

From: [REDACTED]
To: McAuliffe, John@CDCR
Subject: Customs-FDA Materials.pdf
Date: Thursday, September 30, 2010 11:28:57 PM
Attachments: Customs-FDA Materials.pdf
Importance: High

Hi John,
I think What Arizona had done was almost bullet proof.
I have attached the documentation that Arizona had send me to included them in their shipment.
I think this is something you can do.
Please note the contact people are all in Arizona, you need to change those contacts to California and write a similar letter.

We use FedEx as a transportation company, however, Arizona had requested the following:

Fed Ex is not to use their own/contracted Customs Broker to process the shipment. Fed Ex shall document on all necessary areas relating to this shipment the following customs broker selection:

[REDACTED]

The Port of Entry shall be Phoenix, Arizona, without fail.
If Fed Ex ships first to their hub in Memphis, Tennessee, that Port shall only be the Port of Unladen, not the Port of Entry.
Fed Ex shall contact our Customs Broker, provide them all necessary shipping information and enter our Customs Broker's information on all necessary forms.

John,
If you do what Arizona had done, you should not have any problem.

Regards,

[REDACTED]

From: [Cullen, Vincent@CDJR](mailto:Cullen,Vincent@CDJR)
To: [McAuliffe, John@CDJR](mailto:McAuliffe,John@CDJR); [Kernan, Scott@CDJR](mailto:Kernan,Scott@CDJR)
Subject: Fw: Material
Date: Thursday, September 30, 2010 11:04:58 PM

----- Original Message -----

From: [REDACTED]
To: Cullen, Vincent@CDJR
Sent: Thu Sep 30 22:23:24 2010
Subject: Re: Material

Material is stored.

----- Original Message -----

From: Cullen, Vincent@CDJR
To: [REDACTED]
Sent: Thu Sep 30 16:59:47 2010
Subject: Material

John
Please email me when the material is stored.

From: [Kernan, Scott@CDCR](mailto:Kernan.Scott@CDCR)
To: [Alston, Steve M@CDCR](mailto:Alston.Steve.M@CDCR)
Cc: [McAuliffe, John@CDCR](mailto:McAuliffe.John@CDCR)
Subject: RE: Thiopental Injection
Date: Thursday, September 30, 2010 4:47:48 PM

Helps. Thanks. I'll let you know if in fact we have to go this way to procure the drugs.

Scott

From: Alston, Steve M@CDCR
Sent: Thursday, September 30, 2010 3:52 PM
To: Kernan, Scott@CDCR
Cc: McAuliffe, John@CDCR
Subject: RE: Thiopental Injection
Importance: High

Scott,

Here is our take on the issue:

- The attached MSA is a vendor provided agreement covering a number of services, which, based on your note below, we should not sign.
- Based on your note this appears to be a straight purchase and not a service contract. Consequently, if [REDACTED] is in fact the vendor of choice, we will need to see if they will accept a CDCR issued purchase order.
- If you want to pursue a non-competitive bid purchase, then a justification will need to be developed explaining why this cannot go out for bid.
- The dollar value of the purchase will dictate required approvals:
 - Less than \$5,000 can be approved by OBS without an NCB.
 - If the purchase is \$5-25,000 an NCB will be required, but will not require DGS review / approval.
 - If the purchase is in excess of \$25,000 then DGS review / approval will be required.

Hope this helps!

Steve

From: Kernan, Scott@CDCR
Sent: Thursday, September 30, 2010 1:44 PM
To: Alston, Steve M@CDCR
Cc: McAuliffe, John@CDCR
Subject: RE: Thiopental Injection

Steve,

Thanks for your help. Needs to be addressed confidentially.

I assume the 3 year noted in the agreement is standard. Fact is we are buying enough of the drugs to last until 2014 and would not think, but not impossible, that we would need any more during the three years. So one time transaction.

I'll have to get back to you on cost. Don't know.

The contractor would facilitate the one time purchase of the drug and we would take possession for storage at SQ. no need for them to store it.

Scott

From: Alston, Steve M@CDCR
Sent: Thursday, September 30, 2010 11:21 AM
To: Kernan, Scott@CDCR
Subject: RE: Thiopental Injection


Scott,

Pulling our team together this afternoon to discuss in detail after which I will get back to you on this. A few questions for you:

1. Looks like a proposed three year agreement, right?
2. Estimated cost?
3. Will the proposed contractor store the inventory and ship it to CDCR on an as needed basis?

THANKS!

