

Practitioner Diversion Awareness Conference

Registration Loren Miller, Section Chief Policy Section







LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on December 17-18, 2018, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.



Fair Use Act Disclaimer

This presentation is for educational purposes only. This presentation may not be further copied or used, with the embedded images and videos, without an independent analysis of the application of the Fair Use doctrine.

Fair Use

Under section 107 of the Copyright Act of 1976, allowance is made for "Fair Use" for purposes such as criticism, comment, news reporting, teaching, scholarship, education and research.

Fair Use is a use permitted by the copyright statute that might otherwise be infringing. Any potentially copyrighted material used in this presentation has been reviewed and found to be used in a manner consistent with Fair Use. A completed Fair Use checklist is attached.



Course Objectives

s Explain why the DEA issues registrations, the type of registrations that the DEA issues, and how such registrations fit into the closed system of distribution.

s Explain how a practitioner obtains a DEA registration, and what is required by the DEA as part of this process.

§ Explain the limits of a DEA registration, and the coincident activities that a practitioner can perform.





- **s** Outline when a practitioner would need more than one DEA registration.
- **s** Review some common problems practitioners have encountered regarding their DEA registration and how they were resolved.
- S Explain some of the basic steps a practitioner can take to reduce the chance of their DEA registration being used in the diversion of controlled substances.



Questions To Discuss

At the completion of this block of instruction you will be able to answer the following questions:

1. What is the current number of DEA registrants?

2. As an individual practitioner, how many associates in my practice can I authorize to use my registration number to prescribe controlled substances?



Questions To Discuss

3. Is a DEA practitioner registration always for a three year period?

4. Is a DEA registration number publically available?

5. What should I do to prevent my DEA registration from being used for diversion?



Registration Requirements for Practitioners



Registration Requirements

First, let's begin by clarifying a few points.

The truth is that although a DEA registration is a Federal registration it does NOT allow you to prescribe controlled substances anywhere you wish to in the United States.





Registration Requirements

- **§** A DEA registration is NOT required for you to issue prescriptions for non-controlled substances.
- **s** If you change your last name you are NOT required to obtain a new DEA registration number.
- **s** A DEA registration number is NOT privileged information, but is available to the public.



Closed System of Distribution





The Registrant Community

§Total number of DEA registrants: **1,783,147**

STotal number of Practitioners: 1,298,125

STotal number of Mid Level Practitioners: 371,468

STotal number of Pharmacies: 71,636

STotal number of Hospitals: 17,968





s Website: <u>www.DEAdiversion.usdoj.gov</u>

s Go to "Registration" (located at the top of the page)

s Form used by the new applicant: DEA Form 224



How to Apply

What if you encounter problems?

If you encounter problems, contact the DEA Registration Service Center.

DEA.Registration.Help@usdoj.gov Or

1-800-882-9539

Or . . .





Contact the DEA Registration Specialist in your area. To find their contact information go to the above website and look under "About Us."

For example, using this method the Registration Specialist's contact information for Pennsylvania is Phone – (215) 238-5160.



How to Apply

The Registration Specialist for your area can be located on the <u>Diversion Control Divisions</u> web-site.

You can search by zip code, city, county, or state.





How to Apply

The DEA cannot consider an application unless you first have state controlled substance authority, and each state is different:

§ State Medical License
§ State controlled substance registration (if required)
§ Other state licensure (if required)
§ Certificates of advanced training (if required)



Practice Address vs Mailing Address

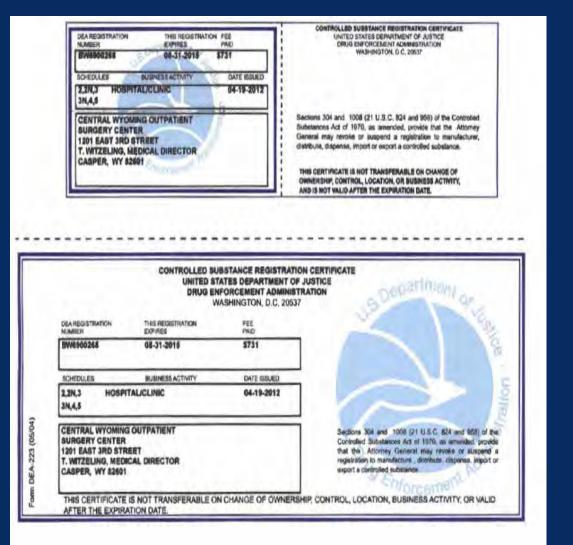
During the application process you are asked for your Practice Address, and you are asked for your Mail-to Address if these two addresses are different.

