South Dakota Board of Pharmacy Update

South Dakota Pharmacists Association Annual Meeting
September 16, 2016

Kari Shanard-Koenders, Executive Director
Melissa DeNoon, PDMP Director
Gary Karel, Pharmacy Inspector
Paula Stotz, Pharmacy Inspector
Carol Smith, Pharmacy Inspector
Presentation Objectives and Disclosures

This CPE activity will ensure that pharmacists and technicians in attendance will:

1. Understand how to be compliant with Federal and State laws and how changes affect them;
2. Identify how federal law protections of the drug supply chain affect pharmacy practice;
3. Identify what the practice of pharmacy allows a pharmacist to do in South Dakota;
4. Describe situations in which a pharmacist should check the SD PDMP;
5. Describe how the DEA’s Disposal of Controlled Substances final rule effective October 9, 2014, impacts pharmacy practice;

None of the presenters has any direct financial relationship to disclose.
1. Which of the following statements are true about the Drug Quality Security Act?
   a. It was signed into law by President Obama on November 27, 2013
   b. Title I of the Act is titled “Compounding Quality Act”
   c. Title II of the Act is titled “Drug Supply Chain Security Act.”
   d. If a facility is compounding non-sterile preparations, they must register as an Outsourcing Facility
   e. None of the above.

2. The Drug Supply Chain Security Act indicates trading partners must provide 3 of
   the following transaction documents?
   a. Transaction Statement
   b. Transaction Traceability
   c. Transaction History
   d. Transaction Reporting
   e. Transaction Information
3. **SDCL 36-11-19.1** allows a pharmacist to do all of the following:
   
a. Administer medications with a drug order
b. Perform drug reviews
c. Conduct scientific research as an investigator
d. Prescribe by protocol signed by a nurse practitioner

4. A pharmacist presented with a Schedule III prescription written by an out-of-state provider on a Friday evening for a new patient should check the SD PDMP.
   
a. True       b. False

5. Retail pharmacies registered with the DEA as a Collector can accept controlled substances from ultimate users for disposal.
   
a. True       b. False
What’s New?

- Licensure Application Changes
- Health Department Regulation Changes
- NAPLEX Changes
- Collaborative Practice Agreements
- Naloxone Legislation
- DQSA
- DSCSA
- USP <800>
- NIOSH
- PDMP UPDATE
- DEA COLLECTOR UPDATE
Pharmacist Application Changes

- In 2012, the Primary Care Task Force (PCTF) was appointed by Governor Daugaard. The purpose of this group was to bring forth recommendations pertaining to ensuring access to primary care across South Dakota. One of the recommendations was to create a data system collecting specific data elements on health care professionals in South Dakota. In addition to this effort, in 2013 SB3 and SB4 were passed which mandated DLR to collect information on any person that is licensed or certified by any department, board, or commission in South Dakota. The decision was made to join forces between DOH and DLR to satisfy both agencies’ needs for information.

- Since the data collection application is built to collect data for two purposes, some of the data elements are required by DLR and some are requested by DOH. The DLR data elements are required by SDCL 13-1-60 through SDCL 13-1-62. The DOH data elements are data elements the PCTF requested regarding health care professionals in South Dakota.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>44:73:08:01</td>
<td>Repealed.</td>
</tr>
<tr>
<td>44:73:08:01.01</td>
<td>Policies and procedures.</td>
</tr>
<tr>
<td>44:73:08:02</td>
<td>Written orders for medication required.</td>
</tr>
<tr>
<td>44:73:08:03</td>
<td>Medication therapy reviewed monthly.</td>
</tr>
<tr>
<td>44:73:08:04</td>
<td>Storage and labeling of medications and drugs.</td>
</tr>
<tr>
<td>44:73:08:05</td>
<td>Control and accountability of medications and drugs.</td>
</tr>
<tr>
<td>44:73:08:06</td>
<td>Documentation of drug disposal.</td>
</tr>
<tr>
<td>44:73:08:07</td>
<td>Medication administration.</td>
</tr>
<tr>
<td>44:73:08:08</td>
<td>Medication records.</td>
</tr>
<tr>
<td>44:73:08:09</td>
<td>Administration of facility pharmacy.</td>
</tr>
<tr>
<td>44:73:08:10</td>
<td>Stock of legend drugs prohibited -- Exception.</td>
</tr>
<tr>
<td>44:73:08:11</td>
<td>Controlled drugs kept for emergency use.</td>
</tr>
</tbody>
</table>
# Health Department Regulation Changes

