Board of Pharmacy Update

South Dakota Pharmacists Association
2023 Annual Conference
September 15, 2023, 9:30 AM MDT

Kari Shanard-Koenders, R.Ph., M.S.J.
Tyler Laetsch, Pharm. D.
Melissa DeNoon, R.Ph.
South Dakota Board of Pharmacy

Disclosure

The South Dakota Board of Pharmacy staff have had no financial relationships over the past 24 months with any commercial sponsor with a vested interest in this presentation.

Objectives for Pharmacists

1. *Understand the latest DEA guidance and regulations that impact pharmacy.*
2. *Describe DSCSA changes that will go into effect on November 23, ~~2023~~ 2024!!*
3. *Describe PDMP Data Integrity and what pharmacies can do to streamline the process.*

Objectives for Pharmacy Technicians

1. *Describe the Donated Drug Redistribution Program in South Dakota.*
2. *Describe how pharmaceutical product ordering, receiving, and availability of transaction information will change after November 2023.*
3. *Describe the licensing and registration requirements that are provided by the board office.*

SD Board of Pharmacy

- *The Mission of the South Dakota Board of Pharmacy is to protect and promote the health and safety of the public by supporting pharmacists and pursuing the highest quality pharmaceutical care through education, communication, licensing, legislation, regulation, and enforcement.*

- Board Members make decisions on licensure, discipline, variances, policy, complaints
  - Appointed for 3-year terms – may serve 3 consecutive terms
  - Current Members
    - Ashley Hansen, Aberdeen
    - Cheri Kraemer, Vice President, Sioux Falls
    - Tom Nelson, President, Non-pharmacist member, Spearfish and Sioux Falls
    - Dan Somsen, Yankton
    - Curt Rising, Rapid City

- You are encouraged to attend a Board Meeting! The Board meets quarterly - see Boards and Commissions Portal for more information

Board Staff

Board staff consists of 8 people or 6 FTE (four full-time and four part-time staff)

- 3 Inspectors 1.75 FTE total

  Tyler Laetsch 1.0 FTE – Sioux Falls, Lee Cordell 0.25 FTE – Spearfish and Mobridge, Carol Smith 0.5 FTE – Groton

- 2 Senior Secretaries – 1.6 FTE

  Beth Windschitl 1.0 FTE, Rhea Kontos 0.6 FTE

- 2 PDMP Staff

  Melissa DeNoon 1.0 FTE, PDMP Program Director, Melanie Houg 0.6 FTE, PDMP Assistant

- Executive Director
  - Kari Shanard-Koenders 1.0 FTE

What does Board staff Do?

- Licensing
  - Pharmacist Licenses – 2,193
  - SD Pharmacy Licenses – 320
    - Full time – 240
    - Part time – 80
  - Non-resident Pharmacy Licenses - 832
  - Intern Registrations - 255
  - Wholesale and Other Distributor Licenses – 1,326
  - Technician Registrations – 1,662
  - Immunization Registrations – 884 (credential on pharmacist license)

Issue Tracking

- Donated Drug Redispensing Program
- DSCSA Updates
- Mainstreaming Addiction Treatment (MAT) Act - X Waiver gone, MATE Act
- New DEA Rules on Telemedicine Prescribing
- End of PHE
- USP Updates
- CS Theft
- Chemical Abortion Enforcement Warning
- Drug Shortages (continuous)
- Suspicious Order Monitoring
- Pharmacist Health and Wellbeing
- Pharmacies Reducing Hours Due to no Staff
- OTC Naloxone???

DRUG SUPPLY CHAIN SECURITY ACT BASICS

Trading partners – manufacturers, wholesale distributors, dispensers, repackagers, and 3PLs – are subject to requirements for enhanced drug distribution security.

The DSCSA, enacted in 2013, outlines steps to achieve interoperable, electronic tracing of products to identify and trace certain prescription drugs as they are distributed throughout the U.S.

Currently, these entities can choose to provide TI, TH, TS information either electronically or in paper format. After DSCSA goes into effect, trading partners must provide, receive, and maintain documentation about products and ownership only electronically. No TH.

These DSCSA requirements were scheduled to change on November 27, 2023.

Now – the DSCSA requirements will be scheduled to be enforced on November 27, 2024.

DSCSA Summary

Components of Law

- Part 2 of the DQSA (Drug Quality & Safety Act)
  - Link to FDA Copy of DSCSA

- Enacted Nov 27, 2013
  - Replaced a growing number of differing state laws
  - Phases rolling out till Nov 2023 from manufacture to dispenser
  - Facilitate the gathering of transaction data in the event of suspect and illegitimate product

- Roles in DSCSA:

Manufacturers

Repackagers

Distributors

Dispensers

Third Party Logistic Providers

DSCSA Summary

Major Milestones

Year	2015	2018	2019	2020	2023
	Foundational		Trading Partners		Interoperability
Major Requirements	• T3 at the lot level (paper allowable) • Authorized TP • Suspect product handling & reporting	• Affix serial number • Provide T3 lot level (electronic) • Serial number retention and verification	• Transact only in serialized products • Accept return only with associated TI & TS • Initiate TH on saleable returns • Verify serial number for saleable returns (Enforcement delayed to 11-27-23)	• Accept only serialized product • Suspect product reporting • Verification of serial numbers for suspect (Enforcement delayed to 11-27-23)	• Implementation of an interoperable, electronic tracing of product at the S/N level (TI & TS) • Facilitate gathering of history for suspect, illegitimate & recalls • Enhanced Verification • “Authorized” direct or indirect partners
Primary Impacted	All Trading Partners	Manufacturers/ Repackagers	Wholesalers	Dispensers/ Wholesaler	All Trading Partners

DSCSA Roles (Multiple Possible)

Based on the Activities Your Organization Performs

Role	Functions
Manufacturer	Entity that holds a product application approval , is license issued and/or manufactured the product or a co-licensed partner of that entity.
Repackager	Entity that repacks/relabels a product or package for further sale or distribution
Distributor	Entity other than above that is licensed in the ship from/to states or under FDA along with annual FDA reporting that sells, purchases, trades, handles product to other distributor or entity for dispensing
Dispenser	Pharmacies, hospital pharmacies or any other entity authorized by law to dispense prescription drugs, and the affiliated distribution centers.
3PL	Entity that handles product for any of above but does not take ownership and is licensed in the state (where applicable) and reporting to annual FDA database

DSCSA Components

Barcodes and human readable labeling

Primary dose
In contact with the drug substance: blisters, vials, ampoules, etc.

Saleable Packaging
Sales pack, Folding Box, Sellable Unit

(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

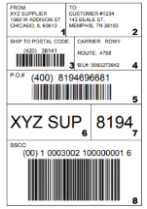
Bundle, Tertiary pack
Two or more saleable units wrapped together

