"SD Board of Pharmacy and PDMP Update – 2021"

September 17, 2021

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None of the presenters has had a financial relationship over the past 12 months with any commercial sponsor with a vested interest in this presentation.

Presentation Objectives for Pharmacists

This CPE activity will ensure that pharmacists in attendance will be able to:

1. Understand the role of NABP in pharmacy practice and the functions they provide for the protection of public health in South Dakota

2. Describe the recent South Dakota Initiated Measure, Legislation, and Proposed Rules regarding medical cannabis.

3. Explain the difference between a biosimilar and an interchangeable biological product.

4. Describe how PDMPs vary state to state in data submission requirements and program mandates.

Presentation Objectives for Technicians

This CPE activity will ensure that technicians in attendance will be able to:

1. Understand the different license types the South Dakota Board of Pharmacy issues.

2. Understand the role of NABP in pharmacy practice and the functions they provide for the protection of public health in South Dakota

3. Describe recent updates regarding COVID-19 and the PREP Act and how they affect immunizations.

4. Describe the role of pharmacy staff in the public's use of a drug take-back receptacle in a DEA-registered "Collector" location.

What is timely and relevant at the Board of Pharmacy office?

Registrations and Licenses

Marijuana

COVID-19

- PREP Act
- COVID-19 Third Shot

Need to Sustainably Fund PDMP

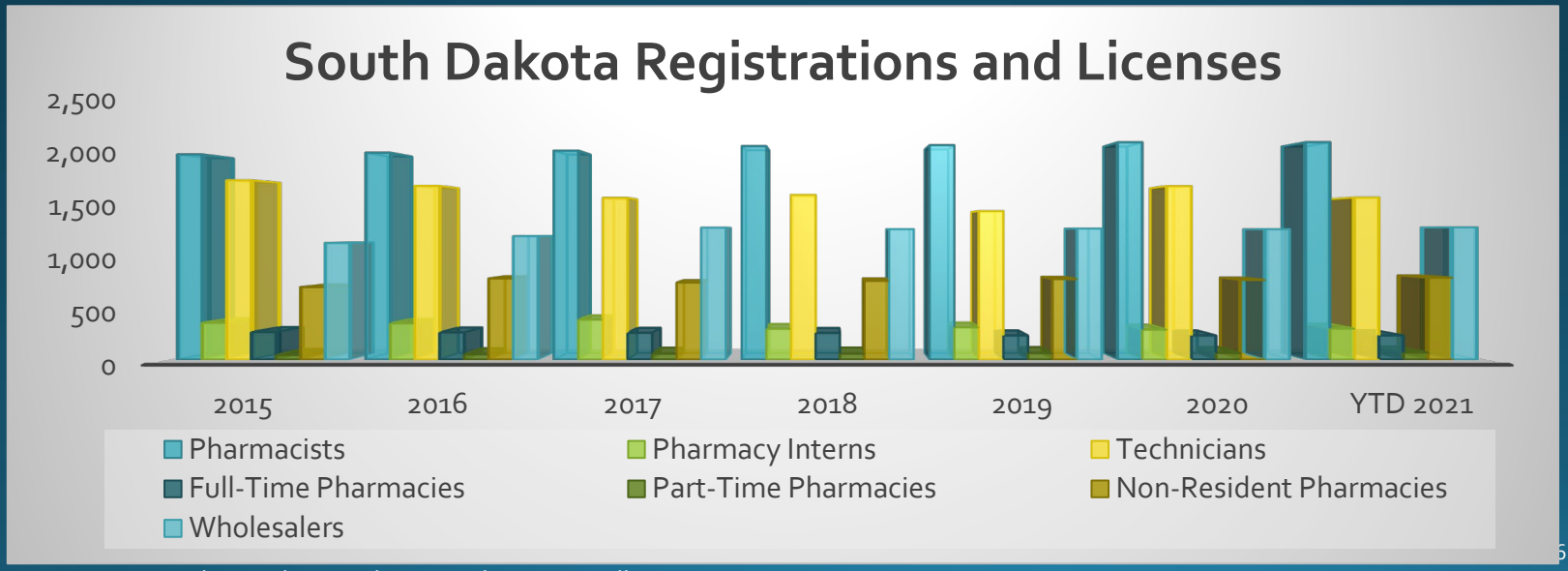
- Proposed Legislation

PDMP Updates

Biosimilars

Registrations and Licenses

South Dakota Registrations and Licenses by Year							
Year	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**YTD 2021**
Pharmacists	1,997	2,014	2,034	2,078	2,087	2,115	2,116
Pharmacy Interns	360	353	390	301	315	293	303
Technicians	1,746	1,691	1,575	1,604	1,446	1,690	1,578
Full-Time Pharmacies	269	265	261	260	235	235	236
Part-Time Pharmacies	45	52	58	59	64	65	70
Non-Resident Pharmacies	706	790	750	767	784	776	798
Wholesalers	1,136	1,202	1,285	1,270	1,276	1,270	1,288
	6,259	6,367	6,353	6,339	6,207	6,444	6,389



*Renewal periods may skew number as not all may renew.

