SOUTH DAKOTA PHARMACIST

IN THIS ISSUE

Game on! Convention 2022 in Brookings
Looking Ahead to the 2023 Legislature
Top 10 Inspection Findings
CE: FDA Safety Communications: Tramadol

SUMMER EDITION 2022

EST. 1886
SOUTH DAKOTA
PHARMACISTS
ASSOCIATION

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

South Dakota
Pharmacists Association
320 East Capitol, Pierre, SD 57501
605-224-2338 // 605-224-1280 *fax*
www.sdpha.org

South Dakota
Board of Pharmacy
4001 West Valhalla Boulevard, Suite 106
Sioux Falls, SD 57106
605-362-2737 // **www.pharmacy.sd.gov**

Calendar

JULY 2022

4 **Independence Day**

5 **SDPhA Office Closed**

14 **Medical Marijuana Oversight Committee**
Room 414, SD State Capitol, Pierre, SD | 9 am CDT

22 **21st Annual GVR Society Open Golf Classic**
Hartford, SD

23-27 **American Association of Colleges of Pharmacy (AACP) Annual Meeting**
Grapevine, TX

AUGUST 2022

1–31 **NCPA Month of Action – Your Pharmacy**
Learn more here.

27-29 **NACDS Total Store Expo**
Boston, MA

SEPTEMBER 2022

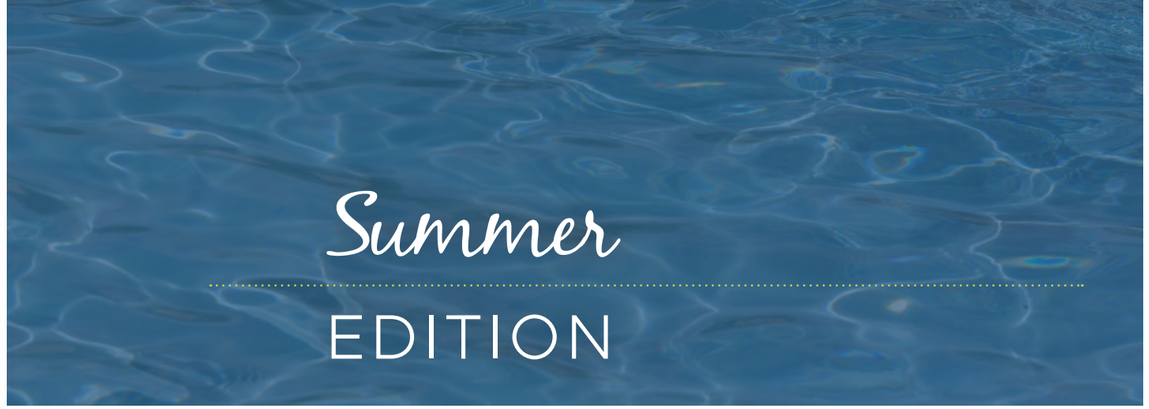
8 **South Dakota Board of Pharmacy Meeting**
Location TBA

9-10 **SDPhA 136th Annual Convention**
Swiftel Center, Brookings, SD
Register here.

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.

Support of our advertisers makes it possible to bring you news in the form of a Journal. When making purchases and other equal factors, please give our advertisers the support they deserve.

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.



Summer EDITION

FEATURES

4–5 Director's Comments
6 President's Perspective
7 C & L and District Contribution Form
8–10 South Dakota Board of Pharmacy
11 South Dakota Society of Health System Pharmacists
12–13 SDSU College of Pharmacy and Allied Health Professions
13 Well-being Index
14 Academy of Student Pharmacists
15–17 Pharmacy Technicians University (PTU)

SDPhA 136th ANNUAL CONVENTION

18 Exibitor / Sponsorship Form
19 Attendee Registration Form

CONTINUING EDUCATION

20–27 FDA Safety Communications: Tramadol

HELPFUL INFORMATION

28 Pharmacy & The Law: Patient Waivers
29 Beyond-Use Date vs. Nursing Home Storage Policy
30 Financial Forum: Retirement Blindspots

ADVERTISERS

31 Pharmacists Mutual Companies
32 Novo Nordisk

Director's COMMENTS

Amanda Bacon // SDPhA Executive Director

Our daughter has recently found a passion for baking. The good news is this can occupy a significant amount of a 10-year-old's time on summer break. The bad news, is mostly found on my waistline, and in the sheer volume of powdered sugar that coats nearly every surface of my kitchen on any given day in which the inspiration for creativity has struck, especially when said inspiration requires buttercream frosting.

On a recent baking project (a birthday cake for America), my budding baker found out buttercream can sometimes be a formidable foe. Not only was the butter too soft, the brilliant blue she was hoping to achieve, was decidedly teal, definitely not blue. Frustration was mounting as she consulted Google, which advised the best solution was to add a few drops of red to create a navy blue. After what seemed like hours of debating the virtues of, "real" blue vs. navy blue, she deemed navy blue, "acceptable, but certainly not optimal." A deep breath and a few drops later, the result was no longer teal, but also decidedly NOT navy blue.

The result was a greyish-purple.

Feeling quite defeated and fighting tears, she came to me with her bowl and her whisk. It's all ruined," she managed. "All that hard work of making buttercream. It's ruined."

I reminded her that in every single baking competition show she watches (can we just take a moment here to talk about how many of these are on television?!) there's at least one of the bakers who has to decide to go a different direction from their initial vision. "They don't have time to panic," I reminded her. "They just have to pivot. So how can you change things, to make what you have available to you, workable?" After wiping a few tears, and some brainstorming, she came up with a solution. Her white buttercream would cover the entire cake, and the red buttercream would make the stripes on the flag. She had some "real" blue fondant she would use to make one giant star for the upper left corner, and the greyish-purple, somewhat melty buttercream would be used to dip graham crackers in. Because every baker knows you need some fuel to get the job done.

The result, was a 4 th of July cake that won great accolades from all who joined the festivities at our house last weekend. More importantly, it was something she was extremely proud of. It wasn't the perfect picture she had in her head. It was the result of real-time problem-solving and a willingness to shift her perspective. And that, WAS perfect.

Last night she said to me as we were talking at bedtime, "You only fail if you quit trying." I told her that was really good, and the writer and journalist that will forever live inside me told her she needed to write that down.

"Where'd you hear that?" I then asked.

"I didn't hear it. I learned it watching you."

Excuse me while I reach for a tissue and work on landing this plane…

Our work at SDPhA feels really messy sometimes. Like the powdered sugar has just blown up all over the kitchen, and your momma is trying REALLY hard to bite her tongue about it, because 10 minutes ago, this room was spotless – that kind of messy. Last legislative session with our PBM legislation felt a little (or maybe a lot) like that. We learned to pivot, and to clean the kitchen as we went. That work continues this summer. We are still learning to pivot, and find what combination of "ingredients" will result in a bill or bills that does what we need it to do, while proving sweet enough to try for those who, quite frankly, just don't like cake. A lot like baking – this is a delicate situation – getting the ingredients and the amount just right. We'll still have to pivot plenty more times along the way. But a wise baker once told me you only fail when you quit trying.

Speaking of, "no quit," we want to send a huge shoutout and thank you to the more than 24,000 organizations and people who joined us in submitting comments to the Federal Trade Commission regarding your experience with PBMs. It's fair to say that given the headlines this week alone – PBMS are feeling the heat.

And, speaking of, "pivot," the 2005 trigger law that went into effect in South Dakota upon the Supreme Court decision that overturned Roe v Wade means new laws and rules, and there will be changes for pharmacy. We've reached out to the South Dakota Secretary of Health for guidance, and you will certainly know as soon as we have some. Gov. Kristi Noem has indicated her desire for a Special Session in light of the ruling, but some political watchers have recently indicated that may not happen – and any related bills could be handled during the regular session. We will keep you updated.

All of this brings me back to the Commercial and Legislative Branch of SDPhA, and the frank fact that this work cannot continue without your support. The C&L branch is the lobbying arm of the association. You can think of it somewhat as the association's PAC (although there are VERY distinct differences we won't go into here).

Some very important things about this fund:

- The funds for our lobbying branch must be maintained separate from the general fund
- It relies nearly exclusively on your contributions
- For many years now, expenses have vastly outpaced contributions

Lobbying is an extremely expensive, but necessary function. We've been represented by the same firm for decades, and the executive director preforms many of the lobbying duties. That's all kept our rate very low. However, we will have additional lobbyists working with us again in 2023. It's a needed move in order to bring PBM reform, as clearly work on this issue is not complete.

If we want to ensure the profession has a seat at the table, we have to pay for the chair. So far for 2022, contributions have covered about half of the lobbying expenses. Put simply – we need your help. $25, $250, 2,500 – whatever you can contribute will help ensure the profession continues to have representation at the Capitol. Because without your contributions – it simply won't. You can support the C&L Fund by contributing online, or sending a check made out to the SDPhA C&L Branch, PO Box 518, Pierre, SD 57501.

On the COVID front, please make sure you have taken note of the Board of Pharmacy's new policy statement regarding the June 17 FDA Authorized use of Moderna and Pfizer vaccines for children as young as 6 months of age. And hot off the press, even as I type this, the U.S. Food and Drug Administration revised the Emergency Use Authorization (EUA) for Paxlovid to authorize state-licensed pharmacists to prescribe Plaxovid to eligible patients with certain limitations to ensure appropriate assessment and prescribing. Kudos to the FDA for recognizing the role pharmacists have played in battling this pandemic.

Last but certainly not least, if you want to be in the know on all things pharmacy in South Dakota (baking tips are free) and stay up to date on the legislative front as we move into 2023, well, Game On! Stop everything else you are doing right now and go register for the 136 th Annual SDPhA Convention. We'll be in Brookings Sept. 9-10, and there's so much awesome CE and things to do that we're still finalizing the lineup and extra curriculars, but rest assured it will be posted within days. Just get your registration in and plan on an awesome time of gathering together – I can't wait to see you all there! Thank you for all you do, and always - keep trying!

AMANDA BACON

President's PERSPECTIVE

Kristen Carter, PharmD, BCGP // SDPhA Board President

Summer is here! The days are longer but somehow this season always goes too fast. I hope you are all packing in as much fun as possible.