Homogenous Case, Tertiary pack
Shipping box containing secondary packs

Full

Partial

Pallet, Tertiary pack
Shipping unit consisting of several cases grouped together



Source: GS1 and HDA Barcode Guidelines

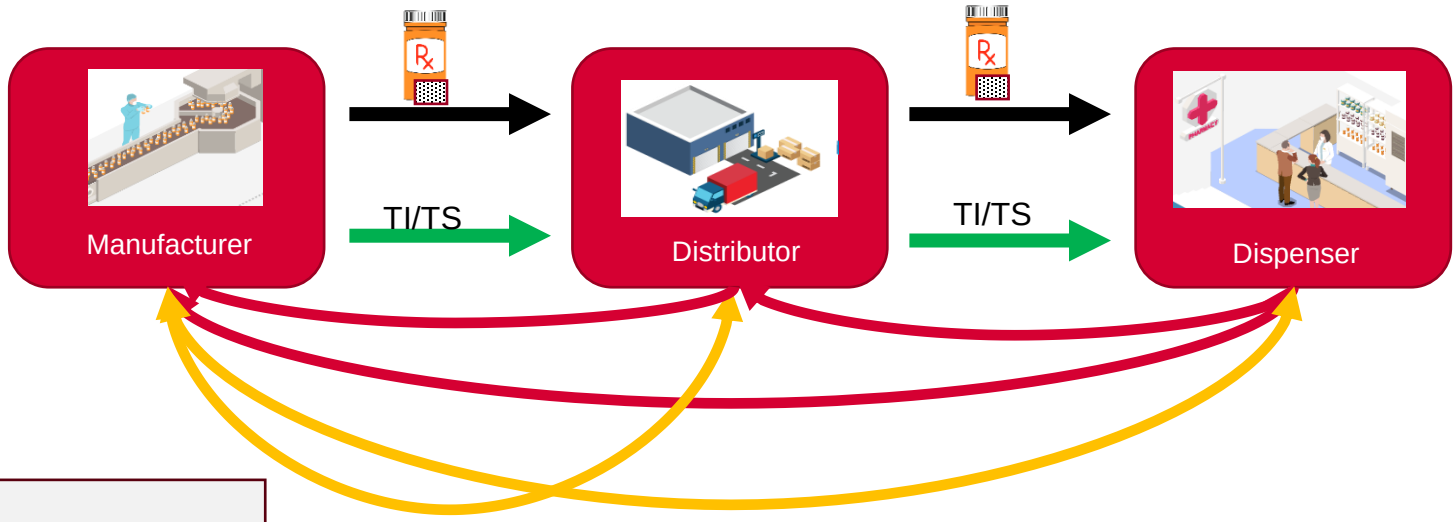
DSCSA Components

What is in that square barcode?

Application Identifier	Data type	Human-readable format
AI (01)	**GTIN**	14 numeric characters with NDC embedded
AI (21)	**Serial Number**	Unique alpha- numeric number up to 20
AI (17)	**Expiration Date (non zero day in YYMMDD)**	FDA recommends YYYY-MM-DD or YYYY-MMM-DD Note: Removal of day field in such cases as space limitations. **Ex. 2020-07-31 or 2020-JUL-31**
AI (10)	**Batch/Lot Number**	1 to 20 numeric/alphanumeric characters

DSCSA Components

Product and Data Flow – A Typical Example



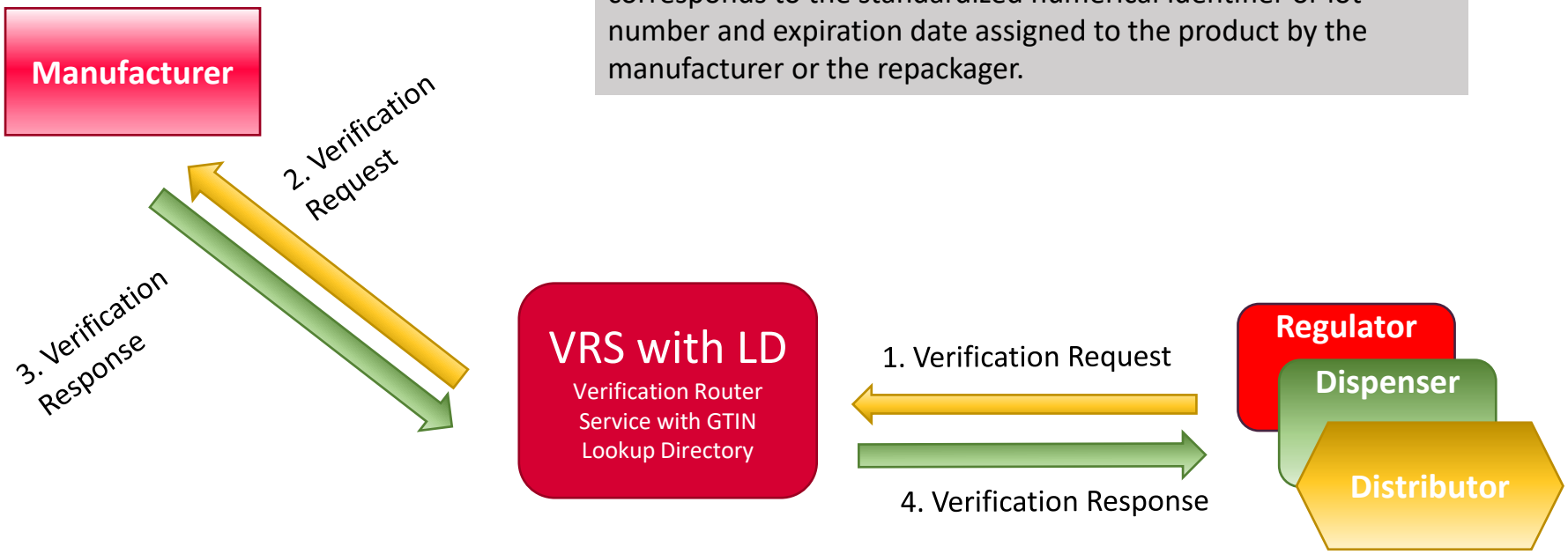
Key:

- Product
- Transaction Data
- Product Tracing
- Product Verification

DSCSA Components

Product Verification Request/Response Flow

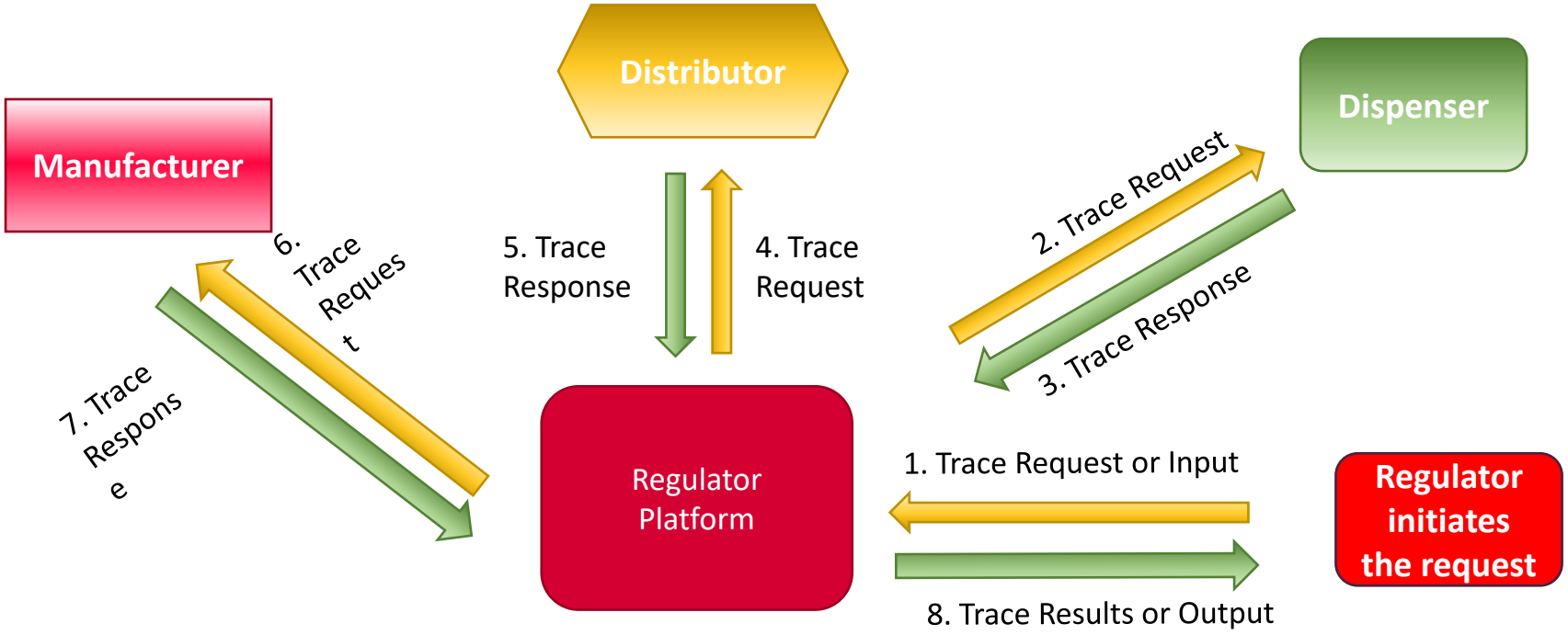
Verification- determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.