License Renewal = Renewal of Authorization to Administer

20:51:28:07. A pharmacist desiring to renew the authorization shall attest to the following:

(1) The pharmacist is certified in cardiopulmonary resuscitation; and

(2) The pharmacist has completed one hour of continuing education related to immunizations.

This hour is one of the twelve total hours needed to renew.

The board does audit for compliance with the CE requirements for renewal of pharmacy licenses.

Public Readiness and Emergency Preparedness (PREP) Act

- The PREP Act and its Nine Amendments provide liability protections for COVID-19 countermeasures provided by covered individuals:
  1. Pharmacists and Interns may test for COVID-19
  2. Pharmacists may order COVID-19 Tests
  3. Technicians may test for COVID-19
  4. Pharmacists may order and pharmacists and interns may vaccinate for COVID-19
  5. Technicians may vaccinate for COVID-19 with training and supervision by IMZ trained pharmacist
  6. Medical Professions with expired licenses (<5 yrs) may vaccinate and pharmacists not previously IMZ trained may vaccinate with CDC training
  7. Pharmacists with expired licenses (<5 yrs) and CDC training may vaccinate and Military and Contracted individuals may vaccinate
  8. Pharmacy Technicians may administer Influenza Vaccine
  9. Pharmacists may order and Pharmacists, Technicians, and Interns may administer monoclonal antibody treatments for COVID-19

COVID-19 Vaccinations

- One Shot Two Shot Three Shot ….
- Three vaccines were approved by EUA for COVID-19 in late 2020/ early 2021
  - Pfizer-BioNTech, Moderna, Janssen
- Guidance is ever-changing – now COVID-19 vaccines may be administered with other vaccines
- On August 18, 2021, the CDC recommended a third dose of the Pfizer and Moderna Vaccines for those "moderately" or "severely" immunocompromised starting in September
  - 8 months after 2nd dose

NABP District Five

- Iowa
- Manitoba
- Minnesota
- Nebraska
- North Dakota
- Saskatchewan
- South Dakota

National Association of Boards of Pharmacy

2021 Membership Benefit Statement – Overview

Competency Assessment Programs		
	North American Pharmacist Licensure Examination (NAPLEX) Multistate Pharmacy Jurisprudence Examination (MPJE) Foreign Pharmacy Graduate Examination Committee (FPGEC) and Foreign Pharmacy Graduate Equivalency Examination (FPGEE)	$294,000
Inspection and Compliance Services		
	Inspection Services and Inspector Training Compounding Inspection Training Consulting Regarding Inspection and Facility Issues	$3,995
Licensure Programs		
	NABP Clearinghouse National Practitioner Data Bank (NPDB) Reporting	$4,400
Professional Services		
	Professional Affairs Research Member Relations and Government Affairs	$3,300
Meetings		
	Annual Meeting Travel Grant Interactive Executive Officer Forum Interactive Member Forum/Interactive Compliance Officer and Legal Counsel Forum Program Review and Training Task Force Meetings & Reports	$10,500
Consumer Protection Initiatives		
	PMP InterConnect .Pharmacy Verified Websites Program Rogue Rx Activity Reports AWAR$_x$E Prescription Drug Safety Program	$7,500
Publications		
	Innovations *Model Act* *Board of Pharmacy Member Manual* State Newsletter Program *Survey of Pharmacy Law* Electronic Newsletters	$4,395

Total 2021 Member Benefits $328,090

NABP

District and Annual Meetings

- 2022- Custer State Park NABP/AACP District 5 Meeting
  - South Dakota Hosting
- 2022- NABP Annual Meeting Phoenix, AS

Recent CBD News

- That ship sailed …
- Certificate of Analysis

Medical Marijuana

- IM 26 passed on November 3, 2020 ballot
  - This became Medical Cannabis Law SDCL 34-20G-31
  - DOH to stand-up program and have cards issued by November 18, 2021
  - DOH Hearing 8/18/21 to promulgate rules for Medical Cannabis DOH Medicalcannabis Proposed Rules
  - Per 34-20G-33 – may issue cards to patient under 18 with conditions
    - DOE passed rules for Schools - ARSD Chapter 24:80
  - Cities and Counties may limit how many but cannot prohibit dispensaries
  - No DEA registered facility may have Medical Cannabis within its doors per the DEA
  - A Physician does not prescribe medical cannabis, they issue a verification of a qualified diagnosis for the patient to apply for a card from the DOH
  - Physician also states in the verification documentation that the patient may grow marijuana at home if they agree

