inspection		PDMP			
11/28/17	FDA Educational Session for State Boards of Pharmacy		Northbrook IL	Education/Training					
11/29/17	NABP Compliance Officer & Legal Counsel Forum		Northbrook IL	Education/Training					
11/30/17	NABP Compliance Officer & Legal Counsel Forum		Northbrook IL	Education/Training					
12/1/17	Sturgis Regional Senior Care		Sturgis	E- Inspection					
12/1/17	Sturgis Regional Hospital		Sturgis	E- Inspection					
12/6/17	Lewis Drug		Chamberlain	E- Inspection		PDMP			
12/8/17	SD Board of Pharmacy Meeting		Sioux Falls	Quarterly Meeting					

Board of Pharmacy - Inspection Report		4th Quarter 2017	
<i>Carol Smith</i>			
Date	Destination	City	Purpose
10/17/17	Matheson Tri-Gas	Watertown	Wholesale Inspection
10/17/17	Air Gas	Watertown	Wholesale Inspection
10/17/17	Alixa-Watertown	Watertown	Inspection
10/19/17	Milbank Area Hospital	Milbank	Inspection
10/19/17	Alixa-Milbank	Milbank	Inspection
10/19/17	Lewis-Milbank	Milbank	Visit
10/24/17	Critical Point Boot Camp	New Jersey	Sterile Cpding Inspector Training
10/25/17	Critical Point Boot Camp	New Jersey	Sterile Cpding Inspector Training
10/26/17	Critical Point Boot Camp	New Jersey	Sterile Cpding Inspector Training
10/27/17	Critical Point Boot Camp	New Jersey	Sterile Cpding Inspector Training
10/31/17	Sanford Hospital	Aberdeen	Inspection
10/31/17	Shopko	Aberdeen	Inspection
11/2/17	Sanford Hospital Webster Pharm	Webster	Inspection
11/3/17	Walmart	Watertown	Inspection
11/8/17	State Street Pharmacy	Aberdeen	Inspection
11/8/17	Midwest Ag	Aberdeen	Wholesale Inspection
11/8/17	Rotech (former PSI)	Aberdeen	Wholesale Inspection
11/8/17	Praxair	Aberdeen	Wholesale Inspection
11/8/17	Shopko	Aberdeen	Visit
11/9/17	Walmart	Aberdeen	Inspection
11/9/17	State Street Pharmacy	Aberdeen	Inspection
11/13/17	DT Pharmacy	Aberdeen	Compounding Inspection
11/13/17	United Clinic Pharmacy	Aberdeen	Inspection
11/15/17	Avera St. Lukes Hospital	Aberdeen	Inspection
11/15/17	Dakota Plains Surgical Center	Aberdeen	Inspection
11/20/17	Prairie Lakes Hospital	Watertown	Inspection
11/20/17	Prairie Lakes Campus Pharm	Watertown	Inspection
11/20/17	Mallard Pointe- Prairie Lakes HS	Watertown	Inspection
11/28/17	I-Surgery	Aberdeen	Inspection



SDPhA UPDATE – South Dakota Board of Pharmacy Dec., 4, 2017

2017 Annual Convention Highlights

Newly-elected Association Officers

Eric Grocott, Salem Community Drug, Salem – President
 Erica Bukovich, Health Management Partners, Sioux Falls – President- elect Lori Ollerich,
 Pharmacy Specialties, Inc., Sioux Falls – Vice President
 Dana Darger, Regional Health, Rapid City – Secretary/Treasurer Bernie Hendricks,
 SDSU, Brookings – At-Large Board Member
 Jan Lowe, Rapid City Regional Hospital, Rapid City – At-Large Board Member Trisha Hadrick,
 Faulkton Drug, Faulkton – Immediate Past President

2017 Convention Award Winners

Bowl of Hygeia	Rob Loe
Hustead Award	David Taffe
Distinguished Young Pharmacists Award	Billie Bartel
Outgoing Presidents Award (Gavel Award)	Trisha Hadrick
Technician of the Year Award	Jessie Spotted Tail
Salesperson of the Year Award	Brent Witte

Fifty Years in Pharmacy

Ralph Gosch-Huron, SD; Timothy Pearson-Sisseton, SD; Vernon Peterson-Mountain Lake, MN; Marilyn Schwans - Belle Fourche, SD; Ronald Schwans – Belle Fourche, SD; Raymond Winsel - Rapid City, SD; Dennis Wollman-Freeman, SD

October American Pharmacists Month – Pharmacists were encouraged to:

Schedule Special Health Events

- Promote vaccinations
- Offer various general health screenings – cholesterol, diabetes, osteoporosis
- Offer blood pressure screenings – talk to patients about the signs of heart attack and stroke
- Schedule an open house
- Decorate the pharmacy with posters/balloons announcing American Pharmacists Month

Offer Medication Check ups

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

OTC Tours

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

Geriatrics and Their Medications

- Brown Bag Event
- Encourage influenza & pneumococcal immunizations

Recognize Pharmacy Technicians on National Pharmacy Technician Day October 16, 2017 Don't Be Shy!

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

Additional SDPhA American Pharmacist Month Activities

- News releases
- Pharmacist spotlights throughout October
- Working with media across the state on various stories to highlight pharmacists and their work.
- APhA-ASP American Pharmacist Month Partnership
The Association once again partnered with SDSU's College of Pharmacy APhA-ASP Chapter who again created some excellent billboard messaging tied into their More than A Count campaign. Two billboards were featured in Sioux Falls and Rapid City during the month of October. To learn more about the More Than a Count Campaign, go to facebook.com/morethanacount.

National Efforts

S.109/H.R.592 The Pharmacy and Medically Underserved Areas Enhancement Act

(Provider Status)

Would enable Medicare beneficiaries access to pharmacist-provided services under Medicare Part B by amending section 1861(s)(2) of the Social Security Act. These services would be reimbursable under Medicare Part B if they are provided in medically underserved communities and consistent with the state scope of practice laws. The bill seeks to increase access and improve quality by enabling pharmacists to provide patient care services as consistent with their education, training and license. The federal legislation would not expand the type of services that pharmacists are permitted to provide. The latest activity was Jan. 12, 2017 when it was referred to the Committee on Finance.

S.413/H.R.1038 - Improving Transparency and Accuracy in Medicare Part D Spending Act

Would prohibit pharmacy direct and indirect remuneration (DIR) fees from being applied after the point-of-sale for prescription drugs dispensed to Medicare beneficiaries. The legislation addresses a top concern for independent community pharmacy owners: monetary clawbacks assessed by Medicare drug plans, or their intermediaries, PBM corporations, long after prescriptions are filled and the pharmacy paid. These fees are often labeled direct and indirect remuneration, or pharmacy DIR fees. The latest activity was on H.R.1038 on March 9, 2017 with sponsor introductory remarks on the measure.

ACA/Health Care Reform

Health care dominated the onset of the 115th Congress's legislative agenda. While there has been no consensus on health care reform, we continue to monitor and remain engaged in the conversation where appropriate.

Legislative Session 2018/SDPhA Legislative Days

The 2018 Legislative Session (38 days) is scheduled to begin January 9th. The Association has no immediate plans to introduce legislation this year, but has been monitoring pharmacy and health-related issues closely. We have been in discussions with industry representatives regarding biosimilar legislation proposed this year.

We are also closely following several initiated measures which may be of consequence to the profession. A medical marijuana measure and a Prescription Drug Pricing Measure which would cap the amount the state pays for medications at the rate the VA pays both met the Secretary of State's test to be added to the 2018 ballot.

Legislative Days is slated for Jan. 23-24, 2018 in Pierre. Pharmacists, technicians, faculty and students are encouraged to attend the Tuesday evening event which will include networking opportunities, the chance to enjoy some good food and Bob Riter and Amanda Bacon will provide a legislative update. The Board of Pharmacy is most welcome to provide an update as well. Wednesday morning, Jan. 24, we will continue with health screenings by SDSU College of Pharmacy students at the Capitol in both the Speaker and President's Lobbies.

A Flu Shot Clinic is once again set for Jan. 11 in Pierre. SDPhA and LRC are working together to hold a flu shot clinic at the Capitol Jan. 11 from 10 a.m. – noon. Additional details forthcoming.

Antibiotic Stewardship Workgroup

This workgroup was established by the Health Department and South Dakota pharmacists are playing a very large role. The work continues with meetings. Kipp Stahl has recently replaced Angela Jackley as the Department of Health's administrative representative of this group.

Prescription Opioid Abuse Advisory Committee

The South Dakota Department of Health has received a grant through the Centers for Disease Control and Prevention Prescription Drug Overdose: Data-Driven Prevention Initiative in response to the growing national problem of opioid drug abuse. As part of the grant, the Department of Health has appointed a Prescription Opioid Abuse Advisory Committee to review opioid use data for the state and develop strategies for preventing prescription opioid misuse and abuse. South Dakota pharmacists are represented on the committee by Steve Lee, Avera Medical Group Pierre. The group has submitted the first draft of its strategic plan to the Substance Abuse and Mental Health Services Administration (SAMHSA). It will then be submitted with any necessary modifications to the CDC. The committee meets again Dec. 13.

Fall Prescription Drug Take Back Event

The Association continues its work to bring awareness to the proper disposal of medications. The DEA dropped and then re-instated their Drug Take Back events. The fall Take Back Event was held Oct. 28, 2017. Visit http://www.deadiversion.usdoj.gov/drug_disposal/takeback/ for more information.

SDPhA Rebranding

SDPhA unveiled a new logo at this year's convention. The updated look is much more modern, but highlights our rich history. You can find it on our Facebook page, the SDPhA's new materials, and as the cover image on the October Journal.

Web Site and Social Media

We continue to work to enhance and update our website to integrate a more comprehensive resource for pharmacists, academia and students. We have recently completed a "virtual facelift" to the website which includes the new logo and color scheme and will soon feature an expanded resources section. Visit SDPhA on the web at www.sdpha.org. Also, please **LIKE** our Facebook page! We will lean on that more heavily in the coming months to distribute information about events and other efforts.