DSCSA Components

Product Tracing Request/Response Flow

Product Tracing- gathering of relevant transaction information and statements in a secure, electronic interoperable manner as defined and outlined by DSCSA.



GS1 US Resources

- DSCSA Webpage
  - DSCSA, Guidance by Stakeholder, GLNs, Resources, FAQs
- Rx Secure Supply Chain Workgroup
  - Implementation Guidelines
    - Supply Chain Scenarios
    - Exception Handling
  - FAQs
  - Verification Messaging Standard
- Education and Training:
  - Overview of GS1 Standards for DSCSA Dispensers (25-30 minutes)
  - GS1 Standards for DSCSA Suppliers Online Certificate (8 Modules)

Resource	What It Will Help With
Frequently Asked Questions in Preparing for the U.S. DSCSA	Answering frequently asked questions about identifying, capturing and sharing information to help meet DSCSA requirements.
GS1 US DSCSA Implementation Guidelines	Understanding technical requirements for encoding your product with GS1 Identifiers and how to capture GS1 product identifiers when receiving shipments.
Applying Lightweight Messaging Standard for Verification of Product Identifiers	Configuring PI verification business scenarios and technical requirements for responding to verification requests from your direct and indirect trading partners.
How to Identify your Location for DSCSA Requirements	Identifying your locations with a Global Location Number to share information related to Transaction Information (TI) and Transaction Statements (TS) and verify product information through a third-party routing system.
Progress on 2023 DSCSA Interoperability	Understanding the quality of barcodes to ensure scannability by your trading partners.
GS1 US Implementation Guideline for Pharmaceutical Chain of Custody	Capturing GS1 product identifiers when packing and shipping when working with 3rd party agents (CMOs, CPOs, and 3PLs).
GS1 US Pharmaceutical Conformance Test Program	Optimizing the data quality of your EPCIS serialized exchanges with the help of a certified third-party testing service.
GS1 US DataHub	Sharing, searching, and retrieving GLN information with your trading partners.

GS1 US DSCSA Implementation Suite

Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.3

- Published in December 2022

Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2

- Published in 2016

Addendum: Guidance and XML Examples for Supply Chain Choreographies in Serialized Item-Level Management

- Published May 2023

Addendum: Diagrams and XML Examples for Serialized Exceptions Processing

- Currently in development

MAT Act Signed Into Law

On December 29, 2022, President Biden signed the Consolidated Appropriations Act of 2023 into law.

This bill included legislation to address the opioid crisis, including the Mainstreaming Addiction Treatment (MAT) Act, which officially eliminated the DATA-Waiver Program and The Medication Access and Training Expansion (MATE) Act which required all practitioners to have at least 8 hours of MOUD education.

The DATA-Waiver Program required prescriber education through the Substance Abuse and Mental Health Services Administration (SAMHSA) and subsequent assignment of the "X DEA number" by DEA to prescribe buprenorphine for OUD.

No X number is required, no note of pain or OUD is required to fill a prescription for buprenorphine going forward

On January 12, 2023, the DEA provided a Dear Registrant letter

More from the DEA

March 1, 2023 – Proposed Rule to eliminate prescribing of controlled substances (excluding buprenorphine) without an in-person medical evaluation, i.e., telemedicine. Extended to November 11, 2024

July 21, 2023 - Final Rule: Partial Filling of Prescriptions for CII's (no change – still not able to do this in SD)

July 27, 2023 – Final Rule: Transfer of Electronic Prescriptions for Schedules II-V Between Pharmacies for Initial Filling (no substantive change, since no one can do this without the software)

August 8, 2023- Final Rule: Dispensing of Narcotic Drugs To Relieve Acute Withdrawal Symptoms of Opioid Use Disorder

COVID PHE Ends – May 11, 2023

- Access to vaccines, Paxlovid, and Lagevrio should not be affected, only they generally won't be at no cost
- Existing EUA's remain in effect and FDA may continue to authorize
- Medicare and Medicaid telehealth flexibilities will not be affected
- Access to buprenorphine in OTPs is not affected w/exam
- Access to expanded methadone take home doses from OTP not affected
- Coverage for COVID-19 testing will change – no more free OTC tests – unless USG decides to distribute from strategic stockpile, Medicaid will cover until Sept 30, 2024, some insurances may cover
- Lab results no longer need to be sent to CDC

For much more information and a copy of table, see

https://www.kff.org/coronavirus-covid-19/issue-brief/what-happens-when-covid-19-emergency-declarations-end-implications-for-coverage-costs-and-access/

last accessed 03/03/2023

Liability Immunity to Administer Medical Countermeasures	
Description	**Expiration**
Liability immunity has been extended to providers based on the PREP Act emergency declaration to allow for greater delivery of and access to medical countermeasures. For example, liability immunity has been extended to: •pharmacists and pharmacy interns to administer COVID-19 vaccines (and other immunizations) to children between the ages of 3 and 18, pre-empting any state law that had age limits •healthcare providers licensed in one state to vaccinate against COVID-19 in any state •physicians, registered nurses, and practical nurses whose licenses expired within the past five years to administer COVID-19 vaccines in any state	End of PREP Act declaration specified duration: October 1, 2024 (with some exceptions, e.g., manufacturers have an additional 12 months to dispose of covered countermeasures and for others to cease administration and use)

Donated Drug Redispensing Program

- Law passed 2022 Legislature – SDCL Chapter 34-20H entitled "REDISTRIBUTION OF DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES"
- Rules approved November 1, 2022, and became effective November 27, 2022 – and are in ARSD 20:51:35
- Allows pharmacies to take back certain medications from patients or family
- Which pharmacies can participate? Complete Form
- Requirement for pharmacist to inspect all products to ensure sealed and in date
- No CS, REMS Drugs, Temperature sensitive drugs

Donated Drug Redispensing Program

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737
Fax: 605-362-2738
Website: www.pharmacy.sd.gov
Email: pharmacyboard@state.sd.us

