

# Registration Under the Controlled Substances Act

Module 18  
April 2, 2018

# Registration Under CSA

- **Who must register?**
  - **Manufacturers of controlled substances**
    - 21 USC 802(15)
      - production, preparing, etc., repackaging
      - Pharmacy - Exclude incidental activities in professional practice
        - A product NMT 20% of a narcotic substance
  - **Distributors of controlled substances**
    - 21 USC 802(11)
      - Deliver other than by dispensing or administering
      - Pharmacy – No register if follow 5% rule
        - Distribute in a calendar year NMT 5% of CS dispensed and distributed in same calendar year.

# Registration Under CSA

- **Who must register?**
  - **Dispensers of controlled substances**
    - **21 USC 802(10)**
      - Deliver to ultimate user, includes prescribing, administering, packaging, labeling, compounding
    - **Practitioner**
      - Examples: MD, DDS, DVM, pharmacy, hospital, or other person authorized....
    - **Individual Practitioner**
      - Examples: MD, DDS, DVM, podiatrist - prescribers
    - **Institutional Practitioner**
      - Examples: Hospital, Nursing Home, etc.
    - **Mid-level Practitioner**
      - Those granted individual prescriptive authority by states
      - Nurse Practitioners, Optometrists, Physician Assistants, **RPh**
  - **Reverse distributing**
  - **Researchers**
  - **Narcotic Treatment Programs**
  - **Chemical Analyses**
  - **Importing/Exporting**

# Exempt from Registration

- **Agent or employee of registered manufacturer, distributor or dispenser.**
  - **Pharmacist does not register**
- **A common or contract carrier..**
- **The ultimate user, using for a lawful purpose.**
- **Armed service, PHS, BOP who are authorized to prescribe, dispense, administer**
  - **No private activities under exemption**

# Activities Requiring Registration

- **Dispensing**
  - “deliver a CS to an ultimate user”
  - **Registration Process**
    - [DEA Form 224](#) – New/Initial Registration (see Manual)
      - **Section 1 – ID**
      - **Section 2 – Business Activity**
      - **Section 3 – Schedules of CS**
      - **Section 4 - State License**
      - **Section 5 - Liability**
      - **Section 6 – 8 – exempt from fee, payment, signature**
    - **Submit to DEA office in Washington DC**
  - **Receive a DEA Number**
    - **Nine-character number**
      - **Two letters and 7 digits, last digit is check digit**
      - **First letter is A, B, C, or F for practitioners**
      - **First letter is M for mid-level practitioners**
      - **Second letter is first letter of registrants last name**
        - **Business with number as first letter - number**

# Activities Requiring Registration

- **Dispensing**
  - **Renewal**
    - Every 3 years
    - [DEA Form 224a](#) – Renewal Registration
    - **Can not renew more than 60 days before expiration. (see manual)**
    - Receive notice about **50** days before expiration if not submitted
      - If not received notice 45 days before expiration, contact DEA
  - **Pharmacy Specific Issues**
    - **Change of Address**
      - Must obtain new certificate
        - Written request for modification of registration sent to DEA.
    - **Retail Chain Renewal**
      - [DEA Form 224b](#)
    - **Termination of Registration (Manual p. 9)**
      - Notify DEA Registration Field Office before terminating
    - **Transfer of Business (Manual p. 10)**
      - Notify DEA Registration Field Office at least 14 days before transfer
      - Name, address, registration # of registrant discontinuing business
      - Name, address, registration # of registrant acquiring business
      - Location of business activities
      - Date of CS transfer

# Who Registers as a Dispenser?

- **Retail Pharmacy**
- **Individual Practitioner**
  - MD, DVM, etc. to prescribe
  - May use hospital or other institution registration if:
    - Abood p. 212
    - Use DEA number of registered hospital or other institution
      - Suffix to registrants DEA number
      - For example: APxxxxxxx - 10
- **Institutional Practitioner**
  - Hospital
    - What about hospital pharmacy??
- **Mid-level Practitioner**
  - Need to register if prescribing
  - Can use hospital or other institution registration (see above)

# Activities Requiring Registration

- **Manufacturing C II – V**

- Registration
  - [DEA Form 225](#) – New/Initial Registration
  - DEA Form 225a – renewal
  - Coincident Activities
    - Manufacture, distribute, research, analysis
- Renewal – Annually
- DEA Number
  - First letter is E

- **Distributing C II – V**

- Registration
  - [DEA Form 225](#) – New/Initial Registration
  - DEA Form 225a – renewal
- Renewal – Annually
- DEA Number
  - First letter is F



# Activities Requiring Registration

- **Research C I – V**

- Registration
  - [DEA Form 225](#) – New/Initial Registration
  - DEA Form 225a – renewal
- Specifics
  - C I = manufacture or import is set forth in the protocol
  - C II – V = manufacture is set forth in a statement filed with the application for registration or re-registration
- DEA Number
  - First letter is G

- **Narcotic Treatment Program C II – V**

- Registration
  - [DEA Form 363](#) – new registration
  - DEA Form 363a – renewal
- Includes compounders
- DEA Number
  - First letter is N, P, R, S, T, or U

# Activities Requiring Registration

## • **Importing/Exporting C I – V**

- Registration
  - [DEA Form 225](#) – New/Initial Registration
  - DEA Form 225a – renewal
- DEA Number: first letter J = import, K = export
- May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.

## • **Chemical Analysis C I – V**

- Registration
  - [DEA Form 225](#) – New/Initial Registration
  - DEA Form 225a – renewal
- DEA Number: first letter H

# Separate Registrations

- **Each pharmacy site must be registered**
- **Separate warehouses owned by manufacturer or distributor do not need to be registered.**
- **Individual practitioners working in multiple offices**
  - **If storing, dispensing and/or administering CS at each site, need to register each site.**

# How to Check a Controlled Substance Rx

This is the old method !

*Example DEA Number: AJ 3274658, Robert Jones, MD*

A	J	3	2	7	4	6	5	8
Digits		1	2	3	4	5	6	CHECK

1. Add digits 1, 3, and 5
2. Add digits 2, 4, and 6 and multiply sum by 2
3. Add results of steps 1 and 2
4. Last digit of the result of step 3 should be the same as the check digit.

**Example:**

1.  $3 + 7 + 6 = 16$
2.  $(2 + 4 + 5) \times 2 = 22$
3.  $22 + 16 = 3\mathbf{\underline{8}}$
4. Check digit (8) is same as last digit in sum from step 3.

# *Question:* Can you verify a DEA number?

- ***Answer:*** NO. It is DEA policy that the verification of DEA registration of a physician may be accomplished by requesting a copy of the physician's current DEA registration certificate, which indicates the issue and expiration dates.
- In addition, the DEA provides a list of active DEA registrants to the National Technical Information Service (NTIS) a component of the United States Department of Commerce.
- This list of active DEA registrants may be obtained from NTIS as a single purchase, monthly or quarterly by calling 1-800-363-2068 or for more information, see them on the web at [www.ntis.gov/product/dea.htm](http://www.ntis.gov/product/dea.htm).

# Verifying DEA Registration

- [www.deanumber.com](http://www.deanumber.com)
  - Subscription service
  - Database of DEA registrants
- [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)
  - Free
  - Must enter your DEA registration and other information