Your Practice Address is your principal place of business or professional practice pursuant to Title 21, C.F.R. 1301.12(a). This is the address on your DEA certificate.

Your mail-to address is for correspondence.

ORIGINAL DEA

REGISTRATION CERTIFICATE



New watermark

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID	CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE
PB0093005	12-31-2016	Exempt	DRUG ENFORCEMENT ADMINISTRATION WASHINGTON D.C. 20537
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE	
1,2,2N 3,3N,4,5	ANALYTICAL LAB	12-15-2015	
DRUG ENFORCE MIAMI FIELD DIVI 2100 N COMMERC ATTN: DIVERSION	SION CE PKWY		Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.
WESTON, FL 333			THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF
]	OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.
	U	LLED SUBSTANCE RI NITED STATES DEPAI DRUG ENFORCEMEN	AND IT IS NOT VALID AFTER THE EXPIRATION DATE.
	U	NITED STATES DEPAR	AND IT IS NOT VALID AFTER THE EXPIRATION DATE. EGISTRATION CERTIFICATE RTMENT OF JUSTICE T ADMINISTRATION
A REGISTRATION	U	NITED STATES DEPAI DRUG ENFORCEMEN	AND IT IS NOT VALID AFTER THE EXPIRATION DATE. EGISTRATION CERTIFICATE RTMENT OF JUSTICE T ADMINISTRATION

1,2,2N

3,3N,4,5

Form DEA-223 (9/2016)

SCHEDULES BUSINESS ACTIVITY ISSUE DATE ANALYTICAL LAB 12-15-2015 DRUG ENFORCEMENT ADMIN Sections 304 and 1008 (21 USC 824 and 958) of the MIAMI FIELD DIVISION Controlled Substances Act of 1970, as amended, 2100 N COMMERCE PKWY provide that the Attorney General may revoke or ATTN: DIVERSION GROUP suspend a registration to manufacture, distribute, WESTON, FL 33326 dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



Public Access

The DEA is required to turn over the practice address to the U.S. Department of Commerce.

The Department of Commerce sells this information through the National Technical Information Service (NTIS) to registrants and others.

Other companies then legally resell this information.



A DEA registration cannot allow you to do something that is otherwise prohibited by state law.

For Example: If you are registered by the state in only schedules III-V the DEA cannot authorize you to handle schedule II.

For Example: If state law says you cannot procure controlled substances, the DEA cannot authorize you to do so.



Final Rule: <u>Clarification of Registration Requirements for Individual</u> <u>Practitioners</u> (December 1, 2006)

A practitioner can only administer, dispense, prescribe, procure, or store controlled substances in a state if they first hold a DEA registration in that state. The authority granted under this registration ends at that state's border.

A practitioner can only administer, dispense, procure, or store a controlled substance at a location where he or she is registered with the DEA.



When more than one DEA registration number is needed:

- **§** If a practitioner plans to administer, dispense, procure or store controlled substances at more than one location in a state.
- **§** If a practitioner plans to administer, dispense, prescribe, procure, or store controlled substances in more than one state.
- **§** If the practitioner is registered with the DEA in one state and is treating a patient in another state by telemedicine.



Unique exception: The Medical Bag. Administering or dispensing a controlled substance inside a state where a practitioner is registered, but at other than the practitioner's DEA registered location.

Note: Random and as needed is – fact specific





Coincident Activities allowed. 21 C.F.R. 1301.13(e)(1)(iv)

Practitioner: May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute.



The applicant does not have appropriate state authority.

The registrant assumes their first registration will be for 36 months.

The applicant, or renewing registrant, fails to mark all appropriate schedules.

The registrant fails to renew their registration in a timely manner.



Failure to maintain state licensure once achieved.

Failure to notify the DEA of an email address change.

Believing that the practitioner needs a separate DEA registration for each location in the same state where they only prescribe, (other than the one registration they already hold in that state).



Renewals submitted simultaneously by both the practitioner and the practitioner's office.