2018 Immunization Resources

The CDC has an excellent resources available at <http://www.cdc.gov/flu/>. This website has a great deal of information for Health Professionals and patients alike. We'll add more information on flu resources on our website as it becomes available. The South Dakota Department of Health's website is <http://doh.sd.gov/diseases/infectious/flu/>. Recommendations by the Advisory Committee on Immunization Practices (ACIP) for the use of influenza vaccine are now updated for 2017/2018.

As you all know, in addition to the important role that the pharmacy profession plays in providing influenza vaccinations for their patients, influenza vaccination of our health care personnel is important to protect themselves, their patients, their family, and the community from influenza. The FDA urges all health care organizations to encourage their professionals to get vaccinated.

National Influenza Vaccination Week

This week is National Influenza Vaccination Week (NIVW), a national observance that was established to highlight the importance of continuing influenza vaccination, as well as fostering greater use of flu vaccine after the holiday season into January and beyond. For more information, visit <http://www.cdc.gov/flu/nivw/>. Please feel free to share the Influenza posts from the SDPhA Facebook page.

Education and Communication

Continuing education for practitioners continues to be a strong emphasis for the Association. The Association prepares and delivers Legislative and Association Update CE and pharmacy-related information at fall and spring district meetings each year, in addition to delivering a variety of educational programs at our recent Annual Convention.

The South Dakota Pharmacist is sent out quarterly (electronically) and offers 1.5 hours of CE. The Journal also provides a source of communication for the association on rules, legislative issues and education that affect the pharmacy practice. In addition, the SDPhA website (sdpha.org) and mass e-mail system has been upgraded, and we plan to place additional emphasis on our Facebook page. We are exploring additional communication platforms, and will update you if those become viable options.

Fall District Meetings

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

Continuing Education Opportunities – New/Continued

The Association collaborates with the SDSU College of Pharmacy to provide interesting continuing education opportunities throughout the year. We have also been engaged from time-to-time to assist pharmaceutical companies in getting the word out on local opportunities for informative programs.

Pharmacy Technician University (PTU)

SDPhA and PTU have secured an agreement as reported via a press release, email blast, social media and the Journal. We already have several technicians enrolled and taking advantage of this opportunity.

Iowa Regional Pharmacy Expo

The Iowa Pharmacists Association has engaged SDPhA to continue to promote their winter conference, which is a comprehensive event offering a great deal of excellent CE for pharmacists and technicians. In exchange, our pharmacists will have access at a great rate to attend, and the agreement also allows us to offer more comprehensive benefits as a professional association. The event has become more regional, with a significant number of states engaged. The dates have been set for February 16-18, 2018 at the Holiday Inn Des Moines Airport and Conference Center in Des Moines, IA. Stay tuned for more details.

Pharmacy Days – SDSU – October 25-26, 2017

Board member Bernie Hendricks represented SDPhA and interact with student pharmacists and faculty to showcase the importance of student involvement in the association. This continues to be an important event for all and helps us develop even stronger relationships with our pharmacy students!

Public Affairs and Professional Relations

The Association continues to strongly support and endorse the SDSU College of Pharmacy students through scholarship donations and other opportunities. The South Dakota Pharmacists Association also attends Pharmacy Days at SDSU and sponsors the “Back to School Picnic” each fall to meet with students and share information about the Association. The SDPhA Board also supports the students by offering free admission to our annual convention, and we provide a number of hotel rooms to help the students with their expenses. Forty-seven students attended convention this year! We believe this is an incredible investment in the association’s future! The student pharmacists work hard assisting SDPhA throughout the meeting, which is greatly appreciated. We

also remain a resource for faculty whenever needed, and collaborate on projects whenever possible, including American Pharmacists Month activities.

We are also incredibly excited and pleased to work with the students on the More Than a Count Campaign. The More than a Count campaign is organized by pharmacy students from the South Dakota State University College of Pharmacy and Allied Health Professions with funding from the South Dakota Pharmacists Association. It aims to educate the public about the role pharmacists play in their health care. The website <https://morethanacountsd.com> is a work in progress, as is the Facebook www.facebook.com/morethanacount page. We highly encourage you to check out both – share, like and repost the items you see there as well as the SDPhA pages.

Health Professional Assistance Program

Our association continues to support the HPAP program, as required by South Dakota statute. A pharmacist may access the program by self-referral, board referral, or referral from another person or agency, employer, coworker or family member.

SD Pharmacists Association
Profit & Loss Budget vs. Actual
 July 1 through December 1, 2017

	Jul 1 - Dec 1, 17	Budget	% of Budget
Ordinary Income/Expense			
Income			
Membership			
C/L Contributions			
Individual C/L Contr.	2,215.00	0.00	100.0%
Corporation/Business C/L Co...	2,000.00	0.00	100.0%
Total C/L Contributions	4,215.00	0.00	100.0%
SD Board of Pharmacy Transfer	0.00	193,000.00	0.0%
Associate Member	400.00	300.00	133.3%
District Dues			
District 9 - Yankton	15.00	0.00	100.0%
District 7 - Sioux Falls	120.00	0.00	100.0%
District 6 - Rosebud	40.00	0.00	100.0%
District 5 - Mobridge	10.00	0.00	100.0%
District 4 - Mitchell	10.00	0.00	100.0%
District 2 - Black Hills	40.00	0.00	100.0%
District 1 - Aberdeen	180.00	0.00	100.0%
Total District Dues	415.00	0.00	100.0%
Student Membership	330.00	1,800.00	18.3%
Total Membership	5,360.00	195,100.00	2.7%
Corp Endorsements			
NASPA-PQC Endorsement	450.00	450.00	100.0%
PAAS Endorsement	90.00	300.00	30.0%
PMG Endorsement	4,179.00	16,000.00	26.1%
Total Corp Endorsements	4,719.00	16,750.00	28.2%
Advertising/Marketing			
Advertising - Journal	0.00	300.00	0.0%
Total Advertising/Marketing	0.00	300.00	0.0%
Interest/Dividends	255.22	1,500.00	17.0%
Other Income	50.00	0.00	100.0%
Convention Income			
Convention Sponsor	2,000.00	0.00	100.0%
Exhibitors	13,650.00	20,000.00	68.3%
Registrations	11,315.00	12,500.00	90.5%
Student Sponsorship	175.00	0.00	100.0%
Total Convention Income	27,140.00	32,500.00	83.5%
Total Income	37,524.22	246,150.00	15.2%
Gross Profit	37,524.22	246,150.00	15.2%

SD Pharmacists Association
 Profit & Loss Budget vs. Actual
 July 1 through December 1, 2017

	Jul 1 - Dec 1, 17	Budget	% of Budget
Expense			
PTU Pass Thru Exp	3,600.00	0.00	100.0%
American Pharmacists Month	1,850.00	1,850.00	100.0%
Accounting/Tax Prep	2,167.28	3,834.00	56.5%
Salary & Benefits			
Payroll Taxes	3,211.40	10,500.00	30.6%
Payroll Expense	33.56	100.00	33.6%
Executive Director	41,979.10	100,750.00	41.7%
Insurance	8,469.96	16,920.00	50.1%
Retirement	2,518.70	9,000.00	28.0%
Total Salary & Benefits	56,212.72	137,270.00	41.0%
Advertising	477.94	3,000.00	15.9%
Dues/Subscriptions	0.00	3,300.00	0.0%
Technology/Net/Software	2,669.04	3,000.00	89.0%
Furniture/Copier/Assets	737.05	2,000.00	36.9%
Hlth Professionals Assist Prog	10,000.00	10,000.00	100.0%
Insurance (D&O, Office)	2,044.00	3,500.00	58.4%
Legal/Professional	2,728.95	4,000.00	68.2%
Merchant Card Fees	1,186.43	2,000.00	59.3%
Phone/Internet	2,250.01	5,200.00	43.3%
Postage	24.87	150.00	16.6%
Office Supplies	635.37	1,500.00	42.4%
Scholarships	150.00	1,000.00	15.0%
Rent	2,178.00	4,400.00	49.5%
Board Travel & Meetings	11,854.95	20,000.00	59.3%
Staff Travel			
In-State	2,069.97	5,000.00	41.4%
Out-of-State	2,714.95	6,000.00	45.2%
Total Staff Travel	4,784.92	11,000.00	43.5%
Convention Expense	11,521.87	30,000.00	38.4%
Education Grant	2,500.00	5,000.00	50.0%
Misc Expense	302.73	500.00	60.5%
Total Expense	119,876.13	252,504.00	47.5%
Net Ordinary Income	-82,351.91	-6,354.00	1,296.1%
Net Income	-82,351.91	-6,354.00	1,296.1%

SD Pharmacists Association C & L
Profit & Loss Budget vs. Actual
July 1 through December 1, 2017

	Jul 1 - Dec 1, 17	Budget	% of Budget
Income			
C & L Income			
South Dakota Pharmacies Transfe	0.00	0.00	0.0%
Business Membership	0.00	0.00	0.0%
Corporate Membership	0.00	1,000.00	0.0%
District Contributions	0.00	0.00	0.0%
Individual Membership	0.00	4,500.00	0.0%
Interest	1.58	0.00	100.0%
Legislative Days	0.00	0.00	0.0%
Other	0.00	0.00	0.0%
C & L Income - Other	0.00	0.00	0.0%
Total C & L Income	1.58	5,500.00	0.0%
Total Income	1.58	5,500.00	0.0%
Expense			
C & L Expenses			
C/L Administration	0.00	0.00	0.0%
Legislative Receptions	0.00	1,000.00	0.0%
Lobbyist	0.00	11,000.00	0.0%
Misc	0.00	200.00	0.0%
Per Diem	0.00	0.00	0.0%
Postage	0.00	0.00	0.0%
Printing/Copies	0.00	100.00	0.0%
C & L Expenses - Other	0.00	0.00	0.0%
Total C & L Expenses	0.00	12,300.00	0.0%
Payroll Expenses	0.00	0.00	0.0%
Total Expense	0.00	12,300.00	0.0%
Net Income	1.58	-6,800.00	-0.0%



NABP

National Association of
Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: November 9, 2017
RE: USP General Chapter <800> Implementation Delay

As you are all probably aware, the United States Pharmacopeial Convention (USP) has postponed the official date of General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings* until December 1, 2019. According to USP, the reason for this delay is to align the official date of this chapter with the official date of the next revision to General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*. To better inform NABP and the boards of pharmacy about this decision, USP has prepared a Frequently Asked Questions document about the decision to postpone, the status of the chapter, USP's support of early adoption of the chapter by boards, and specifically the sections of current Chapter <797> that are not harmonized with Chapter <800> that have been causing confusion in the pharmacy and regulatory community on how to comply with both chapters until <797> is revised. Boards of pharmacy may use and further disseminate the FAQ document as they deem appropriate.

