Board Welcomes New Registered Pharmacists/Pharmacies

The following 15 candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Joshua Alexander, Todd Belgum, Kimberly Davidson, Tyler Finocchio, Nicole Heeren, Cynthia Holy, Sara Menning, Reed Reuman, Grant Strain, Chance Wachholtz, Patrick Warman, Amanda Wehde, Zachary Williams, Christopher Wolbrink, and Nicholas Young. Seven of the candidates were new South Dakota State University graduates, and the others were licensed by reciprocity. There were two new full-time South Dakota pharmacy permits issued over the same time period: Avera 7th Avenue Pharmacy – Sioux Falls, SD (change in ownership from VanHove Prescription Shop); and Lewis Family Drug #41, Centerville, SD (change in ownership from Centerville Pharmacy). There was one new part-time pharmacy license: Omnicare of South Dakota, Firesteel Health Care Center (automated mechanical distribution devices), Mitchell, SD.

What Can Be Changed on a Controlled Substance Prescription?

By Jenna Heyen, P4 Regulatory Rotation at the South Dakota State Board of Pharmacy, in consultation with Sarah Boblenz, Group Supervisor for Drug Enforcement Administration Des Moines, IA Office

Understanding what may or may not be changed on a controlled substance (CS) prescription is confusing, but it is one of the many ways to continue to combat drug diversion while helping patients obtain their medications expeditiously. **The rules regarding what can be modified apply to both written prescriptions and electronically prescribed prescriptions.** The following summarizes changes that may be made to a prescription for a Schedule II-V CS without consulting **or** after consulting with the prescribing practitioner, and what changes may never be made. **Important: A pharmacist is expected to use professional judgment and knowledge to determine when it is appropriate to make changes to any prescription, including a prescription for a CS.**

May Be Added or Modified Without Consulting the Practitioner

♦ **Patient's address**
♦ **Practitioner's address**
♦ **Practitioner's telephone number**
♦ **Quantity** may be modified **only** in conjunction with change of **strength.*** The total quantity dispensed cannot exceed the total dosage initially authorized.
　◊ Example: A prescription is written for methylphenidate 5 mg/5 ml with directions 5 mg (5 ml) by mouth twice daily and a quantity of 300 ml to be dispensed. The pharmacy stocks the 10 mg/5 ml concentration. The pharmacy **may** fill the prescription using the 10 mg/5 ml methylphenidate hydrogen chloride and change the dose and quantity to dispense accordingly. In this example, the pharmacist may change the dose to 2.5 ml (twice daily) and the quantity dispensed to 150 ml.
　　● The pharmacist must **document** the new **quantity, strength, date,** and **pharmacist initials** on the *face of the prescription.*
♦ **Practitioner's Drug Enforcement Administration (DEA) number** may be **added.** However, **do not add a DEA number when the legitimacy of the prescription (ie, prescriber or DEA number) is in question.** Only add the DEA number when it can be obtained from a validated source.

May Be Added or Modified After Consulting the Practitioner

♦ **Date of issue** may be added **but not changed.** A pharmacist may **not change** a "do not fill until" date even if the provider is consulted. A pharmacist **may fill** prior to a "do not fill until" date in extenuating circumstances **and** after consulting the provider.
　◊ Example: A prescription bears a "do not fill until 3/29" notation. Today's date is March 26. The patient is leaving for a two-week vacation tomorrow and requests

WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at *http://who.int/mediacentre/news/releases/2017/medication-related-errors/en.*

Continuous Quality Improvement and Patient Safety Organizations

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.*

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda,* which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit *https://www.pso.ahrq.gov/faq.*

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at *www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.org/Resources/Emergency-Preparedness.*

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

Compliance News

NABPF
National Association of Boards
of Pharmacy Foundation

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda .gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/ AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.*

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

♦ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

♦ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/ Drugs/GuidanceComplianceRegulatoryInformation/Guid- ances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatoryInformation/Guidances/ UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immuniza- tion Services.* "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/ immunization-center.*

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, "STEADI: The Pharmacist's Role in Older Adult Fall Prevention," visit the CDC website at *www.cdc.gov/steadi/training.html* for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/ HealthProfessionals/ucm211957.htm.*

FDA Presents Series of CE Webinars for Students and Clinicians

FDA's Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA's website at *www.fda .gov/DDIWebinars.*

that the prescription be filled today. After obtaining approval by the provider, you may fill the prescription.

- The pharmacist must **document** the **date, reason for early fill, "prescriber consulted,"** and **pharmacist initials** on the *face of the prescription*.
- ♦ **Drug quantity and strength,** *unless it falls under the example previously discussed.**
   - ◊ Includes situations where the acetaminophen strength is incorrect or missing in hydrocodone combination products. The prescriber should be contacted to verify strength of acetaminophen.
- ♦ **Directions** for use, *unless it falls under the example previously discussed.**
- ♦ **Dosage form** (capsules and tablets are not interchangeable)
- ♦ **Refill instructions** for Schedule III-V CS
- ♦ Practitioner's **printed** name (**not** practitioner's signature)
- ♦ **Indication** on prescription for buprenorphine-containing products

May Never Be Modified

- ♦ **Patient's name**
- ♦ **Name of CS** *(except where generic substitution is permitted)*
- ♦ **Signature** of the practitioner