This is my final journal article to write as your SDPhA President. (And the last time poor Amanda will have to kindly remind me it was due yesterday.) When I told my husband I didn't know what to write about, he smiled and said, "write about me," to which I rolled my eyes. But as I start this, I do have something to share about him that can relate to this organization.

My husband, Colton, raises cattle in Haakon County. You may know, the area has been severely dry for over a year. So dry that Colton and other ranchers have had to prepare for the worst case scenario—selling cattle because there is no grass for them to graze.

Earlier this spring, a miracle came on his weather app—100% chance of rain predicted overnight and into the next day, accumulating to over an inch and a half. This would save his cows. Hallelujah. But when we woke up the next morning, not only had it not rained, the forecast had drastically changed to "scattered rain showers possible later." Not one drop ever fell. Colton and I were crushed, but he kept the faith. He compared notes with neighbors and many had gotten rain. I asked if that upset him that everyone but him seemed to have been blessed with some moisture. Without hesitation he said no, he wanted everyone to get rain.

We kept praying for rain and a few weeks later it popped up again on the forecast: 100% chance of rain happening over 2 days—and this time maybe over 2 inches. Colton checked his phone every 10 minutes to make sure the forecast hadn't changed. He said it was like Christmas Eve going to bed so excited to wake up and see a beautiful rain. But it happened again. No rain. Colton was so upset he wanted to email his weather app's meteorologists. How could they get it so wrong, and twice?! Of course yelling at the weather man wouldn't do anything, but I understood how frustrated he was. It was unfair and it wasn't right for him and the others in that business to work so hard only to be in a position to lose cows and have no control over it. Of course, that's the risk going into agriculture, but I get it. He wanted to vent and beyond that, get someone to do something about it because he had been wronged. He wanted to advocate but who could he stand up to to change the weather?

Well, in a way, we did advocate for rain. We told friends and family how desperate we were and I talked to customers in the ranching community about how bad it was for them and for us and the conversation only had one way to end: "let's pray for rain!"

And you know what, it did finally rain. A good rain. And then it rained again. And things will be ok now. So we keep the faith and we keep advocating. And we stay connected to friends and neighbors.

That's what SDPhA is all about. Advocating for the pharmacy profession. And I believe that makes a difference. It might not be overnight, and it might take a lot of prayer, but this organization is making a difference. It helps to have community. One that roots for you and not against you. It helps to connect—at convention, at district meetings, however we can. Because talking about our issues and learning what others do and brainstorming ideas keeps moving this profession forward. Our board is diverse and represents different areas of pharmacy and different areas of the state. We build it like this so more voices can be heard. And if we all decide what we need to do is email the weather man, then we email the weather man and we sign it from all of us. The point is, if your profession matters to you, and I hope it does, be an advocate. I am so grateful to all those that came before me that have shaped pharmacy into what it is today. And I vow to stay involved to help evolve it further.

So now that I am closing out my run as President, I really hope to see you all at convention. Amanda and the board have planned a great lineup of topics along with some really fun social events. If you've never been to a convention before, Brookings is a great place to start. In the meantime, have a fun and safe summer and please reach out to Amanda or any of us on the board if you need anything. (Prayers included.)

Respectfully,

KRISTEN CARTER

2021/2022 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 _____

EMAIL ADDRESS _____

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 $100.00

Includes One Individual Membership

NAME OF PHARMACY / BUSINESS _____

NAME OF INDIVIDUAL INCLUDED _____

CORPORATE MEMBERSHIP $200.00

Two or more stores of the same corporation

NAME OF CORPORATION _____

NAME OF INDIVIDUAL INCLUDED _____

INDIVIDUAL MEMBERSHIP

☐ $50 LEVEL ☐ $75 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

$ _____

MAIL TO: SD PHARMACISTS ASSOCIATION, BOX 518, PIERRE, SD 57501-0518 / FAX: 605-224-1280

South Dakota BOARD of PHARMACY

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

Board Welcomes New Registered Pharmacists /Pharmacies

Congratulations to the following 32 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Allison Bich, Zachary Birchem, Briana Brandt, Breanna Brungardt, Caitlin Daly, Clarissa Fasbender, Anna Fathman, Khalil Ford, Vanessa Gottier, Natalie Gray, Sara Huffman, Mary Kading, Hailey Kloiber, Kiera Kraemer, Luke Lorenz, Dustin Moon, Kayla Pardy, Vishal Patel, Kayley Perkins, Alexandra Peters, Jordan Peterson, Daniel Polcyn, Bethany Robasse, Ashley Rohlfing, Madalyne Schuldt, Jacob Steckelberg, Kamryn Storm, Allie Thompson, Rebecca Thurman, Holly Vietor, Kasey Wanger, and Natalie Wright. Twelve of these were reciprocal licenses.

There were two new SD full-time pharmacy licenses issued: Lewis Family Drug, LLC dba Lewis Family Drug #47, Harrisburg, License # 100-2081 and Avera St Luke's dba Avera Plaza Pharmacy, Aberdeen, License # 100-2080. There were eight SD part-time pharmacy licenses issued during the period: Avantara Clark/Continued Care LTC Pharmacy South Dakota LLC, Clark, License #200-1751; Avantara Groton/Continued Care LTC Pharmacy South Dakota LLC, Groton, License # 200-1750; Avantara Lake Norden/ Continued Care Pharmacy Pharmacy South Dakota LLC, Lake Norden, License # 200-1752; Avantara Norton/ Continued Care LTC Pharmacy South Dakota LLC, Sioux Falls, License # 200-1753; Avantara Pierre, Pierre, License # 200- 1754; Avantara Milbank/Continued Care LTC Pharmacy South Dakota Pharmacy LLC, Milbank, License # 200-1755; Rolling Hills Health Care dba Continued Care LTC Pharmacy LLC, Belle Fourche, License # 200-1749; and Spearfish Canyon Healthcare, Spearfish, License # 200-1748. In the quarter, there were no new SD domiciled wholesale license issued.

Carveth Thompson Honored by NABP

The National Association of Boards of Pharmacy (NABP), at its 118 th Annual Meeting, in June, passed a resolution recognizing Carv Thompson, pharmacist, SD Board of Pharmacy member, civic leader, legislator, gubernatorial candidate, and pharmacy owner from Faith for his many accomplishments to pharmacy during his long career and expressing their sorrow on his passing.

Top Ten Inspection Findings by Inspectors Carol Smith and Tyler Laetsch

In South Dakota, inspections are completed with in-state pharmacies on an annual basis. Over time, with staff turnover and policy changes, some items may be overlooked by pharmacy employees; and we often find them. While on inspections, we discuss items that need to be addressed and areas where we have typically seen compliance issues. We use this communication to help pharmacists be aware of items to improve upon. Below is a list of the top ten items in pharmacies that required correction. If you work in a pharmacy, this list may help you identify items that need to be corrected. Top inspection deficiencies noted:

1. Biennial inventories of controlled substances (CS) not completed correctly. There are often one or more issues with the completion of the CS inventory. Either the inventory is not all completed on the same day, not completed within two years of previous inventory (we strongly encourage annual inventories), there is no signature on the inventory, and forgetting to include the prescriptions that are completed and waiting for the patient to pick up or drugs waiting for destruction. Remember if the CS is in your location, you must count it.

2. Outdated medications found in stock. Everyone is busy, and it is no fun to go through all the medications; unfortunately, we see expired medications on shelves, usually it is just one or two but still one is too many for good patient care. We recommend that all pharmacies have a policy in place to check for outdated medications minimally every quarter.

3. CS dispensing logbook or daily printouts are not being signed attesting to dispensing. Pharmacists are required to verify all CS prescriptions refilled during their shift. This is an issue we encounter from time to time. Surprisingly it is often the bigger stores with multiple pharmacists that have the hardest time, since not everyone works daily or closes the pharmacy. Some sites we see only one pharmacist's signature when multiple worked in a day. Other sites may have no signatures for certain days.

4. CS prescriptions are not being submitted to the SD PDMP correctly. CS prescriptions are filled under a nickname rather than the patient's legal name. Also, some pharmacies are not submitting "schedule V" CS prescriptions. In South Dakota statutes, federal schedule V substances are schedule IV. PDMP rules state that all schedule II, III, and IV prescriptions are submitted by the dispensing pharmacy. This is most likely an error in communication with software vendors and pharmacies when the vendor sets up automated submissions of dispensed medications. This is often an easy fix, but it is a good reminder to regularly spot check the pharmacy's data in PDMP.

5. Combat Methamphetamine Certification is expired. Each pharmacy that sells pseudoephedrine is required to have a current Combat Meth Certificate. It must be renewed annually. This is a task that can easily be forgotten if no reminders are set. We inspect annually and this is one item we check every time.

6. Pharmacist's license is not printed and displayed. When the pharmacist renews their license, they must print and display a copy of their license at each pharmacy where they regularly work. A copy of the primary source verification is not a copy of the pharmacist license.

7. CSOS orders are not received electronically. The CSOS order must be finalized electronically upon receiving and checking in the inventory. If you order electronically, you must receive the medication order documentation electronically as well.

8. Take back receptacle security and documentation. Receptacles must be securely fastened to the floor or wall. The pharmacy is also required to keep a record of all receptacle liners. The pharmacy receives a new serial numbered liner after shipping a full liner. Records need to be kept of dates when a liner is received, placed into the receptacle, and shipped. Also, after receiving documentation that the liner and its contents has been incinerated, must be documented in the receptacle "liner log".

9. Refrigerator monitoring not being completed. To ensure proper medication storage the refrigerator temperature must be recorded manually or electronically, at least daily, when the pharmacy is open.

10. Compounding documentation is lacking significant information. Not often, but sometimes we see a failure to document cleaning of Primary Engineering Control and anteroom. This is especially true with monthly cleaning. We have seen a lack of documentation for staff competencies and compounding records that do not have complete information. It is important to remind everyone of USP <795> and <797> requirements and the need for proper compounding documentation.

Hopefully, this article will help remind staff to reflect upon whether the pharmacy is in compliance with laws and regulations and if there is anything which should be improved. If you work in a South Dakota pharmacy, please know we will look for these items and others during your next inspection.