Attachment

cc: NABP Executive Committee



FAQs for NABP

(Updated 2017-10-26)

1. What is the status of the General Chapter <800> and when will General Chapter <800> become official?

USP announced the [intent to postpone](#) the official date of General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*. The intent of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding — Sterile Preparations*, to provide a unified approach to quality compounding. The next revision to General Chapter <797> is anticipated to be published in the *Pharmacopeial Forum* 44(5) September/October 2018 for a second round of public comment. Both USP General Chapter <797> and USP General Chapter <800> are anticipated to become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

2. What does ‘official date’ mean?

The USP “official date” indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, and other government authorities. USP has no role in enforcement.

3. Other than the change to the official date, are there other expected substantive changes to USP General Chapter?

No. The only part of USP General Chapter <800> that is expected to change is the official date, which is expected to be changed to December 1, 2019.

4. Is <800> currently enforceable in the United States?

From a compendial standpoint, a USP general chapter numbered below <1000> becomes enforceable through reference in the General Notices, a monograph, or another applicable general chapter numbered below <1000>. At this time, <800> is not specifically referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>.

However, states may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. USP has no role in enforcement. As a result, the specific enforceability of <800> depends on the legal framework that you are analyzing.



5. Does the December 1, 2019 official date of <800> impact my current or early adoption of the general chapter?

No. USP encourages adoption and implementation of General Chapter <800> to help ensure a quality environment and protection of healthcare workers and patients when hazardous drugs are handled.

6. How do I adopt USP General Chapter <800> if sections are not harmonized with USP General Chapter <797>?

Two sections that are not harmonized between the two chapters are: Segregated Compounding Area and 'Low volume' hazardous drug compounding. Below please find guidance on how to adopt USP <800> until the revised USP <797> is published.

Segregated Compounding Area (SCA)

- USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area (SCA).
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 30 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in USP <797> and C-SCA in <800>.
 - For early adoption of <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in the chapter and the CSP is assigned a BUD of 12 hours or less.
 - For facilities that have not yet adopted <800>, the standards in USP <797> would apply. Only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA.

"Low volume" hazardous drug compounding

- USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- For early adoption of <800>, HDs must be prepared in a C-SEC meeting the requirements in the chapter.
- For facilities that have not yet adopted <800>, the standards in <797> would apply. Facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.

December 8, 2017

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

Dear Members of the Board of Pharmacy:

To enhance and expand our clinical services and allow the pharmacists more time with patients we would like to request a variance allowing a certified pharmacy technician/intern to complete the final verification for the accuracy of a filled prescription or medication order. We would request a variance to the following law:

20:51:29:22. Tasks a pharmacy technician may not perform. A pharmacy technician may not:
(1) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

Technician Product Verification (TPV) is a way to decrease pharmacist workload so we can maintain/increase patient safety while increasing patient health and well-being. Services to include: Expanded Vaccine administration including Travel Clinic Expertise, expansion of MTM services, expanded counseling services and other clinical services as they become possible.

Length of time of Variance Request- 1 year with option to reapply to continue program.

Locations:

Hy-Vee Pharmacy Sioux Falls #3 (1632)
3000 South Minnesota Ave
Sioux Falls, SD 57105
(P) 605-334-8012
PIC: Judy Zachariasen

Hy-Vee Pharmacy Sioux Falls #5 (1637)
3020 East 10th Street
Sioux Falls, SD 57103
(P) 605-336-8998
PIC: Matt Kaschmitter

Thank you for your consideration and we look forward to hearing from you,

Sincerely,

Judy Zachariasen, PharmD & Matt Kaschmitter, PharmD

Policy and Procedures
Hy-Vee Technician Product Verification
Sioux Falls #3 (1632)
Updated 12/08/17

Implementing a new pharmacy practice model will allow for pharmacists to deliver patient care services in the community pharmacy and have a greater impact on the health and well-being of patients. The "tech-product-verification" program will permit pharmacist to concentrate on the aspects of dispensing that require the expertise of the pharmacist to assure safe and accurate dispensing. Pharmacy staffing shall be adequate to ensure consistent and safe implementation and usage of the TPV program and will optimize pharmacist patient care services.

Variance required with SD Board of Pharmacy:

Rules Waived:

20:51:29:22. Tasks a pharmacy technician may not perform. A pharmacy technician may not:

- (1) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

Ask: Allow technician's to provide the final verification for accuracy of a filled prescription or medication order.

Other laws to be consider:

Requirements are listed with how Hy-Vee is meeting these requirements listed below.

20:51:29:19.02. Exception to ratio for hospital, mail order, and long-term care pharmacy. The maximum ratio of pharmacy technicians to pharmacists that may be on duty in a hospital, mail order, and long-term care pharmacy will be determined by the pharmacist in charge. However, all of the following requirements must be met:

- (1) Medication is dispensed pursuant to a legal prescription;
 - a. Requirement is completed at the Pre-verification step by only a pharmacist.
- (2) The technology includes tablet or product imaging and or bar code scanning, or both, to insure accuracy in the prescription filling process;
 - a. Hy-Vee Enterprise software includes tablet imaging and barcode scanning to ensure accuracy in the prescription filling process
- (3) A role-based access software automation system that places stop points within the prescription filling process is used, which requires a pharmacist's intervention before allowing the prescription to move to the next step in the prescription dispensing process;
 - a. Hy-Vee Enterprise software requires credentials to proceed to the next step in the dispensing process.
- (4) Pharmacy software that screens and detects drug allergies, identifies drug interactions, and checks age appropriate dosage ranges is used;
 - a. This step is completed within our pharmacy software at the Pre-verification step and reviewed by a pharmacist.
- (5) A pharmacist reviews clinically significant computer warnings of drug interactions, therapy duplications, and contraindications;
 - a. This step is completed at the Pre-verification step by only a pharmacist.

- (6) Electronic surveillance technology is used to control access or to provide continuous monitoring of all areas where drugs are stored or dispensed or both;
 - a. Non-pharmacist staff only has access to drugs in the presence of pharmacist on duty. Electronic surveillance is present to monitor the pharmacy.
- (7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, shipping of drugs, or who have access to any areas where drugs are dispensed are registered as pharmacy technicians and meet the requirements in chapter 20:51:29;
 - a. Technicians involved in the "Tech check Tech" program are required to be nationally certified and complete enhanced technician training included in the policy and procedure.
- (8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy have telephone access to a pharmacist 24 hours a day, 7 days a week. In mail order pharmacies, a patient has access to a pharmacist 24 hours a day, 7 days a week on a dedicated pharmacist staff line;
 - a. N/A
- (9) Drug information, both electronic and hard copy, is readily available to pharmacists;
 - a. The pharmacy has both electronic and hard copy formats to Drug information including: Facts and Comparisons, Micromedex, Orange book, Plumb's, etc...
- (10) A quality assurance program that identifies and evaluates dispensing errors, accompanied by a continuous quality improvement program that assures very high dispensing accuracy rates in place;
 - a. Hy-Vee pharmacy participates in the PQC (Pharmacy Quality Commitment) program from the Alliance for Patient Medication Safety
- (11) There are written policies and procedures for all pharmacy functions – clerical, supportive, technical, and clinical;
 - a. Hy-Vee Pharmacy has specific Policy and Procedures related to workflow
- (12) There are written policies and procedures for training personnel, including on-going training programs for all personnel and documentation of that training for each employee;
 - a. Hy-Vee Pharmacy includes online training, as well as training packets done at beginning of employment and yearly reviews. Additional training for the TPV program is included below in this policy.
- (13) There is a strict monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all schedule II controlled drugs as well as selected high-risk schedule III, IV, and V drugs. Routine audits are conducted to review purchases versus dispensing of controlled drugs to deter and detect diversion.
 - a. Hy-Vee pharmacy has a control substance form to assist in audits to help ensure safe dispensing of medications to deter drug diversion.

Training required to be eligible for New Practice Model:

- 1) Technicians:
 - a. Checking technician must be registered with the board of pharmacy, a certified technician, and not currently be subject to disciplinary charges or sanctions.
 - b. Documentation of additional training will be kept in pharmacy personnel files

- c. Upon completed training technicians will be allowed to check medications dispensed by another technician/intern.
 - d. Technicians will NOT be allowed to check:
 - i. Controlled Substances
 - ii. Compounded Medications
 - iii. Injectables
 - iv. Others designated by PIC or staff pharmacists
 - e. Technician shall have 1500 hours of prior technician work experience at the current or a previous pharmacy of which 300 hours is required at the current location
 - f. Technician must complete location specific pharmacy training procedures
 - g. Technician must complete "Advanced Pharmacy Technician Training for Technicians" from CEI successfully with a passing rate of 80% on all modules
- 2) Interns:
- a. Checking Interns must be registered with the board of pharmacy and not currently be subject to disciplinary charges or sanctions
 - b. Documentation of additional training will be kept in pharmacy personnel files
 - c. Upon completed training interns will be allowed to check medications dispensed by another technician/intern.
 - d. Interns will NOT be allowed to check:
 - i. Controlled Substances
 - ii. Compounded Medications
 - iii. Injectables
 - iv. Others designated by PIC or staff pharmacists
 - e. Interns shall have 300 hours of prior work experience at the current or a previous site of which 100 hours is required at the current location
 - f. Interns must complete location specific pharmacy training procedures
 - g. Interns must complete "Advanced Pharmacy Technician Training for Technicians" from CEI successfully with a passing rate of 80% on modules 1, 2, & 6.