Steve



From: McAuliffe, John@CDCR
Sent: Thursday, September 30, 2010 9:20 AM

To: Kernan, Scott@CDCR
Subject: FW: Thiopental Injection

FYI
John

From: [REDACTED]
Sent: Thursday, September 30, 2010 9:15 AM
To: McAuliffe, John@CDCR
Cc: [REDACTED]
Subject: RE: Thiopental Injection

Received.

I have attached our standard contract (MSA). A Statement of Work (SOW) will define exact work to be conducted.

Please review and redline any issues.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: McAuliffe, John@CDCR [mailto:John.McAuliffe@cdcr.ca.gov]
Sent: Thursday, September 30, 2010 12:05 PM
To: [REDACTED]
Subject: FW: Thiopental Injection
Importance: High

[REDACTED]
Thank you again here is the information and email.
John McAuliffe

From: [REDACTED]
Sent: Thursday, September 30, 2010 5:27 AM
To: McAuliffe, John@CDCR
Subject: Thiopental Injection
Importance: High

30-09-10

Dear Mr. McAuliffe,

Thank you for your call and thank you for your interest in [REDACTED]

I would be happy to supply you:

Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's £196.75 (pounds sterling)
The current expiry date is February 2014.

POTASSIUM CHLORIDE 1.5GM 10ML INJ. PACKS OF 10 £15.55
Expiry date: 01/13

Pancuronium Injection, pancuronium bromide 2 mg/mL, 2-mL amp packs of 10's
£58.73
Expiry date: 11/11

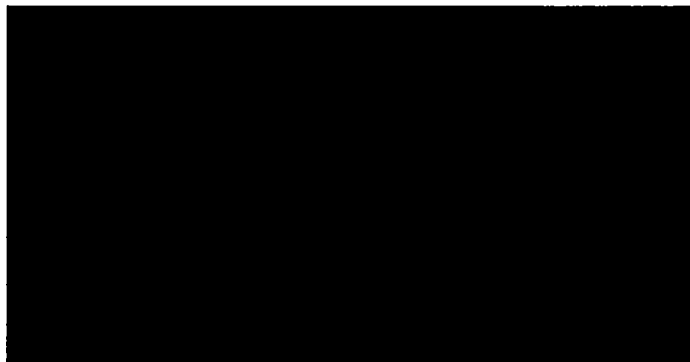
If you could supply me with the following information, I can produce a proforma invoice:
Invoice address
Delivery address, including contact person and contact person phone number

I will dispatch the goods to you by FedEx,
FedEx delivery charges is separate item.

In order to get the product easier through US customs, I think it would be a goods idea for you to write a letter in the department letterhead, attention of US custom and let them know why you need this product. I would include this letter in your shipment.
Please also email or fax me a copy of your DEA license, to include it in your shipment.

Please let me know if you need further information.

Many thanks,
Kind regards



From: [REDACTED]
To: McAuliffe, John@CDOR
Subject: DEA Registrations
Date: Thursday, September 30, 2010 4:02:26 PM
Attachments: [pract_manual012508.pdf](#)

John,

I hope you able to get in contact with our DEA Diversion H.Q. International Drug Unit: [REDACTED] & [REDACTED], for assistance with your international drug import issue. Feel free to contact me if you need any other assistance. For your agency's information, I have attached the "DEA Practitioners Manual" which discusses the rules and regulations that pertain to Practitioner DEA Registrations.

<<pract_manual012508.pdf>>

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Practitioner's Manual

An Informational Outline of the Controlled Substances Act

2006 Edition

Drug Enforcement Administration
Practitioner's Manual

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Mark W. Caverly
Chief, Liaison and Policy Section

This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession.

2006 Edition

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SECTION I - INTRODUCTION

This practitioner's manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), 21 USC 801-890, and the DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316. Pertinent citations to the law and regulations are included in this manual.

Printed copies of the CFR and the complete regulations implementing the CSA may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Both the CFR and the *Federal Register* (which includes proposed and final regulations implementing the CSA) are available on the Internet through the U.S. Government Printing Office (GPO) website. This website, which provides information by section, citation and keywords, can be accessed at:

www.gpoaccess.gov/cfr/index.html

Unofficial copies of pertinent CFR citations may be found at:

www.DEAdiversion.usdoj.gov

This practitioner's manual may also be found on the Internet at DEA's Web Site (under "publications"):

www.DEAdiversion.usdoj.gov

Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be published on the DEA Diversion Website.

If you encounter errors in this document, please notify:

Editor, DEA Practitioner's Manual
c/o DEA, Office of Diversion Control
Liaison and Policy Section
Washington, D.C. 20537

Inquiries regarding topics within this document may be addressed to your local DEA field office (listed in Appendix E) or the address above.