PDMP Update – Data Integrity by Melissa DeNoon, PDMP Director

Ensuring accuracy of the data contained in a PDMP is critically important as healthcare practitioners use this tool in clinical decision-making when providing patient care. PDMP staff are currently focusing on data submission compliance and database error correction. SD law and rule require dispensers to submit dispensed schedule 2, 3, and 4 prescriptions at least every 24 hours or by midnight of the next business day after dispensing. If a pharmacy is found to be out of compliance with these data submission requirements, the pharmacist-in-charge (PIC) will be contacted by the PDMP Assistant with information on how to come into compliance. PDMP database errors fall into two categories: 1) Dispensation records in the database, and 2)

South Dakota BOARD of PHARMACY

(continued)

Dispensation records not in the database. Dispensation records that meet the specifically identified data elements adopted by the board and contained in the 2011 version of the electronic reporting standard for prescription drug monitoring programs, version 4.2 of the American Society for Automation in Pharmacy (ASAP v4.2), will be in the database and viewable on patient reports. These records, however, may contain errors that occurred during prescription data entry and were not identified and corrected prior to dispensing, i.e., incorrect prescription written date or incorrect prescriber DEA number. PDMP staff are typically made aware of these errors by PDMP users after viewing the record on a patient report. SD law requires reported errors be corrected and PDMP staff work with PICs to accomplish this. This corrective action always involves submission of the corrected information into SD's data submission site, PMP Clearinghouse. It's important to note that making the correction to the prescription within the patient's profile does not automatically resubmit the corrected record; PICs must check with their pharmacy dispensing software vendors for their record correction process to ensure resubmission.

Dispensation records that do not meet the board adopted ASAP v4.2 data elements will not be in the database and therefore will be missing patient reports. These data elements can be found in ARSD 20:51:32:03. It is a PIC's responsibility to know what these required data elements are. Further, the PIC must ensure the pharmacy dispensing software vendor or party responsible for their data submissions is also aware. Data submission error reports are generated by PMP Clearinghouse upon file submission. These error reports must be promptly reviewed, and the necessary corrections made so the file can be resubmitted. If data submissions are performed by the pharmacy dispensing software vendor, the PIC must also make sure these error reports are forwarded to them for review and correction and then sent back to the vendor for resubmission. Best practice for PICs in both noncompliance and error correction is to perform a patient query after the corrective action is taken to confirm the missing record is now in the database or the incorrect record is now updated with the correct information. Please email questions to PDMP staff at sdpdmp@state.sd.us.

Respectfully submitted, for the Board,

KARI SHANARD-KOENDERS

BOARD MEETING DATES

Please check the Board Meetings page on the South Dakota Board of Pharmacy website for the time, location, and agenda for future Board meetings.

DIRECTORY

BOARD OF PHARMACY
605-362-2737 | 605-362-2738 *fax*
PharmacyBoard@state.sd.us

EXECUTIVE DIRECTOR
Kari Shanard-Koenders, R.Ph., M.S.J.
kari.shanard-koenders@state.sd.us

PDMP DIRECTOR
Melissa DeNoon, R.Ph.
melissa.denoon@state.sd.us

PDMP ASSISTANT
Melanie Houg · melanie.houg@state.sd.us

PHARMACY INSPECTORS
Tyler Laetch, Pharm. D.
tyler.laetsch@state.sd.us
Carol Smith , R.Ph.
carol.smith@state.sd.us
Lee Cordell, Pharm. D.
lee.cordell@state.sd.us

SENIOR SECRETARIES
Beth Windschitl · beth.windschitl@state.sd.us
Rhea Kontos · rhea.kontos@state.sd.us

PDMP SIGN UP & DATA ACCESS
https://southdakota.pmpaware.net/login

South Dakota SOCIETY of HEALTH-SYSTEM PHARMACISTS

Alyssa Larson, PharmD // SDSHP President

Greetings from the South Dakota Society of Health-System Pharmacists!

I am always astounded at how quickly the summer months go by, and the realization that summer is already in full swing! It's great to see people gathering in-person again, and on that note, SDSHP looks forward to hosting more in-person events.

The 46 th SDSHP Annual Conference was held virtually in April. We were hopeful for an in-person event, especially following a virtual conference in 2021 and cancellation in 2020; however, our plans to reconvene in Deadwood were derailed by a spike in COVID-19 cases during early 2022. Nonetheless, our second virtual conference was a success, featuring 10 hours of high-quality CE over the course of two days, poster presentations from pharmacy residents across the state, and an hour of virtual networking activities. While we have tried to make the most of virtual gatherings, I think it is safe to say that we are all "Zoomed Out" and ready to reconnect, in-person, at our 2023 annual meeting in Sioux Falls. Don't forget to mark your calendars for March 31 st – April 1 st !

Earlier this year, our Board of Directors approved SDSHP's 2022-2023 strategic plan. This plan will help focus our efforts leading up to the 2023 Annual Meeting in addition to providing direction for the upcoming years. A couple highlights include strengthening our online presence through expansion of social media platforms and online CE offerings, along with encouraging completion of the PAI 2030 self-assessment tool among health systems statewide. Additionally, I look forward to working with SDSHP immediate Past President Jeremy Daniel as we aim to develop and implement an SDSHP state affiliate Fellowship program.

The 11th Annual SDSHP Residency Conference will be held on July 11 th . Kathryn Brumels, our resident liaison, has been working diligently to organize a meeting that will be beneficial for incoming pharmacy residents. After a couple years of hosting the conference virtually, we look forward to gathering at Arrowwood Cedar Shore Resort in Oacoma, SD! The conference provides an opportunity for residents from across the state to network while also gaining knowledge about topics that are especially pertinent for them as they hit the ground running toward the beginning of the residency year.

We also look forward to the 20 th Annual GVR Open Society Golf Classic, which will be here before we know it! The golf tournament will be held Friday, July 22 nd at the Central Valley Golf Course in Hartford, SD. Not only is the event sure to be a great time, but proceeds also go to a great cause – supporting SDSU pharmacy students through funding academic scholarships and travel to the ASHP Clinical Skills Competition in December. Keep in mind, this event is open to everyone! You do not need to be a member of SDSHP (or a skilled golfer) to play. Click here to register online!

We look forward to a fun and exciting year ahead within SDSHP! Please visit our Facebook page or website to keep tabs on news and upcoming events!

Respectfully submitted,

ALYSSA LARSON

SDSU COLLEGE of PHARMACY and ALLIED HEALTH PROFESSIONS

Dan Hansen, PharmD // Dean and Professor

Hello from the College of Pharmacy and Allied Health Professions! I'm pleased to share a few of our recent highlights.

This May, we celebrated the outstanding achievements of 74 graduates who received their Doctor of Pharmacy hoods. We honored the graduates' accomplishments and learned of their employment plans. Thirty-two percent of the 2022 Pharm.D. graduates matched with a PGY1 residency program. SDSU's match rate remains strong at 71%.

The Pharm.D. accreditation on-site visit will be October 18 th - 20 th . The self-study document was approved at the faculty May meeting. A huge thank you to the College's faculty, staff, students, and internal and external constituents involved in this process.

Faculty & Staff Congratulations:

The College has an exceptional team of faculty and staff.

- Dr. Alex Middendorf received the Excellence in Teaching Award and the Excellence in Research and Scholarly Activity Award.
- Dr. Jayarama Gunaje received the Students' Association Teacher of the Year Award.
- Dr. Brittney Meyer received the Diversity, Equity, and Inclusion Award and was promoted to full professor.
- Sue Fierstine received the Community Service & Outreach Award.
- Asha Hertler received the College Staff Award.
- Dr. Kyle LaPorte was promoted to associate professor.
- Stacie Lansink was promoted to lecturer.
- Dr. Emily Van Klompenburg was nominated for the Embe Award recognizing Women in Healthcare/STEM.

Student Congratulations:

American Pharmacists Association Academy of Student Pharmacists (APhA-ASP) which is part of the umbrella organization Student Collaboration for the Advancement and Promotion of Pharmacy (SCAPP) was acknowledged during the National APhA-ASP awards ceremony during the annual meeting in San Antonio. They received the first-runner up in Division AAA for Chapter Achievement.

South Dakota State University held its annual Undergraduate Research, Scholarship and Creative Activity Day (URSCAD) this past Spring. The following individuals were recognized at the event:

2021 Undergraduate Research Award Recipients

- Camryn Blackwell, Human Biology, mentored by Joshua Reineke. Project Title: Correlating the Efficacy of Gemcitabine in Pancreatic Cancer Cells with dCK and CDA Expression
- Jadyn Perry, Biology, mentored by Joshua Reineke. Project Title: Intracellular Interactions of Iron-Based Metal-Organic Framework (MOF) Particles with Mycobacterium Avium Infected Alveolar Macrophages

2022 Undergraduate Research Award Recipient

- Grace Nielsen, Pharmacy, mentored by Wenfeng An. Project Title: Transcriptional Activity in Mouse L1

2022 Shultz-Werth Senior Paper Award Recipients

- Kyle Shapcott, Pharmacy, mentored by Dan Hansen. Paper Title: The Techniques of Studying and Other Variables Impact on Initial Drug Card Exam Pass Rates
- Lexi Stumpf, Pharmacy, mentored by Linde Murray. Paper Title: Peer Education: Perceptions of Student Learning in Online and In-Person Tutoring Sessions
- Jada Tschetter, Human Biology, mentored by Wenfeng An. Paper Title: Characterizing mouse L1 5'UTR antisense promoter activity
- Alexa Vanden Hull, Pharmacy, mentored by Aaron Hunt. Paper Title: Development and Evaluation of a Qualitative Documentation Tool to Share High Impact Patient Interventions Through the Lens of Community Pharmacists in South Dakota

2022 URSCAD Outstanding Poster Award Recipients

- Tara Jorgensen – Poster: Diabetes Prevention Lab in Preparation for First Year IPPE
- Megan Rambo – Poster: Effects of Gemcitabine, Squalene Gemcitabine, and Paclitaxel on the Extracellular Matrix of Pancreatic Cancer Spheroids
- Kyle Shapcott – Poster: The Techniques of Studying and Other Variables Impact on Initial Drug Card Exam Pass Rates

2022 URSCAD Outstanding International Poster

- Allie Bladholm – International Poster: Ghanaian Healthcare Research and Reflection

At the State ASCLS Conference, several of our faculty and students were recognized for various achievements.