CEI Modules:

- 1) Advancing the role of Pharmacy Technicians
 - a. Pharmacy technicians practice in a variety of settings and have taken on new and advanced roles and responsibilities as the profession of pharmacy evolves in an ever-changing healthcare system. With those new, complex, advanced, and specialized roles, pharmacy technicians require additional education, training, and demonstration of competence. As pharmacy technicians are the foundation of pharmacy's distributive functions and are being utilized in clinical functions where appropriate, the entire pharmacy team must strongly support the education and training of pharmacy technicians. This advanced training module will set the framework for supporting advanced roles of pharmacy technicians.
- 2) Tech-Check-Tech: A step-by-step Guide for Outpatient Pharmacy
 - a. Once you have decided to go forward with a Tech-Check-Tech program there are many steps to follow. This activity provides a "road map" or documented plan for successful and smooth implementation. Topics discussed include quality assurance, job descriptions, monitoring, liability, roll out, and obtaining "buy in" from all members of the pharmacy team and business.
- 3) Advanced Review of Common Medications
 - a. As an experienced technician, you are likely aware of how medications are classified and you can recognize most common medications by generic name. This activity is a review of those medication classes, and provides a more in-depth approach to identifying medications through heuristics, or name stems. In addition to names, this activity also discusses common adverse effects and drug interactions of the more commonly prescribed medications. This advanced review should assist pharmacy technicians to work with the pharmacist to proactively identify potential problems and prevent medication errors.

- 4) Dosage Forms
 - a. There are many ways in which to deliver medications to patients. This activity reviews the most common dosage forms and the reason different routes of administration exist. It will also discuss advantages and disadvantages of various dosage forms, and what you need to know in order to recognize and prevent dispensing errors related to these medications.
- 5) Calculations Review
 - a. A sound base of pharmaceutical math skills is essential to the daily functions of any pharmacy department. As technicians move into more responsible roles such as Tech-Check-Tech, the assurance of basic pharmacy math knowledge and the ability to keep up those skills, is critical. This review emphasizes basic pharmacy math and tests the knowledge of technicians to identify questionable doses or quantities which may require the pharmacist's attention.
- 6) Accuracy in the Outpatient Pharmacy: Preventing, Identifying and Classifying Medication Errors
 - a. The most important aspect of technicians checking technicians is accuracy of dispensing. This activity discusses common medication errors and steps you must take as a checking technician to prevent those errors. Your role in continuous quality improvement is critical as you move into the tech-check-tech environment, and this activity will help you recognize and excel at this important task.

Procedures:

Workflow procedures in Pharmacy:

- 1) Data Entry of Prescription (completed by technician, intern or pharmacist)
- 2) Pre-verification/DUR check (completed by pharmacist)
- 3) Product dispensing on-site (completed by technician, intern or pharmacist) or at central fill facility
- 4) Verification of product (completed by TPV authorized technician or intern, or pharmacist)
- 5) Patient pick-up and counseling

Safeguards present in pharmacy:

- 1) All hardcopy and faxed prescriptions are scanned into software and visible during multiple steps of the process (data entry, pre-verification, and verification)
- 2) Product dispensing and verification will not be completed by the same TPV authorized technician or intern.
- 3) Pre-verification/DUR check requires the pharmacist credentials to move to next workflow queue
 - a. Pre-verification occurs on all new prescriptions and each refill when a DUR is identified
- 4) Each workflow step has credentials assigned as they are completed
- 5) Product dispensing requires a 2 step verification to ensure the correct product is dispensed to the correct patient
 - a. Barcode scan of prescription label to verify correct patient and prescription being dispensed
 - b. Any bottle not scanned will be sent with the prescription for final verification. Example: finishing an open bottle and then opening a sealed bottle to complete the order.
 - c. Barcode scan of drug product to verify correct drug dispensed
 - i. Overrides of product can only be completed by pharmacist and requires the pharmacist's credentials
- 6) Verification requires scanning of prescription barcode to activate checking process of prescription
- 7) Verification uses drug image verification along with product marking information to identify correct drug dispensed along with additional information to verify quantity
- 8) Point of sale requires scanning of the prescription barcode and verification of at least 2 patient specific identifiers

Evaluation of Program and Technicians/Interns for patient safety:

Technician/Intern filling and checking responsibilities will be monitored daily. Errors will be documented for both filling and checking, and review of all errors will be documented using the pharmacies PQC Program. The records will be maintained in the pharmacy for a minimum of two years.

The PIC shall conduct continuous monitoring and evaluation of each Checking Technician and Checking Intern to ensure the continued competency of the TPV program and the safety of the patients. Errors will be identified and records maintained following the pharmacy's quality measures program.

To ensure patient safety for the first week after the new procedures have been initiated, the pharmacist will double check all technician/intern-verified prescriptions to ensure accuracy and to gather information on the efficacy of the procedures/training. If the error rate is determined to be satisfactory to the PIC, 50 prescriptions or 20% of prescriptions verified by the technician/intern will be double checked each month for errors. If at any time the PIC determines an error rate significantly above the average for the pharmacy, retraining will occur.

Retraining will occur when a checking technician or intern has an error rate significantly above the average for participating pharmacy's technicians or interns. During the retraining period a technician's work will be checked by a pharmacist and the technician will not be allowed to check other technicians. Retraining will consist of a repeat competency evaluation in the area/s where excessive errors have occurred and potential repeat of CEI modules as appropriate. The PIC will determine which sections, or all, of the training modules that must be repeated.

Records:

The pharmacist in charge shall maintain in the pharmacy department records for each certified pharmacy technician and intern authorized by the pharmacist in charge to participate in the TPV program. The records shall be available for inspection and copying by the Board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician's employment.

The records shall include:

- a. The name of the certified pharmacy technician or intern.
- b. The date the certified pharmacy technician or intern completed training
- c. The date the certified pharmacy technician or intern was authorized to participate in the TPV program
- f. The dates of and reasons for any suspension or revocation of the certified pharmacy technician's TPV program authorization, identification of corrective action or retraining completed, and date of subsequent reinstatement of the certified pharmacy technician's TPV program authorization.
- g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician's performance of duties relating to the TPV program.

Policy and Procedures
Hy-Vee Technician Product Verification
Sioux Falls #5 (1637)
Updated 12/08/17

Implementing a new pharmacy practice model will allow for pharmacists to deliver patient care services in the community pharmacy and have a greater impact on the health and well-being of patients. The "tech-product-verification" program will permit pharmacist to concentrate on the aspects of dispensing that require the expertise of the pharmacist to assure safe and accurate dispensing. Pharmacy staffing shall be adequate to ensure consistent and safe implementation and usage of the TPV program and will optimize pharmacist patient care services.

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Ask: Allow technician's to provide the final verification for accuracy of a filled prescription or medication order.

Other laws to be consider:

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- (3) A role-based access software automation system that places stop points within the prescription filling process is used, which requires a pharmacist's intervention before allowing the prescription to move to the next step in the prescription dispensing process;
 - a. Hy-Vee Enterprise software requires credentials to proceed to the next step in the dispensing process.
- (4) Pharmacy software that screens and detects drug allergies, identifies drug interactions, and checks age appropriate dosage ranges is used;
 - a. This step is completed within our pharmacy software at the Pre-verification step and reviewed by a pharmacist.
- (5) A pharmacist reviews clinically significant computer warnings of drug interactions, therapy duplications, and contraindications;
 - a. This step is completed at the Pre-verification step by only a pharmacist.

- (6) Electronic surveillance technology is used to control access or to provide continuous monitoring of all areas where drugs are stored or dispensed or both;
 - a. Non-pharmacist staff only has access to drugs in the presence of pharmacist on duty. Electronic surveillance is present to monitor the pharmacy.
- (7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, shipping of drugs, or who have access to any areas where drugs are dispensed are registered as pharmacy technicians and meet the requirements in chapter 20:51:29;
 - a. Technicians involved in the "Tech check Tech" program are required to be nationally certified and complete enhanced technician training included in the policy and procedure.
- (8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy have telephone access to a pharmacist 24 hours a day, 7 days a week. In mail order pharmacies, a patient has access to a pharmacist 24 hours a day, 7 days a week on a dedicated pharmacist staff line;
 - a. N/A
- (9) Drug information, both electronic and hard copy, is readily available to pharmacists;
 - a. The pharmacy has both electronic and hard copy formats to Drug information including: Facts and Comparisons, Micromedex, Orange book, Plumb's, etc...
- (10) A quality assurance program that identifies and evaluates dispensing errors, accompanied by a continuous quality improvement program that assures very high dispensing accuracy rates in place;
 - a. Hy-Vee pharmacy participates in the PQC (Pharmacy Quality Commitment) program from the Alliance for Patient Medication Safety
- (11) There are written policies and procedures for all pharmacy functions -- clerical, supportive, technical, and clinical;
 - a. Hy-Vee Pharmacy has specific Policy and Procedures related to workflow
- (12) There are written policies and procedures for training personnel, including on-going training programs for all personnel and documentation of that training for each employee;
 - a. Hy-Vee Pharmacy includes online training, as well as training packets done at beginning of employment and yearly reviews. Additional training for the TPV program is included below in this policy.
- (13) There is a strict monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all schedule II controlled drugs as well as selected high-risk schedule III, IV, and V drugs. Routine audits are conducted to review purchases versus dispensing of controlled drugs to deter and detect diversion.
 - a. Hy-Vee pharmacy has a control substance form to assist in audits to help ensure safe dispensing of medications to deter drug diversion.