/ersion 1 5.3.23

DONATED DRUG AND MEDICAL SUPPLY REDISPENSING PROGRAM
PARTICIPATING PHARMACY NOTICE OF INTENT TO PARTICIPATE

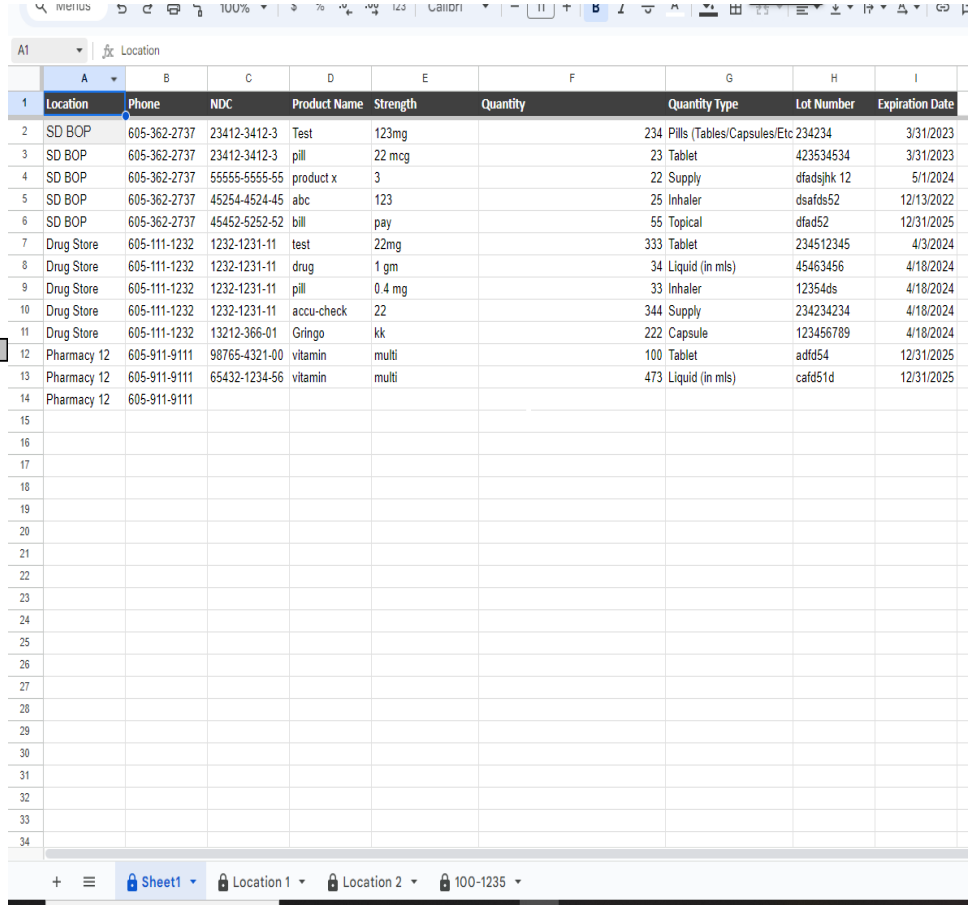
- Completion of this form meets the requirements of SD Board of Pharmacy to rule: ARSD 20:51:35:04(1) Donated drug and medical supply redispensing program
- Questions about completion of this form may be directed to 605-362-2737.
- Complete form and submit to the SD Board of Pharmacy Office, Fax- 605-362-2738, or Email pharmacyboard@state.sd.us

PHARMACY INFORMATION

Name – Pharmacy or Medical Facility Receiving Donation		SD Pharmacy License # (xxx-xxxx)
Pharmacy Address	Pharmacy City	Pharmacy Phone Number
Pharmacist-in-Charge Name	PIC SD License #	

- I attest that medication or medical supply will be stored as recommended by the manufacturer
- I attest that the pharmacy will comply with SDCL 34-20H and ARSD 20:51:35
- I attest that any issue with compliance of the program could result in being removed from the program

Date Submitted



A1 | Location

	A	B	C	D	E	F	G	H	I
1	Location	Phone	NDC	Product Name	Strength	Quantity	Quantity Type	Lot Number	Expiration Date
2	SD BOP	605-362-2737	23412-3412-3	Test	123mg	234	Pills (Tables/Capsules/Etc	234234	3/31/2023
3	SD BOP	605-362-2737	23412-3412-3	pill	22 mcg	23	Tablet	423534534	3/31/2023
4	SD BOP	605-362-2737	55555-5555-55	product x	3	22	Supply	dfadsjhk 12	5/1/2024
5	SD BOP	605-362-2737	45254-4524-45	abc	123	25	Inhaler	dsafds52	12/13/2022
6	SD BOP	605-362-2737	45452-5252-52	bill	pay	55	Topical	dfad52	12/31/2025
7	Drug Store	605-111-1232	1232-1231-11	test	22mg	333	Tablet	234512345	4/3/2024
8	Drug Store	605-111-1232	1232-1231-11	drug	1 gm	34	Liquid (in mls)	45463456	4/18/2024
9	Drug Store	605-111-1232	1232-1231-11	pill	0.4 mg	33	Inhaler	12354ds	4/18/2024
10	Drug Store	605-111-1232	1232-1231-11	accu-check	22	344	Supply	234234234	4/18/2024
11	Drug Store	605-111-1232	13212-366-01	Gringo	kk	222	Capsule	123456789	4/18/2024
12	Pharmacy 12	605-911-9111	98765-4321-00	vitamin	multi	100	Tablet	adfd54	12/31/2025
13	Pharmacy 12	605-911-9111	65432-1234-56	vitamin	multi	473	Liquid (in mls)	cafd51d	12/31/2025
14	Pharmacy 12	605-911-9111							

Sheet1 | Location 1 | Location 2 | 100-1235

Donated Drug Redispensing Program

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737
Fax: 605-362-2738
Website: www.pharmacy.sd.gov
Email: pharmacyboard@state.sd.us

Version 1 5.3.23

DONATED PRESCRIPTION DRUG AND MEDICAL SUPPLY REDISPENSING PROGRAM
DISPENSING/RECIPIENT RECORD

- Completion of this form meets the requirements of SD Board of Pharmacy: ARSD 20:51:35:06 Donated Prescription Drug and Medical Supply Redispensing Program
- Questions about completion of this form may be directed to 605-362-2737.

Name – Recipient	Date Dispensed
Processing Fee (if applicable) Not to Exceed $25.00: $	
Name – Medication	
Medication Strength	Expiration Date	Quantity Dispensed
NDC	Lot Number

- I understand that the medication or supply I am receiving has been donated and has potentially been stored in a non-controlled environment.
- I understand that the pharmacy, pharmacist, and manufacturer cannot be held liable for problems with this medication that has been accepted for donation and dispensed in good faith.
- I understand that the pharmacy is providing the medication free-of-charge and that I will not be charged, nor will my insurance be charged any amount for this specific fill; however, I may be charged a processing or mailing fee pursuant to ARSD 20:51:35:11.
- I understand that this is a one-time transaction dependent on the supply of donated inventory, that there is no guarantee or expectation by the pharmacy to provide a subsequent fill free of charge.

I understand that I may request a copy of this form for my personal records.

SIGNATURE – Recipient Date Signed

SIGNATURE – Dispensing Pharmacist Date Signed

Version 1 5.3.23

DONATED PRESCRIPTION DRUG AND MEDICAL SUPPLY REDISPENSING PROGRAM
DONATION RECORD

- Completion of this form meets the requirements of SD Board of Pharmacy: ARSD 20:51:35:05(3) Donated Prescription Drug and Medical Supply Redispensing Program
- Questions about completion of this form may be directed to 605-362-2737.

DONATION INFORMATION

Name – Donor (print or type) Patient name first, then donor name (if donor is not patient).	Date Donated
Donor Address	Donor Phone Number	SD Professional License # (if applicable)
Name – Participating Pharmacy or Medical Facility Receiving Donation	
Name – Medication (legend) or Medical Supply	
Medication Strength	Expiration Date	Quantity Donated
NDC	Lot Number	Original Dispense Date

- I attest that the above name medication or medical supply was stored as recommended by the manufacturer and has not been tampered with.
- I understand that I will not be reimbursed or otherwise seek financial compensation from the receiving pharmacy for my donation.
- Further, I understand that the pharmacy will neither reverse the original prescription claim, nor reimburse the third party for the claim upon acceptance of the donation. The participating pharmacy cannot charge recipient or recipients insurance for the drug or medical supply.
- I understand that the drug or medical supply I am donating cannot be returned to me, it will either be re-dispensed to a different patient or destroyed upon expiration.

SIGNATURE-Donor Date Signed

Internal Use Only – To be filled out by receiving pharmacist. Does the donation meet eligibility requirements?

Is/does the drug/supply: (all must be checked to accept)

- ☐ Legend drug
- ☐ Non-controlled substance
- ☐ Room temperature stable (non-refrigerated)?
- ☐ In original, unopened, sealed or tamper-evident packaging?
- ☐ Contain lot number & expiration date?
- ☐ Drug does not have a REMs program (i.e. Thalomid or isotretinoin analog)?
- ☐ In good dating (original dispense date must be within previous 9 months and expiration date on package must be greater than 3 months from today's date (unless it can be used prior to 3 months)?

_____

- ☐ Donation Accepted
- ☐ Rejected – did not meet criteria. Product destroyed or returned.