- Callie Frei received an ASCLS-SD scholarship & travel grant.
- April Nelsen and Kassi Erickson received the Keys to the Future award, recognizing their leadership potential in ASCLS.
- Stacie Lansink, April Nelsen, Steph Jacobson, Kassi Erickson, and McKayle Wachlin received Omicron Sigma Awards in recognition of their outstanding service on state, regional and national levels.

Two new people joined the College. Brooke Merry began her duties as the recruitment and outreach coordinator on May 23rd. Hiruni Amarasekara accepted the position of project manager/population health instructor for the Community Practice Innovation Center (CPIC) in the Department of Allied and Population Health.

Dr. Brad Laible, a professor of pharmacy practice and a member of the College of Pharmacy and Allied Health Professions since 2004, was named the college's associate dean for academic programs.

Searches are underway for the following positions: department head of pharmaceutical sciences, MPH program coordinator, respiratory care instructor, director of clinical education for respiratory care, a pharmacy practice faculty, and a program assistant in the Department of Allied and Population Health.

Best regards,

DAN HANSEN

WELL-BEING index

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.

TAKE THE SURVEY NOW IN A FEW EASY STEPS:

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)**

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

Ellie Balken // SCAPP/APhA-ASP SDSU Chapter President

SCAPP members excitedly wrapped up the Spring semester with incredible final events, celebrations, and memories from the unforgettable year together! The Operation Diabetes committee put together care packages for children recently diagnosed with type 1 diabetes at both Avera and Sanford in Sioux Falls. The Public Health and Education committee was also busy spreading awareness during Poison Prevention Week through conducting medication safety activities at the Brookings Boys and Girls Club and taking over the SDSU Instagram and Snapchat accounts to share information about safe medication use and disposal, including the poison control center number. They also organized tabling in the SDSU student union around National Drug Take Back Day in April and hung posters around campus highlighting all the year-round drug take-back locations in Brookings. The Vaping Cessation com-mittee coordinated a presentation from SD QuitLine for members to attend to learn skills for discussing vaping and nicotine cessation with patients. Lastly, 30 committee co-chairs were selected to serve in new leadership roles for the upcoming academic year. Operation Mental Health was introduced, along with Operation Reproductive Health and Operation Substance Use Disorder for the upcoming year. We are excited to see what unique aspects each of these committees will bring to our organization next year!

Five of our members were recognized at Spring Convocation for their contributions to the chapter. Abigail Pape received the pre-pharmacy award which is presented to a pre-pharmacy student for involvement, enthusiasm, and leadership in SCAPP. The networking award was presented to Trenton LaCanne for his excellence in networking and connecting with other pharmacy students and professionals on a local, regional, and national level. Alexa Vanden Hull was awarded the patient care award for demonstrating excellence in providing screenings and exemplifying excellent patient interactions. Rena Nietfeld was selected for the outreach award for her active organization of educational events that directly impacted the community. Lastly, the professional organizations award was presented to Emma Smith for her active participation in SCAPP and dedication to SSHP specifically throughout the past three years. Abby Riesgraf was also selected as the inFLUential member of the semester for her dedication to SCAPP, incredible organizational skills, and commitment to improving the chapter and advancing the profession. Her nominating statement included, "she is an incredible mentor to younger pharmacy students and has big plans for the future of the organization."

P3 student Karly Blaalid recently attended APhA's Institute of Substance Use Disorders in Salt Lake City, Utah in June. She greatly appreciated the experience and said, "I learned how to help treat substance use disorders, what resources are available for providers and pharmacists who are struggling with a substance use disorder, and especially ways to decrease the stigma and shame both for the disorder and the treatment. There were some open 12-step meetings that I attended, which helped me to understand the impact that substance use disorders have both on the person with the disorder and the people around them. I also enjoyed getting to know pharmacists and student pharmacists from around the country both through the sessions and during our time to explore Salt Lake City, including participating in a group hike up a mountain and late-night conversations around a fire."

SCAPP would like to thank SDPhA for the continuous support of student pharmacists on our journey to becoming advocates for patients and the profession and look forward to the partnerships to be formed in the coming year!!

Respectfully,

ELLIE BALKEN

trc healthcare

PHARMACY TECHNICIANS UNIVERSITY

THE BEST-IN-CLASS TRAINING PROGRAM FOR PHARMACY TECHS

Take the headache out of technician training with the No. 1 provider of online learning. Simplify the educational experience, improve efficiency, and help reduce medication errors with Pharmacy Technicians University (PTU).

TRAINING PROGRAM BENEFITS

- Flexible offerings to meet state training requirements across all of your locations
- Fast track to certification, which allows increased staffing ratios for technicians in some states
- Easy-to-use administrator dashboards for managing staff training progress
- PTU 101 provides training program options with fewer hours for completion to limit impact on productivity
- PTU National Standards Entry- and Advanced-Level programs meet new guidelines

pharmacy technicians university®

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.

Pharmacy Technicians University (PTU) offers:

- Programs ranging from 95 to 605 hours of didactic, simulation, and experiential learning
- The highest quality technician training resources in a variety of learning modalities
- The first online tech training program that supports or exceeds the requirements for technician training in 50 states. including Washington, D.C.

CONTACT US:
http://trchealthcare.com/contact-us

WHY TECHNICIANS LOVE PHARMACY TECHNICIANS UNIVERSITY:

Current Course Curriculum
reflects the latest industry trends and complies with state and national regulations.

Practice Skills with Feedback Features
that allow techs to observe, practice, and demonstrate techniques.

Experienced Instructors
review tech demonstrations and provide one-to-one feedback.

Motivating Scenario Simulations
give techs context for active learning and problem solving via "real-life" scenarios that facilitate appropriate information transfer and recall.

Innovative Course Design
helps technicians learn while developing observational and critical thinking skills.

Engaging Content
(including interactive exercises, learning games, and videos) is intermixed with didactic content to accommodate different learning styles.

TRC Healthcare
1720 S Bellaire St, Ste 1250
Denver CO 80222
trchealthcare.com

THE RIGHT SOLUTION FOR YOUR TECHNICIANS

The Pharmacy Technicians University training platform is the first web-based learning and education solution to support the diverse requirements for pharmacy technician training across all 50 states and Washington, D.C. Using a unique combination of technology and tools, Pharmacy Technicians University facilitates and tracks hands-on learning conveniently online.

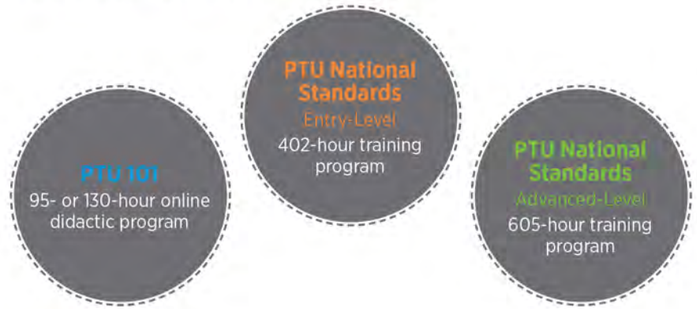
PTU 101, PTU ENTRY-LEVEL NATIONAL STANDARDS, AND PTU ADVANCED-LEVEL NATIONAL STANDARDS PHARMACY TECHNICIAN TRAINING FOR:

- Provider and hospital settings
- Retail and community settings
- Health and wellness institutions such as long-term care and physical therapy centers

TAILORED CURRICULUM TO MEET YOUR ORGANIZATIONAL NEEDS

- "Right-sized" curriculum, program components, and practice setting-specific courses
- National Standards program to meet state-specific compliance requirements
- Convenient, cost-effective online courses, including real-world scenarios, instructor feedback, and rich media content

FLEXIBLE OPTION PACKAGES



CONTACT US:
https://trchealthcare.com/contact-us

Game On!

Please return completed forms and payment to South Dakota Pharmacists Association, PO Box 518, Pierre, SD 57501. We also accept MasterCard, VISA or AMEX with online registration at www.SDPhA.org. Tax ID# 46–019–1834

Questions?

Contact Amanda Bacon at 605-224-2338 or SDPhA@SDPhA.org.

SOUTH DAKOTA PHARMACISTS ASSOCIATION
136th ANNUAL CONVENTION

Register by July 29, 2022

Swiftel Center in Brookings, South Dakota **September 9–10, 2022**

Exhibitor
- 6 foot table for table top exhibits
- Electricity (upon request / fee)
- 1 Convention Registration
- Exhibitor / Sponsor Recognition

Silver
- 1 Exhibit Booth
- 2 Convention Registrations
- Exhibitor / Sponsor recognition
- Recognition in SDPhA Journal
- Recognition in event Program
- Company Logo on SDPhA Website

Gold
- 1 Exhibit Booth
- 2 Convention Registrations
- Exhibitor / Sponsor Recognition
- 2 full-page ads in SDPhA Journal
- Recognition in event Program
- Company Logo on SDPhA Website

Platinum
- 1 Exhibit Booth
- 3 Convention Registrations
- Exhibitor / Sponsor Recognition
- 4 full-page ads in SDPhA Journal
- Recognition in event Program
- Company Logo & Website Link on SDPhA Website

Breakfast
- 1 Exhibit Booth
- 2 Convention Registrations
- Exhibitor / Sponsor Recognition
- Recognition in event Program
- Company name on Breakfast Signs
- Ability to place promotional information at Breakfast Tables

Sponsoring Company responsible for materials and placement.

EXHIBIT AREA
Located at the Swiftel Center in Brookings, SD. Lunch will be available for both the exhibitors and all convention attendees.

SETTING UP
Setup Friday morning from 8-10 am. All materials must be removed by 3 pm.

SHIPPING LOCATION
Exhibitors are welcome to ship materials directly to the Swiftel Center up to 3 days prior to the SDPhA Convention (address below). Please note the Swiftel Center does not have a loading dock. If you have a large shipment, please ensure the truck has lift/drop capabilities, or shipper will provide their forklift.