Training required to be eligible for New Practice Model:

- 1) Technicians:
 - a. Checking technician must be registered with the board of pharmacy, a certified technician, and not currently be subject to disciplinary charges or sanctions.
 - b. Documentation of additional training will be kept in pharmacy personnel files

- c. Upon completed training technicians will be allowed to check medications dispensed by another technician/intern.
 - d. Technicians will NOT be allowed to check:
 - i. Controlled Substances
 - ii. Compounded Medications
 - iii. Injectables
 - iv. Others designated by PIC or staff pharmacists
 - e. Technician shall have 1500 hours of prior technician work experience at the current or a previous pharmacy of which 300 hours is required at the current location
 - f. Technician must complete location specific pharmacy training procedures
 - g. Technician must complete "Advanced Pharmacy Technician Training for Technicians" from CEI successfully with a passing rate of 80% on all modules
- 2) Interns:
- a. Checking Interns must be registered with the board of pharmacy and not currently be subject to disciplinary charges or sanctions
 - b. Documentation of additional training will be kept in pharmacy personnel files
 - c. Upon completed training interns will be allowed to check medications dispensed by another technician/intern.
 - d. Interns will NOT be allowed to check:
 - i. Controlled Substances
 - ii. Compounded Medications
 - iii. Injectables
 - iv. Others designated by PIC or staff pharmacists
 - e. Interns shall have 300 hours of prior work experience at the current or a previous site of which 100 hours is required at the current location
 - f. Interns must complete location specific pharmacy training procedures
 - g. Interns must complete "Advanced Pharmacy Technician Training for Technicians" from CEI successfully with a passing rate of 80% on modules 1, 2, & 6.

CEI Modules:

- 1) Advancing the role of Pharmacy Technicians
 - a. Pharmacy technicians practice in a variety of settings and have taken on new and advanced roles and responsibilities as the profession of pharmacy evolves in an ever-changing healthcare system. With those new, complex, advanced, and specialized roles, pharmacy technicians require additional education, training, and demonstration of competence. As pharmacy technicians are the foundation of pharmacy's distributive functions and are being utilized in clinical functions where appropriate, the entire pharmacy team must strongly support the education and training of pharmacy technicians. This advanced training module will set the framework for supporting advanced roles of pharmacy technicians.
- 2) Tech-Check-Tech: A step-by-step Guide for Outpatient Pharmacy
 - a. Once you have decided to go forward with a Tech-Check-Tech program there are many steps to follow. This activity provides a "road map" or documented plan for successful and smooth implementation. Topics discussed include quality assurance, job descriptions, monitoring, liability, roll out, and obtaining "buy in" from all members of the pharmacy team and business.
- 3) Advanced Review of Common Medications
 - a. As an experienced technician, you are likely aware of how medications are classified and you can recognize most common medications by generic name. This activity is a review of those medication classes, and provides a more in-depth approach to identifying medications through heuristics, or name stems. In addition to names, this activity also discusses common adverse effects and drug interactions of the more commonly prescribed medications. This advanced review should assist pharmacy technicians to work with the pharmacist to proactively identify potential problems and prevent medication errors.

- 4) Dosage Forms
 - a. There are many ways in which to deliver medications to patients. This activity reviews the most common dosage forms and the reason different routes of administration exist. It will also discuss advantages and disadvantages of various dosage forms, and what you need to know in order to recognize and prevent dispensing errors related to these medications.
- 5) Calculations Review
 - a. A sound base of pharmaceutical math skills is essential to the daily functions of any pharmacy department. As technicians move into more responsible roles such as Tech-Check-Tech, the assurance of basic pharmacy math knowledge and the ability to keep up those skills, is critical. This review emphasizes basic pharmacy math and tests the knowledge of technicians to identify questionable doses or quantities which may require the pharmacist's attention.
- 6) Accuracy in the Outpatient Pharmacy: Preventing, Identifying and Classifying Medication Errors
 - a. The most important aspect of technicians checking technicians is accuracy of dispensing. This activity discusses common medication errors and steps you must take as a checking technician to prevent those errors. Your role in continuous quality improvement is critical as you move into the tech-check-tech environment, and this activity will help you recognize and excel at this important task.

Procedures:

Workflow procedures in Pharmacy:

- 1) Data Entry of Prescription (completed by technician, intern or pharmacist)
- 2) Pre-verification/DUR check (completed by pharmacist)
- 3) Product dispensing on-site (completed by technician, intern or pharmacist) or at central fill facility
- 4) Verification of product (completed by TPV authorized technician or intern, or pharmacist)
- 5) Patient pick-up and counseling

Safeguards present in pharmacy:

- 1) All hardcopy and faxed prescriptions are scanned into software and visible during multiple steps of the process (data entry, pre-verification, and verification)
- 2) Product dispensing and verification will not be completed by the same TPV authorized technician or intern.
- 3) Pre-verification/DUR check requires the pharmacist credentials to move to next workflow queue
 - a. Pre-verification occurs on all new prescriptions and each refill when a DUR is identified
- 4) Each workflow step has credentials assigned as they are completed
- 5) Product dispensing requires a 2 step verification to ensure the correct product is dispensed to the correct patient
 - a. Barcode scan of prescription label to verify correct patient and prescription being dispensed
 - b. Any bottle not scanned will be sent with the prescription for final verification. Example: finishing an open bottle and then opening a sealed bottle to complete the order.
 - c. Barcode scan of drug product to verify correct drug dispensed
 - i. Overrides of product can only be completed by pharmacist and requires the pharmacist's credentials
- 6) Verification requires scanning of prescription barcode to activate checking process of prescription
- 7) Verification uses drug image verification along with product marking information to identify correct drug dispensed along with additional information to verify quantity
- 8) Point of sale requires scanning of the prescription barcode and verification of at least 2 patient specific identifiers

Evaluation of Program and Technicians/Interns for patient safety:

Technician/Intern filling and checking responsibilities will be monitored daily. Errors will be documented for both filling and checking, and review of all errors will be documented using the pharmacies PQC Program. The records will be maintained in the pharmacy for a minimum of two years.

The PIC shall conduct continuous monitoring and evaluation of each Checking Technician and Checking Intern to ensure the continued competency of the TPV program and the safety of the patients. Errors will be identified and records maintained following the pharmacy's quality measures program.

To ensure patient safety for the first week after the new procedures have been initiated, the pharmacist will double check all technician/intern-verified prescriptions to ensure accuracy and to gather information on the efficacy of the procedures/training. If the error rate is determined to be satisfactory to the PIC, 50 prescriptions or 20% of prescriptions verified by the technician/intern will be double checked each month for errors. If at any time the PIC determines an error rate significantly above the average for the pharmacy, retraining will occur.

Retraining will occur when a checking technician or intern has an error rate significantly above the average for participating pharmacy's technicians or interns. During the retraining period a technician's work will be checked by a pharmacist and the technician will not be allowed to check other technicians. Retraining will consist of a repeat competency evaluation in the area/s where excessive errors have occurred and potential repeat of CEI modules as appropriate. The PIC will determine which sections, or all, of the training modules that must be repeated.

Records:

The pharmacist in charge shall maintain in the pharmacy department records for each certified pharmacy technician and intern authorized by the pharmacist in charge to participate in the TPV program. The records shall be available for inspection and copying by the Board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician's employment.

The records shall include:

- a. The name of the certified pharmacy technician or intern.
- b. The date the certified pharmacy technician or intern completed training
- c. The date the certified pharmacy technician or intern was authorized to participate in the TPV program
- f. The dates of and reasons for any suspension or revocation of the certified pharmacy technician's TPV program authorization, identification of corrective action or retraining completed, and date of subsequent reinstatement of the certified pharmacy technician's TPV program authorization.
- g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician's performance of duties relating to the TPV program.

InstyMeds Medication Adherence System (IM-MAS)

December 8, 2017, South Dakota Board of Pharmacy

The Role of Medication Adherence in Value Based Care

- Michael Burns RPh, VP Pharmacy Services at Instymeds Corporation

Rationale:

Industry data demonstrates that approximately 24%-31% of prescription orders written by providers are not filled by patients leading to non-compliance, additional doctor visits, and hospitalizations.¹⁻⁴ Nonadherence costs the healthcare system hundreds of billions of dollars every year.⁵

Pharmacy access in rural areas remains challenging, while many urban areas have experienced expansion of brick and mortar pharmacies with conveniences such as drive thru windows. Despite this, the data indicating 24%-31% of prescriptions not being filled has remained relatively unchanged.⁶

The InstyMeds Medication Adherence System has been shown to raise primary adherence.⁷ Improving adherence is a driver of value based care.⁸

Objectives:

- Overview of IM-MAS (video, brief presentation)
- Discuss with the South Dakota Board of Pharmacy the rationale for utilization in hospital, emergency room, urgent care, medical clinics, and retail settings.
- Identify and discuss restrictions, if any, which may impede successful implementation and utilization of the IM-MAS in South Dakota.

Measured Outcomes:

1. Primary Medication Adherence utilizing the InstyMeds-MAS versus Industry Benchmark Data.
 - a. Physician reporting on non-filled medication orders within a 48 hour window (allows for follow up by office).
2. Dispensing Accuracy.
3. Patient Experience Data (convenience, ease of use, understanding drug/directions, compliance).
 - a. Net Promoter Score (NPS)
4. Regulatory Compliance (State and Federal) i.e. PDMP reporting and compliance.