Pharmacist Signature: _____ Date: _____

Donated Drug Redispensing Program

1. Sign up to participate as a pharmacy; The pharmacy will then get a link and password for the Google.Sheet.
2. Complete form for receipt of medication and enter into the Google.Sheet under your pharmacy. Verify the product appears to have been stored in an appropriate manner. Store the product in the pharmacy in a specified area, not to be mixed with your other medications.
3. Prescription obtained for a medication or a request from a pharmacy to ship to them for processing.
4. Complete dispensing form and have patient sign attestation.
5. Use Optum information that will be provided to submit information and zero out cost.
6. Pharmacy may charge up to $25 handling fee for processing/mailing.
7. Remove product from list on your Google.Sheet.
8. Maintain records in pharmacy for 2 years from dispensing.

USP Announcements

- USP has published updated USP <795> and USP <797> Chapters.
- These chapters were published on 11/1/2022
- The chapters will be enforceable on 11/1/2023
- USP now requires all users to have a subscription to access the new compounding chapters

USP <795> Nonsterile Compounding

- Changes in BUDs
- Based on water activity (a_w), USP <1112> Application of Water Activity Determination to Nonsterile pharmaceutical Products
- Nonpreserved aqueous dosage forms ($a_w \geq 0.6$) = BUD of 14 days refrigerated
- Preserved aqueous dosage forms ($a_w \geq 0.6$) = BUD of 35 days room temp or refrigerated
- Oral liquids nonaqueous ($a_w < 0.6$) = BUD of 90 days room temp or refrigerated
- Other nonaqueous dosage forms ($a_w < 0.6$) = BUD of 180 days room temp or refrigerated

USP <795> Nonsterile Compounding

- Training must be documented for all persons compounding
- Initial Training and Every 12 months thereafter
- Training to include the minimum of:
  - Hand hygiene
  - Garbing
  - Cleaning and Sanitizing
  - Handling and transporting components and finished products
  - Measuring and mixing
  - Proper use of equipment and devices
  - Documentation

USP <797> Sterile Compounding

- BUD will change on the environment the product was compounded in.
- Category 1: ISO 5 PEC not within a full clean room suite
  - 12-hour BUD at Controlled Room Temp
  - 24-hour BUD Refrigerated
- Category 2: ISO 5 PEC in a full clean room suite with ISO 7 Buffer room and ISO 7 or 8 Ante room, starting with all sterile products.
  - 4 Day BUD at Controlled Room Temp
  - 10 Day BUD Refrigerated
  - 45 Day BUD Frozen
- Category 3: Full clean room suite and full category 3 testing performed with or without terminal sterilization.

USP <797> Sterile Compounding

New term- Restricted-access barrier system (RABS), which is a CAI or a CACI

This PEC alone will no longer provide full Category 2 BUD. Products compounded in a RABS outside of a full clean room suite will have Category 1 BUD.

- 12-hour BUD at Controlled Room Temp
- 24-hour BUD Refrigerated

USP <797> Sterile Compounding

- Training
- Initial training-
  - Competency of Core Skills
  - 3 gloved fingertip tests with 0 CFU
  - Media Fill Test and gloved fingertip test with ≤ 3 CFU
- Annual training-
  - Competency of Core Skills
- Continued Testing- GARB and gloved fingertip testing and media fill testing
  - Category 1 and 2 compounding retest every 6 months
  - Category 3 compounding retest every 3 months
  - Overseeing staff not compounding must retest every 12 months

USP <800> Hazardous Drugs

- Official Date of Enforcement: 11/1/2023
- 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 2016 list

National Institute for Occupational Safety & Health (NIOSH)

- Under Center for Disease Control (CDC)
- Entity must maintain a list of HD antineoplastics and other HDs used in healthcare
- NIOSH list is generally revised and published every 2 years
- NIOSH 2016 document is available https://www.federalregister.gov/documents/2016/10/03/2016-23719/niosh-list-of-antineoplastic-and-other-hazardous-drugs-in-healthcare-settings-2016
- New list should be coming

Diversion in Pharmacy Setting

What to do if you discover diversion:

- Contact DEA
- Contact DOH
- Contact BOP
- Complete a full investigation
- Complete a DEA form 106 if any diversion discovered.

Diversion Continued

- Story 1-pharmacy employee and C3 and C4 medications
- Story 2- staff replacing controlled substance in unit dose container
- Story 3- clinic staff calling in prescriptions for friends and family
- Story 4- ordering meds and not putting into inventory
- Story 5- access to meds by off duty staff

SD PDMP Update

Program FYIs and Reminders

Users can add/update this information within your user account:

- Mobile phone number for text message password resets
- Employer information
- User email address

Pharmacists are the only pharmacy staff allowed PDMP access

EHR/Pharmacy System/PDMP integrations require an active PDMP account

Consolidation of patient groups can be completed by PDMP staff

Why is my search not finding my patient?

Most common = Patient using a different name at the pharmacy

First and last names entered in reverse fields in web portal searches

Date of birth incorrect; i.e., today's date entered

Dispenser data submission error; PDMP staff works with dispenser to resolve

PDMPs – Same *but* Different

18 states house the PDMP in their State Board of Pharmacy – including all our neighboring states except NE

Most collect CII, CIII, CIV, and CV; 31 also collect 'drugs of concern' including unscheduled gabapentin; all prescription drugs by NE and others considering

Naloxone – states have begun tracking prescribing, dispensing, and/or administration; 22 PDMPs report dispensings and 16 report administrations

Medical Marijuana – 13 states have enacted laws ranging from including patient registry id card info to requiring dispensaries to report the dispensing of medical marijuana

Prescriber mandates – 45 PDMPs mandate enrollment and all but SD and KS mandate use

LE Access – About a 50/50 split of PDMPs that require a court order, search warrant, or subpoena and those that just require an active investigation, probable cause, or proper need

Current Program Focus

Data Submission Compliance

Data Quality

- Inspection Audit Project – addresses errors in the database
- Error Report Notification Rollout – addresses errors not in the database

Ongoing efforts for budget approval of our BJA FY 21 Harold Rogers PDMP Grant

Data Submission

Dispensers must submit data at least every 24 hours; data is available for search for 3 years

Exceptions are:

- Dispenser is a medical facility that dispenses for inpatient care
- Practitioner administration
- Veterinarians
- Waiver granted by the Board of Pharmacy

Pharmacists are key stakeholders as both PDMP users and gatekeepers of the data submitted

Data Quality

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

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

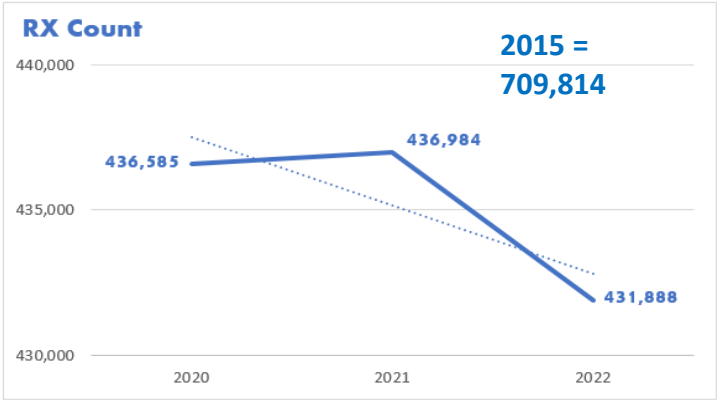
Required data elements can be found in ARSD 20:51:32:03

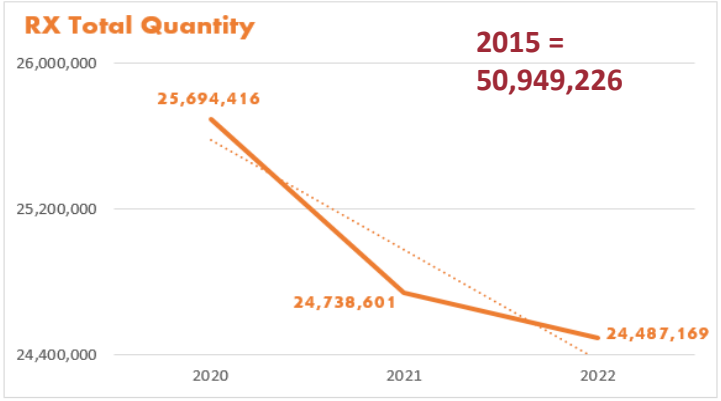
PICs are responsible for accurate and complete data submissions