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Message from the Administrator

The Drug Enforcement Administration is pleased to provide this updated edition of the 1990 Practitioner's Manual to assist you in understanding your responsibilities under the Controlled Substances Act (CSA) and its implementing regulations. This manual will help answer questions that you may encounter in your practice and provide guidance in complying with federal requirements.

DEA remains committed to the 2001 Balanced Policy of promoting pain relief and preventing abuse of pain medications. In enforcing the CSA, it is DEA's responsibility to ensure drugs are not diverted for illicit purposes. Unfortunately, this country is now experiencing an alarming prescription drug abuse problem:

- Today, more than 6 million Americans are abusing prescription drugs—that is more than the number of Americans abusing cocaine, heroin, hallucinogens, and inhalants, combined.
- Researchers from the Centers for Disease Control and Prevention report that opioid prescription painkillers now cause more drug overdose deaths than cocaine and heroin combined.
- Today more new drug users have begun abusing pain relievers (2.4 million) than marijuana (2.1 million) or cocaine (1.0 million).

It is more important now than ever to be vigilant in preventing the diversion and abuse of controlled substances. This manual will help you do that by listing some safeguards you can take to prevent such diversion. It also explains registration, recordkeeping, and valid prescription requirements.

As a practitioner, your role in the proper prescribing, administering, and dispensing of controlled substances is critical to patients' health and to safeguarding society against the diversion of controlled substances. DEA is committed to working jointly with the medical community to ensure that those in need are cared for and that legitimate controlled substances are not being diverted for illegal use.

Karen P. Tandy
Administrator
September 2006

Drug Enforcement Administration Practitioner's Manual

Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary federal agency responsible for the enforcement of the Controlled Substances Act (CSA). The CSA sets forth the federal law regarding both illicit and licit (pharmaceutical) controlled substances. With respect to pharmaceutical controlled substances, DEA's statutory responsibility is twofold: to prevent diversion and abuse of these drugs while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works in close cooperation with state and local authorities and other federal agencies.

Under the framework of the CSA, the DEA is responsible for ensuring that all controlled substance transactions take place within the "closed system" of distribution established by Congress. Under this "closed system," all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and researchers – must be registered with DEA and maintain strict accounting for all distributions.

To carry out DEA's mission effectively, this 2006 Practitioner's Manual seeks to aid DEA registrants in complying with the CSA and its implementing regulations. The DEA understands that it can best serve the public interest by working with practitioners to prevent diversion of legal pharmaceutical controlled substances into the illicit market.

The federal controlled substances laws are designed to work in tandem with state controlled substance laws. Toward this same goal, DEA works in close cooperation with state professional licensing boards and state and local law enforcement officials to ensure that pharmaceutical controlled substances are prescribed, administered, and dispensed for legitimate medical purposes in accordance with federal and state laws. Within this cooperative framework, the majority of investigations into possible violations of the controlled substances laws are carried out by state authorities. However, DEA also conducts investigations into possible violations of federal law as circumstances warrant.

In the event a state board revokes the license of a practitioner, the DEA will take action and request a voluntary surrender of the practitioner's DEA registration. If the practitioner refuses to voluntarily surrender the registration, the DEA will pursue administrative action to revoke the DEA registration. The DEA may also pursue judicial action if there is sufficient evidence of illegal distribution or significant recordkeeping violations. All such actions are intended to deny the practitioner the means to continue to divert or abuse controlled substances as well as to protect the health and safety of the public and the practitioner.

The DEA is authorized under federal law to pursue legal action in order to prevent the diversion of controlled substances and protect the public safety. A lack of compliance may result in a need for corrective action, such as administrative action (that is, Letter of Admonition, an informal hearing or "order to show cause"), or in extreme cases, civil, or criminal action.

SECTION II – GENERAL REQUIREMENTS

Schedules of Controlled Substances

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A complete list of the schedules is published annually on an updated basis in the DEA regulations, Title 21 of the Code of Federal Regulations, Sections 1308.11 through 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States and their relative abuse potential and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are outlined below.

IMPORTANT NOTE:

All drugs listed in Schedule I have no currently accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in Schedules II through V all have some accepted medical use and therefore may be prescribed, administered, or dispensed for medical use.

Schedule I Substances

Substances in this schedule have no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin; lysergic acid diethylamide (LSD); marijuana (cannabis); peyote; methaqualone; and methylene-dimethoxy-methamphetamine ("ecstasy").

The CSA allows for bona fide research with controlled substances in Schedule I, provided that the FDA has determined the researcher to be qualified and competent, and provided further that the FDA has determined the research protocol to be meritorious. Researchers who meet these criteria must obtain a separate registration to conduct research with a Schedule I controlled substance.