Recreational Marijuana

- Amendment A – Recreational Marijuana
  - Also passed on November 3, 2020 ballot
  - Circuit Judge struck it down finding it unconstitutional
  - Appealed to Supreme Court – no ruling to date

Interchangeable Biosimilar

- Biological products are used as a treatment option for diseases and medical conditions
- Biological products typically have more complex structures than those of drugs
  - Examples of biological products include vaccines, monoclonal antibodies, and proteins
- A Biosimilar is a product that is highly similar to a reference product with no clinically meaningful differences
  - A reference product is a biological product that has been approved by the FDA which the biosimilar is compared to

Interchangeable Biosimilar (cont.)

- An Interchangeable product is one that has been approved as a biosimilar that also meets additional requirements, including:
  - Producing the same result as the reference product in any patient
  - There is no additional risk of switching between the reference product and the biosimilar product

- Interchangeable products can be substituted at the pharmacy level without requiring a new prescription
  - However, interchangeable products are not the same as generic drugs
    - Generics contain the same active ingredients as brand name medications, biosimilars are highly similar with no clinically meaningful differences

South Dakota Codified Law

- **36-11-46.3. Notification to person receiving equivalent drug product or interchangeable biological product--Right of refusal.**
  - The pharmacist or the pharmacist's agent shall inform the person receiving the drug or biological product pursuant to the prescription drug order of the selection of an equivalent drug product or interchangeable biological product and of the person's right to refuse the product selected. A pharmacist shall, upon request of the prescribing practitioner, provide information regarding substitutions of equivalent drug products.
- **36-11-46.5. Liability for dispensing equivalent drug product or interchangeable biological product.**
  - A pharmacist who selects an equivalent drug product or interchangeable biological product pursuant to this chapter assumes no greater liability for selecting the dispensed drug or biological product than would be incurred in filling a prescription for a drug or biological product prescribed by its established, generic, or proper name.
- **36-11-46.8. Cause of action for selection of equivalent drug product or interchangeable biological product.**
  - The selection of an equivalent drug product or interchangeable biological product does not, in itself, in the absence of willful misconduct or negligence, constitute a cause of action against the practitioner

South Dakota Codified Law (cont.)

- **36-11-46.9. Dispensing interchangeable biological products.**
  - A pharmacist dispensing a prescription drug order for a biological product prescribed by its brand or proper name may select an interchangeable biological product of the prescribed product. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:
    - (1) An interoperable electronic medical records system;
    - (2) An electronic prescribing technology;
    - (3) A pharmacist benefit management system; or
    - (4) A pharmacy record.
- **36-11-46.10. Notice to practitioner of biological product dispensed.**
  - Any entry into an electronic records system as described in § 36-11-46.9 is presumed to provide notice to the practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the practitioner using facsimile, telephone, electronic transmission, or other prevailing means, if communication is not required where:
  - (1) There is no interchangeable biological product approved by the U.S. Food and Drug Administration for the product prescribed; or
  - (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

South Dakota Codified Law (cont.)

- **36-11-46.11. Labeling of prescription container for biological product.**
  - The pharmacist shall, unless otherwise instructed by the prescriber, label the prescription container with the name of the dispensed biological product. If the dispensed biological product does not have a brand name, the prescription label shall indicate the proper name of the biological product dispensed. If a pharmacist selects an interchangeable biological product for the brand name biological product prescribed, the prescription container label shall identify the proper name and may identify the brand name for which the selection is made. The dual identification allowed under this section shall take the form of the following statement on the prescription container label: (proper name) interchangeable with (brand name). The pharmacy file copy of each prescription shall include the brand name, if any, or the proper name, and the name of the manufacturer of the biological product dispensed. The prescription container label shall include all information required by federal and state law or by rule promulgated by the board pursuant to chapter 1-26.

Insulin Interchangeable Biosimilar

- Semglee (insulin glargine) is the first product to be approved as an interchangeable product, and is interchangeable with the reference product, Lantus
- The reference material for finding interchangeable products is the Purple Book

- https://purplebooksearch.fda.gov/

Findings on Inspections

- DEA biennial inventory requirements
- Take back site requirements
- Outdates
- Updated licenses posted

USP <795> Nonsterile Compounding

USP released a new proposed revision on Sept 1, 2021.