SD PDMP Update

*By Melissa DeNoon, RPh, SD PDMP Director*

The passing and signing of Senate Bill 1 mandated that everyone who has a South Dakota Controlled Substance Registration (SD CSR) be registered with the South Dakota Prescription Drug Monitoring Program (SD PDMP). This took effect July 1, 2017. Please ask the prescribers you work with if they are registered. The number of registrations for new PMP AWAR$_X$E accounts continues to grow as prescribers are informed of the mandate. In February 2017, the SD PDMP approved 97 new accounts; in March 2017, 110 new accounts were approved; and in April 2017, the SD PDMP approved 215 new accounts! The South Dakota Department of Health and the Board office will be sending letters to SD CSR holders who will not be in compliance with Senate Bill 1 as of July 1, 2017.

In March 2017 and April 2017, oxycodone/acetaminophen was displaced from the number 10 spot by lisdexamfetamine dimesylate (Vyvanse®).

April 2017 Most Prescribed Drugs	Prescrip-tions	Quantity	Days Supply	Quantity/Prescrip-tions
Hydrocodone BIT/Acetamino-phen	18,208	1,186,550	234,867	65
Tramadol HCl	12,064	922,518	228,478	76
Zolpidem Tartrate	7,338	255,273	254,240	35
Lorazepam	7,226	361,002	177,732	50
Clonazepam	6,777	426,106	219,680	63

April 2017 Most Prescribed Drugs	Prescrip-tions	Quantity	Days Supply	Quantity/Prescrip-tions
Dextroamphet-amine Sulf-Sacc/Amphetamine Sulf-Asp	6,706	374,883	245,469	56
Methylphenidate HCl	5,544	289,455	194,976	52
Alprazolam	5,108	312,366	144,279	61
Oxycodone HCl	4,119	354,572	79,088	86
Lisdexamfet-amine/Dimesyl-ate	3,651	134,807	131,323	37

Online queries performed by prescribers outpaced pharmacist queries each month since December 2016.

Online Profile Queries Run by Pharmacists and Prescribers Over PDMP Life
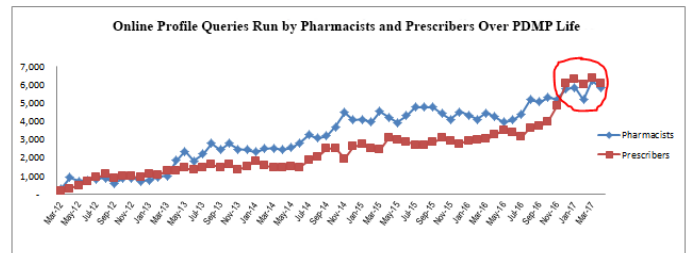
A summary of unsolicited reports/education letters based on the approved SD PDMP Advisory Council determined threshold of **four prescribers** and **four pharmacies** in **30 days** is as follows:

Education Letter Month	Number of Pharmacist Letters	Number of Prescriber Letters	Number of Patients	Total Number of Letters
December 2016	15	25	4	40
January 2017	32	42	9	74
February 2017	7	10	2	17
March 2017	17	17	4	34
April 2017	20	28	6	48

The SD PDMP submitted an application for a 2017 Harold Rogers PDMP Enhancement Grant on April 21, 2017. The grant projects include funds to:

1. integrate Regional Health's electronic health records with the SD PDMP;
2. expand the drug take-back program project from the 2016 Harold Rogers Grant; and
3. integrate PMP AWAR$_X$E with South Dakota licensing boards to automate credentialing.

The awardees will be announced in September 2017.

Relief Work

The Board office keeps lists of individuals who may be interested in relief work or part-time fill-in work, or who are perhaps looking for full-time employment. Please do not hesitate to contact the Board office for this information. If you are on the list and wish to be removed, please contact the Board as well.

Board Meeting Dates

Please check the Board website for the times, locations, and agendas for future Board meetings.

Board of Pharmacy Members

Diane Dady ....Mobridge, SD
Tom Nelson .... Spearfish, SD
Leonard Petrik .... Rapid City, SD
Lisa Rave ....Baltic, SD
Dan Somsen...Yankton, SD

Board of Pharmacy Staff Directory

Office Phone 605/362-2737
Fax..605/362-2738

Kari Shanard-Koenders, RPh,
Executive Director..........kari.shanard-koenders@state.sd.us
Melissa DeNoon, RPh,
SD PDMP Director ....melissa.denoon@state.sd.us
Gary Karel, RPh,
Pharmacy Inspector...........................gary.karel@state.sd.us
Paula Stotz, RPh,
Pharmacy Inspector.........................paula.stotz@state.sd.us

Carol Smith, RPh,
Pharmacy Inspector.........................carol.smith@state.sd.us
Beth Windschitl,
Senior Secretary........................ beth.windschitl@state.sd.us
Melanie Houg,
SD PDMP Assistant .... melanie.houg@state.sd.us
Jessica Neal,
Secretary ....jessica.neal@state.sd.us
Board Website ....*www.pharmacy.sd.gov*
PDMP Sign-up and Data
Access Website....... *https://southdakota.pmpaware.net/login*