partment of Justice
forcement Administration

U.S. Department of Justice
Drug Enforcement Administration

PHYSICIAN'S MANUAL

An Informational Outline of the Controlled Substances Act of 1970

Revised March, 1990

This booklet has been prepared by the Office of Diversion Control as part of DEA's program to assist physicians in their understanding of the Controlled Substances Act and its implementing regulations as they pertain to medical practitioners.

American Dental Association

American Medical Association

American Osteopathic Association

American Podiatric Medical Association

American Veterinary Medical Association

Drug Enforcement Administration
United States Department of Justice

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Administrator

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Revised March, 1990

Contents

Message from the Administrator

Dear Doctor:

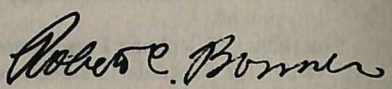
The Drug Enforcement Administration is pleased to provide you with the sixth edition of the Physician's Manual to assist in understanding the provisions of the Controlled Substances Act and the regulations. This booklet will answer questions that you may encounter in your practice and will give you guidance in complying with the regulations.

The sixth edition has been revised to include the provisions of the Comprehensive Crime Control Act of 1984 (Diversion Control Amendments) and the Registrant Protection Act of 1984.

The role of the physician in the proper prescribing of controlled substances is critical both to the health of patients and to safeguard society against drug abuse and diversion. The physician's adherence to the law, together with voluntary service of its objectives, constitute a powerful resource for protecting the public health and safety.

We have included in this edition the "Guidelines for Prescribers of Controlled Substances," which provide acceptable professional responses to the provisions of the Controlled Substances Act.

Sincerely,



Robert C. Bonner
Administrator

Preface

Over 725,000 medical practitioners are registered with the Drug Enforcement Administration to prescribe, handle and dispense controlled substances. The vast majority of this group comply with the law and regulations in a responsible and law-abiding manner.

The Drug Enforcement Administration respects the professional integrity of physicians and recognizes that it can best serve the public interest by working together with physicians to develop acceptable and cooperative programs. Physicians generally comply with the law and have their own self-regulation programs consistent with the highest ethical, moral and legal standards. DEA relies on these programs and concentrates its resources on the more serious problems of practitioner diversion.

Drug abuse continues to be a serious problem. The diversion of legitimate drug products to the illicit market and the abuse of prescription medication, particularly controlled substances, is of great concern to the Drug Enforcement Administration. The importance of the physician in the proper control of prescription drugs cannot be overemphasized. The physician is in a critical position because it is the physician who initiates the process whereby the prescription medication ultimately comes into the hands of the consumer via the dispensing pharmacist. The physician and the pharmacist share the responsibility for controlling and monitoring the drug usage of patients. Patient health and proper drug usage depend upon concerned and interested professionals.

The physician must be aware of the various methods and activities employed to divert controlled substances. There are those activities for which the physician is entirely responsible through criminal intent in the pursuit of profit. The primary source of this criminal activity is "script writing." This method of diverting licit drug products can be extremely profitable. Theft of controlled substances from a physician's office and theft of prescription blanks are other methods for diverting controlled substances. Willful and intentional diversion by a physician is another source of diverted controlled substances.

Misprescribing, overprescribing, and inappropriate prescribing are practices which may lead to drug abuse. Prescribing excessive quantities or issuing prescription orders for longer periods than necessary may create the events necessary to initiate drug abuse or dependence or cause the medication to be diverted to other persons for abuse or for illicit purposes. Moreover, the physician who has not kept current with medication therapy may cause medication to be available to those who may not require it. Another area which must be mentioned is the physician who self-prescribes and administers.

The physician should be aware of gimmicks and techniques used by drug abusers to obtain controlled substances. The physician should be cautious of patients who self-diagnose and self-prescribe. The physician should be alert to a series of "new" patients all complaining of a similar illness. The physician should guard the prescription pads—because a prescription pad left out in the open is a temptation to the addict and forger. Also, the physician should be

alert to schemes perpetrated by financiers such as stress clinics and storefront operations which hire physicians to write prescription orders for controlled substances and other drug products for "patients" where there are nonexisting medical conditions.