**ARSD 44:75:08**

**Hospital, Specialized Hospital, and Critical Access Hospital Facilities MEDICATION CONTROL**

<table>
<thead>
<tr>
<th>Section</th>
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<tr>
<td>44:75:08:01</td>
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<tr>
<td>44:75:08:09</td>
<td>Administration of facility pharmacy.</td>
</tr>
</tbody>
</table>
NAPLEX CHANGES

- The NAPLEX program will transition to a new administration model in November 2016 with changes in:
  - Increase in the number of items from 185 to 250
  - Increase in testing time to six hours
  - Increase in the registration fee from $505 to $575
  - NAPLEX waiting period will be 45 days after obtaining a failing score on the NAPLEX

- NABP will be notifying candidates with open, active NAPLEX registrations of the following deadlines:
  - The last day to take the current NAPLEX is October 22, 2016. Candidates wishing to take the current exam must: Register by October 3, 2016, be granted eligibility and receive an authorization to test, and schedule and take the exam by October 22, 2016
  - The NAPLEX will not be administered October 24-31, 2016
  - The new NAPLEX will launch on November 1, 2016
NAPLEX CHANGES (cont’d)

- Candidates with open, active registrations who are unable to test by October 22, 2016, their registrations will remain active and they may schedule an appointment to take the new NAPLEX on or after November 1, 2016.

- Candidates who graduate in 2017 should not register for the current NAPLEX since they are not eligible to sit for the current exam. Should any such candidates register for the current exam, their record will be closed and a partial refund granted per the NABP refund policy. The candidate would then need to register for the new NAPLEX after November 1, 2016, and pay the new fee of $575.
Authority of Pharmacists

SDCL 36-11-19.1. Authority of registered pharmacists. Registered pharmacists may:

(1) **Perform drug administration pursuant to a prescription drug order.** The Board of Pharmacy shall establish standards for drug administration pursuant to chapter 1-26 with the approval of a committee composed of two persons appointed by the Board of Pharmacy, two persons appointed by the Board of Nursing and two persons appointed by the Board of Medical and Osteopathic Examiners;

(2) Perform drug reviews;

(3) Perform or participate in scientific or clinical drug or drug-related research as an investigator or in collaboration with other investigators;

(4) Interpret and apply pharmacokinetic data and other pertinent laboratory data to design safe and effective drug dosage regimens;

(5) Participate in drug and drug device selection pursuant to a prescription drug order;

(6) **Initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs;** and

(7) Provide information on prescription drugs, which may include advising, consulting, and educating, as necessary or as required, patients, the public, and other health care providers on the rational, safe and cost-effective use of drugs, including therapeutic values, content, hazards and appropriate use.
Policy Statement on Immunizations

South Dakota ARSD 20:51:28 outlines the authority and requirements for the administration of Influenza vaccines. The Board of Pharmacy recognizes that pharmacists are highly trained with regard to immunizations of all types and further rule change is needed in the future to include other immunizations. Further, the Board recognizes that retail pharmacists provide the most convenient access point to medical care and access to immunizations is a critical component of public health and safety.

Under the current rules, pharmacists may administer Influenza vaccine if properly trained and with the required Board immunization authorization. Generally it has been felt that all other immunizations require a prescription from the prescriber. This is not the case. SDCL 36-11-19.1 allows pharmacists to “perform drug administration pursuant to a prescription drug order” and allows pharmacists to “initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs”. There is no prohibition on providing all vaccines if they are included in a prescriber’s protocol. The protocol must be created and signed by the prescriber and pharmacist and should be valid for a period of time not to exceed two years. The protocol should be sent to the Board office for approval and should include:

1. Identity of the participating physician and the pharmacist;
2. Identity of the immunization or vaccination which may be administered;
3. Identity of the patient or groups of patients to receive the authorized immunization or vaccination;
4. Identity of the authorized routes and sites of administration allowed;
5. Identity of the course of action the pharmacist shall follow in the case of reactions following administration;
6. Identity of the location at which the pharmacist may administer the authorized immunization or vaccination; and
7. Recordkeeping and reporting requirements per ARSD 20:51:28:05 and procedures for notification of administration.

