DEA ARCOS and SORS Virtual Training

November 13, 2025

1:00pm	Welcome and Opening Remarks Niketa Prince, Acting Section Chief, Liaison and Outreach
1:01pm	ARCOS Requirements and Retail Buyers Lookup Tool Colin Clark, Senior Program Analyst, DOI
1:30pm	National Drug Code (NDC) Numbers June Howard, Unit Chief, DOI
1:50pm	Overview of SORS and Key Red Flags Virginia McKenna, Staff Coordinator, DOI

(Insert vimeo link info)

Disclaimer

- The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

- This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

- We have no financial relationship to disclose.

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ARCOS Reporting Overview

ARCOS REPORTING

- **Required to report to ARCOS if registered as:**
  - **Manufacturer**
  - **Distributor**
  - **Reverse Distributor**

ARCOS REPORTING

- **Reportable activities include:**
  - **Any change to inventory of ARCOS reportable drugs, including:**

    - Purchases
    - Sales
    - Theft/Loss
    - Destruction
    - Seizures
    - Returns

- **Reportable activities include:**
  - **Manufacturing activities involving ARCOS reportable drugs, including:**

    - Creation of new substances
    - Creation of preparations in another schedule
    - Spillage
    - Samples pulled for testing
    - Recovered waste

ARCOS REPORTING

- **Also reportable:**

  - **Inventory of ARCOS reportable drugs on hand at close of business Dec. 31st**

  - **Inventory of new ARCOS reportable drugs on hand at time of schedule change**

ARCOS REPORTING

❖ Also reportable:

- No inventory of ARCOS reportable drugs on hand at close of business Dec. 31st

- No ARCOS reportable activity during a reporting period

- **ARCOS reportable drugs are:**
  - **All Schedule 1**
  - **All Schedule 2**
  - **Schedule 3 narcotic & GHB**
  - **Schedule 3 & 4 select psychotropics in 21 C.F.R. § 1304.33(d) – manufacturers only**

❖ Examples of ARCOS reportable drugs:

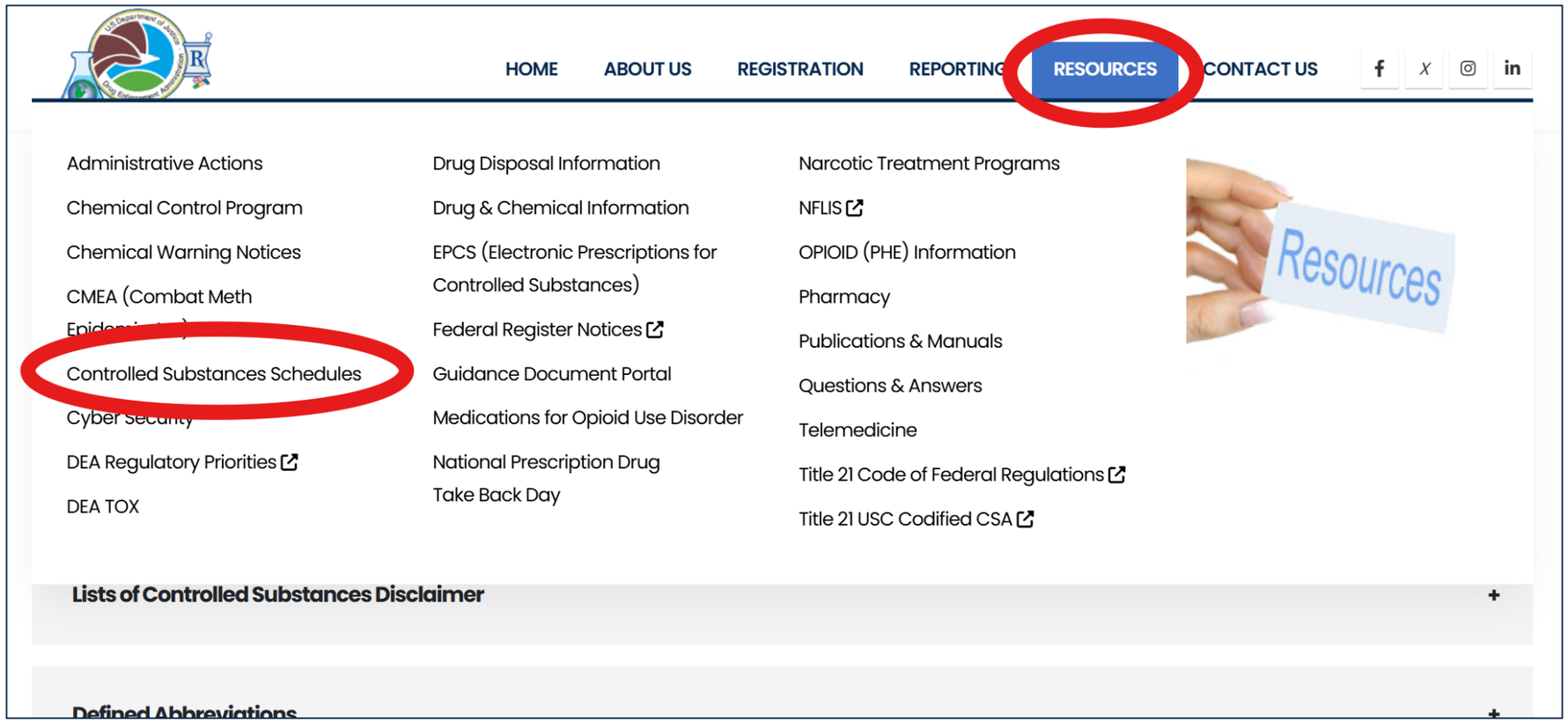
- Schedule 1 = heroin, marihuana, peyote