Swiftel Center
Attn: SD Pharmacists Association "Exhibitor Name"
824 32nd Avenue, Brookings, SD 57006

EXHIBIT SPACE
Includes one 6 foot, skirted table for tabletop exhibits, 2 chairs, electricity (additional cost), 1 convention, and exhibitor/sponsor recognition.

EXHIBIT HOURS
Open Friday, September, 9 from 11 am to 1 pm in the Swiftel Center.

HOTEL RESERVATION
Hampton Inn & Suites Brookings
3017 Lefevre Drive, Brookings, SD 57006
Ask for the South Dakota Pharmacists Association block: 605-697-5232

I wish to be an EXHIBITOR:

_____ **SDPhA Associate Member Exhibitor:** $850

_____ **Non-SDPhA Associate Member Exhibitor:** $995

I wish to be an EVENT SPONSOR:

_____ **SILVER:** $1,200 _____ **GOLD:** $3,000 _____ **PLATINUM:** $5,000

_____ ~~**BREAKFAST: $1,500**~~ **SOLD OUT**

Name _____

Company _____

Address _____

Phone / Fax _____

Email _____

FREE – SDSU STUDENT REGISTRATIONS
Registration must be submitted prior to August 5, 2022.
Hotel not included.

FULL REGISTRATION

	SDPhA Member	Spouse Guest	Children	SDAPT Member	Pharmacy Technician	Pharmacy Student	Non-SDPhA Member	
Before August 5, 2022	$249	$125	$25	$115	$199	FREE	$350	$ _____
After August 5, 2022	$325	$150	$25	$150	$205	FREE	$375	$ _____

Includes all educational sessions, exhibits, meals and evening events, if applicable.

1-DAY REGISTRATION

Friday, September 9, 2022	$200	$100	$15	$105	$179	FREE	$250	$ _____
Saturday, September 10, 2022	$100	$75	$15	$105	$130	FREE	$125	$ _____

Includes educational sessions, exhibits, meals, and evening event, if applicable.

EXTRA TICKETS

Friday Lunch	$25	$25	$15	$25	$25	FREE	$25	$ _____
Saturday Breakfast	$20	$20	$15	$25	$25	FREE	$25	$ _____

I WOULD LIKE TO SPONSOR A STUDENT.
I have included an additional gift of ..... $ _____

I WISH TO CONTRIBUTE TO THE SDPHA COMMERCIAL & LEGISLATIVE FUND.
I have included an additional amount of ..... $ _____

Total Due $ _____

EVENT CANCELLATION POLICY
- Cancellations will be accepted without penalty prior to August 26, 2022.
- A $25 fee will be applied to all cancellations after August 26, 2022.
- Refunds will be issued after October 1, 2022.
- Attendee is responsible for canceling hotel reservations.

Name _____ **eProfile ID** _____

Address _____ **City** _____ **Zip** _____

Business Name _____ **Business Address** _____

Business City _____ **Zip** _____

Business Phone _____ **Cell Phone** _____

Email _____ **Spouse / Guest Name** _____

FDA Safety Communications: Tramadol

Learning Assessment / Post-test Select correct answer(s) for each question.

Course development:
The following public report was published by the U.S. Food and Drug Administration (FDA).

Course development / Sponsorship:
This course is sponsored by the South Dakota State University College of Pharmacy and Allied Health Professions, Brookings, SD.

Permission has been granted by the U.S. Food and Drug Administration for use of this material in the development of CPE activities for pharmacists.

Goal
To provide pharmacists with updated FDA safety advisory regarding the use of tramadol in cited population groups.

Pharmacist Learning Objectives
1. Explain the FDA's current *Contraindication* and *Warnings designations* for tramadol and codeine;
2. Describe the primary metabolism pathways for tramadol and codeine;
3. Evaluate the risks associated with tramadol and/or codeine use by children under than 18 years of age;
4. Describe the characteristics and demographic profile related to the ultra-rapid metabolism of tramadol and codeine;
5. Counsel patients on the dangers of tramadol and/or codeine use by breastfeeding mothers.

US FOOD AND DRUG ADMINISTRATION
Safety Communications Tramadol Information

Tramadol Overview
Tramadol is a specific type of narcotic medicine called an opioid that is approved to treat moderate to moderately severe pain in adults. It is available under the brand names Ultram, Ultram ER, Conzip, and also as generics. Tramadol is available in combination with the pain reliever acetaminophen under the brand name Ultracet and as generics.

FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women

Safety Announcement [4-20-2017]
The Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children.

These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. We are also recommending against the use of codeine and tramadol medi- cines in breastfeeding mothers due to possible harm to their infants.

As a result, we are requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond our 2013 restriction of codeine use External Link Disclaimer in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. We are now adding:

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Caregivers & Patients should always read the label on prescription bottles to find out if a medicine contains co-deine or tramadol. You can also ask your child's health care provider or a pharmacist. Watch closely for signs of breathing problems in a child of any age who is taking these medicines or in infants exposed to codeine or tramadol through breastmilk. These signs include slow or shallow breathing, difficulty or noisy breathing, confusion, more than usual sleepiness, trouble breastfeeding, or limpness.

If you notice any of these signs, stop giving the medicine and seek medical attention immediately by going to an emergency room or calling 911.

Health Care Professionals should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Consider recommending over-the-counter (OTC) or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection, not serious, and usually will get better on its own so treatment may not be necessary.

Codeine and tramadol are a type of narcotic medicine called an opioid. Codeine is used to treat mild to moderate pain and also to reduce coughing. It is usually combined with other medicines, such as acetaminophen, in prescription pain medicines. It is frequently combined with other drugs in prescription and over-the-counter (OTC) cough and cold medicines. Tramadol is a prescription medicine approved only for use in adults to treat moderate to moderately severe pain. However, data show it is being used in children and adolescents despite the fact that it is not approved for use in these patients.

In early 2013 External Link Disclaimer, FDA added a Boxed Warning to the codeine drug label cautioning against prescribing codeine to children of any age to treat pain after surgery to remove tonsils or adenoids. We also issued Drug Safety Communications in July 2015 and September 2015 warning about the risk of serious breathing problems in some children who metabolized codeine and tramadol much faster to their active form than usual (called ultra-rapid metabolism), causing potentially dangerously high levels in their bodies too quickly. At that time, we said we would continue to evaluate this safety issue. As part of that safety review, the codeine-related safety issues were discussed at an FDA Advisory Committee meeting in December 2015External Link Disclaimer.

Our review of several decades of adverse event reports submitted to FDA* from January 1969 to May 2015 identified 64 cases of serious breathing problems, including 24 deaths, with codeine-containing medicines in children younger than 18 years. This includes only reports submitted to FDA, so there may be additional cases about which we are unaware. We also identified nine cases of serious breathing problems, including three deaths, with the use of tramadol in children younger than 18 years from January 1969 to March 2016 (see Data Summary).

The majority of serious side effects with both codeine and tramadol occurred in children younger than 12 years, and some cases occurred after a single dose of the medicine.

In our review of the medical literature[1-19] for data regarding codeine use during breastfeeding, we found numerous cases of excess sleepiness and serious breathing problems in breastfed infants, including one death. A review of the available medical literature[4,5,23,24] for data regarding tramadol use during breastfeeding did not reveal any cases of adverse events. However, tramadol and its active form are also present in breast milk, and tramadol has the same risks associated with ultra-rapid metabolism as codeine.

We will continue to monitor this safety issue. We are considering additional regulatory action for the OTC codeine products that are available in some states. OTC codeine products are available in combination with other medicines for cough and cold symptoms.

We are also considering an FDA Advisory Committee meeting to discuss the role of prescription opioid cough-and-cold medicines, including codeine, to treat cough in children.

We urge patients and health care professionals to report side effects involving codeine-and tramadol-containing medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at end of article.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS).

Use of Codeine and Tramadol Products in Breastfeeding Women - Q & A

Answers to questions about certain opioid medications and their effects on breastfed infants.

1. What is codeine and how is it used?

Codeine is a type of pain medicine called an opioid. Codeine is used to treat mild to moderate pain and also to reduce coughing where treatment with an opioid is appropriate and for which alternative treatments are inadequate. It is usually combined with other medicines, such as acetaminophen, in prescription pain medicines and over-the-counter (OTC) and prescription cough and cold medicines.

- When codeine enters the body, it is changed (metabolized) in the liver to morphine, the active form. Morphine relieves pain and cough and is also responsible for side effects that some people may experience.

2. What is tramadol and how is it used?

Tramadol is a prescription opioid medication approved for use in adults to treat pain that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Similar to codeine, when tramadol enters the body, it is changed in the liver to its active form, O-desmethyltramadol (known as M1). Both tramadol and M1 relieve pain and are responsible for side effects that some people may experience, but M1 has stronger opioid effects than the tramadol.

3. What is an "ultra-rapid metabolizer"?

Codeine and tramadol are metabolized in the liver to their active forms by an enzyme called cytochrome P450 isoenzyme 2D6 (CYP2D6). Some people have a variation of this enzyme that changes codeine to morphine and tramadol to M1 faster and to a greater extent than in other people. These individuals are called CYP2D6 ultra-rapid metabolizers.

- The number of CYP2D6 ultra-rapid metabolizers varies among different population groups (see Table 1).
- For people who are ultra-rapid metabolizers, the specific likelihood of having an adverse event when taking codeine or tramadol is not known.

Table 1

Approximate number of CYP2D6 ultra-rapid metabolizers in different populations

Population	Ultra-rapid metabolizers/100 people
Whites (European, N.American)	1-10
Blacks (African Americans)	3-4
East Asian (Chinese, Korean)	1-2
Oceanian, Northern Africa, Middle Eastern, Ashkenazi, Jews, Puerto Rican	May be >10

Reference: Gaedigk et el, Genet Med 2017 PMID: 27388693

4. What new information is FDA announcing about codeine and tramadol with respect to breastfeeding mothers?

In our review of the medical literature for data regarding codeine use during breastfeeding, we found numerous cases of excess sleepiness and serious breathing problems, including one death, in infants of breastfeeding mothers who were taking codeine. A review of the available medical literature for data regarding tramadol use during breastfeeding did not reveal any cases of adverse events.