The SD Board of Pharmacy would like to encourage pharmacists administering vaccines, pursuant to a protocol, to review patients’ eligibility on the South Dakota Immunization and Information System (SDIIS). Unfortunately providers are not required to enter all vaccines into the SDIIS. Further, we encourage reporting to the SDIIS within 14 days after administration of vaccine.
HB1079 was passed by the 2016 Legislature, signed by the governor, and became effective on July 1, 2016. Section 2 of the Bill states “A licensed health care professional may, directly or by standing order, prescribe an opioid antagonist to a person at risk of experiencing an opioid-related overdose, or prescribe to a family member, friend, or other close third party person the health care practitioner reasonably believes to be in a position to assist a person at risk of experiencing an opioid-related overdose”. This allows pharmacies to develop standing orders (collaborative practice agreements) with physicians to be able to do this.

Mention the availability of Naloxone to individuals who are chronically taking opioids. It is another important tool in the arsenal helping to fight opioid addiction and potentially save lives.
DQSA

- Title I, known as the Compounding Quality Act (CQA)
- Title II, known as the Drug Supply Chain Security Act (DSCSA)
- DSCSA added sections 581-585 to the Food, Drug, and Cosmetic (FD&C) Act and amended section 503(e) of the FD&C Act
Drug Supply Chain Security Act (DSCSA)

Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Product

- What’s covered:
  - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

- What’s not covered:
  - Blood or blood components intended for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Certain IV products
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs

And active pharmaceutical ingredients (APIs) too!

All products are prescription drugs, but not all prescription drugs are products.

Transaction

- Transfer of product where a change of ownership occurs
- Exemptions
  - Intracompany distributions
  - Distribution among hospitals under common control
  - Public health emergencies
  - Dispensed pursuant to a prescription
  - Product sample distribution
  - Blood and blood components for transfusion
  - Minimal quantities by a licensed pharmacy to a licensed practitioner
  - Certain activities by charitable organizations
  - Distributions pursuant to a merger or sale
  - Certain combination products
  - Certain medical kits
  - Certain IV products
  - Medical gas distribution
  - Approved animal drugs

Definitions: Transaction Information, Transaction History, and Transaction Statement

**Transaction Information (TI):**
- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.

**Transaction Statement (TS):** A statement, in paper or electronic form, that the entity transferring ownership in a transaction—
- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.

**Transaction History (TH):** A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

June 18, 2015: Seventy-Three Charged in Southern District of Florida as Part of Largest National Medicare Fraud Takedown in History

34. United States v. Jorge Moreno and Luis Antony Rivera, Case No. 15-2806-mj-Torres

Jorge Moreno, 50, of Tampa, and Luis Antony Rivera, 50, of Punta Gorda, are charged by complaint prescription drug diversion, by selling prescription drugs, with the intent to defraud and mislead, not as a wholesale distributor, and without transaction history, transaction information, and transaction statements as required by Title 21, United States Code, Section 360eee-1(c)(1)(A)(iii), in violation of Title 21, United States Code Sections 331(t) and 333(a)(2). The complaint alleges that between April 6, 2015, and June 15, 2015, the defendants and their co-conspirators improperly sold diverted prescription drugs to undercover agents on three separate occasions during buy operations recorded and controlled by law enforcement. The complaint alleges that the drugs sold on these three occasions were worth, in the aggregate, approximately $200,000.

Mr. Ferrer commended the investigative efforts of the FDA-OCI and HHS-OIG. This case is being prosecuted by Assistant U.S. Attorney James Hayes.
<800> Hazardous Drugs (HD) – Handling in Healthcare Settings

Released February 2016

Chapter to become effective July 1, 2018

This chapter applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport or administer HD
National Institute for Occupational Safety & Health (NIOSH)

- Under Center for Disease Control (CDC)
- Document maintains a list of antineoplastics and other HD’s used in healthcare
- Entity must maintain a list of HD
- Entity’s list must be reviewed at least every 12 months
- Website = www.cdc.gov/NIOSH
- NIOSH 2016 document should be available soon
The United States’ Opioid Epidemic by the Numbers:

- CDC reported 46,471 US citizens died of a drug overdose in 2013 equating to more than 120 people each day.
- Of these deaths, 16,235, involved opioid analgesics which surpasses the deaths due to cocaine and heroin combined.
- Drug overdose deaths are now the leading cause of injury death in the US surpassing the number of deaths by motor vehicles and by firearms every year since 2008.
- The US makes up about 4.6% of the world’s population but consumes 80% of its opioids and 99% of the world’s hydrocodone.
How is South Dakota Doing?

