

# CONTROLLED SUBSTANCES

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A REVIEW OF RULES AND  
REQUIREMENTS

# SCOPE OF PRESENTATION

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REGISTRATION



ACQUISITION



RECORD  
KEEPING;  
INVENTORY



SECURITY



LOSS, THEFT AND  
DISPOSAL



INSPECTIONS



MISCELLANEOUS;  
STATE SPECIFIC  
REGULATIONS



QUESTION AND  
ANSWER

# REGISTRATION

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Every practitioner that wishes to possess or prescribe controlled substances must be registered with the DEA.



[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

# REGISTRATION - RENEWAL

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COMPLETE ON-LINE



COMPLETE 60 DAYS OR LESS  
BEFORE EXPIRATION



RENEWAL DATE  
CORRESPONDS TO THE  
MONTH OF INITIAL  
APPROVAL, EVERY 3 YEARS

# REGISTRATION – COMPONENTS OF A DEA REGISTRATION NUMBER

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Fred Smith, DVM      ASI368174  
A (B,F)  
S

Add #'s 1, 3, & 5       $1 + 6 + 1 = 8$

Add #'s 2, 4, & 6 x 2       $3 + 8 + 7 = 18 \times 2 = 36$

Add sums       $8 + 36 = \underline{44}$

Right digit of sum corresponds to 7<sup>th</sup> digit of registration number



# REGISTRATION

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- Exemption of agents
- Exemption of affiliated practitioners
- All locations where controlled substances are kept must be registered
- Mobile practices
- All changes must be made in writing
  - Move
  - Termination or transfer

# REGISTRATION

CHICAGO DIVISION OFFICE  
230 S DEARBORN ST  
JOHN C. KLUCZYNSKI FED. BLDG.  
SUITE 1200  
CHICAGO, IL 60604

Phone : (571) 362-6251

Fax : (571) 362-6233

[DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov)

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# ACQUISITION

C I

High abuse potential, no medical use  
• ex. Heroin, peyote, marijuana

C II

High abuse potential, safe & effective  
• ex. Morphine, fentanyl, hydrocodone

C III

Moderate abuse potential  
• ex. Stanozolol, buprenorphine

C IV

Low abuse potential  
• ex. Diazepam, phenobarbital

C V

Lowest abuse potential  
• ex. Diphenoxylate w/Atropine



# ACQUISITION


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- Purchase from wholesaler or distributor
  - CIII – CV : Require copy of DEA certificate
  - CII : Require copy of DEA certificate
    - Require complete DEA form 222
- Many distributors require completion of a controlled substance profile

# ACQUISITION

## Filling out DEA Form 222

### DEPICTION of PAGE 1 of DEA FORM-222 U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

<b>See Reverse of PURCHASER'S Copy of Instructions</b>		No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).				<b>OMB APPROVAL No. 1117-0010</b>		
TO: <i>(Name of Supplier)</i>			STREET ADDRESS					
CITY and STATE		DATE		<b>TO BE FILLED IN BY SUPPLIER</b>				
				SUPPLIER'S DEA REGISTRATION No.				
L I N E N o.	<b>TO BE FILLED IN BY PURCHASER</b>						P a c k a g e s S h i p p e d	D a t e S h i p p e d
	No. of Packages	Size of Package	Name of Item			National Drug Code		
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
 <b>LAST LINE COMPLETED</b> <i>(MUST BE 10 OR LESS)</i>			SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT					
Date Issued		DEA Registration No.		Name and Address of Registrant				
Schedules								
Registered as a		No. of this Order Form						

DEA Form-222  
(Oct. 1992)

**U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II**  
DRUG ENFORCEMENT ADMINISTRATION  
SUPPLIER'S Copy 1

# POWER OF ATTORNEY

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- A registrant may authorize one or more individuals to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual.
- The power of attorney must be retained in the files, with executed Forms 222. The power of attorney must be available for inspection together with other order records.
- A registrant may revoke any power of attorney at any time by executing a notice of revocation.
- The power of attorney and notice of revocation must be similar to the format specified in 21 CFR 1305.05

# CSOS

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- DEA's CSOS program allows for secure electronic controlled substances orders without the supporting paper DEA Form 222. CSOS requires that each individual purchaser enroll with DEA to acquire a CSOS digital certificate.
- **Ordering Freedom:** CSOS transactions are the only allowance for electronic ordering of Schedule I and II controlled substances. Additionally, CSOS has no line item limit for a single order.
- **Faster Transactions:** CSOS certificates contain the same identification information as DEA Form 222, which allows for timely and accurate validation by the supplier. Faster transactions allow for just-in-time ordering and smaller inventories.

