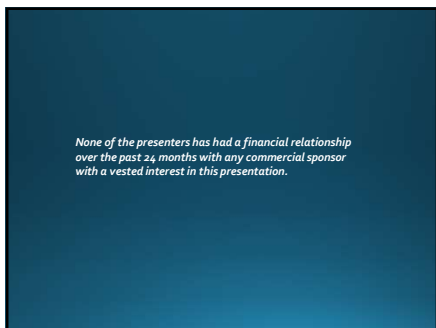
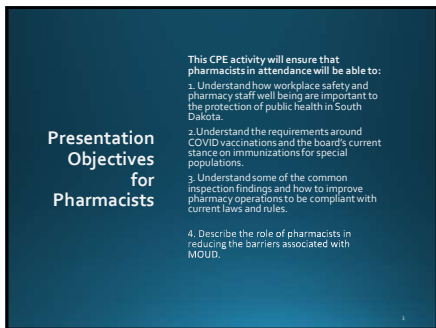




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3

Presentation Objectives for Technicians

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

1. Understand how workplace safety and pharmacy staff well being are important to the protection of public health in South Dakota.
2. Understand the requirements for technicians to administer immunizations in South Dakota under the PREP Act.
3. Describe the medications that are allowed to be accepted into the state repository program.
4. Understand MQUD and the pharmacy's role in substance use disorder treatment.

4

Top 7 Initiatives FY 2023



5

Registrations and Licenses


Year	2015	2016	2017	2018	2019	2020	2021	YTD 2022
Pharmacists	1,997	2,014	2,034	2,078	2,087	2,115	2,116	2,141
Pharmacy Interns	360	353	390	381	315	293	303	273
Technicians	1,746	1,691	1,578	1,624	1,446	1,630	1,578	1,519
Full-Time Pharmacies	269	265	261	260	235	235	236	235
Part-Time Pharmacies	45	52	58	59	64	65	70	82
Non-Resident Pharmacies	706	790	750	767	784	776	798	813
Wholesalers	1,136	1,202	1,285	1,270	1,276	1,270	1,288	1,312
	6,209	6,307	6,050	6,009	5,480	6,444	6,380	6,315

South Dakota Registrations and Licenses



*Renewed records may show number as not all may renew.

6



NABP District Five

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

7

Workplace Conditions and Pharmacy Personnel Burnout

- Do we have issues?
- Has the pandemic helped to make pharmacists the ones that America counted on to save the country from this virus? Do we still have this standing?
- What else has it done to pharmacy?
- The entire country is faced with this.
- As volume increases but the rate limiting step stays the same, there is increased pressure and chance of harm. Think of it like a water hose or balloon.⁽¹⁾
- There is only so much work a pharmacist can do. Demanding more than that amount means something will be overlooked, ignored, or done wrong, which puts patients at risk. Overall, it appears to be a reckless practice.⁽²⁾

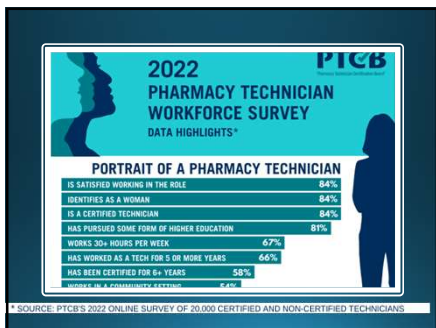
1 & 2: John Clark-Welby, Arkansas BOP Executive Director, NABP Presentation 2020

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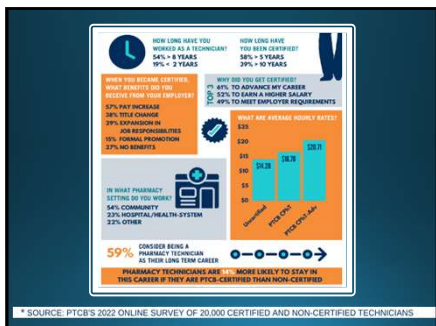
Workplace Conditions and Pharmacy Personnel Burnout

- How Much Is Too Much?
- Metrics – fact or fiction?
- Retaliation – real or fear?
- Employee ratios?
- Legal ability vs training and education – should we let support staff do everything they can to assist.
- Must ensure the pharmacist has the time to do required tasks/duties.
- Pharmacist should not have to do technician tasks – data entry, filling, and checking the same prescription leads to errors.

