

S O U T H D A K O T A PHARMACIST



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WINTER EDITION 2024

Our mission is to promote, serve and protect the pharmacy profession.

South Dakota Pharmacists Association

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2024

JANUARY

- 1 New Year's Day
- 9 99th South Dakota Legislative Session Opens
State of the State Address
South Dakota State Capitol, Pierre, SD
- 12 National Pharmacists Day
- 15 Martin Luther King Jr. Day

FEBRUARY

- 9–10 PharmaCE Expo
Hilton Des Moines Downtown, Des Moines, IA
- 13 Legislative Days: Dinner & Legislative Update
Missouri Events Center, Pierre, SD | 6 pm
([RSVP here](#))
- 14 Legislative Days: Wellness Screenings
South Dakota State Capitol, Pierre, SD | 7–10 am
Courtesy of SDSU Student Pharmacists
- 19 President's Day

MARCH

- 22–25 APhA Annual Meeting and Exposition
Orlando, FL
- 25 99th South Dakota Legislative Session
Reserved for the consideration of gubernatorial vetoes

APRIL

- 4 South Dakota Board of Pharmacy Meeting
Sioux Falls, SD | 1–5 pm
- 5–6 South Dakota Society of Health System Pharmacists 47th Annual Meeting
Holiday Inn City Centre, Sioux Falls, SD

The South Dakota Pharmacist is published quarterly: January, April, July, and October. Opinions expressed do not necessarily reflect the official positions or views of the South Dakota Pharmacists Association.

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If you are not on our mass e-mail system check our website periodically for district meetings and other upcoming events. They will always be posted at: www.sdpha.org.

Winter
EDITION

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Director's COMMENTS

Amanda Bacon // SDPhA Executive Director



Google tells me it is Greek philosopher Heraclitus who is attributed with the idea that has become the modern quote of, "The only constant in life is change." The saying comes from fragments of his ancient writings in which I find a few different versions of the original quote, but the one that resonates with me most: No man ever steps in the same river twice, for it is

not the same river and he is not the same man.

There has been a lot of life, and a lot of change since our last edition of the Journal. While we are being philosophical and honest – a lot of it – personally and professionally – has been, well... really hard.

Not all that long after convention, my husband was diagnosed with follicular lymphoma, a form of Non-Hodgkin's Lymphoma. I am extremely grateful and feel very blessed to say that with treatment, his prognosis is good. But also... so much about our lives are forever changed. The unknown, the waiting, the testing, the surgeries, the treatments – at times it has been like being washed away in the aforementioned river. Other times it has been so still you could hear the nuance of every trickle of water passing over stones on the riverbank.

Life is no longer the same water. And no one in my family is the same man.

I tell you all of this mostly because I want to publicly thank the SDPhA board, some of our recent board members, and our legal team, for stepping in and just handling things when my focus needed to be elsewhere. There is only one of me for the SDPhA office, and only one of me for my family. They never hesitated to be where I could not be, so I could be where I needed to be. Their commitment to this Association, to the profession, and to each of you as

members is unequivocally one of the most incredible and humbling things I have experienced in my professional career. So, while they'll never ask for it, they absolutely deserve recognition. And, you deserve to know who stood in the gap for you (and me).

In the meantime, the Association itself has also been handed a tough blow, and trying to navigate new water as well. At the December 2023 South Dakota Board of Pharmacy (SD BOP) meeting, the board voted to rescind their vote from June 2023 to send SDPhA the 80% of the pharmacist renewal license fees as per [SDCL 36-11-6](#).

The BOP finds itself in financial difficulty, and this also now the position we find the Association in as a result.

Via SDCL 36-11-6, pharmacists renewing their license in South Dakota are SDPhA members (you can opt out should you choose). Here's the history –years ago, the SD BOP and the Association were run out of the same office, by the same executive. When the offices separated, the funding mechanism became essentially what we know now – that a portion of the pharmacist renewal fees may go to the association as detailed in the statute referenced above.

Funds that come to SDPhA through those fees go into the SDPhA General fund and are used in accordance with our obligations as outlined in that statute. Primarily this includes day-to-day operations, continuing education, funding the Health Professionals Assistance Program (HPAP) and other initiatives that advance patient care, enhance public awareness, and serve in the best interest of public health and pharmacy.

These funds are not to be used for lobbying, which is why we maintain a separate Commercial and Legislative Fund. That fund sustains the lobbying arm of SDPhA.

The reality is, to ensure the profession has a seat at the table, first and foremost, the Association needs the funds in the general fund to even exist. (While we have some reserves, like you, SDPhA can't operate without its main

source of income for very long.) Second, we must have the funds in the C&L Fund to pay for the chair. We appreciate the BOP's efforts to work toward solutions and hope to find a resolution that allows SDPhA to continue the good work the legislature has tasked us to do.

On that legislative front, the 2024 Legislative Session got off to a fast start, and that rapid pace continues. As of this writing, 137 House Bills and 136 Senate Bills are in the hopper. We expect hundreds more to drop in the coming days. It is important for you to know - we read every word of every single one. Why would you do that to yourself, you ask? Well, we do it because we know you can't. We do it because in legislation, every word matters. You would be amazed at what you can find in the nuances and the cross-references that end up impacting the profession. It is from that review we decide which bills we need to monitor, and which bills we need to take a position on.

We have a long-standing philosophy here; you don't have to show up to every fight you're invited to. That has served us very well, for a very long time. As a result, when lawmakers hear from us, they know it is important.

When we monitor a bill, that is an active situation. It does not mean that we are simply curious to see what happens next. It means that bill has potential to impact the profession in some way. It means we listen every time that bill has a hearing. It means we are actively talking to stakeholders and legislators to ensure things proceed with the bill the way they are "supposed" to. So with that in mind - I strongly encourage you to take a look at the sheer [number of bills we're already monitoring on your behalf](#).

When we take a position on a bill, it means we see a direct impact on the profession, or our patients - for better or worse. It means that we go on the record with committee testimony and talk to every legislator who will listen (as well as those who do not want to) about that bill's impact on our profession and patients.

So even in a year when we are not bringing legislation – it's an all-hands-on-deck situation. Sometimes, our biggest wins are not the things that make headlines. They are things we kept from being headlines. We strategize daily (sometimes several times) about the next best move both for the bills we are monitoring, and the ones we have taken a position on. It is not unusual that we are conferring by 6 a.m., or as late as midnight.

In short, we ensure you have a seat at the table we talked about earlier. Because the truest thing about the legislative process is that if you aren't at the table, you ARE on the menu. Make sure you read our weekly legislative emails and [join the Facebook group](#) linked here to stay in the know!

Finally, a quick look at our national priorities and PBM Reform. As Congress continues to kick the can down the road on a funding package, our national partners are working hard to ensure this opportunity to pass meaningful PBM reform that can be signed into law isn't missed. In the coming weeks, you're going to hear more calls from us, and others to once again make your voices heard. It is important that even if you've done so before, you reach out and do it again. Congress needs to know we are paying attention, and this action (or inaction) has an enormous impact on pharmacy and our patients.

If you want to learn more about our legislative work, or see the other work we're tasked with in action – the perfect place to do that is our Legislative Days event in Pierre Feb. 13-14. We have more than 30 student pharmacists who will be here – I highly encourage you to join them. The [full agenda](#) is on the website – [just let me know](#) you'd like to come.