- Schedule 2 = oxycodone, amphetamine

- Schedule 3 narcotic = buprenorphine, codeine

ARCOS REPORTING

❖ Information on drug schedules:



ARCOS REPORTING

❖ ARCOS reporting frequencies:

- Quarterly or monthly
  see April 2025 letter from Deputy Assistant Administrator regarding request for monthly reporting

- Reports always due 15th of the month following the end of the reporting period

❖ ARCOS reporting frequencies:

- Manufacturing activities must be reported either per reporting period or totaled up at the end of the year

ARCOS REPORTING

❖ ARCOS reporting frequencies:

- End of year ARCOS reportable inventory must be submitted by January 15th

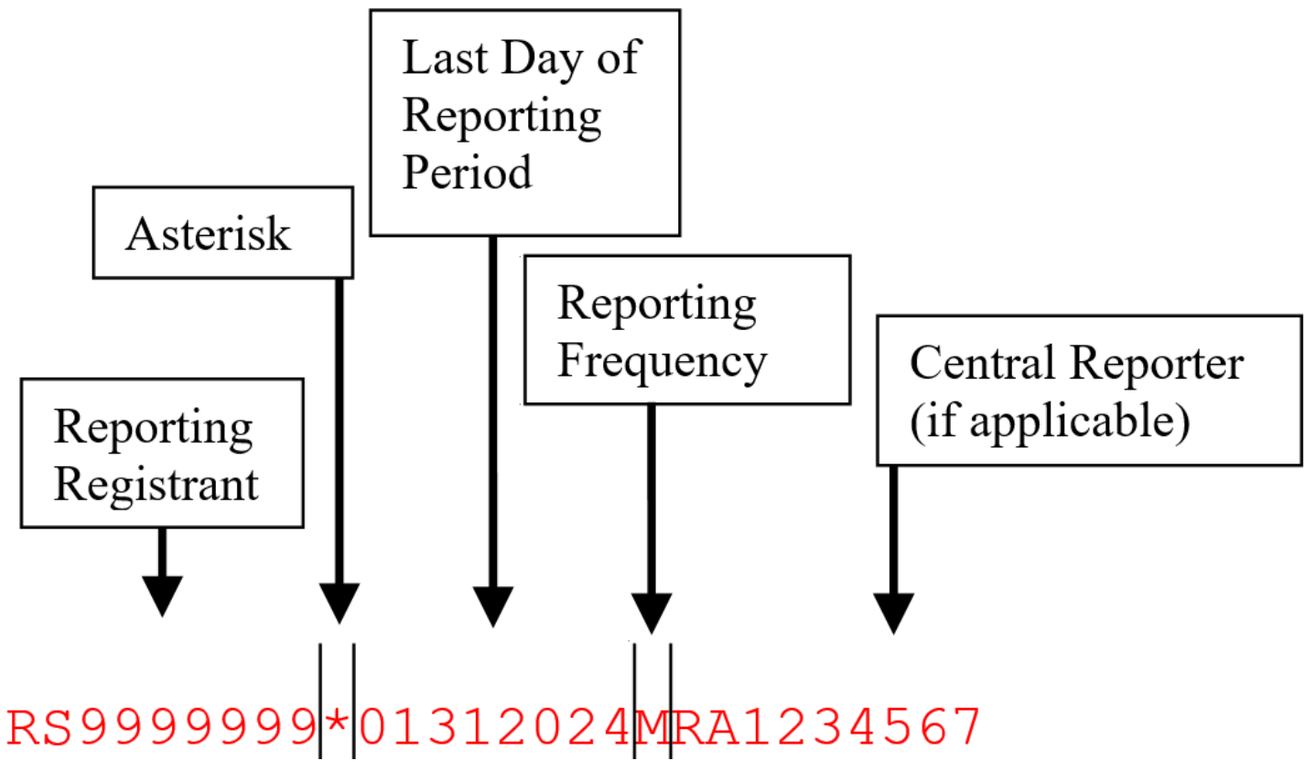
- Only change reporting frequency at the end of a quarter

