

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)





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- 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



❖ **Required to report to ARCOS if registered as:**

❖ **Manufacturer**

❖ **Distributor**

❖ **Reverse Distributor**





- ❖ **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





❖ **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**





❖ **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**





❖ Information on drug schedules:



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Administrative Actions

Chemical Control Program

Chemical Warning Notices

CMEA (Combat Meth
Epidemiology)

Controlled Substances Schedules

Cyber Security

DEA Regulatory Priorities

DEA TOX

Drug Disposal Information

Drug & Chemical Information

EPCS (Electronic Prescriptions for
Controlled Substances)

Federal Register Notices

Guidance Document Portal

Medications for Opioid Use Disorder

National Prescription Drug
Take Back Day

Narcotic Treatment Programs

NFLIS

OPIOID (PHE) Information

Pharmacy

Publications & Manuals

Questions & Answers

Telemedicine

Title 21 Code of Federal Regulations

Title 21 USC Codified CSA



Lists of Controlled Substances Disclaimer

Defined Abbreviations



❖ **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 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**





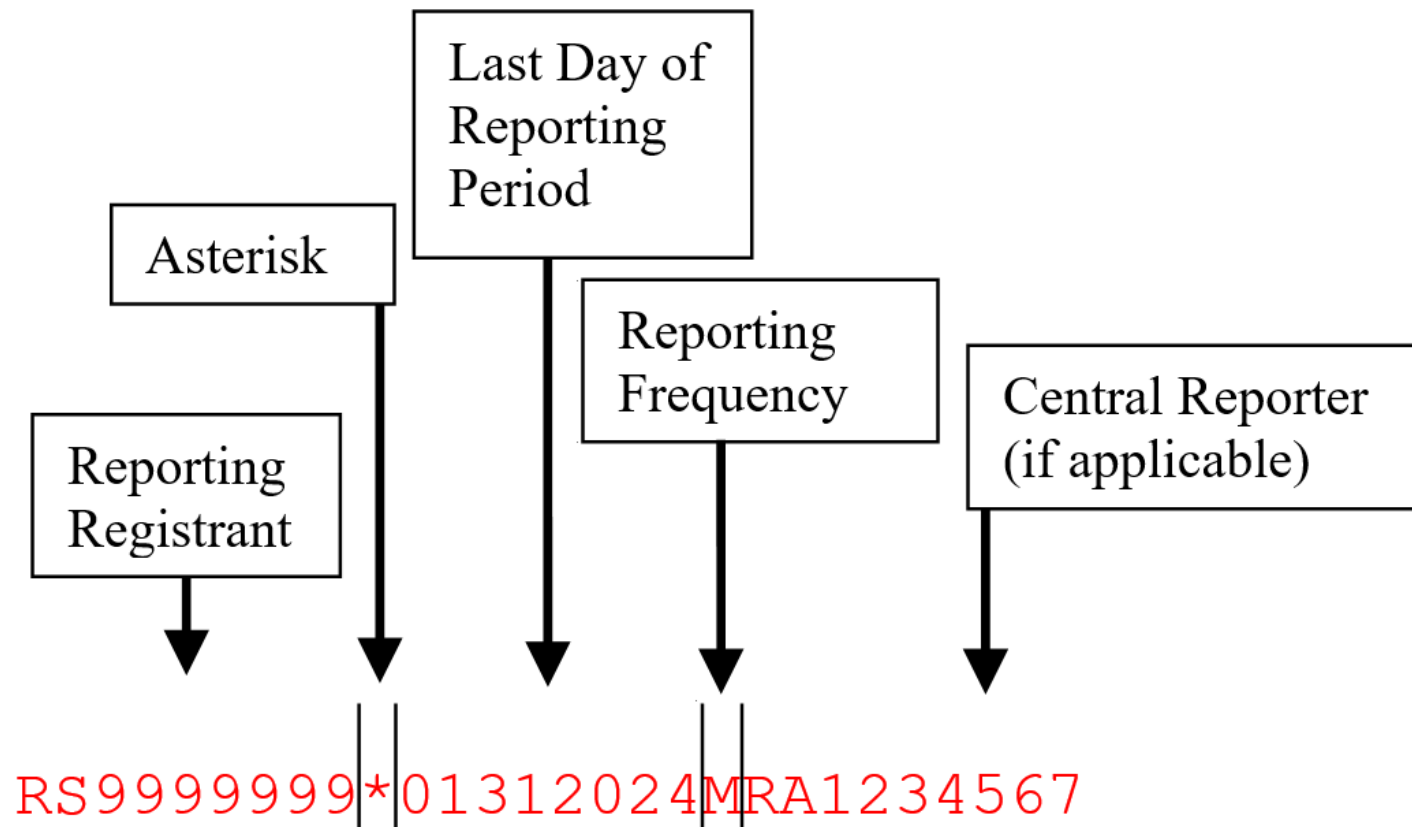
❖ **Text file – Header Record:**

FIELD	POSITION (TEXT FILE)	SAMPLE DATA
REPORTING REGISTRANT	1 - 9	RS99999999
ASTERISK	10	*
LAST DAY OF REPORTING PERIOD	11 - 18	01312024