# ACQUISITION

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## Distribution to another practitioner

- Establish that purchaser is registered with DEA
- Generate an invoice
  - Must contain DEA number of purchaser and seller
  - Must accurately reflect strength and quantity
  - CII requires form DEA 222
- Sale may not exceed 5% of total dosage units in sellers possession

# ACQUISITION

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- **Transfer of business**

Information must be submitted to DEA either in person or via certified mail at least 14 days prior to transfer.

Complete inventory must be taken on date of transfer. Must state “Transfer of Business/ Initial Inventory.” Copies should be signed and maintained by both buyer and seller.

# RECORD KEEPING

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- Every registrant must maintain records
- Must keep records of drugs administered or dispensed

## **Readily retrievable**

- Policies and procedures



# RECORD KEEPING

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Required records include:

- Invoices and packing slips
- Administration and dispensing logs
- DEA Form 222
- Physical Inventories
- Miscellaneous forms



All employees should be familiar with record-keeping requirements



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## RECORD KEEPING

C II

Must be maintained  
separately

C III-V

May be kept separately  
or together with non-  
controlled records

Records for dispensed or  
administered controlled substances  
must contain:

- Name and address of patient
- Date administered
- Name of individual dispensing  
or administering

# INVENTORY

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- DEA states explicitly:
  - Each physical inventory will contain a complete and accurate record of all controlled substances on hand on the date inventory is taken
  - Must be maintained in written or printed form at the registered location
  - Registrant must perform a separate inventory for each registration

# INVENTORY

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## 3 Types

### Initial Inventory

All CS on hand on the date registrant first engages in dispensing CS

### Biennial Inventory

Taken every 2 years unless more frequent as required by state law

### Newly Controlled Substance

Taken on the date a product becomes a controlled substance

# INVENTORY

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## **Inventory Format**

Inventory must include:

- Name of substance
- Finished form: tablet, capsule, patch
- Number of units



## **Must state time of day inventory was taken**

Open or close of business

# SECURITY

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- Controlled substances must be adequately safeguarded and stored in a manner to obstruct theft or diversion
- Restrict employee access
- Hiring employees

# LOSS OR THEFT

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- Loss – DEA Form 106
  - The disappearance of a controlled substance once it is in the registrants possession.
  - Does not include breakage or damage
  - Does not need to be reported to law enforcement officials

# LOSS OR THEFT

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- Theft – DEA Form 106

Theft of a controlled substance is a criminal act.

- Must be reported to local DEA office within 1 day of discovery
- Not required, but advisable to report to police and veterinary or pharmacy board

# DISPOSAL

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- Damaged or expired product – DEA Form 42
- 4 Possible Procedures
  - Reverse distribution
  - Bring to local DEA office
  - Destroy in the presence of a DEA agent
  - Request permission to destroy controlled substances at practice site



# INSPECTIONS

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Make sure employees know what to do in the event of an inspection when practice owner/registrant is absent

- Inspector must show proper identification
- Inspector must disclose purpose of inspection
- Inspector may access records germane to their agency
- Inspector may not remove anything from premises without leaving a detailed, signed receipt
- Always be polite and courteous

# MISCELLANEOUS

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- Corresponding Liability

A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

- Red Flags

- Frequent refill requests or claims of loss
    - Geographic anomalies
    - Shared addresses

# MISCELLANEOUS

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## Combat Methamphetamine Epidemic Act – CMEA

Regulates sale of methamphetamine precursor molecules: Ephedrine, PPA, PSE and related substances.

- Proin
- Compounded Phenylpropanolamine

## Constructive Transfer

It is illegal to transfer controlled substances from pharmacies to treating physicians and veterinarians on behalf of their patients for professional safekeeping and prior to administration of the medication.

- DEA Manufacturer Permit

# STATE SPECIFIC REGULATIONS

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## Prescription Monitoring Program

Public Act 100- 0564 (January 2018): All prescribers possessing an Illinois controlled substances license must register with the Prescription Monitoring Program.

- Each prescriber (or designee) shall also document an attempt to access patient information in the Prescription Monitoring Program to assess patient access to controlled substances when providing an initial prescription for Schedule II narcotics such as opioids.
  - May designate up to 3 people

# STATE SPECIFIC REGULATIONS

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## Prescription Monitoring Program

- Excludes licensed veterinarians from the reporting requirements under the Program.
- Provides that a licensed veterinarian shall report information required under the Prescription Monitoring Program if the person who is presenting an animal for treatment is suspected of fraudulently obtaining any controlled substance or prescription for a controlled substance to the Department of Human Services.

# STATE SPECIFIC REGULATIONS

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## Continuing Education

Veterinarians must obtain 3 hours of Continuing Education on Safe Opiate Prescribing.

- Must be completed by January 2021
- May count toward renewal total

## Miscellaneous

- CS License - \$5.00
  - IDFPR.com
- Record retention – 5 years
- Quantity limitation on C5 liquids
  - NMT 4.5 Liters

# THANK YOU

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Questions?