However, tramadol and its metabolite M1 are also present in breast milk, and tramadol has the same risk as codeine with regard to ultra-rapid metabolism and the potential for life-threatening respiratory depression in an infant breastfeeding from a mother who is an ultra-rapid metabolizer.

- In breastfeeding mothers, the ultra-rapid conversion of codeine to morphine and tramadol to M1 can result in high and unsafe levels of morphine and M1 in blood and breast milk.

5. What is FDA doing in response to this information related to women who are breastfeeding?

The FDA issued a Drug Safety Communication regarding the strengthened warning to mothers (among other warnings) that breastfeeding is not recommended during treatment with codeine or tramadol due to the risk of serious adverse reactions in breastfed infants such as excess sleepiness, difficulty breastfeeding, and serious breathing problems that may result in death.

- The FDA wants breastfeeding mothers or caregivers to watch closely for signs of problems in infants when the mothers are taking any opioid pain medicine, and especially when they are using codeine or tramadol for pain. Because most mothers will not know if they are ultra-rapid metabolizers, they will not know that using codeine or tramadol may place their babies at greater risk for an overdose.

The FDA urges healthcare providers and breastfeeding mothers to report side effects that occur while using codeine or tramadol to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

6. What should health care professionals do in response to this new information?

Healthcare professionals should be aware that breastfeeding is not recommended during treatment with codeine or tramadol due to the risk of serious adverse reactions in breastfed infants such as excess sleepiness, difficulty breastfeeding, and serious breathing problems, which may result in death. We also encourage health care professionals to read the Drug Safety Communication regarding all new warnings the FDA is communicating about these products.

#1 Active learning question: True or False

In certain population groups more than 10 people out of 100 may be ultra-rapid metabolizers.

7. What are the symptoms of opioid overdose in infants?

- Increased sleepiness (breastfed babies usually eat every 2 to 3 hours and should not sleep more than 4 hours at a time)
- Difficulty breastfeeding
- Breathing difficulties

If a breastfed baby shows these symptoms, the baby's doctor must be called right away. An overdose of opioid pain medicine in a baby can cause death. If the doctor cannot be reached right away, the baby should be taken to an emergency room or help should be sought by calling 911 (or local emergency services).

8. What are the symptoms of opioid overdose in a breastfeeding mother?

The signs of opioid overdose in the breastfeeding mother are the same as can occur with any person taking an opioid. These in- clude trouble breathing, shortness of breath, extreme drowsiness, light-headedness when changing positions, or feeling faint. Breastfeeding mothers who are ultra-rapid metabolizers may have symptoms of too much opioid, even if they are taking a dose that would not otherwise be expected to cause an over- dose. If any of these symptoms occur, the mother, family members, or other close contacts should call her doctor or 911 right away.

9. Should a breastfeeding mother using codeine stop breastfeeding?

It is important for health care professionals and breastfeeding women to discuss the use of pain medicines and to consider alternatives to codeine or tramadol. Because most people do not know if they are ultra-rapid metabolizers, and because early signs of opioid overdose in an infant may be difficult to notice, breastfeeding is not recommended during treatment with codeine or tramadol.

10. What should breastfeeding mothers do about this new information?

- A breastfeeding mother should talk to her doctor about pain medicines other than codeine or tramadol.
- A breastfeeding mother should know that some over-the-counter cough/cold combination products contain codeine. Breastfeeding mothers should check the label of all over-the-counter drugs they take to see if codeine is an ingredient. Mothers should also check the label of all over-the-counter medicines for warnings about use while they are breastfeeding and should talk to their doctor before using all over-the-counter medicines.

11. Are there any tests that can be used to help identify mothers who are CYP2D6 ultra-rapid metabolizers?

There is an FDA-cleared test to determine whether a patient is a CYP2D6 ultra-rapid metabolizer. These tests are not routinely done but may help healthcare professionals make individualized treatment decisions for a patient.

12. Should a breastfeeding mother of a newborn ask her doctor to be tested to determine if she is an ultra-rapid metabolizer of codeine or tramadol?

The mother should discuss her concerns with her doctor, and her doctor may select another pain med- ication that is not subject to the risks associated with CYP2D6 ultra-rapid metabolism.

13. Where can consumers and healthcare providers go for additional information?

Visit the Codeine Information page.

Safety Announcement [Current as of 8-1-2017]
The U.S. Food and Drug Administration (FDA) is investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. We are evaluating all available information and will communicate our final conclusions and recommendations to the public when our review is complete.

Tramadol is not FDA-approved for use in children; however, data show it is being used "off-label" in the pediatric population. Health care professionals should be aware of this and consider prescribing alternative FDA-approved pain medicines for children.

Parents and caregivers of children taking tramadol who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness should stop tramadol and seek medical attention immediately by taking their child to the emergency room or calling 911. Parents and caregivers should talk with their child's health care professional if they have any questions or concerns about tramadol or other pain medicines their child is taking.

Treating pain in children is important because it can lead to faster recoveries and fewer complications. Untreated pain can potentially result in long-term physical and psychological consequences. There are other pain medicines available that do not have this side effect of slowed or difficult breathing associated with tramadol and are FDA-approved for use in children.

Tramadol is a specific type of narcotic medicine called an opioid that is approved to treat moderate to moderately severe pain in adults. It is available under the brand names Ultram, Ultram ER, Con-zip, and also as generics. Tramadol is also available in combination with the pain reliever acetaminophen under the brand name Ultracet and as generics.

In the body, tramadol is converted in the liver to the active form of the opioid, called O-desmethyltramadol. Some people have genetic variations that cause tramadol to be converted to the active form of the opioid faster and more completely than usual. These people, called ultra-rapid metabolizers, are more likely to have higher-than-normal amounts of the active form of the opioid in their blood after taking tramadol, which can result in breathing difficulty that may lead to death.

Recently, a 5-year-old child in France experienced severely slowed and difficult breathing requiring emergency intervention and hospitalization after taking a single prescribed dose of tramadol oral solution for pain relief following surgery to remove his tonsils and adenoids.[1]

The child was later found to be an ultra-rapid metabolizer and had high levels of O-desmethyltramadol in his body. We urge health care professionals, parents, and caregivers to report side effects involving tramadol to the FDA MedWatch program: 1-888-INFO-FDA / (1-888-463-6332) or https://www.fda.gov/about-fda/contact-fda

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

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

References

1. Halder, et al. Codeine and breastfeeding mothers. International Journal of Obstetric Anesthesia. 2015. 24 (1):5-7.

2. Willmann S, Edginton AN, Coboeken K et al. Risk to the breastfed neonate from codeine treatment to the mother: a quantitative mechanistic modeling study. Clin Pharmacol Ther. 2009;86:634-43.

3. Madadi P, Koren G. Pharmacogenetic insights into codeine analgesia: implications to pediatric codeine use. Pharmacogenomics. 2008;9:1267-84.

4. Hale, Thomas, Ph.D. Medications and Mother's Milk: A Manual of Lactational Pharmacology-2017, 17th edition. Hale Publishing, L.P.

5. Briggs, G and Freeman, R. A Reference Guide to Fetal and Neonatal Risk: Drugs in Pregnancy and Lactation, 10th ed. Wolters Kluwer, 2015.

6. Sachs, H and Committee on Drugs. The Transfer of Drugs and Therapeutics into Human Breast Milk: An Update on Selected Topics. Pediatrics. 2013;132(3):e796-e809.

7. Reece-Stremtan, Marinelli, K. and The Academy of Breastfeeding Medicine. ABM Clinical Protocol #21: Guidelines for Breastfeeding and Substancve Use or Substance Use Disorder, Revised 2015. Breastfeeding Medicine. 2015;10(3):135-141.

8. Madadi P, Ross CJ, Pape T et al. A Toxicogenetic case-control study of codeine toxicity during breastfeeding. Clin Pharmacol Ther. 2008;83(Suppl 1):S2.

9. Koren, et al. Pharmacogenetics of morphine poisoning in a breastfed neonate of a codeine-prescribed mother. The Lancet. 2006.368(9536):704.

10. Findlay JW, DeAngelis RL et al. Analgesic drugs in breast milk and plasma. Clin Pharmacol Ther.1981;29:625-33.

11. Smith JW. Codeine-induced bradycardia in a breastfed infant. Clin Res. 1982;30:259A. Abstract.

12. Davis JM, Bhutani VK. Neonatal apnea and maternal codeine use. Pediatr Res. 1985;19(4 pt 2):170A. Abstract.

13. Naumburg EG, Meny RG. Breast milk opioids and neonatal apnea. Am J Dis Child. 1988;142:11-12.

14. Ito S, Blajchman A, Stephenson M et al. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. Am J Obstet Gynecol. 1993;168:1393-9.

15. Madadi P, Ross C, Hayden M et al. Pharmacogenetics of neonatal opioid toxicity following maternal use of codeine during breastfeeding: a case-control study. Clin Pharmacol Ther. 2009;85:31-5.

16. Ciszkowski C, Madadi P, Sistonen J et al. The incidence of CNS depression of neonates breastfed by mothers receiving codeine for postpartum analgesia. Clin Pharmacol Ther. 2011;89(Suppl 1):S94. Ab- stract.

17. Lam J, Kelly L, Ciszkowski C et al. Central nervous system depression of neonates breastfed by mothers receiving oxycodone for postpartum analgesia. J Pediatr. 2012;160:33-37.e2.

18. Juurlink DN, Gomes T, Guttmann A et al. Postpartum maternal codeine therapy and the risk of adverse neonatal outcomes: a retrospective cohort study. Clin Toxicol (Phila). 2012;50:390-5.

19. Lam J, Matlow JN, Ross CJ et al. Postpartum maternal codeine therapy and the risk of adverse neonatal outcomes: the devil is in the details. Ther Drug Monit. 2012;34:378-80.

20. IMS Health, Vector One®: Total Patient Tracker. Year 2014. Data extracted June and August 2015.

21. Symphony Health Solutions' Integrated Dataverse (IDV). Year 2014. Data extracted October 2015.

22. Orliaguet G, Hamza J, Couloigner V, Denoyelle F, Loriot MA, Broly F, Garabedian EN. A case of respiratory depression in a child with ultrarapid CYP2D6 metabolism after tramadol. Pediatrics 2015;135:e753-5.