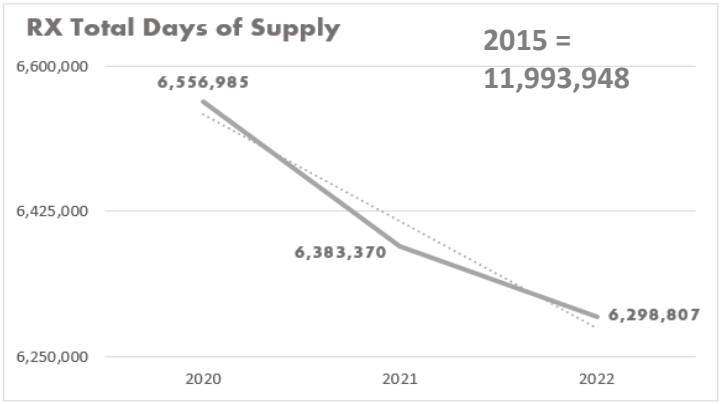
To assist PICs in error correction, we've rolled out our vendor's Error Report Notification emails and the Rx Management/Error Correction feature within PIC PMP AWARxE user accounts

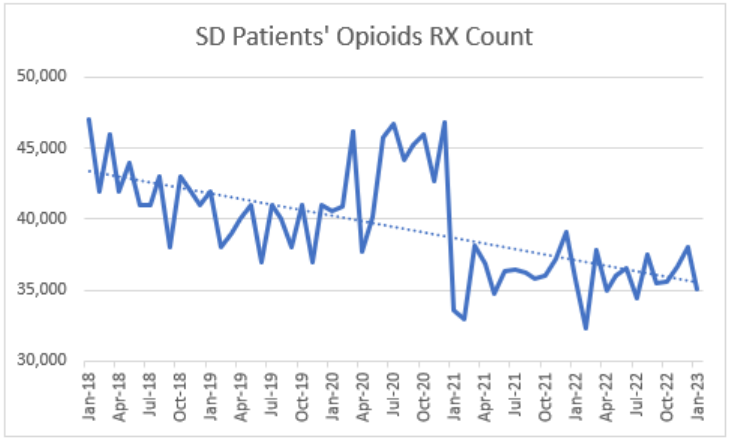
PDMP by the Numbers

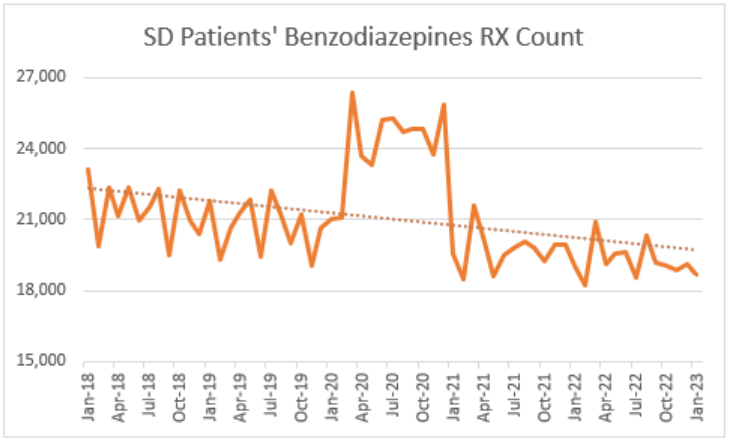
Trending SD Patients' Opioid Prescriptions

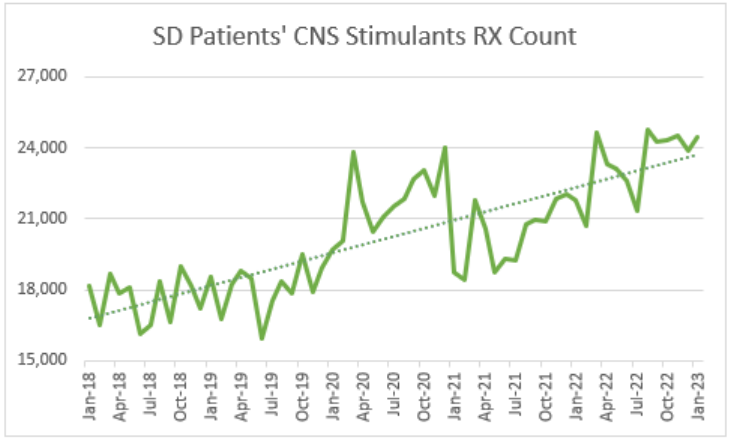




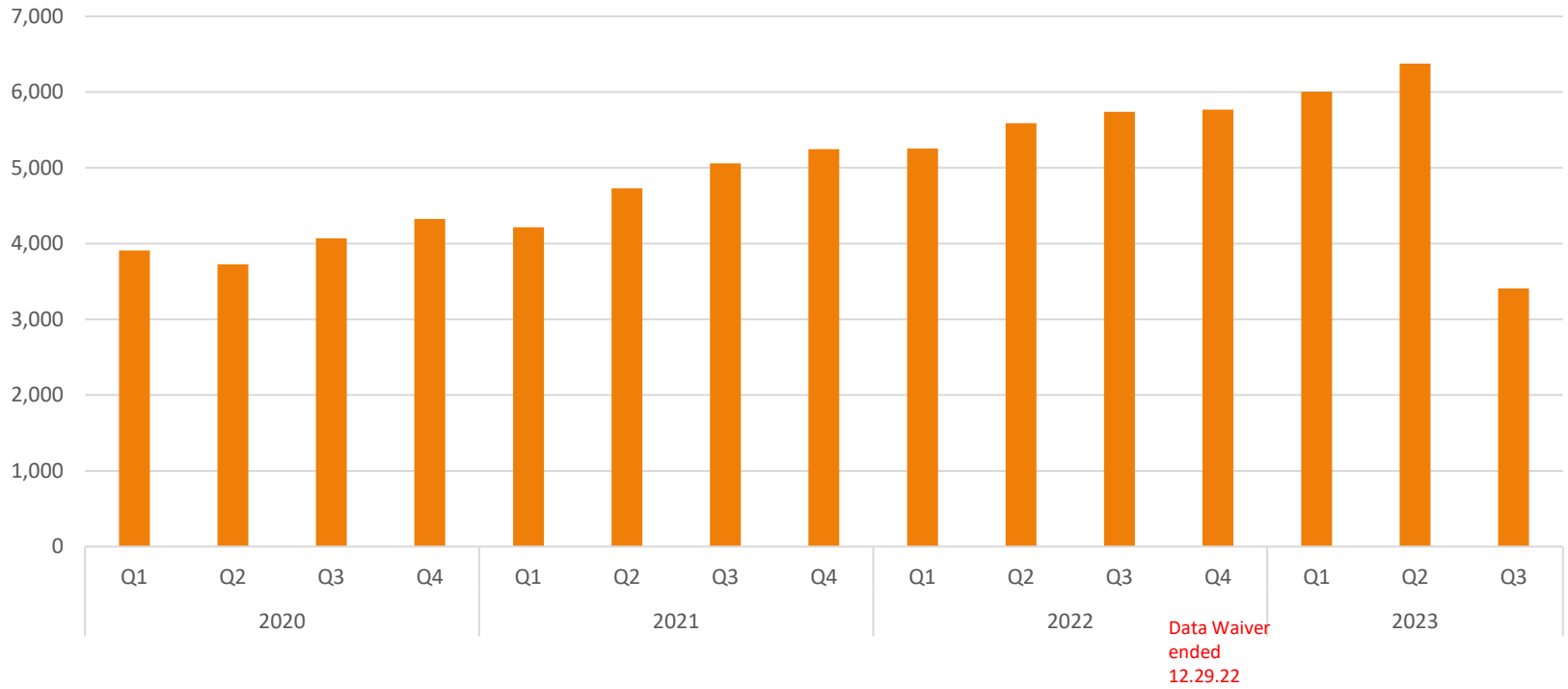



SD Patients' Opioids RX Count
50,000
45,000
40,000
35,000
30,000
Jan-18
Apr-18
Jul-18
Oct-18
Jan-19
Apr-19
Jul-19
Oct-19
Jan-20
Apr-20
Jul-20
Oct-20
Jan-21
Apr-21
Jul-21
Oct-21
Jan-22
Apr-22
Jul-22
Oct-22
Jan-23