Recognizing the important role of the physician in prescribing controlled substances, the Drug Enforcement Administration and the national medical associations prepared a number of prescribing guidelines for professionals to establish acceptable professional responses to the demands of the Controlled Substances Act.These guidelines have received wide distribution and were published by all groups in their major publications. They are reprinted in this booklet. Close cooperation between the medical professions and law enforcement will ensure that legitimate drugs remain in legitimate channels.

Application of State and Federal Law

Nothing in this pamphlet shall be construed as authorizing or permitting any person to do any act which is not authorized or permitted under other Federal or State laws. In addition, none of the policy and information in this pamphlet may be construed as authorizing or permitting any person to do any act which is not authorized or refuse to meet any requirements imposed under the regulations published in the most recent publication of Title 21, Chapter II of the Code of Federal Regulations (21 CFR, Part 1300 to End). Printed copies of the complete regulations implementing the Controlled Substances Act of 1970 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.* Proposed and finalized amendments to the regulations are published in the Federal Register.

In many cases State law is much more stringent than Federal law and imposes additional requirements. This pamphlet is an example of Federal law covering specific situations as outlined in the Federal regulations.

*Editor's Note: Selected portions of the regulations promulgated under the Controlled Substances Act that are of most concern to physicians and pharmacists and students of medicine and pharmacy are presented in the United States Pharmacopeia as a service to the professions. They are provided at the suggestion of the Drug Enforcement Administration.

Drug Enforcement Administration

The Drug Enforcement Administration is the Federal law enforcement agency charged with the responsibility of combating drug diversion. The Administration was established July 1, 1973, by Presidential Reorganization Plan No. 2 of 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs, the Office of Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, those elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The Administration was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out its mission, the Administration cooperates with other Federal agencies, foreign as well as State and local governments, private industry, and other organizations.

Since 1914, the Congress has enacted more than 50 pieces of legislation relating to control and diversion of drugs. The Controlled Substances Act of 1970 became effective May 1, 1971. It collects and conforms most of these diverse laws into one piece of legislation. The law is designed to improve the administration and regulation of manufacturing, distribution, and the dispensing of controlled substances by providing a "closed" system for legitimate handlers of these drugs. Such a closed system should help reduce the widespread diversion of these substances out of legitimate channels that find their way into the illicit market.

This informational outline has been prepared to acquaint the physician with requirements set up under the Controlled Substances Act of 1970 and 1984 Diversion Control Amendments as they affect various classes of practitioners.

NOTE: The word "physician" as used in this pamphlet, means any physician, dentist, podiatrist, veterinarian, or other practitioner authorized to administer, dispense and prescribe controlled substances.

Schedules of Controlled Substances

The drugs and drug products that come under the jurisdiction of the Controlled Substances Act are divided into five schedules. Some examples in each schedule are outlined below. For a complete listing of all the controlled substances contact any office of the Drug Enforcement Administration. The addresses are listed in the back portion of this outline.

*Examples of drugs in these Schedules are as follows:

Schedule I Substances

The substances in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Some examples are heroin, marihuana, LSD, MDMA, peyote, mescaline, psilocybin, N-ethylamphetamine, acetylmethadol, fenethylline, tilidine, dihydromorphine, and methaqualone.

Schedule II Substances

The substances in this schedule have a high abuse potential with severe psychic or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant and depressant drugs. Some examples of Schedule II narcotic controlled substances are: opium, morphine, codeine, hydromorphone (Dilaudid), methadone, pantopon, meperidine (Demerol), cocaine, oxycodone (Percodan), and oxymorphone (Numorphan). Also in Schedule II are amphetamine (Dexedrine), methamphetamine (Desoxyn), phenmetrazine (Preludin), methylphenidate (Ritalin), amobarbital, pentobarbital, secobarbital, fentanyl (Sublimaze), sufentanil, etorphine hydrochloride, phenylacetone, dronabinol and nabilone.