Public comment period is open until January 31, 2022.

There are several open forum discussions.

www.usp.org/compounding

USP <795> highlights

Some key points in the new version

- Documented training by all compounding staff, both initial and annual training by staff.
- Storage areas must have documented temperature readings
- Manipulation of components must be assessed to determine if the manipulation needs to be done in a closed environment.
- Beyond Use Date (BUD), assignment done by water activity (a_w)

- Area of note for retail pharmacy- Flavoring of oral suspensions is not excluded currently under this chapter.

*This is only a simple summary, not inclusive of the requirement changes for pharmacy.

USP <797> Sterile Compounding

USP released a new proposed revision on Sept 1, 2021.

Public comment period is open until January 31, 2022.

There are several open forum discussions.

www.usp.org/compounding

USP <797> highlights

Some key points in the new version

- Change of categories to simplify the chapter
- Immediate use changed from 1 hour to 4 hours
- 6 month Gloved Fingertip Test and media fill test
  - Sterile to Sterile every 6 months
  - Non-Sterile to Sterile every 3 months
- Viable air sampling
  - Sterile to Sterile every 6 months
  - Non-Sterile to Sterile every month
- Surface Sampling must be done
- Beyond Use Dates (BUD)
- Separate section on compounding Allergenic Extracts

*This is only a simple summary, not inclusive of the requirement changes for pharmacy.

USP <800> Hazardous Drugs

Timeline

- Official Date of Enforcement: undetermined, Iowa and other states have required.

USP <800> Hazardous Drugs

- If compounding with NIOSH Table 1 medications or any API on NIOSH list, the chapter will have to be followed.
- Assessment of risk
- Training to know what drugs are hazardous and pose a risk on employees
- NIOSH Hazardous Drug List

NIOSH Changes

- NIOSH proposed a new 2020 list which now contained 2 tables of drugs instead of 3.
- All antineoplastic or API will follow USP 800 and any other regardless of what table it is on can have an AOR, Assessment of Risk.
- Removed BCG and other drugs
- We are currently still using the NIOSH 2016 list.

SD PDMP Update

What's New at the PDMP?

Interstate Data Sharing

As of Q2 2021, SD PDMP users can query 36 other PDMPs

This includes all our neighboring states: ND, MN, IA, NE, WY, and MT

License Integration Project

- New account auto-approval and daily auto reverification of current accounts are now live for licensees of these SD professional licensing boards:
  - SD Board of Nursing
  - SD Board of Dentistry
  - SD Board of Podiatry Examiners
  - SD Board of Examiners in Optometry
  - SD Board of Pharmacy

PMP AWARxE User Account FYIs

- Addition of a mobile phone number to a user account provides a text message option to the 'Reset Password' function on the program's log in page
- Navigate to Menu/User Profile/My Profile to update employer info and the account's user email address
- Consolidation of patient groups can be completed by PDMP staff
- Pharmacists are the only pharmacy staff allowed PDMP accounts in SD

PDMP Grant Funded Projects & Enhancements

- PDMP BJA COAP Grant
  - NarxCare Enhanced PDMP Report
  - Statewide Gateway Integration
- SD DOH CDC Overdose Data to Action Grant
  - Clinical Alerts
  - Prescriber Reports
  - Advanced Analytics
- SD DSS/DBH SAMHSA SOR Grant
  - MedDrop Drug Take-Back Program

Pending Grant Submission

- BJA FY21 Harold Rogers PDMP Grant
  - Grant Period is 10/1/2021 through 9/30/2024
  - Proposed Grant Projects:
    - Continued funding of the NarxCare platform enhancement
    - Continues funding of statewide Gateway integrations

PDMPs – Same *but* Different

- 20 states house the PDMP in their State Board of Pharmacy
- Most collect CII, CIII, CIV, and CV; 30 also collect 'drugs of concern' including unscheduled gabapentin; NE collects all prescription drugs
- Naloxone – states have begun tracking prescribing, dispensing, and/or administration; 21 PDMPs report dispensings and 19 report administrations
- Medical Marijuana – 11 states have enacted laws ranging from including patient registry id card info to requiring dispensaries to report the dispensing of medical marijuana
- Prescriber mandates – 44 PDMPs mandate enrollment and 48 mandate use
- LE Access – 28 PDMPs require a court order, search warrant, or subpoena and 29 require an active investigation, probable cause, or proper need

MedDrop Drug Take-Back Program

- Began as a 2016 PDMP grant project
- Locations available on the website, www.avoidopioidsd.com
- To participate, a pharmacy must update their DEA license to "Collector" status
- Program reminder: DEA-authorized collectors can *only allow* the **ultimate user** to deposit their medications into the collection receptacle at a registered location