Respectfully,

AMANDA BACON

99th SOUTH DAKOTA LEGISLATIVE SESSION CALENDAR

2024 38 Legislative Days



Please refer to the Joint Rules, Chapter 17 for complete information.

	Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
January 2024		1	2	3	4	5	6
	7	8	9 Session Opens 12 Noon(CST) (Constitution, Art. III, Sec. 7) State of the State LD 1	10 State of the Judiciary 11:00am State of the Tribes 1:00pm LD 2	11	12	13
	14	15 Martin Luther King Jr. Day	16 Executive orders filed (Constitution, Art. IV, Sec. 8) LD 5	17	18 Jt. Memorial Service 3:00pm LD 7	19	20
	21	22	23 Bill and resolution draft requests due to LRC by 5:00pm (for unlimited introduction) LD 9	24	25 Last day for unlimited bill and resolution introduction (JR 6B-3) (TWO HOURS prior to session) LD 12	26	27
	28	29 All bill and resolution draft requests due to LRC by 5:00pm LD 13	30 Committee bill and resolution draft requests due to LRC by 5:00pm LD 14	31 Last day for introduction of individual bills and resolutions (TWO HOURS prior to session) LD 15	1 Last day for introduction of committee bills and resolutions (TWO HOURS prior to session) LD 16	2	3
February 2024	4	5	6	7	8	9	10
	11	12	13	14	15 Last day for JCA selection of general fund revenue targets (JR 7-11.1) LD 25	16	17
	18	19 Presidents' Day	20 Last day to use JR 5-17, AND Last day to move required delivery of bills or resolutions by a committee to the house of origin LD 26	21 Last day to invoke JR 7-7 in the house of origin, AND Last day to pass bills or joint resolutions by the house of origin (Crossover Day) LD 27	22	23 Last day for JCA to move required delivery of special appropriation bills to house of origin (JR 17-1) LD 29	24
	25	26 Commemoration requests due to LRC by 5:00pm, AND Last day for house of origin to pass special appropriation bills referred from JCA (JR 17-1) LD 30	27	28 JR 5-13 in effect, AND Last day for introduction of commemorations (TWO HOURS prior to session) LD 32	29 Last day to move required delivery of bills or joint resolutions by a committee to the second house LD 33	1	2
	3	4 Last day for a bill or joint resolution to pass both houses, and Last day to invoke JR 7-7 in the second house LD 34	5	6	7	8	9
March 2024	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25 Reserved for consideration of gubernatorial vetoes LD 38	26	27	28	29	30

Adopted: 3/7/2023

STANDING COMMITTEES

99th Legislative Session Meeting Schedule – 2024



TIME	ROOM	MONDAY WEDNESDAY FRIDAY	TUESDAY THURSDAY
7:45 – 9:45 a.m.	414	House State Affairs <i>Rep. Will Mortenson, Chair John McCullough, Staff</i>	House Ag & Natural Resources <i>Rep. Roger Chase, Chair Lance Nixon, Staff</i>
7:45 – 9:45 a.m.	413	House Education <i>Rep. Mike Stevens, Chair Jacob Carlson, Staff</i>	Senate Judiciary <i>Sen. Helene Duhamel, Chair Melanie Dumdei, Staff</i>
7:45 – 9:45 a.m.	412	Senate Health & Human Services <i>Sen. Erin Tobin, Chair Anna Madsen, Staff</i>	House Health & Human Services <i>Rep. Kevin Jensen, Chair Anita Thomas, Staff</i>
7:45 – 9:45 a.m.	423	Senate Transportation <i>Sen. Joshua Klumb, Chair Amanda Marsh, Staff</i>	Senate Education <i>Sen. Kyle Schoenfish, Chair Jacob Carlson, Staff</i>
7:45 – 9:45 a.m.	464		House Taxation <i>Rep. Kirk Chaffee, Chair John McCullough, Staff</i>
10:00 a.m. – Noon	414	Senate State Affairs <i>Sen. Casey Crabtree, Chair Amanda Marsh, Staff</i>	House Local Government <i>Rep. Becky Drury, Chair Anna Madsen, Staff</i>
10:00 a.m. – Noon	413	House Judiciary <i>Rep. Jon Hansen, Chair Melanie Dumdei, Staff</i>	House Transportation <i>Rep. Rocky Blare, Chair Amanda Marsh, Staff</i>
10:00 a.m. – Noon	412	Senate Local Government <i>Sen. Tim Reed, Chair Jacob Carlson, Staff</i>	Senate Commerce & Energy <i>Sen. David Wheeler, Chair Hillary Larsen, Staff</i>
10:00 a.m. – Noon	423	Senate Taxation <i>Sen. Jim Stalzer, Chair Lance Nixon, Staff</i>	Senate Ag & Natural Resources <i>Sen. Herman Otten, Chair Anita Thomas, Staff</i>
10:00 a.m. – Noon	464	House Commerce & Energy <i>Rep. Mike Weisgram, Chair Hillary Larsen, Staff</i>	
8:00 a.m. – Noon	Appropriations 362	Joint Committee on Appropriations <i>Rep. Mike Derby, Lead Co-Chair, Sen. Jean Hunhoff, Co-Chair Mehlhaff, Jessop, Knofczynski, Douglas, Honan, Staff</i>	
Meets at the Call of the Chair	Government Operations & Audit (Chairs: Sen. Wink & Rep. Otten/Auditor General/Melanie Dumdei) Legislative Procedure (Chairs: Rep. Bartels & Sen. Schoenbeck/John McCullough) Mil. & Vet. Affairs (Chairs: [H/MWF PM] Rep. Reisch & [S/TTH PM] Sen. D. Johnson/Jacob Carlson) Retirement Laws (Chairs: Sen. Bolin & Rep. Bartels/Mitch Honan)		

This schedule and all Legislative Research Council documents are available on the LRC home page: sdlegislature.gov.

2023/2024 COMMERCIAL & LEGISLATIVE
DISTRICT DUES CONTRIBUTIONS

FIRST NAME

LAST NAME

ADDRESS

CITY

STATE

ZIP CODE

HOME PHONE

MOBILE PHONE

EMPLOYER / COMPANY

WORK ADDRESS

WORK CITY

STATE

ZIP CODE

WORK PHONE

WORK FAX

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Do you wish to receive SDPhA email alerts regarding important pharmacy issues? ☐ YES ☐ NO

COMMERCIAL & LEGISLATIVE FUND Memberships set by SDPhA C & L Executive Committee, 2007

PHARMACY OR BUSINESS MEMBERSHIP \$500.00 Includes One Individual Membership

NAME OF PHARMACY / BUSINESS

NAME OF INDIVIDUAL INCLUDED

CORPORATE MEMBERSHIP \$1,000.00 Two or more stores of the same corporation

NAME OF CORPORATION

NAME OF INDIVIDUAL INCLUDED

INDIVIDUAL MEMBERSHIP

☐ \$100 LEVEL

☐ \$200 LEVEL

☐ OTHER \$

DISTRICT DUES Circle your District

ABERDEEN – \$20.00

BLACK HILLS – \$20.00

HURON – \$10.00

MITCHELL – \$10.00

MOBRIDGE – \$10.00

ROSEBUD – \$10.00

SIOUX FALLS – \$20.00

WATERTOWN – \$20.00

YANKTON – \$15.00

TOTAL ENCLOSED

\$

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President's PERSPECTIVE

Jessica Strobl, PharmD // SDPhA Board President



“When preaching to the choir, remember they are already believers so focus on inspiring them to action” - Unknown

Have you ever heard the term “preaching to the choir?” It’s a term I grew up with. When someone was telling a group of people the same message they’ve already heard and believed in. When someone was trying to convince

someone who already agreed with them. Or when someone was explaining a lesson to listeners that already understood. My mom would dub this “preaching to the choir.” I have a sneaking suspicion that my mom might be a little disappointed because “preaching to the choir” is exactly what I’m about to do. Because if you are reading this article in our SDPhA Quarterly Journal you have probably already heard about the current issues and know the challenges facing pharmacy.