- Enough doses of opiates were prescribed to South Dakotans in 2015 to medicate every SD adult around-the-clock for 19 straight days.
- Between 2004-2011: 82 Opioid Deaths (approximately 10 per year).
- 2013: 17 Opioid Deaths.
- 2014: 16 Opioid Deaths (including one death where heroin was present).
- In the last year, controlled substances were prescribed by 3,847 prescribers of which 15.9% are registered with the SD PDMP for online access.
## South Dakota Prescription Drug Monitoring Program

### SD POMP Statistical Information

#### June 2016

<table>
<thead>
<tr>
<th>Count of Prescription Records</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 1, 2011 - December 31, 2011</td>
<td>411,326</td>
</tr>
<tr>
<td>January 1, 2012 - December 31, 2012</td>
<td>1,101,417</td>
</tr>
<tr>
<td>January 1, 2013 - December 31, 2013</td>
<td>1,152,900</td>
</tr>
<tr>
<td>January 1, 2014 - December 31, 2014</td>
<td>1,218,367</td>
</tr>
<tr>
<td>January 1, 2015 - December 31, 2015</td>
<td>1,297,804</td>
</tr>
<tr>
<td>January 1, 2016 - June 30, 2016</td>
<td>718,425</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5,893,239</strong></td>
</tr>
</tbody>
</table>

#### June Most Prescribed Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>RX’s</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>Quant/Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCODONE BITARTRATE/ACETAMINOPHEN</td>
<td>20,553</td>
<td>1,345,195</td>
<td>251,939</td>
<td>66</td>
</tr>
<tr>
<td>TRAMADOL HCL</td>
<td>13,664</td>
<td>1,016,991</td>
<td>247,288</td>
<td>74</td>
</tr>
<tr>
<td>LORAZEPAM</td>
<td>7,818</td>
<td>393,873</td>
<td>192,258</td>
<td>50</td>
</tr>
<tr>
<td>ZOLPIDEM TARTRATE</td>
<td>7,596</td>
<td>271,316</td>
<td>270,043</td>
<td>36</td>
</tr>
<tr>
<td>CLONAZEPAM</td>
<td>7,290</td>
<td>468,074</td>
<td>237,721</td>
<td>64</td>
</tr>
<tr>
<td>DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAN</td>
<td>6,833</td>
<td>419,576</td>
<td>270,993</td>
<td>61</td>
</tr>
<tr>
<td>ALPRAZOLAM</td>
<td>5,764</td>
<td>361,546</td>
<td>165,685</td>
<td>63</td>
</tr>
<tr>
<td>METHYLPHENIDATE HCL</td>
<td>5,359</td>
<td>305,232</td>
<td>202,758</td>
<td>57</td>
</tr>
<tr>
<td>OXYCODONE HCL</td>
<td>4,548</td>
<td>386,702</td>
<td>92,934</td>
<td>85</td>
</tr>
<tr>
<td>OXYCODONE HCL/ACETAMINOPHEN</td>
<td>4,035</td>
<td>256,746</td>
<td>52,852</td>
<td>64</td>
</tr>
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</table>

*POM reporting began in Dec 2014*

#### Online Profile Queries

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmacist</th>
<th>Prescriber</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>5,398</td>
<td>5,377</td>
<td>10,775</td>
</tr>
<tr>
<td>2013</td>
<td>53,776</td>
<td>46,369</td>
<td>99,145</td>
</tr>
<tr>
<td>2014</td>
<td>56,670</td>
<td>52,647</td>
<td>109,317</td>
</tr>
<tr>
<td>2015</td>
<td>52,965</td>
<td>53,307</td>
<td>106,272</td>
</tr>
</tbody>
</table>

#### Profile Reports (Staff)

<table>
<thead>
<tr>
<th>Year</th>
<th>Staff</th>
<th>% Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>532</td>
<td>4%</td>
</tr>
<tr>
<td>2013</td>
<td>517</td>
<td>1%</td>
</tr>
<tr>
<td>2014</td>
<td>646</td>
<td>1%</td>
</tr>
<tr>
<td>2015</td>
<td>644</td>
<td>1%</td>
</tr>
</tbody>
</table>

*Law Enforcement (LE) authorized to run query and view only after POMP approval.*
Trending Usage Graphs

On-Line Profile Queries Run by Pharmacists and Prescribers over PDMP Life

- Pharmacists
- Prescribers
How Do I Access?