REPORTING FREQUENCY	19	M
CENTRAL REPORTER	20 - 28	RA1234567





❖ Text file – Header Record:





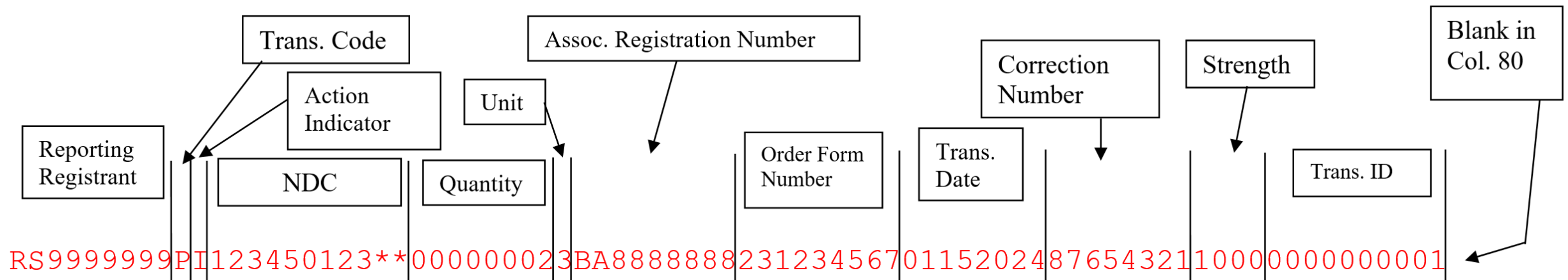
❖ Text file – Transaction Record:

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:

A screenshot of a text editor window with a light blue title bar and a menu bar containing 'File', 'Edit', and 'View'. The main text area displays two lines of data: a header line 'RS9999999*01312024MRA1234567' and a transaction line 'RS9999999PI123450123**000000023BA888888231234567011520248765432110000000000001'. The window has standard minimize, maximize, and close buttons in the top right corner, and a settings gear icon in the bottom right corner.

```
RS9999999*01312024MRA1234567
RS9999999PI123450123**000000023BA888888231234567011520248765432110000000000001
```

ARCOS REPORTING



❖ Direct entry/web interface:



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

Welcome, [Logout](#) [ARCOS User Manual](#)
[SORS User Manual](#)

ARCOS/SORS Online: Add/Edit Report

Reporting Period: Jan 01 2024 - Jan 31 2024

ARCOS/SORS Online: Add Transaction

? Trans Code Key (Enter '=' to set a field to the value from the most recently entered transaction, which, if present, is shown next)

? Help

Tr. Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
-?-▼	- -		-Optional-▼				



❖ **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



- ❖ **Research potential customers before supplying controlled substances**
- ❖ **Industry requested this feature to help improve their due diligence processes.**





❖ Available in the ARCOS Online system:

The screenshot displays the 'ARCOS/SORS Online: Main Menu' interface. On the left, there is a sidebar with 'ARCOS MENU' and 'SORS MENU' buttons, and a 'Change Password' link. The main area shows a dropdown menu for 'ARCOS MENU' with the following options: 'Enter ARCOS Reports', 'Enter ARCOS Corrections', 'Enter New NDC Number', 'Manage Participant Data', 'Upload and Manage ARCOS Report Files', 'Look up Retail Buyer Statistics' (highlighted with a red box), and 'Manage Users'. Below the menu, there is a 'Notice' section with the text: 'New User features have been added. Please see the ARCOS/SORS User Manuals for information on new User Management features that have been added. These features allow creation of administrator and data-only users for ARCOS, SORS, and Retail Statistics. Additionally, you may specify access to only certain DEA Numbers for a user (for those accounts reporting for more than one DEA number).'

ARCOS/SORS Online: Main Menu

ARCOS MENU
SORS MENU

[Change Password](#)

Notice:
New User features have been added. Please see the ARCOS/SORS User Manuals for information on new User Management features that have been added. These features allow creation of administrator and data-only users for ARCOS, SORS, and Retail Statistics. Additionally, you may specify access to only certain DEA Numbers for a user (for those accounts reporting for more than one DEA number).

- Enter ARCOS Reports
- Enter ARCOS Corrections
- Enter New NDC Number
- Manage Participant Data
- Upload and Manage ARCOS Report Files
- Look up Retail Buyer Statistics**
- Manage Users



- ❖ **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





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DIVERSION CONTROL DIVISION

Welcome, [Logout](#) [ARCOS User Manual](#)
[SORS User Manual](#)

ARCOS/SORS Online: Retail Buyer Statistics Lookup

Enter a Retail or NTP DEA Number and Drug Code to see the number of distinct sellers for that DEA Number and Drug Code.

Retail or NTP DEA Number: *

The time span for lookup data is:
Time Span Start: 04/01/2020
Time Span End: 09/30/2020

Drug Code Selection

Available Drugs

	Code	Name
☐		
☐	1100	AMPHETAMINE
☐	1105	METHAMPHETAMINE
☐	1205	LISDEXAMFETAMINE
☐	1724	METHYLPHENIDATE
☐	9050	CODEINE
☐	9064	BUPRENORPHINE
☐	9143	OXYCODONE

Clear Text Filters

Add -->

<-- Remove

Selected Drugs

Code	Name
No Drugs Entered	

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: 9113 - OXYCODONE	1	2,3274	25000



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

- Pharmacies, Hospitals, Practitioners, Mid-Level Practitioners, Teaching Institutions**
- Narcotic Treatment Programs**
- Importers, Exporters, Analytical Labs**





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





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:

12345 – 0123 – 01

↑ ↑ ↑

Labeler Product Package
Code Code Code



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

 **U.S. FOOD & DRUG**
ADMINISTRATION

[← Home](#) / [For Industry](#) / [FDA Data Standards Advisory Board](#) / [Structured Product Labeling Resources](#) / [NDC/NHRIC Labeler Codes](#)

NDC/NHRIC Labeler Codes

**Structured Product
Labeling Resources**

[Business Entity Identifiers](#)

[Electronically Submitted NDC/NHRIC Labeler Codes](#)

This is a list of NDC/NHRIC Labeler Codes which have been electronically submitted.



- ❖ **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**





- ❖ **Formatting changes may be necessary if and when FDA moves to a 6-digit labeler code**
- ❖ **Federal Register: 87 FR 44038, July 25, 2022**





- ❖ **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)**





- ❖ **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





- ❖ **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**





- ❖ **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**





- ❖ **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**





- ❖ **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)



- ❖ **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:



DEA.Registration.Help@dea.gov | 1.800.882.9539

HOMEABOUT USREGISTRATIONREPORTINGRESOURCESCONTACT US

ARCOS

BCM Online

Chemical Import/Export
Declarations

Chemical Suspicious
Order Reporting (CORT) 

Theft/Loss Reporting

Import/Export

Medical Missions

Quotas

Registrant Record of
Controlled Substances Destroyed

Regulated Machines
(Tableting and Encapsulating)