You have heard the combination of lower reimbursements and the last DIR fee pull in the first quarter of 2024 are creating an issue adequately dubbed the “DIR hangover.” You also know that 340B has become a lifeline for many health systems and pharmacies in our state and is at the forefront of reform, which may be needed but could be devastating. You know that no matter what the practice setting, pharmacies in South Dakota and throughout the nation are strained by margin erosion and intensifying labor and supply shortages.

You most certainly know that SDPhA and our dedicated partners worked to get HB 1135 passed to limit PBM’s egregious behaviors in South Dakota. But did you know that SDPhA has put together resources on how and where to report violations when you see them? Go to page 13 for a preview, and just click on that page to utilize all the recourses on the [SDPhA website](#).

You’ve heard that the current state of pharmacy has created burnout and wellness issues in the workforce. But did you know that there are unlimited resources available to help

you learn more or talk to someone if needed? SDPhA has some of them easily available at <https://www.sdpha.org/wellbeing>

You might be sitting there thinking, “I’m aware of these issues and many more in the pharmacy profession right now, but what can I do about it?” I have been in that seat, feeling like a small fish in a big pond and feeling like these are issues for someone else to work on. Someone with a bigger voice or more dominating presence. And in these busy times it’s especially common to feel like you don’t have time for these issues, so they need to be left to someone with much more time on their hands. People with fewer responsibilities and obligations that occupy their time and priorities.

What you may not know is that alone your voice may feel small, TOGETHER, in unison, is the best way to amplify our voices and be heard. Your presence may not be intimidating but when every pharmacist from the state stands together we can and have historically been a force to be reckoned with. And no one has any more time on their hands than you do, we are all busy parents, employees, volunteers, and friends but when we join in and take action with any amount of time we have - it is impactful. Action is necessary now, working together is necessary now.

So my friends and colleagues, in these uncertain times, even being referred to as “Pharmageddon” by some - every voice is needed. Our association is being called to stand together for all pharmacists in our great state and for the profession of pharmacy as a whole. We need YOU and everyone at your pharmacy practice who isn’t sitting in the choir. Now more than ever, it will take all of us. I know you believe in the message, or you wouldn’t be here. So now take that step into action.

Not sure how to get started? Meet us at Pharmacy Legislative Days February 13 & 14 in Pierre.

I’ll see you there!

Respectfully,

JESSICA STROBL

South Dakota BOARD of PHARMACY

Kari Shanard-Koenders, RPh, MSJ // Executive Director



Board Welcomes New Registered Pharmacists /Pharmacies

Congratulations to the following 15 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: I-Trinity Bernier-Nachtwey, Timothy Berry, Donna Cook, Loretta Dy, Kimberly Dykstra, Giby George, Ashley Howard, Nathan Imre, Roxana

Joseph, Dana Moore, Josey Poppens, Lacey Steele, Renee Tichy, Sheri Woitalewicz, and Samira Zantout.

There were five new SD full-time pharmacy licenses issued: Lewis Drug Inc, dba Falls Community Health – Lewis Drug #29, Sioux Falls, SD License #100-2092; SD Department of Corrections Pharmacy – Pierre Women’s Prison, Pierre, SD License # 100-2093; Lewis Drug Inc, dba Lewis Drug #17, Sioux Falls, SD License #100-2094; Monument Health Nuclear Pharmacy, Rapid City, SD License # 100-2095; and Avera McKennan dba Avera Long-Term Care Pharmacy –Rapid City, SD License # 100-2096. There were no SD Part-time pharmacy licenses issued. There was one new SD Wholesaler license issued: Helget Inc dba Helget Home Medical, Sioux Falls, SD License # 600-3582.

December 8, 2023 Board Meeting Notes

At this writing, the Governor’s Office has not agreed to allow the Board to take the fee increase bill to the 2024 legislative session. Most of you know the Board does not receive any State general funds and is only funded through Board licensure fees. Per SDCL 36-11-6, the Board may pay the South Dakota Pharmacists Association 80% of collected pharmacist license renewal fees, which the Board has voted to do each year. The Board has been told to spend down before any fee increase bill could be brought to the

Legislature. The Board has been fiscally responsible during the spend down but due to it and several other factors including employee pay increases by the Legislature, rising costs, and the loss of federal grant funding for the PDMP, the Board’s finances are now at a critical low. Because of this current financial state, the Board is unable to pay the 80% of pharmacist license fees to the Association this year. This decision was very difficult for Board members as they have an overall concern about the Association remaining viable, but the Board must remain viable for public protection. The Board is hoping for the fee increase bill but understands the Governor’s office is determined to repeal SDCL 36-11-6 and this will be a part of the Board’s bill. This is an unfortunate situation for all involved.

Board Approves Policy Statement on USP Compounding Chapters

During the September 14, 2023 board meeting, the board adopted a policy statement to clarify the expectations for pharmacies to follow the new United States Pharmacopeia (USP) standards. Board Policy Statement #23-09-14 can be found on the [board website](#). The board expects all pharmacies that are compounding or handling hazardous drugs, to follow the latest USP chapters <795>, <797>, <800>, and <825> which became enforceable on November 1, 2023. This policy statement will be used for guidance until the compounding section of the administrative rules can be updated through the full rule-making process in the spring.

In addition, for pharmacies that regularly compound most of their business or ship compounds to other states, NABP has updated the NABP Blueprint Inspection Form to the current USP compounding chapters. This form is utilized by our inspectors to perform annual inspection of these pharmacies. This tool has been most helpful for inspectors and for pharmacies to ensure they are following the current compounding standards.

PDMP Assistant Hired to Replace Long Time Board Employee

As most of you know, long time Board of Pharmacy employee, Melanie Houg, has retired and is enjoying her grandchildren even more!! We miss her. The Board has hired Certified Pharmacy Technician Brandi Dux as the new PDMP Assistant. Brandi is highly skilled in pharmacy management and understands the pharmacy world in a very big way. She is a fantastic asset to our small board office, and we are thrilled to have her assisting the PDMP program.