Schedule II Substances

Substances in this schedule have a high potential for abuse with severe psychological or physical dependence.

Examples of single entity Schedule II narcotics include morphine, codeine, and opium. Other Schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

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Examples of Schedule II stimulants include amphetamine (Dexedrine® or Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other Schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Substances

Substances in this schedule have a potential for abuse less than substances in Schedules I or II.

Examples of Schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (i.e., Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (i.e., Tylenol with codeine®).

Examples of Schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, dronabinol (Marinol®), ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

Schedule IV Substances

Substances in this schedule have a lower potential for abuse relative to substances in Schedule III.

Examples of a Schedule IV narcotics include propoxyphene (Darvon® and Darvocet-N 100®).

Other Schedule IV substances include alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Substances

Substances in this schedule have a lower potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs. These are generally used for antitussive, antidiarrheal and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, and Phenergan with Codeine®).

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Registration Requirements

Under the CSA, the term “practitioner” is defined as a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the practitioner practices or performs research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research. Every person or entity that handles controlled substances must be registered with DEA or be exempt by regulation from registration.

The DEA registration grants practitioners federal authority to handle controlled substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located. When federal law or regulations differ from state law or regulations, the practitioner is required to abide by the more stringent aspects of both the federal and state requirements. In many cases, state law is more stringent than federal law, and must be complied with in addition to federal law. Practitioners should be certain they understand their state as well as DEA controlled substance regulations.

Application for Registration

To obtain a DEA registration, a practitioner must apply using a DEA Form 224. Applicants may submit the form by hard copy or on-line. Complete instructions accompany the form. To obtain the application, DEA may be contacted at:

- www.DEAdiversion.usdoj.gov (DEA Diversion Internet Web Site)
- any DEA field office (see listing in Appendix E of this manual)
- DEA Headquarters' Registration Section in Washington, D.C. at 1-800-882-9539 (Registration Call Center)

The DEA Form-224 may be completed on-line or in hard copy and mailed to:

Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083

A sample DEA Form 224 – New Application for Registration, is located at Appendix H, DEA Forms.

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Certificate of Registration

The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and kept available for official inspection.

The CSA requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed. DEA has historically provided an exception that a practitioner who is registered at one location, but also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed. If the practitioner maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the practitioner must obtain a separate DEA registration for that location. The exception applies only to a secondary location within the same state in which the practitioner maintains his/her registration. DEA individual practitioner registrations are based on state authority to dispense or conduct research with respect to controlled substances. Since a DEA registration is based on a state license, it cannot authorize controlled substance dispensing outside that state. Hence, the separate registration exception applies only to locations within the same state in which practitioners have their DEA registrations.

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A duplicate Certificate of Registration may be requested on-line. It appears on DEA's website, www.DEAdiversion.usdoj.gov, as follows:



DEA Form 223 Duplicate Certificate Login:

DEA Number (Required - Not Case Sensitive)

Last Name or Business Name (Required - Not Case Sensitive)
As it appears on your registration. Example:
If "Smith, John Q MD" is on your registration, then enter: **Smith**
If "Smith's, Pharmacy" is on your registration, then enter: **Smith's**
If "Smith's Pharmacy" (no comma) is on your registration,
then enter: **Smith's Pharmacy**

SSN (Required if given on application)

Tax ID (Required if given on application)

Note: If you renewed your registration recently, your duplicate certificate may not contain the new expire date, as some processing time is required.

Login

Registration Renewals

Practitioner registrations must be renewed every three years. Renewal registrations use DEA Form 224a, Renewal Application for DEA Registration (see example at Appendix H, DEA Forms). The cost of the registration is indicated on the application form.

A renewal application is sent to the registrant approximately 45 days before the registration expiration date. The renewal application is sent to the address listed on the current registration certificate. If the renewal form is not received within 30 days before the expiration date of the current registration, the practitioner should contact the DEA registration office for their state, or DEA Headquarters at 1-800-882-9539, and request a renewal registration form.

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The registration renewal application may be completed on-line at
www.DEAdiversion.usdoj.gov, or in hard copy and mailed to:

Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083



[Drug Registration](#) > ODWIF

Registration Applications

Office of Diversion Control Web Interactive Forms (ODWIF)

RENEWAL APPLICATIONS

Log-in to Begin Renewal Process	Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner, Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter, Domestic Chemicals
Obtain Receipt	This link may be used ONLY if you have previously submitted a Renewal Application through this tool and need an additional receipt.
Duplicate Certificate	On-line tool to request certificates for additional, misplaced, illegible, or destroyed originals.