MedDrop Stats

Receptacles in SD Retail Pharmacies and Hospitals

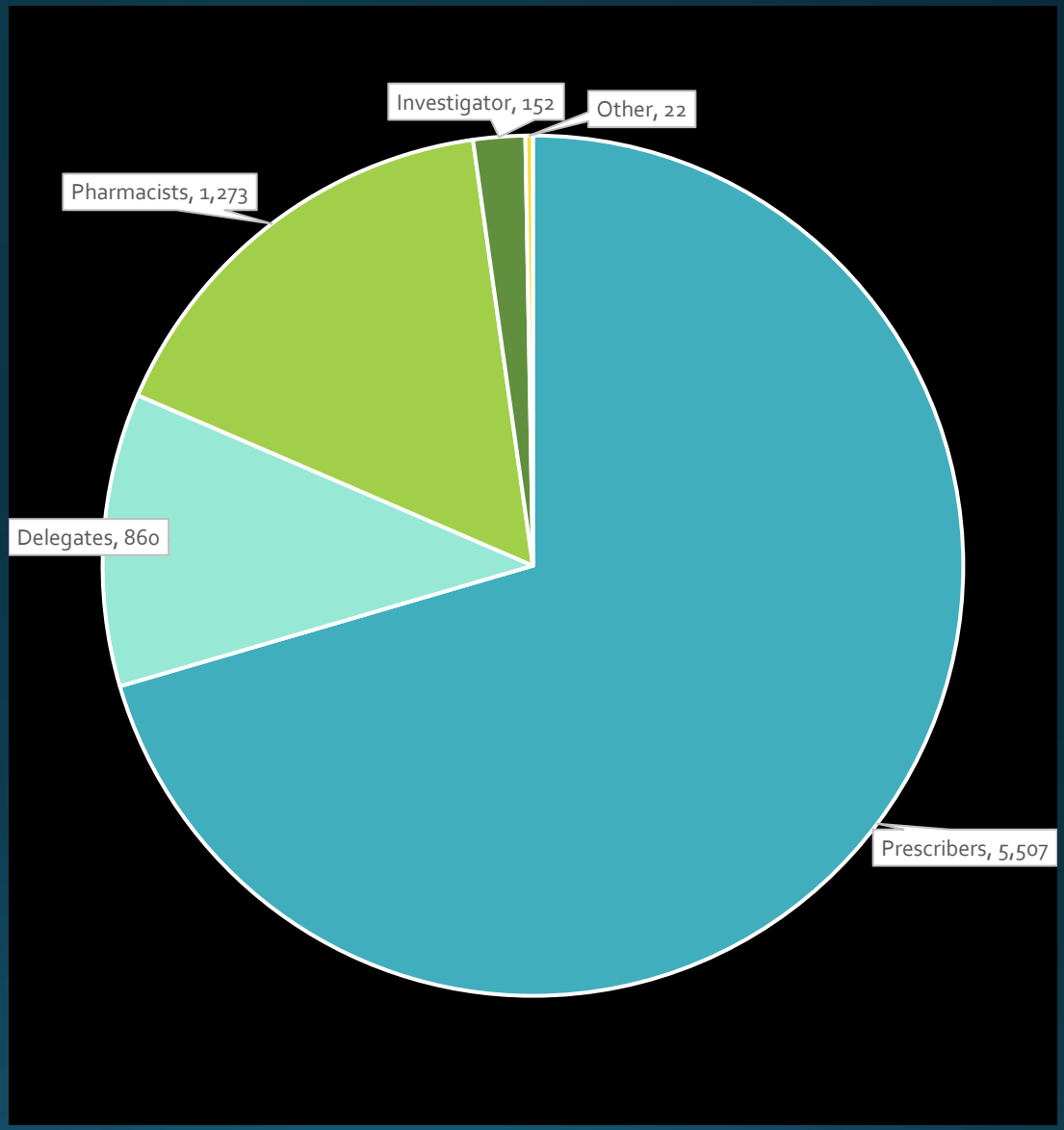
- 2017 – 2 in place
- 2018 – 12 in place
- 2019 – 38 in place
- 2020 – 83 in place (added 6 HyVee locations to "Automatic Reload")
- 2021 – 84 in place – Davis Pharmacy in Vermillion