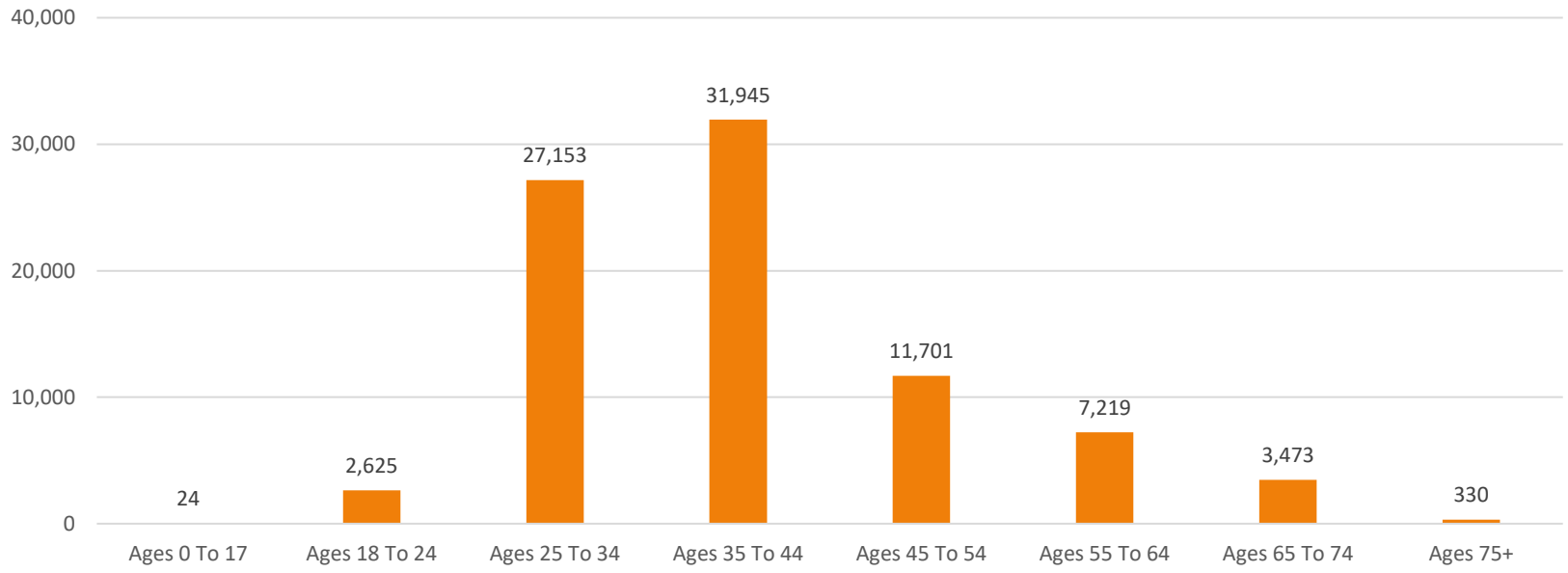

SD Patients' Benzodiazepines RX Count
27,000
24,000
21,000
18,000
15,000
Jan-18
Apr-18
Jul-18
Oct-18
Jan-19
Apr-19
Jul-19
Oct-19
Jan-20
Apr-20
Jul-20
Oct-20
Jan-21
Apr-21
Jul-21
Oct-21
Jan-22
Apr-22
Jul-22
Oct-22
Jan-23


SD Patients' CNS Stimulants RX Count
27,000
24,000
21,000
18,000
15,000
Jan-18
Apr-18
Jul-18
Oct-18
Jan-19
Apr-19
Jul-19
Oct-19
Jan-20
Apr-20
Jul-20
Oct-20
Jan-21
Apr-21
Jul-21
Oct-21
Jan-22
Apr-22
Jul-22
Oct-22
Jan-23

MOUD Buprenorphine RX Count – SD Patients by SD Prescribers *January 2020 through August 20, 2023



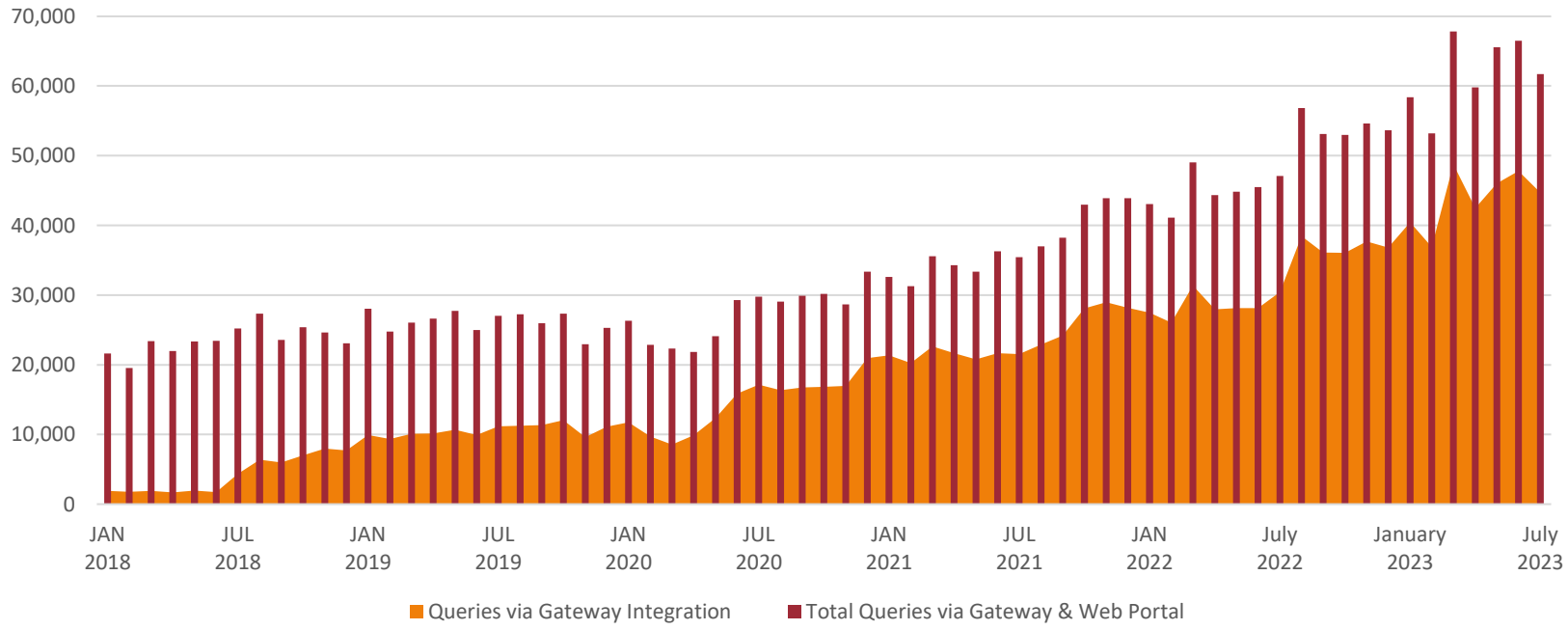
Buprenorphine MOUD RX Ct by SD Patient Age *January 2020 to August 2023