MINIMUM ON-LINE REQUIREMENTS

The DEA Forms listed below are for those applying to DEA for a controlled substance registration. Data will be entered through a secure connection to the ODWIF on-line web application system. Your web browser must support 128-bit encryption.

You will need to have the following information handy in order to complete the form:

- Tax ID number and/or Social Security Number
- State Controlled Substance Registration Information
- State Medical License Information
- Credit Card (VISA, MasterCard, Discover or American Express)

The ODWIF system can only process credit card transactions at this time. If you are paying by check, you will need to use the PDF version of the form, then print and mail the form to the address listed on the form.

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Change of Business Address

A practitioner who moves to a new physical location must request a modification of registration. A modification of registration can be requested on-line at www.DEAdiversion.usdoj.gov or in writing to the DEA field office responsible for that state. If the change in address involves a change in state, the proper state issued license and controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). A Renewal Application for Registration (DEA Form-224a) will only be sent to the registered address on file with DEA. It will not be forwarded.

Termination of Registration

Any practitioner desiring to discontinue business activities with respect to controlled substances must notify the nearest DEA field office (see Appendix E) in writing. Along with the notification of termination of registration, the practitioner should send the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222) to the nearest DEA field office.

Denial, Suspension or Revocation of Registration

Under the CSA, DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has:

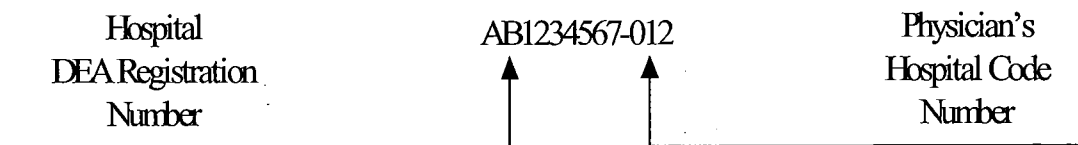
1. Materially falsified any application filed
2. Been convicted of a felony relating to a controlled substance or a List I chemical
3. Had their state license or registration suspended, revoked, or denied
4. Committed an act which would render the DEA registration inconsistent with the public interest
5. Been excluded from participation in a Medicaid or Medicare program

In determining the public interest, the CSA states the following factors are to be considered:

1. The recommendation of the appropriate state licensing board or professional disciplinary authority
2. The applicant's experience in dispensing or conducting research with respect to controlled substances
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances
4. Compliance with applicable state, federal, or local laws relating to controlled substances
5. Such other conduct which may threaten the public health and safety

Practitioner's Use of a Hospital's DEA Registration Number

1. The dispensing, administering, or prescribing is in the usual course of professional practice
2. Practitioners are authorized to do so by the state in which they practice
3. The hospital or institution has verified that the practitioner is permitted to dispense, administer or prescribe controlled substances within the state
4. The practitioner acts only within the scope of employment in the hospital or institution
5. The hospital or institution authorizes the practitioner to dispense or prescribe under its registration and assigns a specific internal code number for each practitioner so authorized (See example of a specific internal code number below):



Inappropriate Use of the DEA Registration Number

The Centers for Medicare and Medicaid Services has developed a National Provider Identification (NPI) number unique to each healthcare provider. The Final Rule for establishment of the NPI system was published in the Federal Register (FR 3434, Vol. 69, No. 15) by the Department of Health and Human Services on January 23, 2004. The effective date of this Final Rule was May 23, 2005; all covered entities must begin using the NPI in standard transactions by May 23, 2007.

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Exemption of Federal Government Practitioners from Registration

The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in Title 21, CFR § 1306 regarding prescriptions, but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

If a Federal Government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, they must be fully licensed to handle controlled substances by the state in which they are located. Under these circumstances, the Federal Government practitioner will not be eligible for the fee exemption and must pay a fee for the registration.

SECTION III – SECURITY REQUIREMENTS

Required Controls

Title 21, CFR Section 1301.71(a), requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances. A list of factors is used to determine the adequacy of these security controls. Factors affecting practitioners include:

1. The location of the premises and the relationship such location bears on security needs
2. The type of building and office construction
3. The type and quantity of controlled substances stored on the premises
4. The type of storage medium (safe, vault, or steel cabinet)
5. The control of public access to the facility
6. The adequacy of registrant's monitoring system (alarms and detection systems)
7. The availability of local police protection

Practitioners are required to store stocks of Schedule II through V controlled substances in a securely locked, substantially constructed cabinet. Practitioners authorized to possess carfentanil, etorphine hydrochloride and/or diprenorphine, must store these controlled substances in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances
2. Any person who has been denied a DEA registration
3. Any person who has had a DEA registration revoked
4. Any person who has surrendered a DEA registration for cause

Lastly, practitioners should notify the DEA, upon discovery, of any thefts or significant losses of controlled substances and complete a DEA Form 106 regarding such theft or loss.