Pounds Returned for Destruction

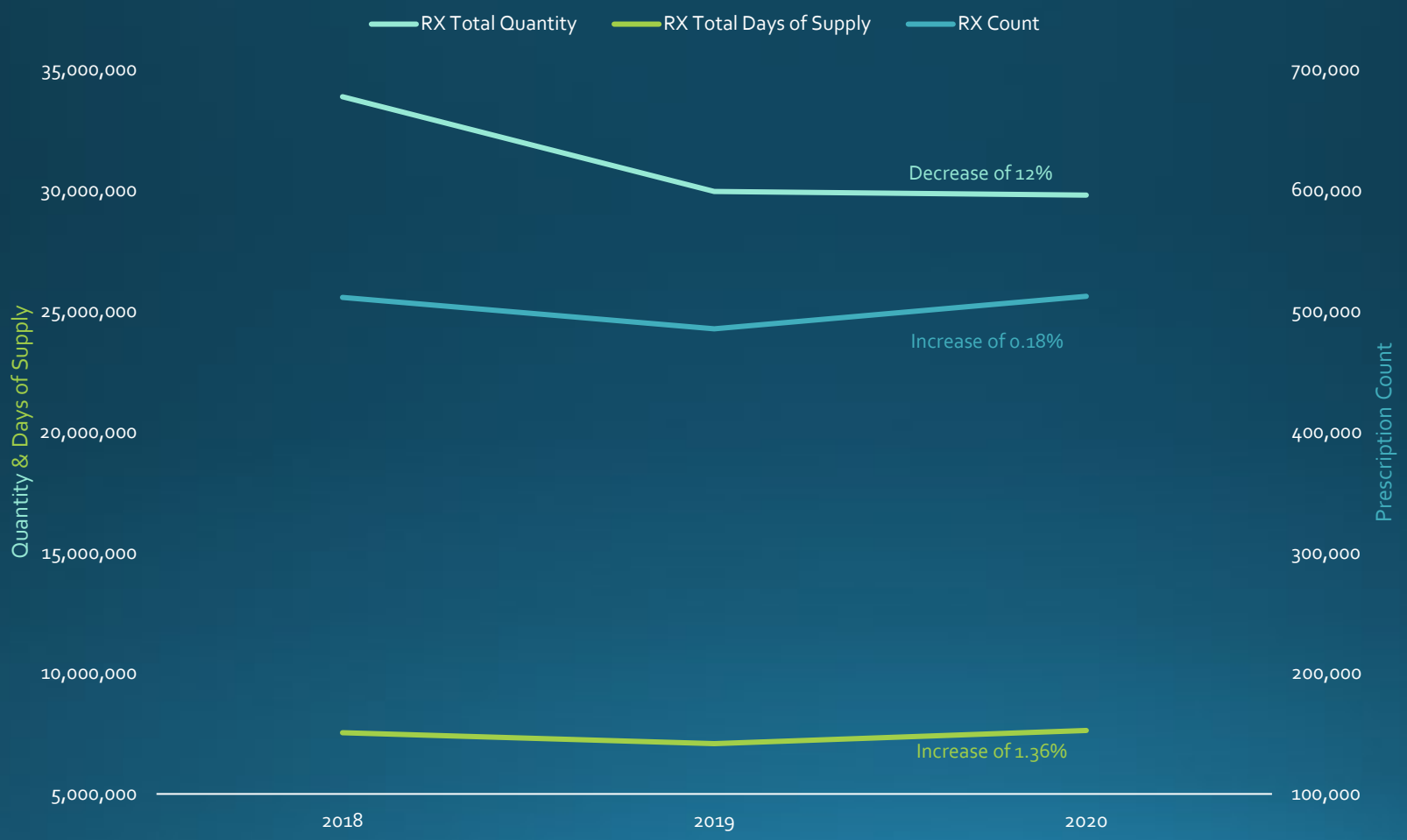
- 2017 – 35 lbs.
- 2018 – 1,496 lbs.
- 2019 – 4,287 lbs.
- 2020 – 7,302 lbs.
- Total Inception to July 2021 – 18,925 lbs.