Beware of Fraud and Counterfeit Popular Weight Loss Products

The FDA is warning of fraud in the supply chain for weight loss products in the glucagon-like peptide 1 (GLP-1) agonists (i.e., semaglutide) and the glucose-dependent insulinotropic polypeptide (GIP) receptor plus GLP-1 mixed (tirzepatide) receptor classes. The FDA Office of Criminal Investigations has identified cases of wholesalers selling and the purchaser does not receive product after they pay for it. Be sure to question any behavior that seems abnormal for these classes of agents. https://nabp.pharmacy/news/blog/regulatory_news/fda-warns-of-fraud-pertaining-to-distribution-of-ozempic-other-medications/

These products do cause significant weight loss, are in high demand, and are on the FDA shortage list as a result. FDA allows 503B and 503A pharmacies to compound shortage list items if the Active Pharmaceutical Ingredient (API) is not a salt or other form of the drug. For instance, Semaglutide (Ozempic) may only be compounded with the API semaglutide base. Most of the spas and wellness centers are dispensing non-FDA approved compounded products due to this. Some send prescriptions for brand name products to a pharmacy. This is preferred. The board is aware of one adverse reaction in SD due to patient’s misunderstanding the dose and injecting ten times the

amount prescribed. Additionally, wherever there is high demand, it provides opportunity for potential criminal activity. Thirty-eight cases of counterfeit semaglutide that caused adverse events have been reported to the FDA Adverse Events Reporting System (FAERS) since 2020. The majority of these were serious ADR’s. One syringe was found to contain insulin glargine. The FAERS has limitations, due to the reports being voluntary, so there may be many more cases. Be on the lookout for counterfeit product. Notable characteristics of counterfeits are that labels have poor quality, boxes may have grammatical or spelling errors, may lack tamper resistant system, and the batch number on the counterfeit box might not correspond to the product strength listed on the same box and pen. <https://www.forbes.com/sites/ariannajohnson/2023/11/09/counterfeit-ozempic-wegovy-mounjaro-pens-reported-to-fda-how-to-spot-a-fake/?sh=433b47b31439>

Pharmadrop™ Drug Take-Back Program By Melissa Denoon

The South Dakota Board of Pharmacy established a drug take-back program in 2017 to reduce the avenue of diversion created by unused, unwanted, and expired drugs in an individual’s medicine cabinet. Trilogy MedWaste’s PharmaDrop™ receptacles were placed in South Dakota hospitals and retail pharmacies. This program was initially funded through a federal PDMP grant and is currently being funded through a SD Department of Social Services federal grant. Since program inception, the program has placed 89 permanent drug take-back receptacles across South Dakota and enrolled an additional 5 locations that already had their own receptacles to the South Dakota PharmaDrop™ program, bringing the total number of locations managed through the program to 94. A comprehensive list of permanent drug take-back sites can be found on [AvoidOpioidSD.com](#), ‘Take Action’, ‘Safe Medication Disposal’. This program provides an option for the safe disposal of an individual’s non-prescription and prescription drugs,

including controlled substances, and is a key component in South Dakota’s strategy to address our state’s misuse, abuse, and diversion of controlled prescription drugs. If your pharmacy is not currently participating and would like to, please email Melissa.DeNoon@state.sd.us.

Respectfully submitted for the Board,

KARI SHANARD-KOENDERS

BOARD MEETING DATES

Please check the [Board of Pharmacy page on Boards and Commissions Website](#) page on the South Dakota Board of Pharmacy website for the time, location, and agenda for future Board meetings. Scroll down to the Board Meetings on the main page of our website and the link is there.

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PDMP SIGN UP + DATA ACCESS
<https://southdakota.pmpaware.net/login>



Have you ever wondered how your Well-Being compares to others? Consider investing six minutes in your well-being. The Well-Being Index is a brief online self-assessment, invented by the Mayo Clinic and brought to you through a partnership with the American Pharmacists Association (APhA), which provides you immediate individualized feedback including tools and local and national resources to address your well-being. You can set-up the frequency you wish to assess your well-being and track your progress.

Your information and score are private and your individual score will not be shared with APhA or anyone else. You do not have to be an APhA member to participate.



- 1. Go to: www.mywellbeingindex.org/signup
- 2. If asked for a participation code, use APhA
- 3. Register (approx. 3 minutes)
- 4. Take the survey (approx. 3 minutes)

PBM AND PAYER RESOURCES

[Home](#) / [Resources](#) / PBM and Payer Resources

PBM RESOURCES

[PBM Enforcement](#)

[PBM Complaint Form](#)

ADDITIONAL PAYER RESOURCES

[South Dakota Medicaid](#)

[Medicaid Provider Enrollment](#)

PBM REFORM IN SOUTH DAKOTA

South Dakota Pharmacists Association advocates for meaningful pharmacy benefit manager (PBM) reform that benefits patients and pharmacies together. SDPhA supports efforts in PBM oversight on the federal and state level. We work closely with our South Dakota Congressional Delegation, the South Dakota Legislature, the South Dakota Division of Insurance and other stakeholders to ensure adequate payment and meaningful reform.

References to current SD law for PBMs are linked on right. Should you know of any PBM in violation of this code, we encourage you to file a complaint (link left and below) with the South Dakota Division of Insurance to help enforce law for which we advocated.

TIPS FOR FILING COMPLAINTS:

- A phone call doesn't do it. You must fill out the complaint form.
- Include a clear and concise description of the non-compliance (i.e., state law prohibits clawbacks and PBMs continue to clawback funds after the point of sale).
- Cite the specific state statute (list on the right).
- Include records/claim/other evidence of the PBMs' violations.
- Include all other information required by the state's complaint form.
- Quantity is important, but quality is too - please make sure you have all the necessary documentation for each complaint.

[PBM Complaint Form](#)

SOUTH DAKOTA PBM REGULATIONS

PBM licensure/registration requirement

[S.D. Laws 58-29E-2](#)

Prohibition against retroactive claim adjustments

[S.D. Laws 58-29E-13](#)

Prohibition against adjudication fees

[S.D. Laws 58-29E-16](#)

Fair pharmacy audit procedures

[S.D. Laws 58-29F](#)

Prohibition against anti-mandatory mail-order

[S.D. Laws 58-18-37](#)

Any Willing Pharmacy

[S.D. Laws 58-18-37](#)

Not less reimbursement than PBM-owned pharmacies

[S.D. Laws 58-29E-19](#)



South Dakota SOCIETY of HEALTH-SYSTEM PHARMACISTS

Khia Walser // SDSHP President



Greetings and Happy New Year from the South Dakota Society of Health-System Pharmacists! As we enter the new year, I am excited to provide a brief recap of recent happenings and to share a preview of upcoming events as well.

In December, we hosted **Dakota Night** during ASHP's Midyear Clinical Meeting in Anaheim,

California. The event was well-attended, and it was wonderful to see some familiar faces again this year. Each year, this event brings such happiness as our colleagues and friends gather together in a lively, bustling environment. We would like to extend our sincere gratitude to SDSU, NDSU, and NDSHP for making this event possible!

With the new year also comes time for **SDSHP membership renewal**. Membership terms coincide with the calendar year, so now is a great time to renew your membership! Membership fees are \$75 for pharmacists, \$20 for technicians, and \$5 for students. Membership renewal (or joining as a new member) can be done quickly and easily on our website (www.sdsdp.com). As in previous years, SDSHP also continues to offer a 50% discount on membership for any current member who recruits a new member (membership is also discounted 50% for the new member). Anyone interested in this offer should contact SDSHP directly at info@sdsdp.com rather than renewing or joining online.

It's hard to believe, but the **2024 SDSHP Annual Conference** is just around the corner! This year's annual conference will be held at the Holiday Inn City Centre

in Sioux Falls April 5-6th. The Annual Meeting Planning Committee has a wide variety of relevant and high-quality continuing education planned, including a noteworthy keynote speaker, Dr. Alex Barker, PharmD, who is founder of the Happy PharmD. He leads a nationwide coaching firm to help guide pharmacists to inspiring careers and more fulfilling lives. In addition to Dr. Barker, our Annual Meeting committee has an exciting schedule of topics including heart failure, clinical trials and guideline updates, preceptor development, anticoagulation and much more! We look forward to gathering to learn and network with each other during this fun event!