Website for initial account set up: https://southdakota.pmpaware.net

- To request a new account in PMP AWARxE, on the login screen, click “Create an Account”

- You will be guided through steps to enter an email address and create a password, select user roles, click on a link in a verification email sent to the registered email address, enter personal and employer demographics, then click on “Submit Your Registration” to complete the process

- You will then be taken to a page with a notification of any additional documentation required that will be sent in an email to be completed and uploaded

- Your account will go through an approval process and when completed, an email will be sent from the SD PDMP office

- [http://doh.sd.gov/boards/pharmacy/assets/AWARxE-RegistrationNewUsers.pdf](http://doh.sd.gov/boards/pharmacy/assets/AWARxE-RegistrationNewUsers.pdf)
Guidelines to perform a patient search when the patient’s last name is two words, separated either with a hyphen or a space: (1) Perform a patient search with the two words together as one word, and (2) Perform a patient search with the hyphen, and/or (3) Perform a patient search with a space. Even though a pharmacy’s profile may include the hyphen or space, the data may get submitted into our repository without the hyphen or space making it into one word, therefore performing these multiple searches will return the most complete data.

Due to new information regarding how states share data when the states are utilizing different vendor platforms, please follow these guidelines: (1) If MN is a desired state for the search, include the patient’s first name, last name, date of birth, and NO zip code and ONLY select MN. This will return data from SD and MN. (2) For SD and other out-of-state searches (IA, ND) include the patient’s first name, last name, date of birth, and INCLUDE a zip code. This may mean performing two searches on a patient for the most complete return of data.

AWARxE requires a new password every 90 days.
What Can Pharmacists Do?

- Make fact based decisions when presented with a potential situation
- Communicate, Communicate, Communicate with your patients, doctors, and other pharmacists – ask questions if suspicious
- Be level headed in any action you take
- Follow Guidelines for Pharmacists
Guidelines for Pharmacists #1

Pharmacists should check the SD Prescription Drug Monitoring Program before dispensing controlled substances, and specifically in the following circumstances:

- All Schedule II or Schedule III drugs for:
  - Every new or unknown patient
  - All weekend and late day prescriptions
  - Prescriptions written far from the location of the Pharmacy or the patient’s residence
  - Any time suspicious behavior is noted

- Controlled substances in high doses or high quantities

- Any prescription considered an outlier to what is normally prescribed

- Any prescription for Oxycodone 15mg or 30mg

- Regular patients at least once per year

- Document in the patient’s file to indicate that the PDMP was checked

- All pharmacists, including “floaters” receive education on the PDMP
Guidelines for Pharmacists #2

- Pharmacists should use clinical judgment for when to communicate with Prescribers, but should specifically contact Prescribers in the following circumstances:
  - Pharmacist suspects a **forged, altered or counterfeited prescription**
  - Patient is repeatedly requesting **early refills** of controlled substances
  - Patient is specifically requesting **early refills** of Opioids, Benzodiazepines or Carisoprodol
  - Patient presents with a **high quantity** from the Emergency Department
  - Any time **suspicious behavior** is noted
  - Establish face-to-face contact with the Emergency Department Director, if you receive high traffic from ED patients
  - Call the phone number for the prescriber listed in their computer vs. the phone number on the prescription
Guidelines for Pharmacists #3

Pharmacists should use clinical judgment for when to communicate with other Pharmacies, but should specifically contact other Pharmacies in the following circumstances:

- If you receive a prescription that you know has been denied by another dispenser

- If you deny a patient a prescription, it is recommended that you call other local Pharmacies (within a 5 mile radius) to alert them or call the Board of Pharmacy office and request that an alert be sent to pharmacies

- It is important to note that cross-communication between pharmacies is NOT a violation of HIPAA
Guidelines for Pharmacists #4

➤ Pharmacists should not fill a prescription if they believe it is forged, altered, or counterfeited

• Call the prescriber to verify first

• Be familiar with the characteristics of forged prescriptions

• If you deny a prescription, notify other local pharmacists or call the Board of Pharmacy office to have an alert sent to other pharmacies

• If you discover a pattern, contact the authorities - can be anonymous

• Be familiar with the law and your legal and ethical responsibilities
  – It is unlawful to knowingly dispense controlled substances for anything other than a “legitimate medical purpose.”
  – There is no legal obligation to dispense a prescription, especially one of doubtful, questionable, or suspicious origin.