PDMP by the Numbers

PMP AWARxE Users

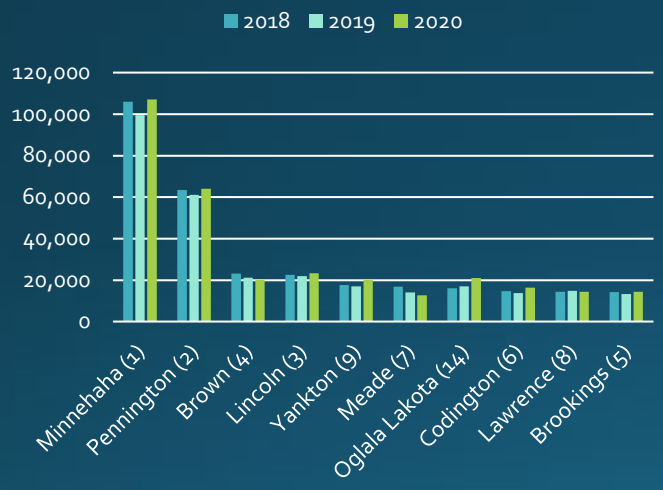


Opioid Prescriptions – SD Patients

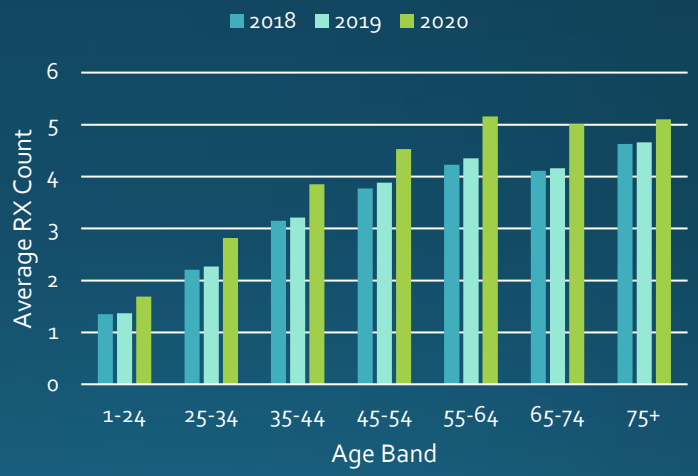


Opioid Prescriptions – SD Patients

Top Patient Counties by Opioid RX Count

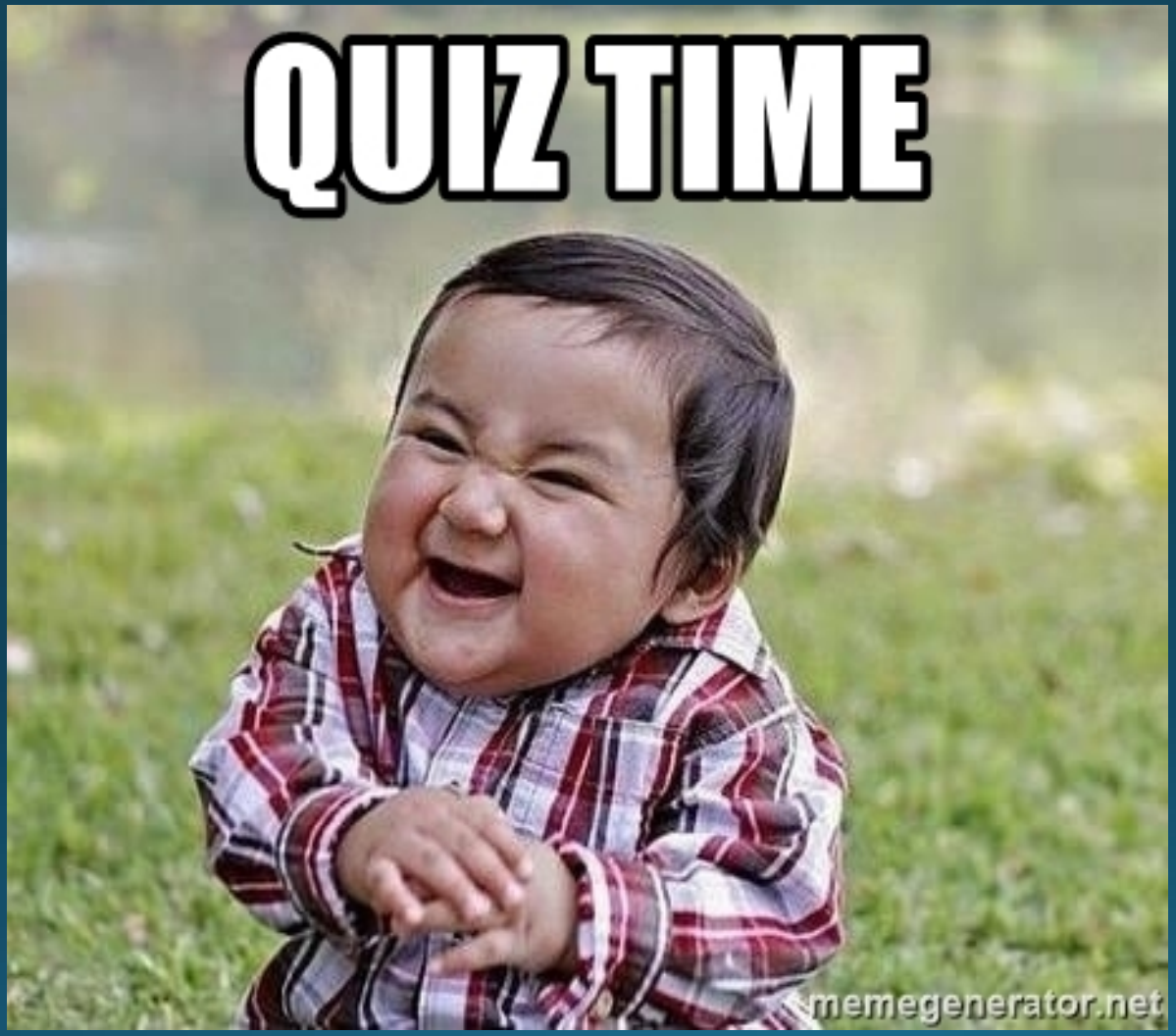


Average Opioid RX Count per Patient by Age Band



Top Ten Controlled Substances to SD Patients

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


QUIZ TIME
memegenerator.net

Post-test Pharmacists

1. NABP assists the Board with protecting the health and safety of the patients in South Dakota.

   True or False

2. It is required under IM 26 that a physician issues a prescription for medicinal marijuana.

   True or False

3. According to South Dakota codified law, a pharmacy must notify the prescriber within how long of substituting an interchangeable biological product?

   A. 48 hours
   B. 5 days