Last, but certainly not least, our Continuing Education Committee has been hard at work preparing for our upcoming **Resident CE Seminars** presented by pharmacy residents from across the state. The CE Seminars will be hosted in-person with the opportunity to attend virtually as well. This format will allow residents to present in front of a live audience while also allowing pharmacists from across the state to tune in. SDSHP is partnering with Avera this year to provide these continuing education presentations for our members and after a brief one-year hiatus, the presentations will be ACPE-accredited once again.

To keep up with information regarding the Annual Conference, Resident CE Seminars, and other SDSHP updates, don't forget to check out our Facebook page, LinkedIn page, Instagram account (@sdsdp_rx), or website!

Respectfully submitted,

KHIA WALSER

SDSU's Student Collaboration for the ADVANCEMENT and PROMOTION of PHARMACY

Madison Hamel // SCAPP/APhA-ASP SDSU Chapter President



SCAPP members wrapped up the Fall semester with some fun events to engage our members and the community! This semester we have expanded upon our patient care outreach in the community by providing education at the Brookings Farmers Market on Saturdays throughout the semester. Additionally, we celebrated National Diabetes

Awareness Month in November with a variety of events such as patient screenings at Lewis, provided education to after-school care students, and played bingo with local nursing home residents. Thank you so much for your continued support in helping connect our students with the community!

We were also fortunate to host APhA-ASP President-Elect, Miranda Montoya, on campus at the end of September. Miranda was able to tour campus, speak at our chapter meeting, and connect with our leaders at co-chair and executive board meetings. Her visit allowed students to learn more about national leadership opportunities and current happenings within APhA! We also hosted a watch party for APhA-ASP's MRM (Midyear Regional Meeting). While the meeting was virtual this year, nine students attended our watch party event, participated in networking events, and listened to a variety of impactful speakers. NCPA President, Bria Sutton, attended the NCPA Annual Convention in Orlando, FL and connected with students and pharmacists from across the country to learn more about the impact and future for community pharmacists.

SCAPP also had seven P4 students attend ASHP Midyear to attend their residency showcase and network with other students and programs!

Other events throughout the semester included vaccine information night, Korean language class, and bingo night at Cubby's. We also constructed a Wizard of Oz themed Hobo Day float and won the award for the "Most Hobo" float! The service committee hosted an event to pack Thanksgiving bags at the Brookings Backpack Project. Also, SSHP hosted two successful residency showcases and launched a new professional development week. These events helped students connect with each other and the community while building upon their professional skills.

It has been a busy semester for students, and we are excited to start the Spring semester with new events and ideas! This semester, students are looking forward to our annual trip to Pierre for Legislative Days, APhA Annual in Orlando, FL, as well as screening events and education surrounding American Heart Month! We are also planning ahead for a new cultural experience in bringing SCAPP education and screenings to the Pine Ridge Reservation that will occur in April!

SCAPP would like to thank SDPhA for the continuous support of student pharmacists as we learn the importance of advocating for both our patients and the profession. We look forward to building up current relationships and seeing many familiar faces in Pierre for Legislative Days!

Respectfully,

MADISON HAMEL



SDSU COLLEGE of PHARMACY *and* ALLIED HEALTH PROFESSIONS

Dan Hansen, PharmD // Dean and Professor



Hello from the College of Pharmacy and Allied Health Professions! We have wrapped up another semester at SDSU. Our students and faculty have completed finals week and are looking forward to celebrating the holidays with family and friends. I'm pleased to share a few of our highlights from the semester.

In October it was announced that Bruce Laughrey, an SDSU College of Pharmacy alumni, had made a commitment to endow the dean position in the College of Pharmacy and Allied Health Professions. His gift marks the second largest gift ever given to our college and will have a lasting impact on faculty, staff, and students.

This semester we were also excited to announce that, through our partnership with Lewis Drug, we will expand the PGY1 Community Pharmacy Residency program from one to two residents. The PGY1 Community Pharmacy Residency is an important program that offers students an opportunity to gain valuable community pharmacy experience.

Our Medical Laboratory Science program held their White Coat ceremony, celebrating our MLS2 and Upward Mobility students earning their white coats. Additionally, the program was also ranked as having one of the "Best Online Phlebotomy Classes and Certifications" by EduMed. This is the second year in a row we have received this recognition.

Also in October, we also celebrated Hobo Week, SDSU's annual homecoming celebration. Our faculty, staff, and students celebrated in many ways, including a potluck, a bonfire, the bum-a-meal, and participating with a float in SDSU's Hobo Day parade, where we were awarded the "The Most Hobo" award for our float.

Faculty and Staff Highlights

The college has an outstanding team of faculty and staff who regularly make impressive achievements. Some of these achievements are listed below:

- Two new individuals were hired to our Community Practice Innovation Center research team. Keri Pappas will serve as Community Clinic Specialist and will play a key role in the new BIRTH-SD-AIM program, and Sarah Schweitzer joins the team as a Community Care Coordinator and will play a key part in SDSU's role in the South Dakota Heart Disease and Stroke Prevention Program.
- Teresa Seefeldt was awarded the Hustead Award (also called SD Pharmacist of the Year) by the South Dakota Pharmacists Association.
- Tadd Helwig was awarded the "Lifetime Achievement Award" from the Center for Family Medicine. This award was given in recognition for all he has done during his time working with the folks at CFM.
- Alex Middendorf was notified that he was selected for the inaugural class of the ACT Collaborative Community Pharmacy Practice Transformation Educators' Badge.
- Abby Wortman was awarded the PHIL Award, a "nationally recognized hospital-based recognition program dedicated to honoring outstanding respiratory therapists who provide exemplary care and treatment for patients with respiratory illnesses."
- Lacy Patnoe, John Kappes, and Abby Wortman had an article published in the *Respiratory Care Journal* titled "Levalbuterol Utilization in Hospitalized Patients."
- Shanna O'Connor co-authored a commentary on regulation in the pharmacy profession that was published in the *Journal of the American Pharmacists Association*.
- Jordan Baye gave a podium presentation titled "Pharmacogenetics to Guide the Management of Depression and Anxiety" at the ACCP Annual Meeting in Dallas, TX.

- Kassi Erickson and April Nelson not only had their presentation, "When Virtual Reality Becomes Reality: Navigating the Past, Present, And Future of Virtual Reality and Artificial Intelligence", selected amongst a record number of submissions, they were featured as 1 of the 10 sessions to attend at the 2024 CLEC Annual Meeting.
- Two abstracts from our faculty were accepted for presentation at the American Academy of Health Behavior conference in Savannah, Ga in April.
 - Chris Robbins, Alex Middendorf, Deidra Van Gilder, Stephanie Hanson, and Erin Miller, will be presenting a poster titled "Improving the Health of South Dakotans with Pharmacy Based Education, Counseling, and Clinical Management of Diabetes and CVD."
 - Chris Robbins will be presenting a poster titled "Impact of One-Way SMS Health Communication to Increase PrEP Intake in Non-HIV, STI Testing Patients: A Pre-Post Intervention Demographic Study."
- SDSU held its 1st Annual Scholarship of Teaching and Learning Symposium and presentations were given by four faculty from our college:
 - Alex Middendorf – "Promoting Student Engagement through Routine Brief Reflection Replacing Participation Points in an Integrated Pharmacy Lab Series."
 - Hemachand Tummala – "A Student-Driven Laboratory Teaching Model Focusing on Problem-Solving Skills Using Patient Case Studies."
 - Brittney Meyer – "Evaluating the Impact of a Change to a Virtual Interprofessional Poverty Simulation."
 - Kassi Erickson – "Ungrading: Competency Based Manual Differentials for Individualized Learning."