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Safeguards for Prescribers

In addition to the required security controls, practitioners can utilize additional measures to ensure security. These include:

1. Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
2. Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
3. Use prescription blanks only for writing a prescription order and not for notes.
4. Never sign prescription blanks in advance.
5. Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
6. Contact the nearest DEA field office (see Appendix E) to obtain or to furnish information regarding suspicious prescription activities.
7. Use tamper-resistant prescription pads.

SECTION IV – RECORDKEEPING REQUIREMENTS

Recordkeeping Requirements

Each practitioner must maintain inventories and records of controlled substances listed in Schedules I and II separately from all other records maintained by the registrant. Likewise, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the practitioner. All records related to controlled substances must be maintained and be available for inspection for a minimum of two years.

A registered practitioner is required to keep records of controlled substances that are dispensed to the patient, other than by prescribing or administering, in the lawful course of professional practice. A registered practitioner is not required to keep records of controlled substances that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment. A registered practitioner is not required to keep records of controlled substances that are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. A registered practitioner is also required to keep records of controlled substances administered in the course of maintenance or detoxification treatment of an individual.

Inventory

Each registrant who maintains an inventory of controlled substances must maintain a complete and accurate record of the controlled substances on hand and the date that the inventory was conducted. This record must be in written, typewritten, or printed form and be maintained at the registered location for at least two years from the date that the inventory was conducted. After an initial inventory is taken, the registrant shall take a new inventory of all controlled substances on hand at least every two years.

Each inventory must contain the following information:

1. Whether the inventory was taken at the beginning or close of business
2. Names of controlled substances
3. Each finished form of the substances (e.g., 100 milligram tablet)
4. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
5. The number of commercial containers of each finished form (e.g., four 100 tablet bottles)

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6. Disposition of the controlled substances

It is important to note that inventory requirements extend to controlled substance samples provided to practitioners by pharmaceutical companies.

Disposal of Controlled Substances

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office (See Appendix E) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

SECTION V – VALID PRESCRIPTION REQUIREMENTS

Prescription Requirements

A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include:

1. drug name
2. strength
3. dosage form
4. quantity prescribed
5. directions for use
6. number of refills (if any) authorized

A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.

The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice
2. Registered with DEA or exempted from registration (that is, Public Health Service, Federal Bureau of Prisons, or military practitioners)
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements as set forth in the CFR are met.

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Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. In addition, a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription within the meaning and intent of the Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Schedule II Substances

Schedule II controlled substances require a written prescription which must be signed by the practitioner. There is no federal time limit within which a Schedule II prescription must be filled after being signed by the practitioner.

While some states and many insurance carriers limit the quantity of controlled substance dispensed to a 30-day supply, there are no specific federal limits to quantities of drugs dispensed via a prescription. For Schedule II controlled substances, an oral order is only permitted in an emergency situation.

Refills

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited (Title 21 U.S. Code § 829(a)).

Issuance of Multiple Prescriptions for Schedule II Substances

DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

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2. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
4. The issuance of multiple prescriptions is permissible under applicable state laws.
5. The individual practitioner complies fully with all other applicable requirements under the Controlled Substances Act and Code of Federal Regulations, as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a Schedule II prescription to the pharmacy by facsimile. The original Schedule II prescription must be presented to the pharmacist for review prior to the actual dispensing of the controlled substance.

In an emergency, a practitioner may call-in a prescription for a Schedule II controlled substance by telephone to the pharmacy, and the pharmacist may dispense the prescription provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. The prescribing practitioner must provide a written and signed prescription to the pharmacist within seven days. Further, the pharmacist must notify DEA if the prescription is not received.

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Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for Schedule II controlled substances. The facsimile of a Schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing Schedule II narcotic controlled substances to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further prescription verification is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing Schedule II controlled substances for residents of Long Term Care Facilities (LTCF) may transmit a prescription by facsimile to the dispensing pharmacy. The practitioner's agent may also transmit the prescription to the pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy.
3. A practitioner prescribing a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent may transmit the prescription to the pharmacy. The practitioner or agent will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription.

Schedule III-V Substances

A prescription for controlled substances in Schedules III, IV, and V issued by a practitioner, may be communicated either orally, in writing, or by facsimile to the pharmacist, and may be refilled if so authorized on the prescription or by call-in.