- **ARCOS reporting methods:**
  - **Text file upload (Electronic Data Interchange & ARCOS Online)**
  - **Direct entry into web interface (ARCOS Online)**
  - **User manuals available on respective sites**

❖ Text file – Header Record:

FIELD	POSITION (TEXT FILE)	SAMPLE DATA
REPORTING REGISTRANT	1 - 9	RS9999999
ASTERISK	10	*
LAST DAY OF REPORTING PERIOD	11 - 18	01312024
REPORTING FREQUENCY	19	M
CENTRAL REPORTER	20 - 28	RA1234567

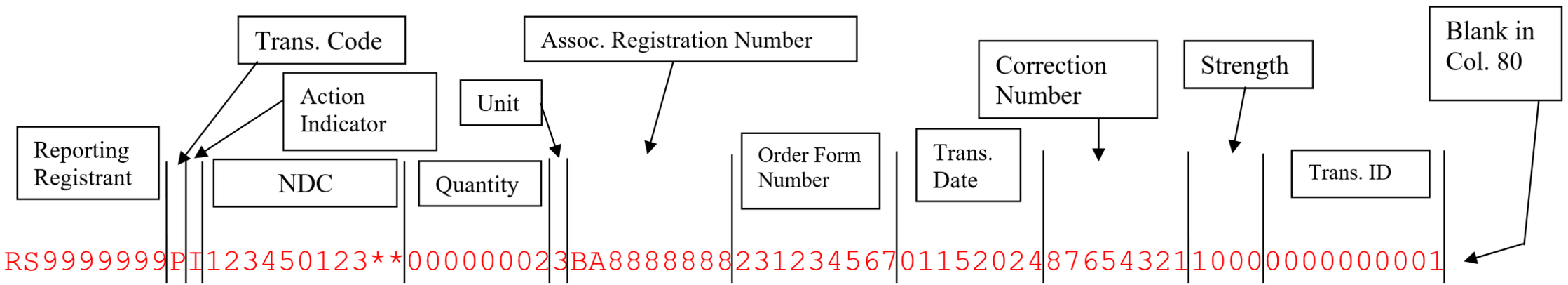
❖ Text file – Header Record:



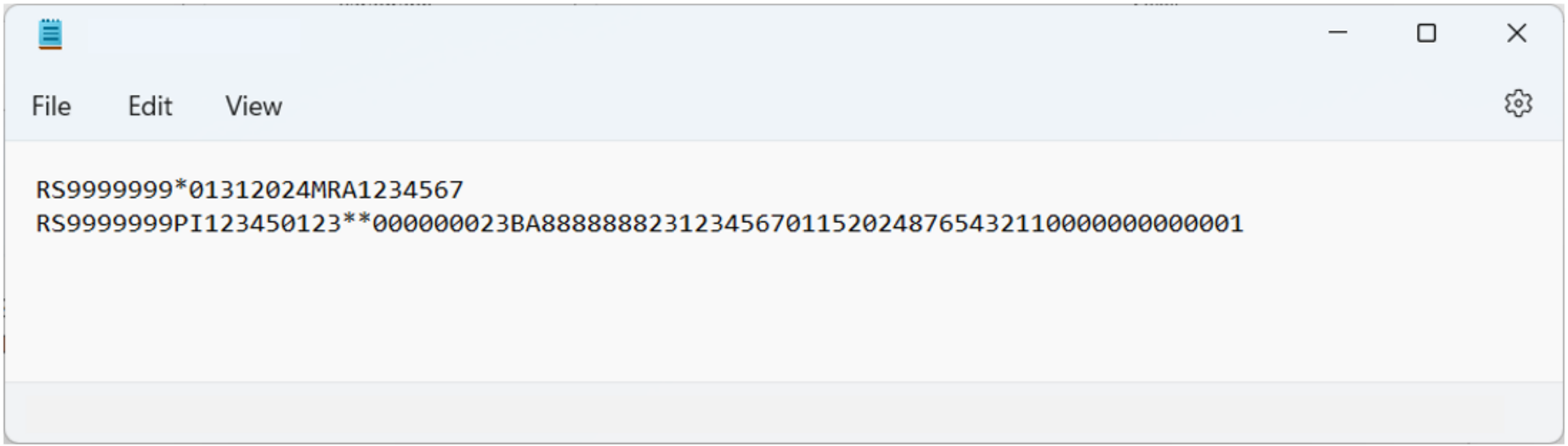
❖ Text file – Transaction Record:

FIELD	POSITION (TEXT FILE)	SAMPLE DATA
REPORTING REGISTRANT	1 - 9	RS9999999
TRANSACTION CODE	10	P
ACTION INDICATOR	11	I
NATIONAL DRUG CODE	12 - 22	123450123**
QUANTITY	23 - 30	00000002
UNIT	31	3
ASSOCIATE REGISTRATION	32 - 40	BA8888888
ORDER FORM NUMBER	41 - 49	231234567
TRANSACTION DATE	50 - 57	01152024
CORRECTION NUMBER	58 - 65	87654321
STRENGTH	66 - 69	1000
TRANSACTION IDENTIFIER	70 - 79	0000000001
(BLANK)	80	

❖ Text file – Transaction Record:

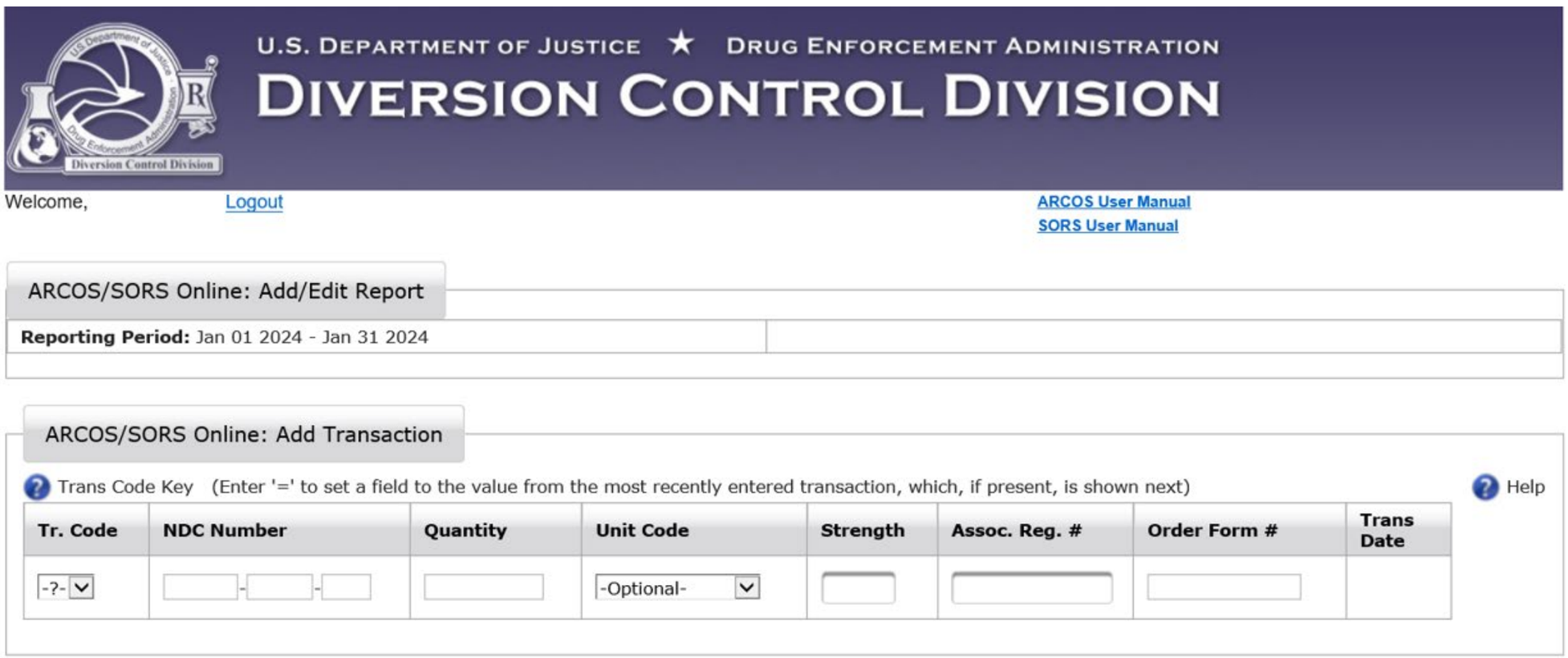


❖ Text file – Header + Transaction:



ARCOS REPORTING

❖ Direct entry/web interface:



- **Update on ARCOS Registrant Handbook:**

  - **Online 1997 version is no longer available**

  - **Revised Handbook is under review**

❖ ARCOS vs. CSOS

- The electronic ordering of controlled substances (CSOS) does not satisfy the requirements of 21 C.F.R. § 1304.33 (ARCOS)