   C. 14 days
   D. No requirement

4. SD has mandated for prescribers both PDMP enrollment and PDMP use.

   True or False

Post-test Technicians

1. Technicians are the category with the largest number of licenses/registrations in 2021 to date.

True or False

2. One of the roles of NABP is to provide technicians with certification.

True or False

3. Which PREP Act amendment allows for technicians to administer influenza vaccinations?

A. First

B. Third

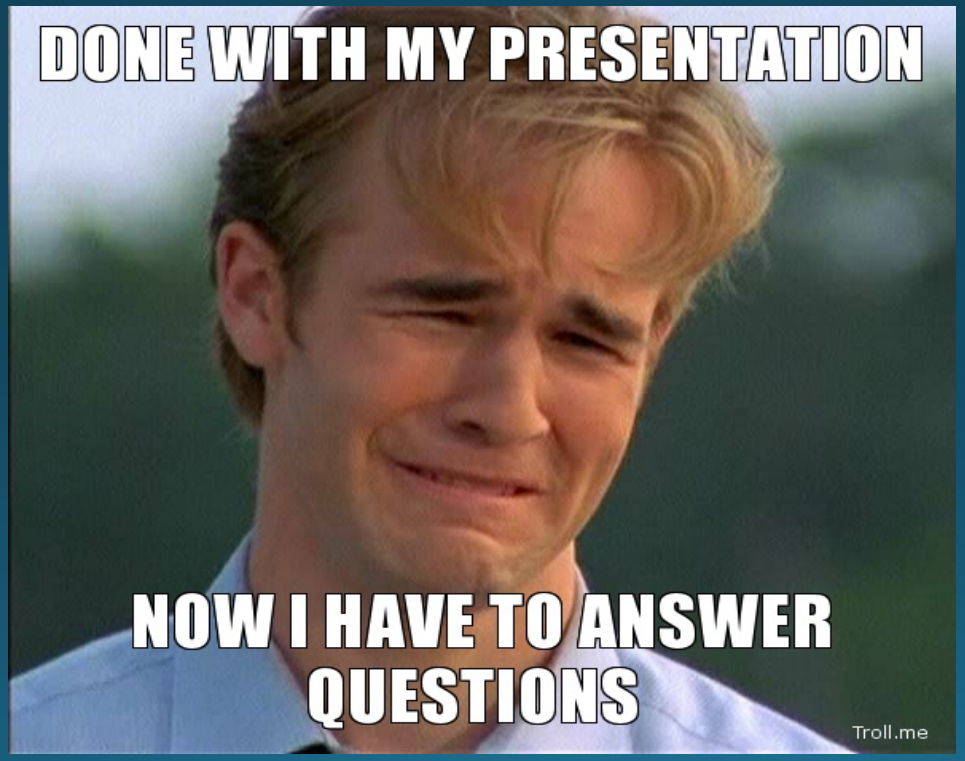
C. Fifth

D. Eighth

4. It is allowable for a patient to give his/her unwanted medications to a technician working in the pharmacy to place in the drug take-back receptacle.

True or False

QUESTIONS?


DONE WITH MY PRESENTATION
NOW I HAVE TO ANSWER QUESTIONS
Troll.me

South Dakota Board of Pharmacy

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Thank You
Yes!
Finally Over!