Student Achievements

Our students have similarly seen achievements over the semester.

- A few of our Pharm.D. students had the opportunity to present research at the Sanford Improvement Symposium.
 - Brynn Van Eldik, Katie Moser, Andrew Egge, and Sarah Voytilla presented "Comparing length of stay in hospitalized patients receiving remdesivir treatment for COVID-19."
 - Sunniva Dunagan, Tyler Weddle, Bri Amundson, Morgan Eick, Ashley Hess, Hyunji Oh, and Jordan Baye (faculty advisor) presented "Extrapyramidal side effects in CYP2D poor vs normal metabolizers receiving metoclopramide" and received 1st place in the Clinical Care Category.

- The American Society of Health-System Pharmacists held its Mid-Year Meeting and we had several students present research.
 - Ashley Hess, Morgan Eick, Hyunji Oh, Tyler Weddle, and Jordan Baye (faculty advisor) presented a poster entitled "Examining Extrapyramidal Side Effects in CYP2D6 Poor Versus Normal Metabolizers Receiving Metoclopramide."
 - Ellie Balken, Alexandra Bladholm, Tara Gilk, and Jaden Gossen presented a poster entitled "Evaluation of Clostridium Difficile Treatment in Pediatrics."
 - Kaylee Ayers, Sara Smith, Karly Blaaid, Tomineee Sorenson, and Faith Bader are presented a poster entitled "Evaluation of Antimicrobial Stewardship for Urinary Tract Infections After Pharmacist-Led Provider Education."
- Two recent graduates of our Master of Public Health program presented posters at the American Public Health Association annual meeting and exposition.
 - Sarah Schweitzer presented a poster titled "Public stigma towards substance use disorder (SUD): Pilot survey study in South Dakota."
 - Cedric Cogdill presented a poster titled "Stigma experienced by people who use substances in rural South Dakota."

On October 16th we hosted a celebration honoring Dr. Dwivedi and his wife, Prabha. A couple of years ago, a handful of SDSU alumni spearheaded a fundraising effort to endow a scholarship in their name. The scholarship is awarded yearly to an international student. The event was held to celebrate the Dwivedi's and to recognize the scholarship's first-ever recipient.

We also held College's Scholarship and Awards Banquet where we recognized our alumnus of the year, Dr. Thomas Majerus, and this year's scholarship recipients. 229 scholarships were awarded, for a total of \$406,050 – both record highs.

Finally, in October we celebrated both National Pharmacists Week and Respiratory Therapists Week. Faculty and staff from across our college were celebrated for the contributions they make to the important fields of pharmacy and allied health education and research.

Best regards,

DAN HANSEN



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FAQS

What is *Pharmacy Technicians University (PTU)*?

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Why should I use *PTU*?

You will get:

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- Modules divided into short parts you can complete at your own pace
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Today, pharmacy technicians are increasingly important members of the pharmacy team. Skilled pharmacy technicians are critical for the economic and efficient function of a pharmacy. However, training requirements for pharmacy technicians change often and are becoming more complex, creating a shortage of qualified pharmacy technicians.

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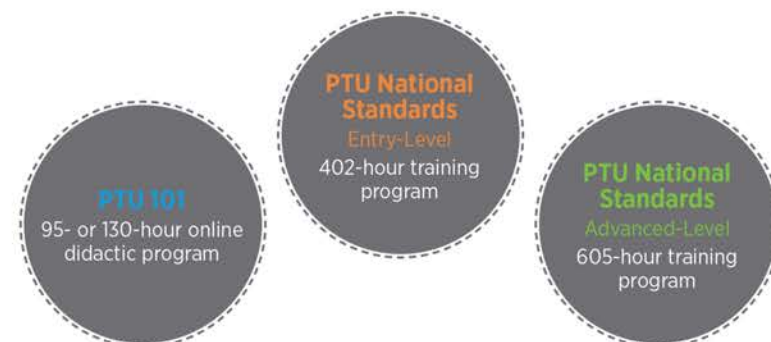
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FEATURED SESSIONS:

[Caution Ahead: Prioritizing Patient Safety](#) (0.1 CEU)

[The Secret Ingredient: Blending CHWs and Pharmacy Practice](#) (0.1 CEU)

[Byte-Size Chats: Obtaining Insights on Technology in Pharmacy](#) (0.1 CEU)

[Don't Miss a Beat: Updates in the Management of Heart Disease](#) (0.1 CEU)

[Beyond the Rainbow: A Practical Review of Gender-Diverse Care](#) (0.1 CEU)

SDPhA members can register for PharmaCE Expo 2024 at a preferred rate! One and two-day [registration](#) available. Make sure to register under “Other State Association Member” to secure the low rate. **Registration closes February 5, 2024.**

[Register today!](#)

[2024 Event Schedule](#) | [CPE General Information](#).



® **Accreditation Information** | The South Dakota State University College of Pharmacy and Allied Health Professions is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

It is the policy of the South Dakota State University College of Pharmacy and Allied Health Professions that all sponsored CPE programming present evidence-based information that is professionally objective and non-commercial / non-promotional.

PRECEPTOR TRAINING AND CONTINUING EDUCATION

Continuing Education Course Listings

Current Courses

- [Do You Hear What I Hear? A Call for Change in the Language Used by Pharmacists in Diabetes Care](#)
- [Pharmacist Consult: An Update on Parkinson's Disease Prevalence and Treatment](#)
- [Simple Ways to Help Reduce Medication Errors and Patient Harm in the Community Pharmacy](#)

[Register for a CPE course today!](#)

Course Information

Course Development	Disclosure Statement
This course was developed under the guidance and review protocols of the Office of Continuing Education, South Dakota State University College of Pharmacy and Allied Health Professions.	The author and developer of this course have had no relevant financial relationships with any commercial entity having a vested interest in this material.

Course Details

Do You Hear What I Hear? A Call for Change in the Language Used by Pharmacists in Diabetes Care

Course Authors

- Marla J. Hayes, TC Columbia University

Credit Information

- **ACPE Universal Activity Number:** 0063-0000-22-024-H01-P
- **Credits:** 1.5 hour (0.15 CEU)
- **Activity Type:** Knowledge
- **Target Audience:** Pharmacists and Pharmacy Technicians
- **Course release date:** 3-16-2022
- **Expiration date:** 3-16-2025
- **Cost:** \$8.50

PRECEPTOR TRAINING AND CONTINUING EDUCATION

Do You Hear What I Hear? A Call for Change in the Language Used by Pharmacists in Diabetes Care

Course Development

The following public report was published by the South Dakota State University College of Pharmacy and Allied Health

Goal

To provide pharmacists with actionable information on Diabetes Care and Glucose Monitoring.

Contact Hour Details

To receive 1.5 Contact Hours (0.15 CEUs) of continuing education credit, participants will read the provided article, answer the test questions, and complete the course evaluation. A test score of 75% or better is required to earn continuing pharmacy education credit. If a score of 75% (9/12) is not achieved on the first attempt, participants can complete one retest at no additional charge. Credit upload to a participant's eProfile account will be completed within 2 weeks following successful completion of this course.