- ARCOS and CSOS are two separate systems

Retail Buyer Lookup Tool

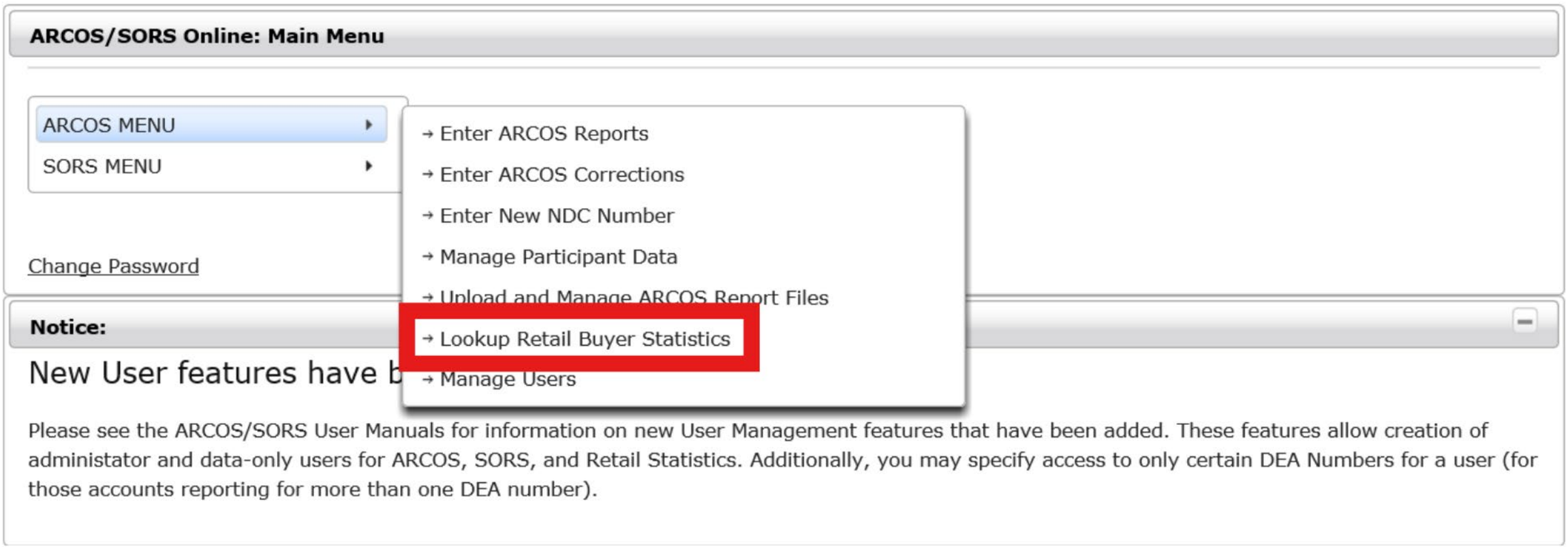
RETAIL BUYER LOOKUP TOOL

- **Research potential customers before supplying controlled substances**

- **Industry requested this feature to help improve their due diligence processes.**

RETAIL BUYER LOOKUP TOOL

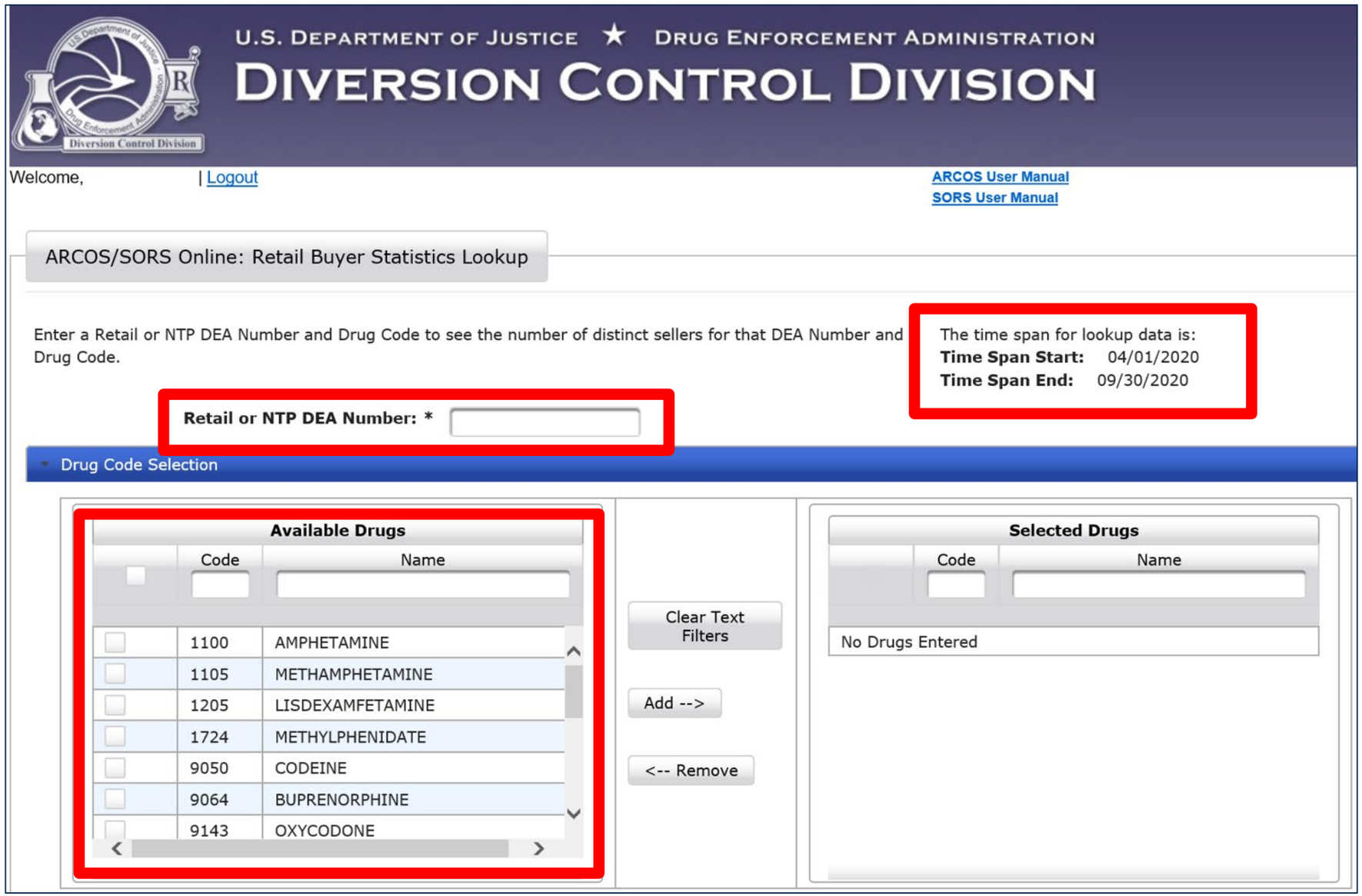
❖ Available in the ARCOS Online system:



RETAIL BUYER LOOKUP TOOL

- Enter registration number of potential customer and select drugs on left-hand side of the screen
- Timeframe for data is in the upper right-hand corner of the screen and covers a rolling 6-month period

RETAIL BUYER LOOKUP TOOL



RETAIL BUYER LOOKUP TOOL

- **Results show the number of suppliers for that registrant and the number of grams (liquids/powders) and dosage units ordered**

Drug	Supplier #	Grams	Dosage Units
Drug: 1100 - AMPHETAMINE	1		2050
	Total		**2050**
Drug: 1205 - LISDEXAMFETAMINE	1		1700
	Total		**1700**
Drug: 1724 - METHYLPHENIDATE	1		4100
	Total		**4100**
Drug: 9050 - CODEINE	1		200
	Total		**200**
Drug: 9064 - BUPRENORPHINE	1		478
	2		28
	3		20
	Total		**526**
Drug: 9143 - OXYCODONE	1	2.2274	25000

RETAIL BUYER LOOKUP TOOL

- **Registration types available for look-up:**

  - **Pharmacies, Hospitals, Practitioners, Mid-Level Practitioners, Teaching Institutions**

  - **Narcotic Treatment Programs**

  - **Importers, Exporters, Analytical Labs**

RETAIL BUYER LOOKUP TOOL

- **Registration types *not* available for look-up:**
  - **Manufacturers, Distributors, Reverse Distributors**
  - **Currently no plans to make this information available**

National Drug Codes (NDCs)

NATIONAL DRUG CODES (NDCS)

- **The Labeler code identifies the firm that owns the product; Product Code identifies the strength of the controlled substance; Package Code identifies the size of the package:**

NATIONAL DRUG CODES (NDCS)

- Labeler codes with their associated firm can be found on FDA's website

NATIONAL DRUG CODES (NDCS)

- For ARCOS reporting, NDCs must be in a 5-digit labeler code, 4-digit product code, and 2-digit package code sequence

- A leading zero must be added to the beginning of the section that falls short of the required number of digits

NATIONAL DRUG CODES (NDCS)

- **Formatting changes may be necessary *if* and *when* FDA moves to a 6-digit labeler code**

- **Federal Register: 87 FR 44038, July 25, 2022**

NATIONAL DRUG CODES (NDCS)

- **NDCs are not automatically added to the ARCOS NDC dictionary**

- **Submit with supporting documentation through the ARCOS Online system or by email (ARCOS_Unit@dea.gov)**

NATIONAL DRUG CODES (NDCS)

- ARCOS input team member will reach out with any questions or to provide notification that the addition is complete
- Generic NDCs can be requested when an NDC is not assigned to a product

NDC FORMATTING EXAMPLES:

12345 – 123 – 01

12345 – 0123 – 01

1234 – 1234 – 01

01234 – 1234 – 01

NDC FORMATTING EXAMPLES:

12345 – 1234 – 1

12345 – 1234 – 01

NATIONAL DRUG CODES (NDCS)

- **Reporting quantities using the Quantity, Unit, and Strength fields depend on the NDC**

  - **NDC ending ** → Represents bulk dosage units; bulk liquid; bulk powder or raw material**

  - **NDC ending 00 to 99 → Represents a finished package**

NATIONAL DRUG CODES (NDCS)