1. Fischer MA, Stedman MR, Lii J, et al. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. *Journal of general internal medicine*. 2010;25(4):284-290.
2. Hayes BD, Zaharna L, Winters ME, Feemster AA, Browne BJ, Hirshon JM. To-Go medications for decreasing ED return visits. *The American journal of emergency medicine*. 2012;30(9):2011-2014.
3. Fischer MA, Choudhry NK, Brill G, et al. Trouble getting started: predictors of primary medication nonadherence. *The American journal of medicine*. 2011;124(11):1081. e1089-1081. e1022.
4. Tamblyn R, Egale T, Huang A, Winslade N, Doran P. The Incidence and Determinants of Primary Nonadherence With Prescribed Medication in Primary Care: A Cohort Study. *Annals of Internal Medicine*. 2014;160(7):441-450.
5. Iuga AO, McGuire MJ. Adherence and health care costs. *Risk Manag Healthc Policy*. 2014;7:35-44.
6. DiMatteo MR. Variations in Patients' Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research. *Medical Care*. 2004;42(3):200-209.
7. Moroshek JG. Improving outpatient primary medication adherence with physician guided, automated dispensing. *ClinicoEconomics and outcomes research: CEOR*. 2017;9:59.
8. Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health affairs*. 2011;30(1):91-99.
9. Flynn EA. A Study of the Accuracy of the InstyMeds Automated Prescription Dispensing System. 2013

From: Peterson, Scott [<mailto:SPeterson@regionalhealth.org>]
Subject: [EXT] Asteres Scriptcenter technology and Controlled Substances

I would like to formally request that the Board of Pharmacy permit Regional Health Home Plus Pharmacy to place completed controlled substance prescriptions in Scriptcenter automation for pick-up by patients.

In order to provide some background information, Regional Health Home Plus Pharmacy has Board of Pharmacy approval for three Asteres Scriptcenter pickup locations. One is inside Regional Health Rapid City Hospital. One is inside Regional Health Medical Clinic – Flormann Street in Rapid City. One is inside Regional Health Medical Clinic – Elm Street in Hill City. At this time, controlled substance prescriptions are only dispensed from the location within Regional Health Rapid City Hospital.

The Asteres Scriptcenter automation is a pickup location and not a dispensing location, as all of actions of dispensing have taken place at the pharmacy before the completed prescription is placed inside the automation ready for pickup by the patient. The technology is terrific, with safeguards that exceed the Board of Pharmacy's Policy Statement on Remote "Pickup" Sites. The patient must provide a matching user name/fingerprint to password for each pickup. In addition, a picture is taken of the person picking up the prescription by the automation at the time of pickup.

Current direction from the regional DEA office is that only the location within Regional Health Rapid City Hospital may contain controlled substances. This direction is not consistent with that of other regional DEA offices which are allowing controlled substances to be placed within the Scriptcenter automation for pickup. Both Regional Health and Asteres have engaged with the DEA to gain clarity on this lack of consistency from region to region. Unfortunately but not unexpectedly, the DEA has been silent in response to our inquiries.

Not being able to place controlled substances inside all of the Scriptcenters is very problematic for our patients in that many of them cannot receive all of their medications from the automation. Instead, they have to either receive those in the mail or go to the pharmacy for pick-up. In many ways, the current direction from a single regional DEA office defeats the purpose of the automation, which is to provide better access to prescriptions for patients.

I would ask that the Board of Pharmacy grant permission in the form of a waiver or letter for Regional Health Home Plus Pharmacy to place controlled substances inside the Scriptcenter automation for pickup by patients.

I would certainly make myself available by phone during the next Board of Pharmacy meeting if desired.

Thank you so much for your consideration.

Respectfully,

Scott Peterson, Pharm. D.
Director of Pharmacy, Regional Health Home Plus

 **Regional Health**

Helping Patients and Communities Live Well

Hospice House | 224 Elk Street | Rapid City, SD, 57701

p: 605-755-7141 | e: speterson@regionalhealth.org

Prescribers and Prescribing Authority Approved by the South Dakota Board of Pharmacy
 Prescribing of Controlled Substances (CS) Requires a DEA Registration Number and a State Controlled Substance Registration (CSR)

PRESCRIBER DRUG CLASS	MD/DO	OD ¹ (Optometrist)	DDS ² (Dentist)	PA ³ (Physician Assistant Certified)	CNP ⁴ (Certified Nurse Practitioner)	RPH or PHARM D ⁵ (Pharmacist)	DVM ⁶ (Veterin- arian)	CNM ⁴ (Certified Nurse Midwife)	DPM ⁷ (Podiatrist)	ND ⁸ (naturopathic doctor)
		discouraged	discouraged	discouraged	discouraged	discouraged	discouraged	discouraged	discouraged	discouraged
CII	YES	YES ¹	YES ²	YES ³	YES ⁴	NO	YES ⁶	YES ⁴	YES ⁷	NO
CIII to CV	YES	YES ¹	YES ²	YES ³	YES	NO	YES ⁶	YES	YES ⁷	NO
Legend Drugs	YES	YES ¹	YES ²	YES ³	YES	(see below) ⁵	YES ⁶	YES	YES ⁷	NO
Contraception	YES	NO	NO	YES ³	YES	NO	YES ⁶	YES	NO	NO
Nicotine Cessation	YES	NO	YES ²	YES ³	YES	NO	NO	YES	NO	NO
Anti-Anxiety	YES	NO	YES ²	YES ³	YES	NO	YES ⁶	YES	YES ⁷	NO
Weight Loss	YES	NO	NO	YES ³	YES	NO	YES ⁶	YES	NO	NO
CS for self	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
CS for prescriber spouse or children	YES	YES ¹	YES ²	YES ³	YES	NO	NO	YES	YES ⁷	NO
	discouraged	discouraged	discouraged	discouraged	discouraged			discouraged	discouraged	

- Optometrists are limited to prescribing for the eyes. Optometrists may prescribe, administer or dispense oral and topical pharmaceutical agents including analgesic and antibiotic agents rational to the diagnosis and treatment of the human eye and its appendages. They may not prescribe, administer or dispense any oral therapeutic agent to any child less than 12 years of age, or any oral steroid to any person, without prior consultation with a licensed physician. They may not prescribe injectable products.
- A dentist may prescribe or administer drugs only in connection with dental related ailments or conditions. Anti-Anxiety medications may only be prescribed for dental visit.
- PA's are considered agents of a supervising physician and may prescribe medications, including controlled substances. For products listed in Schedule II, they may prescribe for one period of not more than 30 days; except as authorized by federal law which allows for multiple CII prescriptions written for a period not to exceed 90 day supply if appropriately dated on the day of issue and which include a date in which the subsequent prescriptions may be filled. They may also write for a 60 day supply for partial filling for long term care and hospice patients as allowed by state and federal law.
- CNP's and CNM's no longer have supervisory physician requirements or CII prescribing limits as of the 2017 legislative session.
- Registered pharmacists may initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed healthcare facility or by a practitioner authorized to prescribe drugs.
- Veterinarians can only prescribe to treat non-human animals.
- Podiatrists may only prescribe to treat conditions of the foot.
- Naturopathic physicians or naturopathic doctors are not licensed in SD and have no prescribing authority.

State of South Dakota

Draft Print: 12/5/2017

NINETY-THIRD SESSION LEGISLATIVE ASSEMBLY, 2018

729Z0350

SENATE BILL NO. _____

Introduced by: _____

1 FOR AN ACT ENTITLED, An Act to establish certain provisions regarding the dispensing of
2 biological products.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

4 Section 1. That § 36-11-2 be amended to read:

5 36-11-2. Terms used in this chapter mean:

6 (1) "Association," the South Dakota Pharmacists Association;

7 (2) "Biological product," as defined in 42 U.S.C. 262(i), as of January 1, 2018;

8 (3) "Board" or "board of pharmacy," the State Board of Pharmacy in South Dakota;

9 ~~(3)~~(4) "Brand name," the proprietary or registered trademark name given to a drug product
10 by its manufacturer, labeler or distributor and placed on the drug or on its container,
11 label or wrapping at the time of packaging;

12 ~~(4)~~(5) "Chemicals," the chemical materials or medicine;

13 ~~(5)~~(6) "Compounding," the preparation, mixing, assembling, packaging or labeling of a
14 drug or drug device as the result of a practitioner's prescription drug order or an
15 initiative based on the pharmacist/patient/practitioner relationship in the course of
16 professional practice or for the purpose of or as an incident to research, teaching or



- 1 chemical analysis and not for sale or dispensing. ~~Compounding~~ The term also
2 includes the preparation of drug or drug devices in anticipation of prescription drug
3 orders based on routine, regularly observed prescribing patterns;
- 4 ~~(6)~~(7) "Delivery," the actual, constructive or attempted transfer of a drug or drug device
5 from one person to another, whether or not for a consideration;
- 6 ~~(7)~~(8) "Dispense" or "Dispensing," the preparation and delivery of a drug to a patient or a
7 patient's agent pursuant to a prescription drug order in a suitable container with
8 appropriate labeling for subsequent administration to or use by a patient. ~~Dispensing~~
9 The term includes preparation of labels for drug devices if the labeling is related to
10 the dosage and administration of drugs;
- 11 ~~(8)~~(9) "Distributing," the delivery of a drug or drug device other than by administration or
12 dispensing;
- 13 ~~(9)~~(10) "Drug administration," the direct application of a drug or drug device by
14 injection, inhalation, ingestion or any other means to the body of a patient or
15 research subject;
- 16 ~~(10)~~(11) "Drug device," equipment, process, biotechnological entity, diagnostic agent
17 or other product used in combination with a drug to provide effective
18 management of medication regimens;
- 19 ~~(11)~~(12) "Drug utilization review program," any program operated solely or partially
20 as a professional standards review organization whose purpose is to educate
21 pharmacists and practitioners on severe adverse reactions to drugs, therapeutic
22 appropriateness, overutilization and underutilization, appropriate use of
23 generic products, therapeutic duplication, drug-disease contraindications,
24 drug-drug interactions, incorrect drug dosage or duration of drug treatment,

1 drug-allergy interactions and clinical abuse or misuse, as well as to identify
2 and reduce the frequency of patterns of potential and actual fraud, abuse, gross
3 overuse, inappropriate care or medically unnecessary care associated with
4 specific drugs or groups of drugs among practitioners, pharmacists and
5 patients;