Refills

Schedule III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date on which the prescription was issued. After five refills or after six months, whichever occurs first, a new prescription is required.

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Facsimile Prescriptions for Schedule III-V Substances

Prescriptions for Schedules III-V controlled substances may be transmitted by facsimile from the practitioner or an employee or agent of the individual practitioner to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription.

Telephone Authorization for Schedule III-V Prescriptions

A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except for the signature of the practitioner.

Delivery of a Controlled Substance to Persons Outside the U.S.

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in another country. Any such delivery or shipment is a prohibited export under the CSA.

SECTION VI – OPIOID (NARCOTIC) ADDICTION TREATMENT PROGRAMS

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of addiction. These laws established the procedures for approval and licensing of practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Practitioners wishing to administer and dispense approved Schedule II controlled substances (that is, methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program. Application for registration as a Narcotic Treatment Program is made using DEA Form 363. In addition to obtaining this separate DEA registration, this type of activity also requires the approval and registration of the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS), as well as the applicable state methadone authority.

If a practitioner wishes to prescribe, administer, or dispense Schedule III, IV, or V controlled substances approved for addiction treatment (i.e., buprenorphine drug products), the practitioner must request a waiver (Form SMA-167) and fulfill the requirements of CSAT. CSAT will then notify DEA of all waiver requests. DEA will review each request. If DEA approves this waiver, the practitioner will receive a Unique Identification Number. If a practitioner chooses to dispense controlled substances, the practitioner must maintain, separate from all other records, for a period of at least two years, all required records of receipt, storage, and distribution. If a practitioner chooses to prescribe these controlled substances, the practitioner must utilize their Unique Identification Number on the prescription in addition to his/her regular DEA registration number. The practitioner must also maintain a record of each such prescription for a period of at least two years. Practitioners should be aware that there may be limits on how many patients they may treat for opioid addiction at any given time and should check with SAMHSA to determine these limits.

Note that not all treatment programs utilize controlled substances, that is, some are drug free. Accordingly, these activities do not require DEA registration or approval.

Practitioners can find additional information regarding addiction treatment by visiting DEA's Office of Diversion Control website at www.DEAdiversion.usdoj.gov. Click on "Publications," then "Narcotic Treatment Programs: Best Practices Guidelines." The DEA application Form 363 may be completed on-line.

To learn more about CSAT's requirements, practitioners may visit one or more of the following websites: www.samhsa.gov/centers/csat2002/csat_frame.html, www.csat.samhsa.gov, or www.buprenorphine.samhsa.gov.

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If the practitioner has a patient who is in need of addiction treatment, but does not wish to treat the individual, the practitioner can refer the patient to an existing facility through the following website: www.findtreatment.samhsa.gov.

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APPENDIX A

CSA & CFR Definitions

Administer

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his presence) by his authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.

Dispense

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.

Dispenser

An individual practitioner, institutional practitioner, pharmacy or, pharmacist who dispenses a controlled substance.

Individual Practitioner

A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Institutional Practitioner

A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Inventory

All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

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Long Term Care Facility

A nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.

Mid-level Practitioner

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily Retrievable

Certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

APPENDIX B

Questions and Answers

The following questions are those that are frequently encountered by DEA's Office of Diversion Control and its field units. These questions and their accompanying answers are provided in context of the CSA and its federal regulations.

Q Are separate registrations required for separate locations?

A A separate registration is required for each principal place of business or professional practice where controlled substances are stored or dispensed by a person.

Q Does a practitioner need a separate registration to treat patients at remote health care facilities?

A Separate registration is not required in an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

Q Do all practitioners in a group practice need to be registered?

A 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.

Q Do medical residents assigned to hospitals need to register?

A 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 provided that additional requirements as set forth in the CFR are met.

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Q Are military personnel exempted from registration?

A Registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, or Coast Guard who is authorized to prescribe, dispense, or administer, but not procure or purchase, controlled substances in the course of his/her official duties. Such officials must follow procedures set forth in 21 CFR Part 1306 regarding prescriptions. Branch of service or agency and the service identification number of the issuing official is required on the prescription form in lieu of the DEA registration number.

If any exempted official engages as a private individual in any activity or group of activities for which registration is required, that individual must obtain a registration for those private activities.

Further, practitioners serving in the U.S. Military are exempt from registering with DEA, but are not authorized to procure or purchase controlled substances in the course of their official duties.

A number of states also require military practitioners to acquire a separate state license if they issue prescriptions that are filled outside the military facility where they practice.

Q Are contract practitioners working at U.S. Military Installations also exempt from registration?