- NDC ends in ** and represents bulk dosage units:
  - Quantity = number of individual units
  - Unit = blank; “D” to multiply by 12 or “K” to multiply by 1,000
  - Strength = blank

- NDC ends in ** and represents bulk liquid:
  - Quantity = number of milliliters or liters
  - Unit = “5” for milliliters; “6” for liters
  - Strength = “0001” (0.1%) to “1050” (105%) purity

NATIONAL DRUG CODES (NDCS)

- NDC ends in ** and represents bulk powder or raw material:
  - Quantity = number of micrograms, milligrams, grams, or kilograms
  - Unit = “1” for micrograms; “2” for milligrams; “3” for grams; “4” for kilograms
  - Strength = “0001” (0.1%) to “1050” (105%) purity

NATIONAL DRUG CODES (NDCS)

- **NDC ends in 00 to 99 and represents a finished package:**
  - **Quantity = number of packages**
  - **Unit = blank; “D” to multiply by 12 or “K” to multiply by 1,000**
  - **Strength = blank *or* – with a Quantity of 1 – indicate the percentage of the original package size, i.e., a partial package**

Suspicious Orders Reporting (SORS)

SUSPICIOUS ORDERS REPORTING (SORS)

- **The SUPPORT Act requires *all* DEA registrants that *distribute* controlled substances report suspicious orders to DEA (21 U.S.C. § 832)**

- **Online reporting is accessible through the ARCOS/SORS Online system**

❖ ARCOS/SORS Online system:

- ARCOS reportable registrants will automatically be given access

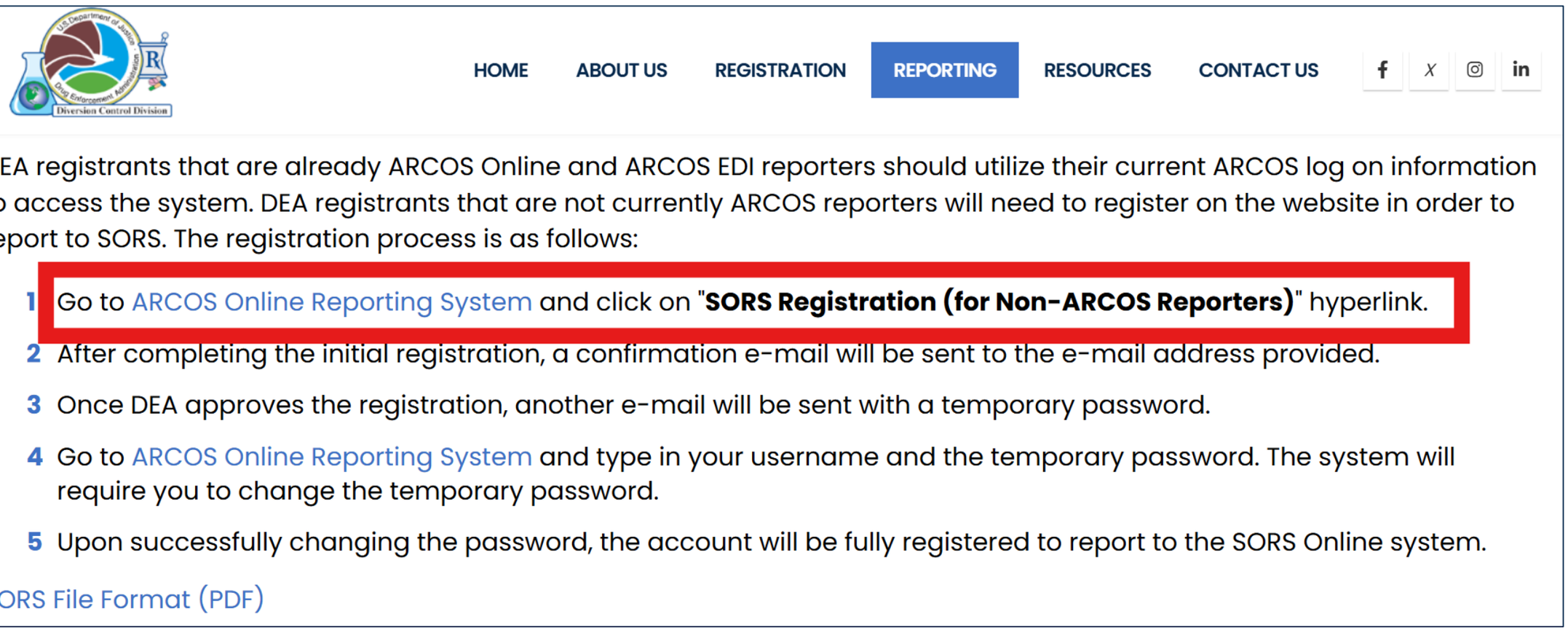
- Non-ARCOS reportable registrants must request access