23. Allegaert K, Rochette A, Veyckemans F. Developmental pharmacology of tramadol during infancy: ontogeny, pharmacogenetics and elimination clearance. Paediatr Anaesth. 2011;21:266-73.

24. Bloor, et al. Tramadol in pregnancy and lactation. International Journal of Obstetric Anesthesia. 2012;21:163-167.

FDA Safety Communications: Tramadol

Learning Assessment / Post-test Select correct answer(s) for each question.

1. Tramadol is a specific type of opioid that is _____.

a. Approved to treat moderate to severe pain in children and adults.
b. Available under the brand names such as Ultram, Conzip and certain generics.
c. Available in combination with acetaminophen in the brand name product Ultracet.
d. All of the above.

2. Tramadol, approved to treat pain, and codeine, approved to treat pain and cough, _____.

a. Carry serious risks, like slowed or difficult breathing.
b. Should not be used in children younger than 12 years.
c. Should not be used by breastfeeding mothers.
d. All of the above.

3. The FDA has issued a Tramadol Contraindication alert against its use to treat pain in children younger than 18 years following tonsil removal and adenoid removal surgeries.

a. True b. False

4. The FDA has issued a Tramadol *Warning* against its use in adolescents between 12 and 18 years who suffer from the following conditions_____.

a. Obesity
b. Sleep apnea
c. Severe lung disease
d. Anorexia

5. Codeine is used to treat mild to moderate pain and is often combined with other OTC medications:

a. Cough and Cold products
b. Acetaminophen
c. Laxatives
d. Athletes' Foot creams

6. Tramadol is metabolized in the liver to _____, and this active metabolite has_____opioid effects than tramadol itself.

a. Morphine / stronger
b. Morphine / weaker
c. O-desmethyltramadol (MI) / stronger
d. O-desmethyltramadol (MI) / weaker

7. Codeine and tramadol are metabolized in the liver to their active forms by an enzyme called cytochrome P450 isoenzyme 2D6 (CYP2D6). All people metabolize tramadol and codeine at the same relative rate.

a. True b. False

8. Tramadol has the same risks associated with ultra-rapid metabolism as codeine.

a. True b. False

9. CYP(2D6) ultra-rapid metabolizers include these rates (per 100 people in different populations: Whites_____; Blacks_____; Asians_____.

a. 1-2 / 3-4 / >10
b. 1-2 / 8-10 / 3-4
c. 1-10 / 3-4 / 1-2
d. All are the same.

10. Breast-feeding mothers should be counseled about these FDA warnings:_____.

a. Tramadol and its active metabolite (MI) are both present in breast milk.
b. Breast-feeding is not recommended during treatment with tramadol or codeine.
c. Signs of opioid overdose in infants.
d. All of the above.

11. The major signs of **opioid overdose in infants include**:

a. Increased sleepiness (breastfed babies usually eat every 2 to 3 hours and should not sleep more than 4 hours at a time)
b. Difficulty breastfeeding
c. Breathing difficulties
d. Limpness in the baby

12. Pharmacists should be aware that_____.

a. While tramadol is not FDA-approved for use in children, data show that it is being used "off-label" in the pediatric population.
b. Parents / caregivers should seek immediate medical for children taking any products containing codeine or tramadol who exhibit signs of shallow/difficult noisy breathing, confusion, or unusual sleepiness.
c. Treating pain in children is rarely needed, and does not lead to faster recovery times.
d. All of the above.

FDA Safety Communications: Tramadol

Knowledge-based CPE

To receive 1.5 contact hours (0.15 CEUs) of continuing education credit, preview and study the attached article and answer the 12-question post-test by circling the appropriate letter on the answer form below and completing the evaluation. A test score of at least 75% is required to earn credit for this course. If a score of 75% (9 / 12) is not achieved on the first attempt, another answer sheet will be sent for one retest at no additional charge.

Participants should verify credit upload to their NABP accounts within two weeks of submission of this answer sheet to insure appropriate credit award.

The South Dakota State University College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Universal Program Identification number for this program is: #0063-0000-20-061-H08-P.

Learning Objectives – Pharmacists: *1. Explain the FDA's current Contraindication and Warnings designations for tramadol and codeine; 2. Describe the primary metabolism pathways for tramadol and codeine; 3. Evaluate the risks associated with tramadol and/or codeine use by children under than 18 years of age; 4. Describe the characteristics and demographic profile related to the ultra-rapid metabolism of tramadol and codeine; 5. Counsel patients on the dangers of tramadol and/or codeine use by breastfeeding mothers.*

Circle Correct Answer:

1. A B C D	5. A B C D	9. A B C D
2. A B C D	6. A B C D	10. A B C D
3. A B	7. A B	11. A B C D
4. A B C D	8. A B	12. A B C D

Course Evaluation: *must be completed for credit.* ***Disagree*** ***Agree***

Material was effectively organized for learning: 1 2 3 4 5 6 7

Content was applicable for re-licensing / recertification: 1 2 3 4 5 6 7

Each of the stated learning objectives was satisfied: 1 2 3 4 5 6 7

*List any learning objectives above not met in this course:*_____

*List any important points that you believe remain unanswered:*_____

Course material waswas evidence-based, balanced, noncommercial: 1 2 3 4 5 6 7

*List any details relevant to commercialism:*_____

Learning assessment questions appropriately measured comprehension 1 2 3 4 5 6 7

Length of time to complete course was reasonable for credit assigned 1 2 3 4 5 6 7

Approximate amount of time to preview, study, complete and review this 1.5 hour CE course: _____

Comments: list any future CE topics of interest (and related skill needs): _____

_____

NAME:_____RPh LICENSE #:_____TECHNICIAN #:_____

STREET: _____ CITY: _____STATE: _____ ZIP: _____

EMAIL:_____ PHONE: _____ INTEREST IN ADDITIONAL CE COURSES? Y / N

e-PROFILE ID # (ePID):_____ DATE OF BIRTH (MMDD): _____

Course release date: 11–18–20 / Expiration date: 11–18–23 / Target audience: Pharmacists
Please mail this ***completed answer sheet*** *with your check of* ***$8.50*** *to:* ***SDSU College of Pharmacy-C.E. Coord., PO Box 2202C,*** **Brookings, SD 57007** / *Office: 605-688-6646* / ***Scout.ForbesHurd@sdstate.edu***

PHARMACY MARKETING GROUP, INC.

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.*

PATIENT WAIVERS

We received a number of questions through the years about patients signing a waiver to protect the pharmacy and its pharmacists. These questions usually arise when looking for protection from mis-filling prescriptions, delivering prescriptions to the incorrect patient, or dispensing unapproved medications (like ivermectin). This article explores waivers, their content requirements, and the likelihood of enforcement.

A waiver is an agreement between a patient and the pharmacy. The patient agrees to give up a legal right to sue the pharmacy if he or she is injured as the result of an activity or due to goods or services provided by the pharmacy.

Waivers are contracts and are interpreted by the courts using contract law. Courts generally do not look favorably on waivers and will strictly construe them against the drafter. Waivers are governed by state law, so there are no national requirements that this article can provide. However, there are a handful of states where waivers are unenforceable and will not be useful. Your first step in deciding whether to use waivers in your pharmacy is whether your state will enforce them.

There are some general requirements to consider. The waiver must be clear, unambiguous, and avoid legalese. Waivers should stand alone and should not be made part of other documents where they could be overlooked. The risks that the patient is waiving their right to must be complete and clearly listed. The waiver should only address ordinary negligence and inherent risks.

Waivers are not enforceable when waiving intentional or reckless behavior or gross negligence. They do not absolve the pharmacy of the duty to exercise due care and take appropriate safety measures for the protection of the patient. Failure to take basic, industry-standard safety steps could be seen as gross negligence and therefore not waived by the agreement.

Because waivers are contracts, there must be consideration given to make the contract legally enforceable. Consideration is the benefit that each party gets from the contract. This benefit can be a promise to do something you are not legally obligated to do or a promise not to do something you have a right to do. What consideration or benefit is the patient receiving in this bargain? If that cannot be identified, the waiver will be invalid and unenforceable.

Even if you have a well-drafted waiver, there are still hurdles to overcome. Courts will not enforce waivers that are contrary to public policy or that are seen as unconscionable. Each state has its own criteria for determining what is against public policy. However, some common unenforceable waivers involve a highly-regulated activity (pharmacy practice arguably is one) or a service upon which the public depends (pharmacy practice again). A waiver could be deemed unconscionable if it is too one sided or if one party is in a superior bargaining position that leaves the other party with no choice but to agree. This leads us back to the consideration concern. You need to be able to articulate what benefit the patient receives by signing the waiver. Providing pharmacy services to the patient may not be sufficient consideration.

The existence of the waiver does not prevent the pharmacy from being sued. The waiver is a defense that can be raised. Even if it is raised successfully and there is an early dismissal, the pharmacy incurs expenses. For this reason, a waiver can never replace an insurance policy. One of the benefits of an insurance policy is the defense expenses coverage resulting from a covered claim.

Another factor to consider is the impression a waiver may give to your patients. Asking them to sign a waiver in case they ever receive a mis-filled prescription that leaves them injured and without legal recourse will reduce their confidence and loyalty in your pharmacy and pharmacists.

The waiver is not a panacea. In the right jurisdiction, it can be a legally enforceable agreement. However, when drafting a waiver, several factors have to be considered when determining its enforceability. The ability to draft an enforceable waiver is difficult for a pharmacy operation because of public policy reasons. If the idea of a release like this was viable, every professional would use one with every WWtransaction or encounter. The effort is probably more effectively spent on a patient safety program.

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.

Beyond-Use Date vs. Nursing Home Storage Policy

Avoid this Recoupment Trap!

Manufacturers go through rigorous testing to bring their products to market and part of the tedious approval process includes stability, sterility, and beyond-use date (BUD) testing. Pharmacies should be familiar with a product's stability, sterility, and BUD information since these timeframes may come into play when determining the correct quantity and days' supply to bill. Insulin pens and vials are the most commonly billed products where the BUD may influence the days' supply. For example, a single vial of Lantus ® or NovoLog ® is good for 28 days once the top is punctured; therefore, a single vial of either of these insulins should always be billed for 28 days or less. Alternatively, a single vial of Levemir ® is good for 42 days once it has been punctured; therefore, a single vial of Levemir ® should always be billed for 42 days or less. For additional BUD information, refer to Section 16 of the manufacturer product labeling, or PAAS Audit Assistance [1] members can view various Days Supply Charts found in the Tools & Aids [2] section of the PAAS Member Portal.