A They are not exempt. A contract practitioner who is not an official of the military on active duty, but is engaged in medical practice at a military installation, must possess a current DEA registration. The individual must also possess a valid state license for the same state in which he/she is registered with DEA.

Q What should a practitioner do if he/she discovers a theft or loss?

A Registrants must notify the DEA field office in their area of the theft or significant loss of any controlled substances upon discovery. The registrant must also complete DEA Form 106 documenting the loss or theft.

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Q What is meant by “acceptable medical practice?”

A The legal standard that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice has been construed to mean that the prescription must be “in accordance with a standard of medical practice generally recognized and accepted in the United States.”

Federal courts have long recognized that it is not possible to expand on the phrase “legitimate medical purpose in the usual course of professional practice” in a way that will provide definitive guidelines to address all the varied situations physicians may encounter.

While there are no criteria to address every conceivable instance of prescribing, there are recurring patterns that may be indicative of inappropriate prescribing:

- An inordinately large quantity of controlled substances prescribed or large numbers of prescriptions issued compared to other physicians in an area;
- No physical examination was given;
- Warnings to the patient to fill prescriptions at different drug stores;
- Issuing prescriptions knowing that the patient was delivering the drugs to others;
- Issuing prescriptions in exchange for sexual favors or for money;
- Prescribing of controlled drugs at intervals inconsistent with legitimate medical treatment;
- The use of street slang rather than medical terminology for the drugs prescribed; or
- No logical relationship between the drugs prescribed and treatment of the condition allegedly existing.

Each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient.

For example, what constitutes “an inordinately large quantity of controlled substances,” can vary greatly from patient to patient. A particular quantity of a powerful Schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient.

Q What information is required to be provided on a written prescription?

A All written prescriptions for controlled substances must be dated as of, and signed on, the date when issued. Each prescription must indicate the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed,

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directions for use and the name, address, and DEA number of the practitioner. Further, prescriptions must be written in ink, indelible pencil, or by typewriter, and must be manually signed by the practitioner.

Q What is meant by “date of issuance?”

A The date a prescription is issued is the same date that the prescribing practitioner actually writes and signs the prescription.

Q Is there a time limit for filling Schedule II prescriptions?

A There is no federal time limit for filling Schedule II prescriptions. However, some state laws do set time limits.

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APPENDIX C

Summary of Controlled Substances Act Requirements

	<i>Schedule II</i>	<i>Schedule III & IV</i>	<i>Schedule V</i>
<i>Registration</i>	Required	Required	Required
<i>Receiving Records</i>	Order Forms (DEA Form-222)	Invoices, Readily Retrievable	Invoices, Readily Retrievable
<i>Prescriptions</i>	Written Prescription (See exceptions*)	Written, Oral, or Fax	Written, Oral, Fax, or Over The Counter**
<i>Refills</i>	No	No more than 5 within 6 months	As authorized when prescription is issued
<i>Distribution Between Registrants</i>	Order Forms (DEA Form-222)	Invoices	Invoices
<i>Security</i>	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage
<i>Theft or Significant Loss</i>	Report and complete DEA Form 106	Report and complete DEA Form 106	Report and complete DEA Form 106

Note: *All records* must be maintained for 2 years, unless a state requires a longer period.

* **Emergency prescriptions** require a signed follow-up prescription.

Exceptions: A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, Hospice patients, or compounded IV narcotic medications.

** Where authorized by state controlled substances authority.

APPENDIX D

Internet Resources

DEA's Diversion Control Program Website

www.DEAdiversion.usdoj.gov

DEA Homepage

www.dea.gov

U.S. Government Printing Office

www.gpoaccess.gov/cfr/index.html

Provides access to the Code of Federal Regulations (21 CFR, Parts 1300 to end), primary source for the Practitioner's Manual, and the Federal Register which contains proposed and finalized amendments to the CFR.

Office of National Drug Control Policy (ONDCP)

www.whitehousedrugpolicy.gov

Food and Drug Administration

www.FDA.gov

HHS & SAMHSA's National Clearinghouse for Alcohol and Drug Information

www.health.org

SAMHSA/CSAT

www.csat.samhsa.gov

Federation of State Medical Boards

www.FSMB.org

National Association of Boards of Pharmacy

www.nabp.net

National Association of State Controlled Substances Authorities

www.nascsa.org

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APPENDIX E

Drug Enforcement Administration **Diversion Field Office Locations**

For address and telephone number updates, please see the DEA website:
www.deadiversion.usdoj.gov/offices_n_dirs/index.html

Appendix E pages 34-39 of this manual contained outdated Field Office Information and therefore have been removed. Please refer to the above link for current Diversion Field Office Locations.