SUSPICIOUS ORDERS REPORTING (SORS)

❖ ARCOS/SORS Online system:

SUSPICIOUS ORDERS REPORTING (SORS)

❖ ARCOS/SORS Online system:



HOME | ABOUT US | REGISTRATION | REPORTING | RESOURCES | CONTACT US

DEA registrants that are already ARCOS Online and ARCOS EDI reporters should utilize their current ARCOS log on information to access the system. DEA registrants that are not currently ARCOS reporters will need to register on the website in order to report to SORS. The registration process is as follows:

1. Go to ARCOS Online Reporting System and click on "**SORS Registration (for Non-ARCOS Reporters)**" hyperlink.
2. After completing the initial registration, a confirmation e-mail will be sent to the e-mail address provided.
3. Once DEA approves the registration, another e-mail will be sent with a temporary password.
4. Go to ARCOS Online Reporting System and type in your username and the temporary password. The system will require you to change the temporary password.
5. Upon successfully changing the password, the account will be fully registered to report to the SORS Online system.

SORS File Format (PDF)

SUPPORT for Patients & Communities Act of 2018
SUPPORT ACT

The Substance-Use Disorder Prevention that Promotes Opioid Treatment and Recovery (SUPPORT) for Patients and communities Act.

In 2018, Congress passed the SUPPORT Act in response to the opioid crisis which plagued America. As part of the Act, DEA was mandated to create a system which would identify and track controlled substance orders which

- Signed by the House June 2018
- Signed by the Senate September 2018
- Signed by the President October 2019

SUSPICIOUS ORDERS

DEFINITIONS

The United States Code (USC) & Code of Federal Regulations (CFR):

21 USC § 802:

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Definitions Continued:

21 USC § 802:

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(57) The term "suspicious order" may include, but is not limited to-
(A) an order of a controlled substance of unusual size;
(B) an order of a controlled substance deviating substantially from a normal pattern; and
(C) orders of controlled substances of unusual frequency.

The Act established reporting requirements for suspicious orders of controlled substances, and the information was to be "collected in a centralized DEA database and shared with states." (HR6, Chap 4, Sec 3232; https://www.congress.gov/bill/115th-congress/house-bill/6, accessed 10-22-25.)

Suspicious Orders per United States Code

21 USC § 832:

(a) Reporting

Each registrant shall-

(1) design and operate a system to identify suspicious orders for the registrant;

(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(b) Suspicious order database

(1) In general

Not later than 1 year after October 24, 2018, the Attorney General shall establish a centralized database for collecting reports of suspicious orders.

Suspicious Orders per United States Code – con't

21 USC § 832:

(2) Satisfaction of reporting requirements
If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have complied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(c) Sharing information with the States

(1) In general
The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as designated by the Governor or chief executive officer of the State.

(2) Timing
The Attorney General shall provide information in accordance with paragraph (1) within a reasonable period of time after obtaining the information.

Definitions Continued

21 CFR § 1300.01 Definitions

“Dispenser” means an individual practitioner, institutional practitioner, pharmacy or pharmacist who *dispenses* a controlled substance.

21 CFR § 1300.74(b)

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

RED FLAGS – Distributors and Manufacturers!!!

This list is NOT all inclusive – Controlled Substance (CS) Orders:

- **Of an unusual size**
- **Deviates substantially from normal pattern(s)**
- **Of unusual frequency**
- **Inconsistent recordkeeping or lack of documentation**
- **Customer base concerns**
- **Not be responsive to distributor's compliance requests or inquiries**
- **More Controlled Substance than Non- Controlled Substance sales**
- **Using numerous distributors**
- **Practitioner purchases of high volume of CS by NDC and/or type**
- **Practitioner purchase of single drug strength for extended period**
- **Large purchases of buprenorphine only vs buprenorphine with naloxone**

RED FLAGS - Pharmacies

Again, not all inclusive for pharmacists and technicians to watch for:

- Practitioner with high patient volume
- Excessive Controlled Substance prescriptions
- Multiple patient deaths
- Increasing dosage of particular Controlled Substances and maintaining for long periods
- Refills requested and authorized often
- Inappropriate Controlled Substance combinations
- Multiple patients from same clinic arriving at same time with similar prescriptions
- Failing to utilize non-controlled substances as alternative to Controlled Substance
- Controlled Substance prescribed not logical for issue prescribed for
- Cash payments when Medicaid or private insurance carried
- Multiple members of same household with similar prescriptions
- Long distances from patient home and/or practitioner’s office to pharmacy
- No individualized dosing by practitioner

RESOURCES

DEA Website
www.DEADiversion@usdoj.gov

eCFR.gov

Input/Liaison Team: ARCOS_Unit@dea.gov

Output/Data Team: Targeting.Analysis @dea.gov (SORS & Drug Theft)

Thank you for attending the ACROS/SORs virtual training.