• A fraudulent prescription is private property – return if requested – keep otherwise

• No legal requirement to contact the police but advisable that you do
Guidelines for Pharmacists #5

- Pharmacists should educate their patients about proper storage and proper disposal during the patient consultation prior to dispensing controlled substances
  - Especially if there are youth in the home
  - **Never** leave any controlled substance out “in the open”
  - **Never flush** prescriptions down the toilet or throw as-is in the trash
  - Information on take-back events and permanent drop box locations or instruct your patients to use the DEA disposal guidelines and FDA tips:
    - Take out of original container and mix with undesirable substance (e.g., coffee grounds or kitty litter); then put in a sealable bag, empty can, or other container to prevent leakage
    - Scratch out all identifying information on the prescription label to protect their identity and personal health information
  - **Never share medication with friends, family or others**
The Future of PDMPs

- Integration of PDMP data into health system’s electronic health records (EHR) and pharmacy’s software systems
  - Addresses a major concern of prescribers and pharmacists which is accessing the PDMP requires additional steps that are not in the clinical workflow
  - Integration benefits include:
    - Immediate improvement in the patient care process
    - User workflows were streamlined and improved
    - Pharmacist and prescriber satisfaction was highest when technology automated the majority of workflow tasks

- Integration of SD PDMP data into Avera Health System’s EHR went live May 25, 2016

- Kroger’s pharmacy software system integrates with several states’ PDMPs, one of which is Ohio
Drug Take-Back Program

- One of the goals of the PDMP is to deter and reduce diversion of controlled substances in South Dakota.
- Occasional nonmedical users of prescription pain relievers are most likely to obtain their drugs for free from a relative or friend.
- A disposal program for unused, unwanted, and expired drugs decreases this avenue of diversion.
- The SD Board of Pharmacy is proposing a partnership with SD pharmacies in a statewide drug take-back program.
Final Rule of the Disposal of Controlled Substances

- Became effective on October 9, 2014 and can be found in Title 21 of the Code of Federal Regulations (CFR) Part 1317
- These regulations implement the Secure and Responsible Drug Disposal Act of 2010 by expanding the options available to collect controlled substances (CS) from ultimate users for the purpose of disposal, including collection receptacle locations at retail pharmacies
- With this final rule, the DEA is implementing a standard of destruction, “non-retrievable”
How Does My Pharmacy Become a Collection Site?

- Modify your current DEA registration to obtain authorization to be a collector. This authorization is subject to renewal.

- Collectors may install, manage, and maintain collection receptacles located at their authorized collection location.

- Only CS listed in Schedule II, III, IV, or V may be collected.

- Controlled and non-controlled substances may be collected together and co-mingled.

- Collectors can only allow the ultimate user to deposit their medications into the collection receptacle at a registered location.

- Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.
How Does My Pharmacy Become a Collection Site? cont’d

- Collection receptacles need to be securely placed and maintained in the immediate proximity of the pharmacy, i.e. can be seen from inside the pharmacy.

- The collection receptacle must meet certain design specifications including being securely fastened to a permanent structure so it can not be removed*, be securely locked, and display a sign indicating what substances may be deposited. (*The opening to the receptacle must be inaccessible to the public when an employee is not present such as when the pharmacy is closed.)

- The sealed containers may be delivered or picked up as set forth by the contracted agency.
Available Take-Back Programs

- Yellow Jug Old Drugs Program
- Med Rx Return Drug Collection Units
- Medsafe by Sharps, Inc.
1. Which of the following statements are true about the Drug Quality Security Act?
   a. It was signed into law by President Obama on November 27, 2013
   b. Title I of the Act is titled “Compounding Quality Act”
   c. Title II of the Act is titled “Drug Supply Chain Security Act.”
   d. If a facility is compounding non-sterile preparations, they must register as an Outsourcing Facility
   e. None of the above.

2. The Drug Supply Chain Security Act indicates trading partners must provide 3 of the following transaction documents?
   a. Transaction Statement
   b. Transaction Traceability
   c. Transaction History
   d. Transaction Reporting
   e. Transaction Information
3. **SDCL 36-11-19.1 allows a pharmacist to do all of the following:**
   a. Administer medications with a drug order
   b. Perform drug reviews
   c. Conduct scientific research as an investigator
   d. Prescribe by protocol signed by a nurse practitioner

4. **A pharmacist presented with a Schedule III prescription written by an out-of-state provider on a Friday evening for a new patient should check the SD PDMP.**
   a. True       b. False

5. **Retail pharmacies registered with the DEA as a Collector can accept controlled substances from ultimate users for disposal.**
   a. True       b. False
QUESTIONS?

Questions are guaranteed in life; Answers aren't.