Learning Assessment

Active learning quiz questions and Learning Assessment test questions for this course were developed by the South Dakota State University College of Pharmacy and Allied Health Professions.

Financial Disclosure

The developer of this course has no financial relationships to declare.

Pharmacist learning objectives

Upon completion of this activity, participants should be able to:

- Understand the emerging trend to utilize pharmacists as care extenders in diabetes care.
- Evaluate the history of present-day healthcare language and identify its shortcoming in diabetes care.
- Analyze why the language used in diabetes care matters.
- Apply the impact of a pharmacist's language on diabetes self-care.
- Create examples of disengaging language used by pharmacists in diabetes care.
- Remember two guiding principles for transitioning to person-centered language.

QuestionPro Post-Test and Evaluation [TAKE NOW](#)

Introduction

The role of pharmacists in diabetes care

History of present-day healthcare language

Why language matters

Impact of a pharmacist's language on diabetes self-care

Examples of disengaging language used by pharmacists

Guiding principles for transitioning to person-centered language

Conclusion

References

Appendix A

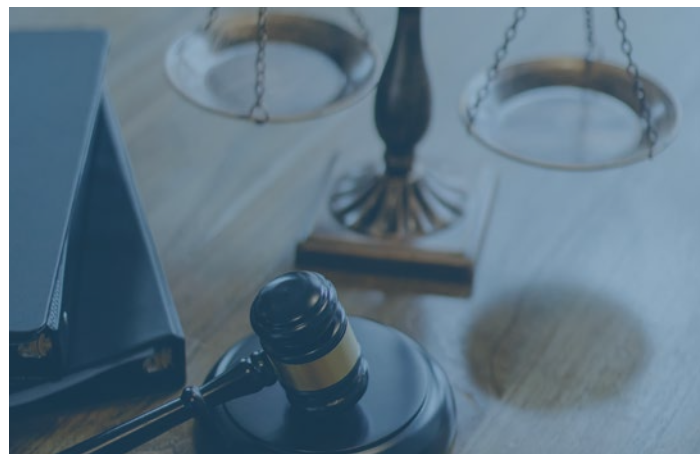
Appendix B

PHARMACY & THE LAW

BY DON. R. MCGUIRE JR., R.PH., J.D.

*This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.*

COMPOUNDING DIFFICULTIES



The Food and Drug Administration (FDA) has a number of lists concerning compounding, especially compounding from bulk drug substances. There are lists for both 503A and 503B compounders and there are substantial differences in the lists for these two types of compounders. This article is focused on 503A compounding. The relevant lists are: bulk drug substances that can be used to compound, the withdrawn or removed list, and the Demonstrably Difficult to Compound list. One current issue is the addition of bio-identical hormones being added to the Demonstrably Difficult to Compound list.

Under current law, pharmacies wishing to compound preparations using bulk drug substances under Section 503A of the Food, Drug and Cosmetic Act must use bulk drug substances that meet one of the following criteria: (a) comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding, (b) are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or (c) appear on FDA's list of bulk drug substances that can be used in compounding if such a monograph does not exist and the substance is not a component of an FDA-approved drug product. Provision (c) is the list of bulk drug substances that are permitted to be used for compounding for humans.

Pharmacies' compounded preparations that meet these criteria are exempted from some requirements of the Food, Drug and Cosmetic Act, such as the New Drug approval requirements, labeling with adequate directions for use, and current Good Manufacturing Practices requirements. Compounding by pharmacies that is not done within this framework is not exempted from the Food, Drug and Cosmetic Act requirements and those products are considered misbranded and/or adulterated.

The Demonstrably Difficult to Compound list is intended to identify drug products that are, as the name implies, difficult to compound. These difficulties result in an adverse effect on the safety or effectiveness of the preparation. Inclusion of a drug product on the Demonstrably Difficult to Compound list also precludes it being exempted from the Food, Drug and Cosmetic Act requirements as outlined above. The current battle is over the inclusion of bio-identical hormones on the Demonstrably Difficult to Compound list. Pharmacy groups, especially pharmacy compounding groups, are opposing the addition due to the long safety record of compounded bio-identical hormone use and the potential reduction in therapy choices for patients. The FDA commissioned a report by the National Academies of Sciences, Engineering, and Medicine to investigate compounded bio-identical hormone therapy. Their report was published in July 2020 and recommends the inclusion of hormone compounds on the Demonstrably Difficult to Compound list.

The controversy here is the rationale on which the committee based the recommendation. The stated basis for inclusion on the Demonstrably Difficult to Compound list is complexities involving the formulation, the drug dose delivery mechanism, the dosage form, the ability to control bioavailability, analytical testing, or the compounding process itself. The presence of one or more of these complexities then causes a negative effect on the safety or effectiveness of the compounded preparation.

The report cites the lack of data regarding the safety and effectiveness of bio-identical hormone therapy, but does not necessarily cite that this concern stems from the difficulty in compounding these preparations.

The concern is the lack of safety and effectiveness data that meets the standards of FDA approved products. Preparations compounded within the regulatory framework are exempt from meeting the New Drug approval requirements. It seems like a very circular argument that a preparation should not be allowed to be compounded because of the

lack of safety and effectiveness data that it is not required to have. This could be said for any compounded preparation, not just bio-identical hormones.

Another concern was the lack of complete labeling for compounded bio-identical hormones. Preparations compounded within the regulatory framework are exempt from the labeling requirements of the Food, Drug and Cosmetic Act. Again, not meeting a requirement that they are not required to meet.

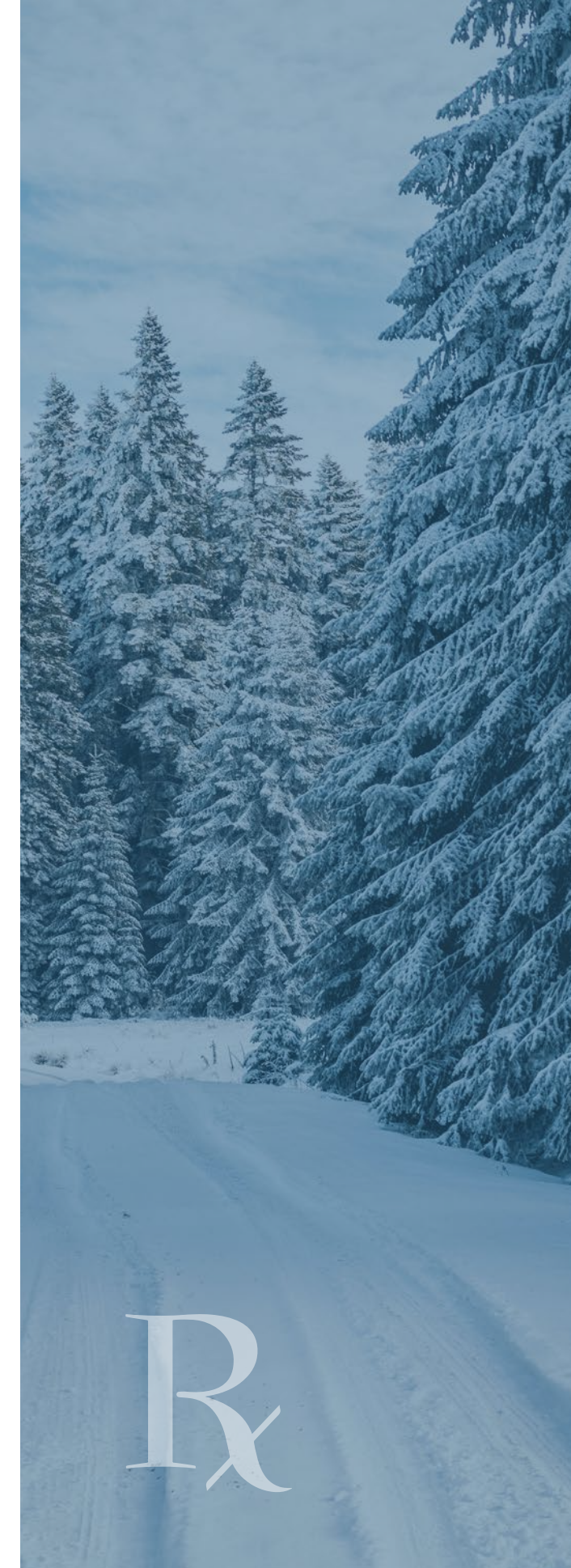
The report highlights other risks and complexities associated with compounding in general that are not necessarily restricted to only compounded bio-identical hormones, with the exception of pellets.