6 ~~(12)~~(13) "Equivalent drug product," a drug product, other than a biological product, that
7 is considered to be therapeutically equivalent to other pharmaceutically
8 equivalent products as determined by the latest edition of Approved Drug
9 Products with Therapeutic Equivalence Evaluations, as adopted by the ~~South~~
10 ~~Dakota Board of Pharmacy~~ board pursuant to chapter 1-26;

11 (14) "Interchangeable biological product," a biological product that the U.S. Food and
12 Drug Administration either has licensed and determined meets the standards for
13 interchangeability pursuant to 42 U.S.C. 262(k)(4), as of January 1, 2018, or has
14 determined is therapeutically equivalent as set forth in the latest edition of, or any
15 supplement to, the Food and Drug Administration's Approved Drug Products with
16 Therapeutic Equivalence Evaluations publication as adopted by the board pursuant
17 to chapter 1-26;

18 ~~(13)~~(15) "Labeling," the process of preparing and affixing a label to any drug or drug
19 device container exclusive of the labeling by the manufacturer, packer or
20 distributor of a nonprescription drug or commercially packaged legend drug
21 or drug device;

22 ~~(14)~~(16) "Medical device," an instrument, apparatus, implement, machine, contrivance,
23 implant, in vitro reagent or other similar or related article, including any
24 component, part or accessory, ~~which~~ that is intended for use in the diagnosis

1 of disease or other conditions or in the cure, mitigation, treatment or
2 prevention of disease in man or other animals or is intended to affect the
3 structure or any function of the body of man or other animals, ~~which~~ that does
4 not achieve any of its principal intended purposes through chemical action
5 within or on the body of man or other animals and ~~which~~ that is not dependent
6 upon being metabolized for achievement of any of its principal intended
7 purposes;

8 ~~(15)~~(17) "Medicines," drugs or chemicals or their preparations in suitable form for the
9 prevention, relief or cure of diseases when used either internally or externally
10 by man or for animals;

11 ~~(15A)~~(18) "Nonprescription drugs," drugs ~~which~~ that are labeled for use by the general
12 public in accordance with § 502 of the Federal Food, Drug and Cosmetic Act
13 as amended through January 1, 1997, and may be sold without a prescription
14 drug order in accordance with § 503 of the Federal Food, Drug and Cosmetic
15 Act as amended through January 1, 1997. The term does not include drugs
16 which are required by federal law to bear the statement, "Caution: federal law
17 prohibits dispensing without prescription," drugs intended for human use by
18 hypodermic injection, or animal remedies regulated by chapter 39-18;

19 ~~(16)~~(19) "Patient counseling," oral communication by the pharmacist of information to
20 the patient or caregiver, as defined in rules promulgated pursuant to chapter
21 1-26, to improve therapy by ensuring proper use of drugs and drug devices;

22 ~~(17)~~(20) "Pharmaceutical care," provision of drug therapy and other pharmaceutical
23 patient care services intended to achieve outcomes related to cure or
24 prevention of a disease, elimination or reduction of a patient's symptoms or

- 1 arresting or slowing of a disease process;
- 2 ~~(18)~~(21) "Pharmacist," ~~an individual~~ a person licensed by the ~~State Board of Pharmacy~~
- 3 board to engage in the practice of pharmacy;
- 4 ~~(19)~~(22) "Pharmacy," any place within or outside this state licensed by the ~~State Board~~
- 5 ~~of Pharmacy~~ board where drugs are dispensed and pharmaceutical care is
- 6 provided to residents of this state;
- 7 ~~(20)~~(23) "Practitioner," ~~an individual~~ a person licensed, registered or otherwise
- 8 authorized by the jurisdiction in which ~~he~~ the person is practicing to prescribe
- 9 drugs in the course of professional practice;
- 10 ~~(21)~~(24) "Prescription drug order," a written or oral order of a practitioner for a drug or
- 11 drug device for a specific patient;
- 12 ~~(25)~~ "Proper name," the nonproprietary name for a biological product designated by the
- 13 U.S. Food and Drug Administration license for use upon each package of the
- 14 product;
- 15 ~~(22)~~(26) "Registered pharmacy technician," a person registered by the board who is
- 16 employed by a pharmacy to assist licensed pharmacists in the practice of
- 17 pharmacy by performing specific tasks delegated by and under the immediate
- 18 personal supervision and control of a licensed pharmacist, as permitted by the
- 19 board;
- 20 ~~(23)~~(27) "Retail place of business," any place where merchandise is sold at retail and
- 21 from which original packages of nonprescription drugs are sold or taken to be
- 22 sold at retail;
- 23 ~~(24)~~(28) "Reverse distributor," any person or business registered with the Drug
- 24 Enforcement Administration that accepts drug products from vendors and

1 returns the drug products to manufacturers for credit or destruction.

2 Section 2. That § 36-11-11 be amended to read:

3 36-11-11. The Board of Pharmacy may promulgate rules pursuant to chapter 1-26 as
4 follows:

- 5 (1) Pertaining to the practice of pharmacy;
- 6 (2) Relating to the sanitation of persons and establishments licensed under the provisions
7 of this chapter;
- 8 (3) Pertaining to establishments licensed under the provisions of this chapter wherein any
9 drug is compounded, prepared, dispensed or sold;
- 10 (4) Providing for minimum equipment and standards of establishments licensed under
11 the provisions of this chapter;
- 12 (5) Pertaining to the sale of drugs by or through any mechanical device;
- 13 (6) In cooperation with other governmental agencies where there exists a joint
14 responsibility for protecting the public health and welfare;
- 15 (7) Pertaining to the sale of nonprescription drugs;
- 16 (8) To adopt such publications or supplements thereto as shall from time to time be
17 deemed necessary to describe the drugs, medicines, prescription drugs, dispensing
18 physician or other terms used in § 36-11-2;
- 19 (9) Pertaining to the posting of prescription prices on the premises of a pharmacy
20 department to provide consumers with comparative pricing information;
- 21 (10) Pertaining to registration of drug wholesalers and manufacturers;
- 22 (11) Pertaining to home health care and service;
- 23 (12) Pertaining to computerized pharmacy;
- 24 (13) Pertaining to the registration of registered pharmacy technicians and the suspension

1 or revocation of registration; an annual registration fee not to exceed thirty dollars;
2 and tasks that may not be delegated by a licensed pharmacist to a registered
3 technician;

4 (14) Redispensing of pharmaceuticals;

5 (15) Pertaining to the dispensing of biological products.

6 Section 3. That § 36-11-19.7 be amended to read:

7 36-11-19.7. No nonresident pharmacy may dispense an equivalent drug product or an
8 interchangeable biological product if a brand name has been prescribed, unless the dispensing
9 is done in compliance with the laws of this state nor may dispense an equivalent drug product
10 or an interchangeable biological product to a resident of this state without informing the patient
11 of the selection and the right to refuse the product selected either by telephone or in writing.

12 Section 4. That § 36-11-46.2 be amended to read:

13 36-11-46.2. A practitioner may prohibit a pharmacist from selecting an equivalent drug
14 product or interchangeable biological product by handwriting on the prescription drug order the
15 words, "brand necessary", or words of similar meaning. The prohibition may not be preprinted
16 or stamped on the prescription drug order. This selection does not preclude a reminder of the
17 procedure required for the practitioner to prohibit selection by a pharmacist from being
18 preprinted on the prescription drug order. If an oral prescription is given to a pharmacist, the
19 practitioner or practitioner's authorized agent shall instruct the pharmacist if selection of an
20 equivalent drug product or interchangeable biological product is prohibited. The pharmacist
21 shall note the instructions on the file copy of the prescription drug order.

22 Section 5. That § 36-11-46.3 be amended to read:

23 36-11-46.3. The pharmacist or the pharmacist's agent shall inform the person receiving the
24 drug or biological product pursuant to the prescription drug order of the selection of an

1 equivalent drug product or interchangeable biological product and of the person's right to refuse
2 the product selected. A pharmacist shall, upon request of the prescribing practitioner, provide
3 information regarding substitutions of equivalent drug products.

4 Section 6. That § 36-11-46.5 be amended to read:

5 36-11-46.5. A pharmacist who selects an equivalent drug product or interchangeable
6 biological product pursuant to this chapter assumes no greater liability for selecting the
7 dispensed drug or biological product than would be incurred in filling a prescription for a drug
8 or biological product prescribed by its established ~~or~~, generic, or proper name.

9 Section 7. That § 36-11-46.7 be amended to read:

10 36-11-46.7. The requirements of §§ 36-11-46.1 to 36-11-46.3, inclusive, ~~and~~ § 36-11-46.6,
11 and sections 9 to 11, inclusive, of this Act do not apply to an order to dispense a drug or
12 biological product to a hospital patient.

13 Section 8. That § 36-11-46.8 be amended to read:

14 36-11-46.8. The selection of an equivalent drug product or interchangeable biological
15 product does not, in itself, in the absence of willful misconduct or negligence, constitute a cause
16 of action against the practitioner.

17 Section 9. That chapter 36-11 be amended by adding a NEW SECTION to read:

18 A pharmacist dispensing a prescription drug order for a biological product prescribed by its
19 brand or proper name may select an interchangeable biological product of the prescribed
20 product. Within five business days following the dispensing of a biological product, the
21 dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product
22 provided to the patient, including the name of the product and the manufacturer. The
23 communication shall be conveyed by making an entry that is electronically accessible to the
24 prescriber through:

- 1 (1) An interoperable electronic medical records system;
- 2 (2) An electronic prescribing technology;
- 3 (3) A pharmacist benefit management system; or
- 4 (4) A pharmacy record.

5 Section 10. That chapter 36-11 be amended by adding a NEW SECTION to read:

6 Any entry into an electronic records system as described in section 9 of this Act is presumed
7 to provide notice to the practitioner. Otherwise, the pharmacist shall communicate the biological
8 product dispensed to the practitioner using facsimile, telephone, electronic transmission, or
9 other prevailing means, if communication is not required where:

- 10 (1) There is no interchangeable biological product approved by the U.S. Food and Drug
11 Administration for the product prescribed; or
- 12 (2) A refill prescription is not changed from the product dispensed on the prior filling of
13 the prescription.