9



10



11

COVID and the Public Readiness and Emergency Preparedness (PREP) Act

What should we retain?

- The PREP Act and its Nine Amendments provide liability protections for COVID-19 countermeasures provided by covered individuals and then granted permissions
 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 and all Children's vaccinations
 5. Technicians may vaccinate for COVID-19 with training and supervision by IMZ trained pharmacist
 6. Pharmacy Technicians may administer Influenza Vaccine and children's vaccines to age 3
 7. Pharmacists may order and Pharmacists, Technicians, and Interns may administer monoclonal antibody treatments for COVID-19
- On June 17, 2022, the U.S. Food and Drug Administration (FDA) Authorized emergency use of Moderna and Pfizer-BioNTech COVID-19 Vaccines for children as young as 6 months of age
- On July 6, 2022, the FDA Authorized Pharmacists to Prescribe Paxlovid with Certain Limitations

12

South Dakota Codified Law SDCL 34-20H

- Legislature passed (unanimously) HB 1086 which allows for the redistribution of donated prescription drugs
- This is now SDCL CHAPTER 34-20H REDISTRIBUTION OF DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES
- The rules will be in ARSD 20-51: 35 and have been drafted— hearing TBD
 - On website
 - Please comment
- This allows unused, sealed, unopened prescription drugs to be returned to a participating pharmacy for re-dispensing with certain qualifications

13

Findings on Inspections

- DEA biennial inventory requirements
- Outdated Medications
- Take back site requirements
- Updated licenses posted, combat meth
- Controlled substance logbook or print out
- PDMP submissions
- CSOS
- Fridge monitoring
- Compounding documents missing/incomplete

14

DEA Requirements

- 21 CFR 1304.11 Inventory Requirements-
 - At the registered location, not centrally located
 - All drugs "on site" at time of inventory, this includes all meds ready for pick up. We recommend to keep these separate in inventory to determine if included in perpetual inventory from time inventory was taken.
 - All inventory that is in e-kits, if provided from your pharmacy
 - Time inventory is taken, open of business or close of business
 - All inventory completed at same time
 - Signed by person(s) completing inventory

15

DEA-CSOS requirements

- 21 CFR 1305.22 (g)- "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
- 21 CFR 1305.27(a)- Records kept onsite, or accessible onsite, for a period of 2 years.
- 21 CFR 1306.22 (3)- Each pharmacist working each day must sign a daily printout or logbook stating that all refills for CIII, CIV, and CV substances has been reviewed and is accurate.

16

Licenses and signs to be posted

- State pharmacy license
- DEA license
- State CSR
- Regular pharmacists that work
- Combat Meth certificate
- 5 signs required by law/rule and PDMP sign
- Optional
 - Tech registrations
 - CPR cards, must be on site and available for review during inspection
 - Intern registrations

17

Takeback site location requirements 21 CFR 1317 Subpart B

- DEA license updated
- Outer box is secured to permanent fixture (wall or floor)
- Inventory sheet maintained for all liners
 - Date received
 - Date put into receptacle
 - Date removed and sealed
 - Date sent for destruction
 - Certificate of destruction
- Collector receptacle should be monitored by staff at all times
- "Ultimate User" must be the one to put items into receptacle

18

PDMP Submissions

- Starting in 2022, during inspection data has been collected to assure proper PDMP submission. During the audit we have found the following:
 - CV not being submitted
 - Reversals not processed
 - Incorrect DEA number/Provider
- These corrections will be addressed after inspection by our PDMP staff and they will work with the pharmacist in charge to correct the data.