One of the givens of compounding is that the resulting preparation is not approved by FDA and FDA does not evaluate these medicines for safety, effectiveness, and quality. However, compounded preparations are prescriptions; there is a provider prescribing the compounded drug, it is labeled according to state pharmacy regulations, and pharmacists are performing drug utilization reviews and counseling patients.

Regardless of the basis for inclusion, adding bio-identical hormones to the Demonstrably Difficult to Compound list will remove exemptions from meeting requirements of the Food, Drug and Cosmetic Act and regulatorily prohibit their compounding. Bio-identical hormones have not been added to the list yet, so the battle is not over. The conflict will certainly continue in the courts if they are added.

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© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.
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This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.



Rx



USP 800 SETS NEW “NATIONAL PROFESSIONAL STANDARD”

The United States Pharmacopeia (USP) revealed that more than 8 million U.S. healthcare workers are exposed to hazardous drugs each year and that more than 12 billion doses of hazardous drugs are handled by U.S. providers each year, with pharmacists and pharmacy technicians at the top of the list.

Community pharmacies have been dispensing hazardous drugs long before the potential for harm (due to low dose, long term exposure) was known. Exposure to a hazardous drug is often inadvertent and unknown to the employee. There is some surprise when presented with the list of hazardous drugs which includes pharmaceuticals that you may handle on a daily basis including; fluconazole, fluoxetine, carbamazepine, warfarin and oral contraceptives. There are more than 400 hazardous drugs and their unique dosage forms.

Occupational exposure to hazardous drugs, or their residue, can be an everyday experience and the true effect of this exposure is unknown for many, and may result in both acute and chronic health issues due to trace exposure to hazardous drugs. Acute toxicity may present as nausea, rashes, hair loss, kidney damage, hearing loss and cardiac toxicity. Long term effects may include cancer, infertility, and other reproductive health issues. Certain populations, including, those that are immunosuppressed, and women and men of childbearing age may therefore be more at risk.

This occupational exposure extends to everyone working in the pharmacy, from the pharmacists and pharmacy technicians who handle HDs, to those who work at the pharmacy counter or in the receiving and delivery areas. The exposure risk extends to anyone who may come into contact with HD particles or residue.

Exposure can occur:

- thru the skin or oral mucosa when counting and pouring
- by inhalation of dust particles when splitting a tablet or when working with an uncoated tablet that simply creates a lot of dust
- by ingestion if eating or with hand to mouth contact without cleaning or hand washing
- by injection, as is the case with an accidental needlestick

Different activities in the pharmacy come with different levels of potential risk:

- dispensing a unit of use or a blister package of a hazardous drug may have a very low risk of exposure
- counting and pouring an uncoated hazardous drug tablet or capsule increases the risk
- splitting a hazardous drug tablet where dust can be created creates potential for increased exposure
- cleaning a spill of a liquid hazardous drug introduces another level of risk

The key is developing good practices to contain or greatly reduce risk. Per OSHA, the safe handling of hazardous drugs in accordance with USP 800 is now considered a “national professional standard” as a pharmacy process “to protect the safety and health of employees”. A USP 800 compliance program is a necessary step to protect the health and safety of your employees, patients in your pharmacy, and the environment. It can also help reduce employer liability from frivolous lawsuits through employee training, competency documentation and employee acknowledgements.

PAAS National® is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact PAAS today at (608) 873-1342 or info@paasnational.com to see why PAAS Audit Assistance membership might be right for you.

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AUDIT TARGET: LINZESS® PRESCRIPTIONS

PAAS National® analysts have noticed an increase in audits targeting Linzess®. Linzess® is a focus of PBM audits not only because of the high cost, but also the manufacturer dispensing requirements. Not following FDA approved guidelines when dispensing this medication will likely result in full recoupment.

Allergan, the manufacturer of Linzess®, has not provided evidence to the FDA for the safety and efficacy of this medication outside the original container. PAAS has reached out to Allergan looking for additional stability information to appeal audit recoupments; however, they have only confirmed the current requirements. Pharmacies can visit [DailyMed](https://dailymed.nlm.nih.gov/dailymed/)¹ for medication information, including How Supplied/Storage and Handling requirements under Section 16 of the drug label information.

While Linzess® is not the only medication required to be dispensed in the original container, it is frequently prescribed for patients in long-term care and for those who have medications in compliance packaging. Unfortunately, there are no exceptions for these situations, and the original container must be given.

Billing Linzess® for quantities other than increments of 30 capsules will make the claim an easy audit target for any PBM to identify the medication was not dispensed in the original container. This is true for many other medications with specific dispensing requirements as well. PAAS Audit Assistance members can view the Dispense in Original Container Chart and view many other charts and tips on the PAAS Member Portal.

PAAS Tips:

- When receiving a prescription of Linzess® written for a quantity less than 30 capsules, consult with the prescriber to discuss packaging requirements and obtain authorization for an appropriate quantity
- Check all current prescriptions for Linzess® to ensure they are being dispensed per FDA guidelines
- Consider adding shelf tags to this medication to flag pharmacy personal of requirement
- Check if your software vendor can create an alert when NDCs are billed for quantities not valid with package size
- Remember the Medicare Part D “short cycle dispensing” requirement to dispense no more than a 14-day supply on brand name oral solid medications in LTC settings has an exclusion for products that must be dispensed in their original container
- Notify and discuss with LTC facilities the packaging requirements of this medication
- Patients with compliance packaging will need to be educated on the importance of keeping this medication in the original container
- Self-audit claims on a weekly or monthly basis to ensure appropriate dispensing

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References:



1. <https://dailymed.nlm.nih.gov/dailymed/>



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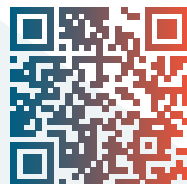
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LEGISLATIVE DAYS



February 13-14, 2024

Legislative Update and Dinner

February 13, 2024 – 6 p.m. at Missouri Ave. Event Center

Health Screenings

February 14, 2024 – beginning at 7 a.m.

by SDSU College of Pharmacy Students at the Capitol Building

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