Reports Required by 21 CFR

SORS

Submit a Tip to DEA

Year-end Reports



On October 23, 2019, DEA launched the Suspicious Orders Report System (SORS) Online, a new centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (**SUPPORT Act, Pub. L. 115-271**). The SUPPORT Act requires that **all** DEA registrants that **distribute** controlled substances report suspicious orders to DEA. Therefore, the SORS Online system should only be used by DEA registrants that distribute controlled

SUSPICIOUS ORDERS REPORTING (SORS)



❖ ARCOS/SORS Online system:

[HOME](#)[ABOUT US](#)[REGISTRATION](#)[REPORTING](#)[RESOURCES](#)[CONTACT US](#)[f](#)[x](#)[@](#)[in](#)

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.





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**

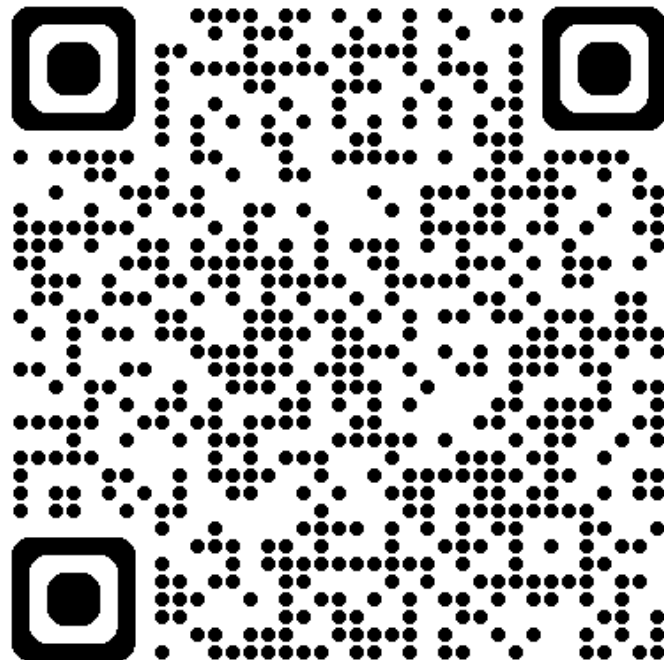


RESOURCES

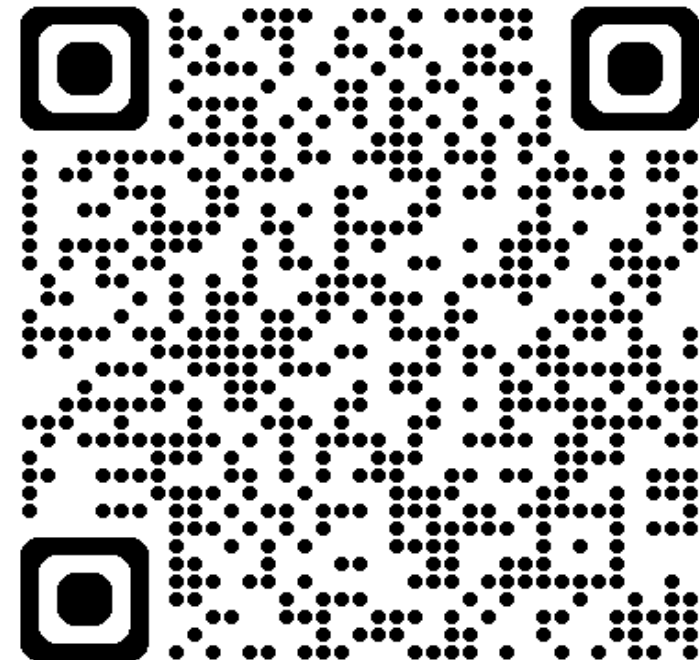


DEA Website

www.DEADiversion@usdoj.gov



[eCFR.gov](https://www.ecfr.gov)





Input/Liaison Team: ARCOS_Unit@dea.gov

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



**Thank you for attending
the ACROS/SORs
virtual training.**