19

Pharmacy issues

- Refrigerator temps not being recorded, or not addressed if out of range
- Room temps-AC not working in summer, pharmacy was reported to board office > 82 degrees, meds were quarantined and sent for destruction
- Outdates- most common in compounding areas. Most common item found outdated is flavorings for oral meds.
- Compounding records for every compound missing information or missing all together.
- Excess clutter/inventory in pharmacy making difficult to work.

20

USP <795> & <797> Compounding

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

Public comment period is open until March 31, 2022.

No further information to date on next step, release of draft, or publish date.

There are several open forum discussions.

www.usp.org/compounding

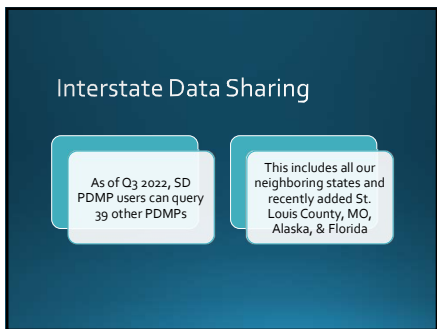
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23



24

Current Program Focus

- Data Submission Compliance
- Data Integrity
- Inspection Audit Project

25

Data Submission Compliance

- SDCL 34-20E-3. *Each dispenser shall submit the information required by this chapter to the central repository at least every twenty-four hours unless the board waives this requirement for good cause shown by the dispenser.*
- ARSD 20:54:32.02 furthers the twenty-four-hour requirement adding *or by midnight of the next business day after dispensing.*
- PICs at pharmacies out of compliance will be contacted by PDMP staff with information on how to come into compliance

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Data Integrity

- Ensuring accuracy of PDMP data is critically important since this tool aids in clinical decision-making impacting patient care
- Database errors fall into two categories:
 - Dispensation records in the database
 - Dispensation records not in the database
- Database error correction is required by law

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Errors in the Database

- Records with the required data elements for submission per SD law and rule but contain errors that occurred during rx data entry that were not identified and corrected prior to dispensing; i.e., wrong prescriber/wrong DEA or incorrect rx written date
- PDMP staff are made aware by users upon review of a patient report and will work with PICs on corrective action
- Submission of the corrected information into SD's PMP Clearinghouse is always required; PICs may need to work with their pharmacy software vendor to ensure success of this resubmission

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Errors Not in the Database

- Records missing one or more of the required data elements for submission per SD law and rule resulting in the absence of rx information on patient reports
- Required data elements can be found in ARSD 20:51:32:03
- PICs are responsible for accurate and complete data submissions
- PMP Clearinghouse generates data submission error reports upon file submission
- Error reports must be reviewed, corrective action taken, ending with file resubmission

29

APhA
Institute on
Substance
Use
Disorders

- Preferred acronym is *MOUD* vs *MAT* and is defined as using FDA-approved medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach in treating OUD.

30

APhA Institute on SUDs

- What are the major pharmacy-related barriers surrounding MOUD access?
 - Stigma
 - Legislation/Politics
 - Availability
 - Education/Misinformation
 - Cost/Prior Auth requirement
 - Fear of DEA/DOJ by prescribers and pharmacists
 - 20% of pharmacies in the US don't stock buprenorphine

31

APhA Institute on SUDs

- What can pharmacists do to decrease barriers to MOUD?
 - Advocate for pharmacist-led prescribing and managing of buprenorphine
 - Utilize telehealth to reach at-risk patients
 - Availability of a drug take-back receptacle in your pharmacy
 - Utilize the PDMP – "Concern should lead to a discussion NOT a decision."
 - Seek additional training on SUDs
- Goal is to establish the pharmacy as a safe place for patients with SUD