14 Section 11. That chapter 36-11 be amended by adding a NEW SECTION to read:

15 The pharmacist shall, unless otherwise instructed by the prescriber, label the prescription
16 container with the name of the dispensed biological product. If the dispensed biological product
17 does not have a brand name, the prescription label shall indicate the proper name of the
18 biological product dispensed. If a pharmacist selects an interchangeable biological product for
19 the brand name biological product prescribed, the prescription container label shall identify the
20 proper name and may identify the brand name for which the selection is made. The dual
21 identification allowed under this section shall take the form of the following statement on the
22 prescription container label: (proper name) interchangeable with (brand name). The pharmacy
23 file copy of each prescription shall include the brand name, if any, or the proper name, and the
24 name of the manufacturer of the biological product dispensed. The prescription container label

- 1 shall include all information required by federal and state law or by rule promulgated by the
- 2 board pursuant to chapter 1-26.

What are information sharing/20.88 agreements?

Chapter 21 of the Code of Federal Regulations (CFR) 20.88 allows FDA to share certain non-public information with state and local government officials (referred to collectively as state officials below). FDA commonly refers to these agreements as '20.88s' and they are used to sharing confidential commercial information (CCI), personal privacy information (PPI), and pre-decisional information (PDI). However, 20.88s do not allow for the sharing of trade secret information (TSI).

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What are the rules governing the sharing of non-public information?

In order for FDA to share any non-public information under a 20.88 agreement, there must be:

1. A written statement establishing that the state government agency entering into the agreement with FDA has the authority to protect certain non-public information, and
2. A written commitment that the state agency will not further disclose any such information provided to it.

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What is Confidential Commercial Information?

CCI is valuable data or information which is used in a business and is of such type that it is customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to whom it belongs. Examples of CCI include raw material supplier lists, finished product customer lists, trace back information, etc. CCI is exempt from Freedom of Information Act requests, but can be shared through a 20.88 agreement.

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What is Trade Secret Information?

A trade secret includes the characteristics of CCI and further includes any commercially valuable plan, formula, process, or device that is used for making, preparing, compounding, or processing of commodities, and it can be said to be the end product of either substantial effort or innovation. In order for CCI to be considered a trade secret, there must be a direct relationship between the trade secret and the manufacturing methods and processes. An example of a trade secret would be the formula for the natural flavorings in a carbonated soft drink. Trade secret information is exempt from Freedom of Information Act requests, but cannot be shared, even with a 20.88 agreement, unless the owner of the information agrees or puts in writing that the information is no longer confidential.

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Who do I contact to ask questions about Information Sharing Agreements?

Questions regarding Information Sharing Agreements should be directed to InfoShare-ORA@fda.hhs.gov.

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**South Dakota
Board of Pharmacy**

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Approvals, Variances, and Pharmacy Closings for December 8, 2017 Board Meeting

Approvals

1. Ameripharm dba MedVantx "off-site" storage of prescription drugs renewal

Variances/Waivers

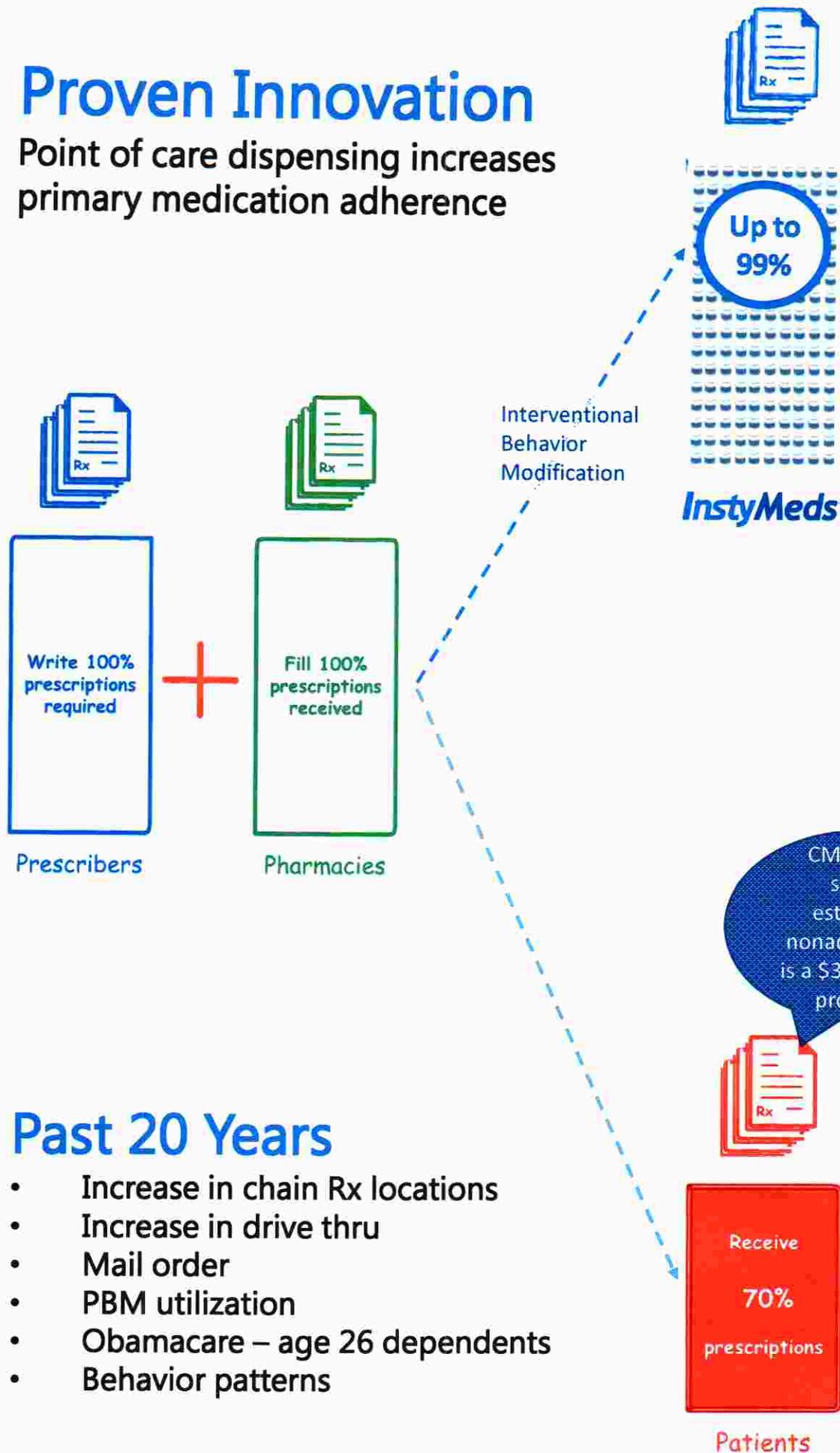
1. Minnehaha Co Jail – Aristada Renewal
2. Shane's Pharmacy – Hughes County Jail Emergency Kit
3. Correct Rx – Pennington County Jail Emergency Kit (pharmacy change)
4. Regional Home Plus LTC Pharmacy – Pennington County Detox Emergency Kit
5. PharMerica – RxNow Ekit Variance Luther Manor renewal

Pharmacy Closings

1. K Mart Pharmacy #7023, Aberdeen, Lic # 100-0950, November 29, 2017

Proven Innovation

Point of care dispensing increases primary medication adherence



Past 20 Years

- Increase in chain Rx locations
- Increase in drive thru
- Mail order
- PBM utilization
- Obamacare – age 26 dependents
- Behavior patterns

South Dakota State University
College of Pharmacy and Allied Health Professions Report
Board of Pharmacy
12/8/2017

College's activities since the 9/21/2017 South Dakota Board of Pharmacy Meeting

PharmD – All **73** of our 2017 SDSU pharmacy graduates took the NAPLEX during the second trimester testing window and **72 passed (98.6%)**. The national first time pass rate was 90.2%.

The revised PharmD curriculum is moving through the University system and will be voted on by the BOR in their March meeting. If approved, implementation will be fall 2018.

Strategic Planning – On January 4th the College will host our strategic planning workshop to kickoff our planning process. Dr. Melchert, Dean of UMKC will lead the planning workshop.

Faculty Positions – Update –

Lisa Otterson, the College's new development director, joined the College in September. She replaces Mike Birgen who is now Associate Vice President for Development at the South Dakota State University Foundation.

Sue Fierstine is the College's new budget coordinator replacing Andrea Hogie. Sue joined the College on October 1.

Search –

Dean - The search process is being extended into the spring semester with the goal of having the new Dean in place by July 1.

Endowed Positions - Recruitment is underway for the Hoch Family Endowed Professor in Community Pharmacy Practice and the Haarberg Chair in Oncology Research.

Pharmacogenomics/Ambulatory Care - We are currently recruiting for a faculty member specializing in pharmacogenomics.

Avera Brookings Clinic Ambulatory Care – We are currently recruiting for this ambulatory care position.

Other searches include our Grant Proposal Specialist.

MPH Program

The accreditation process is underway for this SDSU/USD online program. The SDSU arm of this program is under the direction of the College of Pharmacy and Allied Health Professions.

The MPH Curriculum is undergoing revision with this 42 credit program increasing the elective hours from 6 to 12. This revision is moving through the University review process and will be voted on by the BOR in March.

Currently 74 students are enrolled in the program (21 SDSU).

Congratulations:

Congratulations to the APhA-ASP chapter for receiving the 2016-2017 Region V Operation Immunization Award. The award was presented at the Midyear Regional Meeting in Des Moines last weekend. The students were recognized for the influenza immunizations clinics held in Brookings and Sioux Falls as well as efforts to educate the community about the importance of immunizations. The committee was led by Jade Kutzke and Bailey Buenger.

Respectfully submitted,
Jane Mort
Interim Dean
College of Pharmacy and Allied Health Professions