Top Ten Controlled Substances to SD Patients

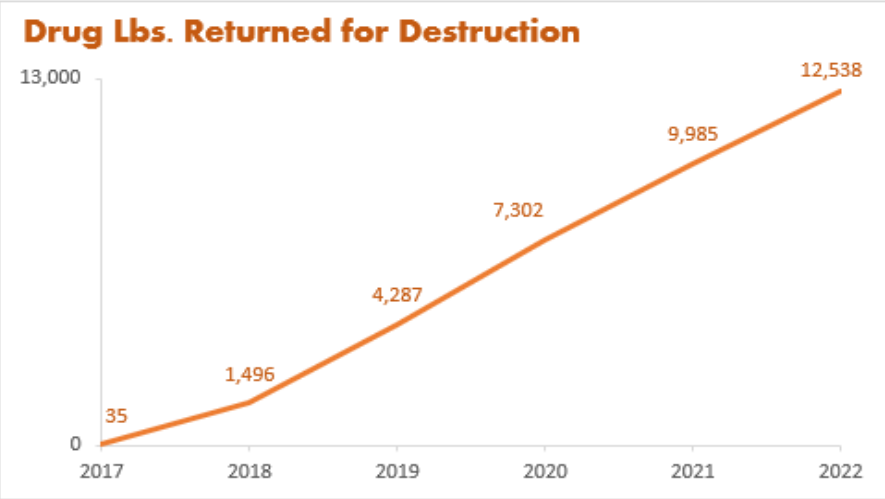
Year 2022 Top Ten Controlled Substances (CS) to SD Patients	RXs	Quantity	Days of Supply	Avg Quant/Rx	2021 Rank	2020 Rank
HYDROCODONE BITARTRATE/ACET	142,988	7,645,348	1,793,101	53	1	1
DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE SULF-ASPARTATE	112,591	4,960,521	3,339,725	44	3	3
TRAMADOL HCL	111,543	6,688,229	1,890,020	60	2	2
LORAZEPAM	75,913	3,218,030	1,664,110	42	4	4
METHYLPHENIDATE HCL	71,352	2,987,793	2,129,299	42	7	7
CLONAZEPAM	69,781	3,778,605	2,050,274	54	5	5
ZOLPIDEM TARTRATE	69,388	2,430,871	2,426,286	35	6	6
OXYCODONE HCL	52,172	2,686,596	651,153	51	8	9
ALPRAZOLAM	49,487	2,559,719	1,277,355	52	9	8
LISDEXAMFETAMINE DIMESYLATE	47,170	1,437,899	1,422,196	30	10	10

Trending PDMP Utilization by SD Prescribers & Pharmacists



PharmaDrop Drug Take-Back Program

93 receptacle sites participating located in 45 SD counties



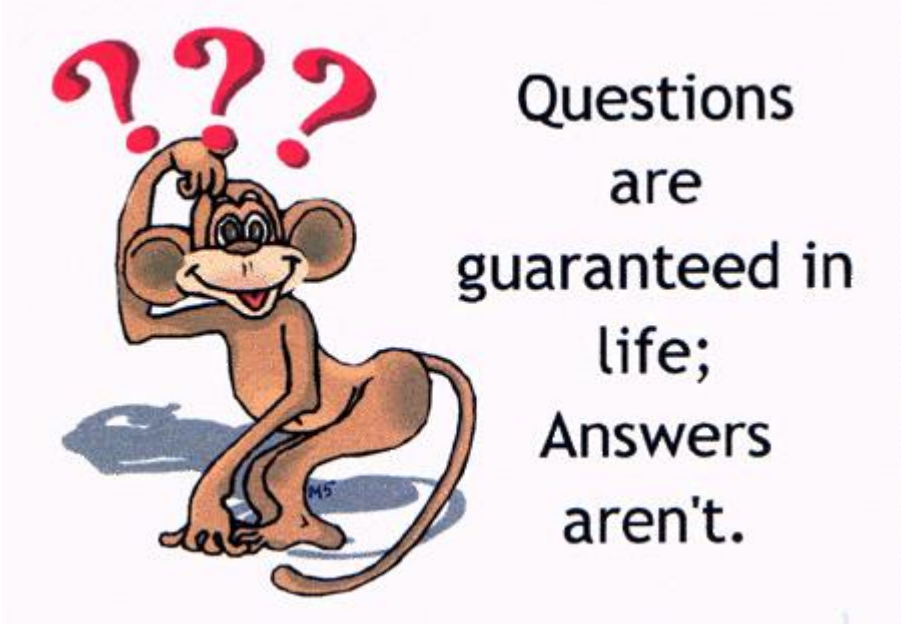
Pharmacist Post Test Questions

1. Which of the following items did the MAT Act do?
    1. Allowed all prescribers to have ability to prescribe buprenorphine without a waiver
    2. Requires all prescribers that have undergone training for opioid or other substance use disorders
    3. Allow for OTP providers to start patients on buprenorphine via Telemedicine visit without first having a face to face visit
    4. All of the above
2. What can pharmacies do to prepare for the November 27, 2023, DSCSA changes (select all that apply)?
    A. Be prepared to receive or exchange transaction information electronically.
    B. Implement systems for package level verification when needed (i.e., investigating suspicious product).
    C. Implement systems/processes to produce serialized transaction information if the FDA, a state regulator, or a trading partner requests information for an investigation.
3. A pharmacist-in-charge has the ability to correct missing data online in the PMDP.
    A. True
    B. False

Technician Post Test Questions

1. Which of the following medications can be accepted by a patient to the Donated Drug Redistribution Program assuming all are in sealed manufacturer packaging?
   A. 1 box of insulin glargine pens
   B. 90- pregabalin 150mg capsules
   C. 60- isotretinoin 40mg capsules
   D. 60- apixaban 5mg tablets
2. Pharmaceutical products should only be purchased from verified primary wholesale distributors or manufacturers who are licensed in South Dakota. This information may be found on the Board of Pharmacy verification website:
   A. True
   B. False
3. How many hours of CE is required to renew a certified technician registration with the South Dakota Board of Pharmacy annually?
   A. 12 hours
   B. 30 hours
   C. 15 hours
   D. Zero hours

QUESTIONS?



BOARD OF PHARMACY DIRECTORY

Office Phone: 605-362-2737 **Office Fax: 605-362-2738**

Kari Shanard-Koenders, R.Ph., Executive Director	kari.shanard-koenders@state.sd.us
Melissa DeNoon, R.Ph., PDMP Director	melissa.denoon@state.sd.us
Tyler Laetsch, Pharm. D., Pharmacy Inspector	tyler.laetsch@state.sd.us
Carol Smith, R.Ph., Pharmacy Inspector	carol.smith@state.sd.us
Lee Cordell, Pharm. D., Pharmacy Inspector	lee.cordell@state.sd.us
Beth Windschitl, Senior Secretary	beth.windschitl@state.sd.us
Melanie Houg, PDMP Assistant	melanie.houg@state.sd.us
Rhea Kontos, Senior Secretary	rhea.kontos@state.sd.us

PDMP Sign up and Data Access Website https://southdakota.pmpaware.net/login


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
merci
obrigado
dziękuję
bedankt
go raibh maith agat
mochchakkeram
sukriya
kop khun krap
terima kasih
감사합니다
ありがとう
arigatô
grazie
dakujem
takk
tapadh leat
спасибо
Баярлалаа
рахмат
mersi
kia ora
barka
welalin
tack
spas
dank je
misaotra
matondo
paldies
grazzi
mahalo
faafetai lava
vinaka
спасибі
blagodaram
kiitos
dankie
dhanyavad
nanni
nandri
maururu
köszönöm
hvala
gràcie
bayarlalaa
enkosi
akun
dankon
aciú
chnorakaloutioun
gratias ago
gràcies
sulpáy
taiku
хвала
asante
manana
obrigada
murakoze
tenki
djiere dieuf
tau
дякую
mamnun
chokrane
sobodi
dėkuji
mèsi
sagolun
didi madloba
najis tuke
kam sah hamnida
rahmat
tanemirt
rahmet
ευχαριστώ
xièxie
diolch
dhanyavadagalu
shukriya
mercé
мерси
trugarez