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APhA Institute on SUDs

Naloxone Communication

What	How	Remember
Precis medicines	Stigma persists	•Be empathetic and unbiased
Substance use disorder (SUD) opioid use disorder	"Abuse/abuser" "opioid abuse disorder" "drug addict"	•Express positive body language and appropriate eye contact
Patient with an opioid use disorder (person-first language)	"Addict," "junkie," "someone like you"	•Ask the patient you are speaking out of concern for their safety
Patient in long-term recovery	A person who is "clean"	•Ask open-ended questions
Opioid syringes, used	"Cleaner" "dirty" needles	•Acknowledge the potential stigma and impact of biases about opioid use disorder on patient care
Medication-assisted treatment (MAT) or substance use disorder (SUD) medication therapy	Opioid substitution therapy (OST), opioid replacement therapy	•Use active listening techniques with clear, nonjudgmental words
Bad reaction, breathing emergency, accidental overdose	Overdose, OD	•Make permission before giving unsolicited advice
		•Use a respectful professional approach as with any patient consultation

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APhA Institute on SUDs

- Utilize SD's standing order to increase your pharmacy's dispensing of naloxone which may ultimately assist pharmacists in obtaining provider status
- Language matters
 - Instead of, "You may overdose from this medication."
 - Say, "This medication may cause a bad reaction and you may stop breathing. There's a medication to reverse that called naloxone."

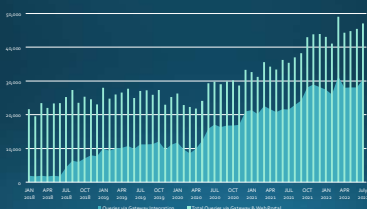
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PDMP by the Numbers



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Trending PDMP Utilization by SD Drs & RPhs



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Dispensations to SD Patients

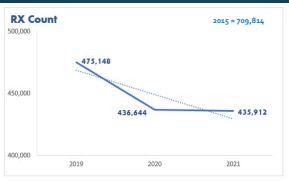


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Year 2021 Top Ten Controlled Substances (C/S) to SD Patients		Rx	Quantity	Days of Supply	Days Capacity	2020 Same 2021 Ratio
HYDROCODONE BITARTANOL/ACETAMINOPHEN		147,891	7,886,284	1,431,024	14	2
TRAMADOL C/S		113,493	1,741,131	1,460,354	11	3
PERCUTANEA TABLET 3.6/320 (CARBAMAZEPINE/AMPHETAMINE 3.6/320) ASPIRIN/ATV		86,880	1,307,425	739,044	43	4
LORAZEPAM		57,529	1,237,473	293,337	11	5
OXYBUTAMINE TABLET		51,338	1,440,488	2,435,337	23	4
METOPROLOLOL C/S		49,889	1,702,043	1,271,070	43	7
ALPRIMOL C/S		33,874	1,202,000	738,000	13	8
HYDROCODONE C/S		32,292	1,174,081	1,286,381	33	10
PERCUTANEA TABLET		22,292	1,174,081	1,286,381	33	10
Year 2020 Top Ten Controlled Substances (C/S) to SD Patients		Rx	Quantity	Days of Supply	Days Capacity	2020 Same 2021 Ratio
HYDROCODONE BITARTANOL/ACETAMINOPHEN		149,342	4,135,336	1,485,432	45	
TRAMADOL C/S		140,887	1,646,381	1,017,017	41	
PERCUTANEA TABLET 3.6/320 (CARBAMAZEPINE/AMPHETAMINE 3.6/320) ASPIRIN/ATV		84,287	1,405,343	1,101,047	41	
LORAZEPAM		55,590	1,237,473	1,282,047	43	
OXYBUTAMINE		51,348	1,440,488	1,101,047	41	
OXYBUTAMINE TABLET		51,487	1,440,488	1,101,047	41	
METOPROLOLOL C/S		50,021	1,702,043	1,101,047	41	
ALPRIMOL C/S		33,874	1,202,000	1,101,047	41	
HYDROCODONE C/S		46,276	1,174,081	1,101,047	41	
PERCUTANEA TABLET		46,276	1,174,081	1,101,047	41	
Year 2019 Top Ten Controlled Substances (C/S) to SD Patients		Rx	Quantity	Days of Supply	Days Capacity	2020 Same 2021 Ratio
HYDROCODONE BITARTANOL/ACETAMINOPHEN		148,261	1,618,331	1,245,000	41	
TRAMADOL C/S		135,127	1,646,381	1,101,047	41	
LORAZEPAM		50,118	1,101,047	1,101,047	41	
PERCUTANEA TABLET 3.6/320 (CARBAMAZEPINE/AMPHETAMINE 3.6/320) ASPIRIN/ATV		79,880	1,307,425	1,101,047	41	
LORAZEPAM		50,118	1,101,047	1,101,047	41	
OXYBUTAMINE		50,118	1,101,047	1,101,047	41	
METOPROLOLOL C/S		50,118	1,101,047	1,101,047	41	
ALPRIMOL C/S		50,118	1,101,047	1,101,047	41	
HYDROCODONE C/S		50,118	1,101,047	1,101,047	41	
PERCUTANEA TABLET		50,118	1,101,047	1,101,047	41	