Pharmacies billing for nursing home patients may come across yet another "date of importance" - the maximum time a product may be stored according to the facility's storage policy. PAAS National® analysts see pharmacies billing eye drops, inhalers, and insulin products as a 28-day or 30-day supply even though the directions on the prescription, the manufacturer product sterility information, and the BUD all support a longer days' supply. Using the Levemir ® example from above, if a pharmacy had a prescription for a Levemir ® vial 100 units/mL, injecting 12 units subcutaneously nightly (dispense 10 mL), a single vial would have 83.3 doses or 83 days of medication. However, the BUD of a single vial is only 42 days; therefore, this should be billed as a 42-day supply. If a nursing home facility has a policy to discard all insulin vials after 28 days, then a pharmacy would be tempted to bill this as a 28-day supply but be aware of the repercussions this billing process could have! Nursing home practices and policies do not invalidate FDA/manufacturer sterility testing. Adjusting the days' supply to 28 days to follow the facility's policy often leads to "invalid day supply" penalty fees and full recoupments on early refills since PBMs will not take into consideration nursing home policies when determining days' supply.

PAAS Tips:

- Always attempt to bill the true/accurate days' supply on a claim.
- PAAS Audit Assistance members can utilize the following tools and additional billing resources on the PAAS Member Portal [2] to facilitate correct billing:
  - o Insulin Medication Chart
  - o Eye Drop Chart
  - o Can You Bill It as 30 Days?
  - o Oral Inhaler Chart
  - o Find additional manufacturer storage information on DailyMed [3].
- If there is no state law to substantiate a facility's storage policy which is more restrictive than manufacturer's storage guidance (i.e., billing eye drops, inhalers, insulins, etc. for 28 or 30 days due to facility policy when they truly would last longer according to directions and manufacturer sterility information):
  - o Consider talking to the facility's Director of Nursing about revising their policy so your pharmacy can avoid penalty fees and recoupment issues, or
  - o Insist that the pharmacy must bill for the true days' supply according to directions and product labeling. If the facility's storage policy requires early fills, then the facility will have to pay for those early fills. This is unlikely to be well- received by any facility and may help open lines of communication about changing the facility's policy.

PAAS National® is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact us today at (608) 873-1342 or info@paasnational.com to see why membership might be right for you. By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance. ©2022 PAAS National® LLC All Rights Reserved

References:
1. https://paasnational.com/audit-assistance/
2. https://portal.paasnational.com/Paas/Resource/Tools
3. https://dailymed.nlm.nih.gov/dailymed/

FINANCIAL FORUM

*This series, **Financial Forum**, is presented by PRISM Wealth Advisors, LLC and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.*

Retirement Blindspots

Some life and financial factors that can sometimes be overlooked.

We all have our "blue sky" visions of the way retirement should be, yet our futures may unfold in ways we do not predict. So, as you think about your "second act," you may want to consider some life and financial factors that can suddenly arise.

You may end up retiring earlier than you expect. If you leave the workforce at "full" retirement age (FRA), which is 67 for those born in 1960 and later, you may be eligible to claim "full" Social Security benefits. Working until 67 may be worthwhile because it will reduce your monthly Social Security benefits if you claim them between age 62 and your FRA.[1] Now, do most Americans retire at 67? Not according to the annual survey from the Employee Benefit Research Institute (EBRI). In EBRI's 2020 Retirement Confidence Survey, 16% of pre-retirees expected to retire between ages 66-69, and 31% thought they would retire at age 70 or later. The reality is different. In surveying current retirees, EBRI found that only 6% had worked into their seventies. In fact, 70% percent of them had left work before age 65, and 33% had retired before age 60.[2]

You may see retirement as an extension of the present rather than the future. This is only natural, as we all live in the present – but the future will arrive. The costs you have to shoulder later in retirement may exceed those at the start of retirement. As you may be retired for 20 or 30 years, it is wise to take a long-term view of things.

You may have a health insurance gap. If you retire before age 65, what do you do about health coverage? You may shoulder 100% of the cost. Looking forward, you may need extended care, and it seems to get more expensive each year. Wealthy households may be able to "self-insure" against extended care, but many other households struggle. In Genworth's 2020 Cost of Care Survey, the median monthly cost of a semi-private room in a nursing home is $7,738. In California, it is $9,023; in Florida, $8,803.[3] Suppose you become disabled or seriously ill, and working is out of the question. How do you make ends meet?

Age may catch up to you sooner rather than later. You may stay fit, active, and mentally sharp for decades to come, but if you become mentally or physically infirm, you need to find people to trust to manage your finances.

You could be alone one day. As anyone who has ever lived alone realizes, a single person does not simply live on 50% of a couple's income. Keeping up a house, or even a condo, can be tough when you are elderly. Driving can be a concern. If your spouse or partner is absent, will there be someone to help you in the future?

These are some of the blind spots that can surprise us in retirement. They may quickly affect our money and quality of life. If you age with an awareness of them, you may have the opportunity to manage the outcome better.

Citations.

1. Social Security Administration, December 1, 2020
2. Employee Benefit Research Institute, December 1, 2020
3. Genworth Cost of Care Survey, March 30, 2020

Pat Reding and Bo Schnurr may be reached at 800-288-6669 or pbh@berthelrep.com. Registered Representative of and securities and investment advisory services offered through Berthel Fisher & Company Financial Services, Inc. Member FINRA/SIPC. ***PRISM Wealth Advisors LLC is independent of Berthel Fisher & Company Financial Services Inc.***

Ozempic® Dispensing Quick Reference Guide

OZEMPIC semaglutide injection 0.5mg, 1mg, 2mg

For adults with type 2 diabetes	Ozempic® 0.25-mg or 0.5-mg dose pen pack Delivers 0.25 or 0.5 mg doses only			Ozempic® 1-mg dose pen pack Delivers 1 mg dose only		Ozempic® 2-mg dose pen pack Delivers 2 mg dose only	
Trade Pack							
NDC	0169-4132-12			0169-4130-13		0169-4772-12	
Days Supply	**Sample or Initial** (42 days)	**1 Month** (28 days)	**3 Months** (84 days)	**1 Month** (28 days)	**3 Months** (84 days)	**1 Month** (28 days)	**3 Months** (84 days)
Intent of Prescription	Sample or initial prescription for new starts	1-month prescription for maintenance on 0.5 mg	3-month prescription for maintenance on 0.5 mg	1-month prescription for maintenance on 1 mg	3-month prescription for maintenance on 1 mg	1-month prescription for maintenance on 2 mg	3-month prescription for maintenance on 2 mg
Strength	2 mg per 1.5 mL (1.34 mg/mL)		2 mg per 1.5 mL (1.34 mg/mL)	4 mg per 3 mL (1.34 mg/mL)	4 mg per 3 mL (1.34 mg/mL)	8 mg per 3 mL (2.68 mg/mL)	8 mg per 3 mL (2.68 mg/mL)
Dosage Form	Solution		Solution	Solution	Solution	Solution	Solution
SIG	**Sample or Initial Rx:** 0.25 mg SC once weekly for 4 weeks, then 0.5 mg SC once weekly for 2 weeks	**Maintenance Rx:** Inject 0.5 mg SC once weekly for 4 weeks	**Maintenance Rx:** Inject 0.5 mg SC once weekly for 12 weeks	**Maintenance Rx:** Inject 1 mg SC once weekly for 4 weeks	**Maintenance Rx:** Inject 1 mg SC once weekly for 12 weeks	**Maintenance Rx:** Inject 2 mg SC once weekly for 4 weeks	**Maintenance Rx:** Inject 2 mg SC once weekly for 12 weeks
Dispense Quantity	1.5 mL		4.5 mL	3 mL	9 mL	3 mL	9 mL
Needles	6 included		18 included	4 included	12 included	4 included	12 included
Number of Boxes	1 box		3 boxes	1 box	3 boxes	1 box	3 boxes

⚠ Ozempic® pen packs are not interchangeable. Always ensure prescriptions and dispensing quantities match the intended dosage.

NOC=National Drug Code; SC=subcutaneously

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (eg, a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.

Indications and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, or nonfatal stroke) in adults with type 2 diabetes mellitus and established CV disease.

- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not indicated for use in patients with type 1 diabetes mellitus.

Important Safety Information (cont'd)

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a hypersensitivity reaction to semaglutide or to any of the excipients in Ozempic®. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with Ozempic®.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared with placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.
  Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.
- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia:** Patients receiving Ozempic® in combination with an insulin secretagogue (eg, sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity:** Serious hypersensitivity reactions (eg, anaphylaxis, angioedema) have been reported in patients treated with Ozempic®. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Acute Gallbladder Disease:** Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients treated with Ozempic® 0.5 mg and 1 mg, respectively, and not reported in placebo-treated patients. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- When initiating Ozempic®, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Reference: Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc..; March 2022.

Please see additional Important Safety Information, including Boxed Warning, on previous page.
Please click here for full Prescribing Information, including Boxed Warning.

OZEMPIC semaglutide injection 0.5mg, 1mg, 2mg

SDPhA

GAME ON

136th Annual CONVENTION

SAVE the DATE

SEPT. 9-10, 2022

Brookings, SD

SWIFTEL CENTER

EST. 1886
SOUTH DAKOTA
PHARMACISTS ASSOCIATION

PO Box 518 Pierre, SD 57501
(605) 224-2338

www.SDPhA.org

sdpha@sdpha.org

Classifieds

Classified Rates

Classified ads are $25 per five line ad per issue. Additional lines will be billed at $1 per line. Including your company logo will be an extra $5 charge.

Place a Classified

To place a classified ad, please write, email, call or fax:
SD Pharmacist Classified, PO Box 518, Pierre, SD 57501
sdpha@sdpha.org | 605-224-2338 | 605-224-1280 *fax*