Applying or renewing using an expired credit card or using a check from a closed account.

Relying upon an office manager to renew for the practitioner (but they do not).

Applying for new DEA # due to a name change.



Changing practice address:

§ In same state

§ To another state

§ In a national emergency



Going inactive, and what to do with the registration:

Semi-retired

Health Issues

Sabbatical





Discontinuing Practice:

Permanently



Hospitals and DEA Registrations

Title 21 C.F.R. § 1301.22(c)(1-6)

An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that 6 conditions are met.



Hospitals and DEA Registrations

Using the number off-site:

When you can use it off-site

When you cannot use it off-site



Group Practice Setting

Title 21 C.F.R. 1301.22(b)

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.



Group Practice Setting

What this lets you do

What this does not let you do





Fee Exempt Registrations

Conditions under which it is granted

Limits of this registration

Conversion to a fee paid registration

U.S. Drug Enforcement Administration Diversion Control Division



U.S. Military – DEA Registration

Conditions under which it can be used.

Conditions under which it cannot be used.

When you leave the military.

U.S. Drug Enforcement Administration Diversion Control Division



Steps you can take to reduce the chance of your registration being used in the diversion of controlled substances.

Check your PMP for use:

- **§** False prescriptions
- **§** Sloppy use by pharmacies
- **§** Misuse by office staff





Solution Monitor the use of your practice's credit card and checking account.

Solution Have all controlled substances you purchase be checked in upon delivery by two employees.

U.S. Drug Enforcement Administration Diversion Control Division



If you dispense controlled substances, including samples, conduct random audits to ensure they are not getting diverted.

Do not create an atmosphere of self-use in your practice by your staff.



U.S. Drug Enforcement Administration Diversion Control Division



Do not print your full DEA registration number on your prescription. Instead add the last few digits yourself.

Limit the amount you prescribe and the refills you authorize, if this is not already required by your state.



Stick with certain controlled substances, and strengths thus calling to attention any deviation from this pattern.

When issuing paper prescriptions, list both the # being prescribed and write out the amount.

Cooperate with your local pharmacists.

Do not leave your prescription pad unattended, and lock it up if not in use.



SCAM!!!

Criminals posing as DEA employees are targeting practitioners using an extortion scam. They use a disguised telephone number that appears on a practitioners' caller ID as the "DEA's 800 registration support number". The criminals then demand money and threaten to suspend a practitioner's DEA registration if they do not comply. You were sent an email about this on April 2, 2018



Qualified Practitioners and Other Qualified Practitioners

The Unique Identification Number, often called the X number, is not a DEA registration. It is certification that the prescriber has met all the necessary requirements to use FDA approved Schedules III-V narcotics for the treatment of opioid use disorder.

Unlike the DEA registration number, only one Unique Identification Number is issued.



Qualified Practitioners and Other Qualified Practitioners

When prescribing FDA approved Schedules III-V narcotics for the treatment of opioid use disorder the prescriber must place both their DEA registration number and their Unique Identification Number on the prescription.



Course Review

We reviewed why the DEA issues registrations, how to apply, and how registrations fit into the closed system of distribution.

We identified and discussed what a DEA registration does, and does not let you do.

We reviewed some common problems practitioners have encountered regarding their DEA registration, and how these are resolved.

We listed some of the steps a practitioner can take to reduce the chance that their DEA registration will be used to divert controlled substances.





1. What is the current number of DEA registrants?

- A. Under 250,000
- **B.** 780,000
- C. 1, 100,000
- **D.** Over 1,700,000





- 2. As an individual practitioner, how many associates in my practice can I authorize to use my registration number to prescribe controlled substances.
 - A. NoneB. OneC. Up to threeD. Up to five





3. Is a DEA practitioner registration always for a three year period?

A. YesB. No





4. Is a DEA registration number publically available?

A. YesB. No

U.S. Drug Enforcement Administration Diversion Control Division





- 5. What should I do to prevent my DEA registration from being used for diversion?
 - A. Lock up my prescription pads.
 B. Limit my prescribing to the amount I believe is currently medically necessary.
 C. Check my state's prescription monitoring program.
 - **D.** All of the above.



Thank you for your time and attention !



U.S. Drug Enforcement Administration Diversion Control Division