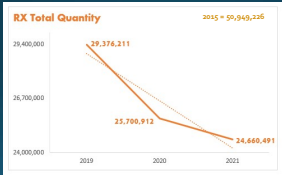
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Trending SD Patients' Opioid Prescriptions



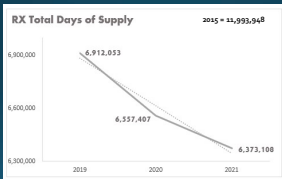
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Trending SD Patients' Opioid Prescriptions



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Trending SD Patients' Opioid Prescriptions

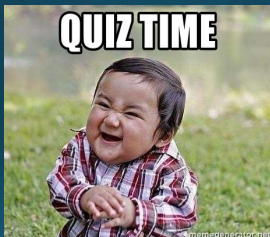


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PharmaDrop Drug Take-Back Program



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Post-test Pharmacists

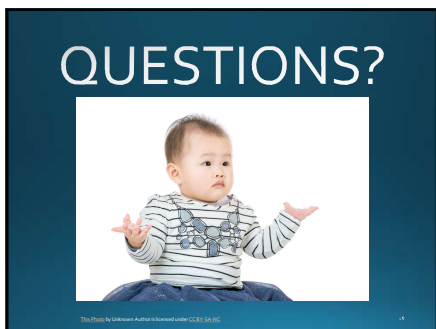
1. Pharmacists have a responsibility to make decisions and seek resolutions regarding workplace concerns without fear of intimidation or retaliation from their employer or supervisors. True or False?
2. The Pfizer COVID-19 vaccine has been approved for infants aged 3 months and older. True or False?
3. DEA requires the following to be documented when doing pharmacy inventory of Controlled Substances. Select all that apply:
 - A. Completion of inventory at BOB or EOB on date.
 - B. Actual hour of the day completed.
 - C. Signature of pharmacist and technician.
 - D. Accurate count of all CI, CII, CIV, and CV substances in pharmacy only.
4. Which of the following are ways pharmacists can reduce the barriers associated with MOUD? Select all that apply:
 - A. Have a drug take-back receptacle in your pharmacy.
 - B. Utilize the PDMP as a tool to remove patients from your practice.
 - C. Advocate for pharmacist ability to prescribe and manage buprenorphine.
 - D. Assure your pharmacy stocks buprenorphine.

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Post-test Technicians

1. Technicians should expect that workplace conditions will be appropriate to the level of work that is required of them. True or False?
2. Which of the following is true about the PREP Act:
 - A. PREP stands for Public Readiness and Emergency Preparedness.
 - B. The PREP Act provided new authorities for pharmacy staff to provide COVID countermeasures to patients.
 - C. The PREP Act has expired because there is no longer a COVID state of emergency.
 - D. All of the above
 - E. #1 and #2
 - F. #1 only
3. If a patient enters the pharmacy with a bag of medications to donate to the drug repository. It includes insulin, syringes, and lancets. What should the technician do?
 - A. Ask the pharmacist to speak to the patient and review the donated medications and devices.
 - B. Have the patient complete the donation form and give her a big hug to thank her.
 - C. Since the pharmacist is busy, help the patient complete the donation form.
 - D. The insulin expires in a month, but a patient can use a vial of insulin in less than a month so collect the donation.
4. MOUD is the acronym for Medication for Opioid Use Disorder. True or False?

45



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