*Examples of trademark products appear in parenthesis. Scheduling applies to all similar drug products of all other pharmaceutical manufacturers within each generic drug classification.

Schedule III Substances

The substances in this schedule have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs such as: derivatives of barbituric acid except those that are listed in another schedule, glutethimide (Doriden), nalorphine, benzphetamine, chlorphentermine, clortermine, phendimetrazine, paregoric and any compound, mixture, preparation or suppository dosage form containing amobarbital, secobarbital or pentobarbital.

Schedule IV Substances

The substances in this schedule have an abuse potential less than those listed in Schedule III and include such drugs as: barbital, phenobarbital, methylphenobarbital, chloral hydrate, ethchlorvynol (Placidyl), ethinamate (Valmid), meprobamate, (Equanil, Miltown), paraldehyde, methohexital, fenfluramine, diethylpropion, phentermine, chlordiazepoxide (Librium), diazepam (Valium), oxazepam (Serax), clorazepate (Tranxene), flurazepam (Dalmane), clonazepam (Clonopin), prazepam (Verstran), alprazolam (Xanax), halazepam (Paxipam), temazepam (Restoril), triazolam (Halcion), lorazepam (Ativan), midazolam (Versed), Quazepam (Dormalin), mebutamate, dextropropoxyphene dosage forms (Darvon) and pentazocine (Talwin-NX).

Schedule V Substances

The substances in this schedule have an abuse potential less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs generally for antitussive, antidiarrheal and analgesic purposes. Some examples are buprenorphine and propylhexedrine.

Registration

Every physician who administers, prescribes or dispenses any controlled substance must be registered with the Drug Enforcement Administration.

"Administer" means to instill a drug into the body of the patient.

"Prescribe" means to issue a prescription order for the patient.

"Dispense" means to deliver a controlled substance in some type of bottle, box, or other container to the patient. *(Under the Act, the definition of "dispense" also includes the administering of a controlled substance).*

A physician is required to register with the Drug Enforcement Administration, Registration Unit, P.O. Box 28083, Central Station, Washington, D.C. 20005. A physician who seeks to become registered must apply on Form DEA-224, which can be obtained from the Registration Unit or from any DEA field office. Complete instructions accompany the form.

The registration must be renewed every three years and the certificate of registration must be maintained at the registered location and kept available for official inspection. The cost of this certificate to a physician for the three year period is $60.00. Every physician currently registered with the Drug Enforcement Administration will receive a re-registration application approximately 60 days before the expiration date of his registration. If a registered physician does not receive such a form within 45 days before the expiration date of registration, notice of such fact and a request for the re-registration form must be made in writing to the Registration Unit of the Drug Enforcement Administration.

If a physician has more than one office where controlled substances are administered and/or dispensed, then each office must be registered. However, if a physician only administers and/or dispenses at the principal office and only writes prescription orders at the other office or offices, only the principal office need be registered, provided each office is within the same state. A physician who moves a place of practice must request a modification of registration. The request must be made in writing to the nearest DEA field office and approved prior to the effective date of the move. This is a requirement of the 1984 Diversion Control Amendments.

Public Interest Provision

Diversion of legitimately manufactured controlled substances is a serious problem and contributes greatly to the drug abuse problem in the United States. It has been determined that a small percentage of practitioners are responsible for a large portion of the diversion of these substances. The Diversion Control Amendments, a part of the Comprehensive Crime Control Act, provide an additional legal avenue by which the Federal Government can impact on those practitioners contributing to the diversion problem.

The 1984 Diversion Control Amendments give the Attorney General authority to deny an application for registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall 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."

Sample Form DEA-224

Below is a sample format of a completed Form DEA-224. Attention should be paid to item (2) as triplicate order forms (DEA-222) will not be issued unless the appropriate drug schedules are checked.

Form DEA – 224 (Sul, 1981) OMB No. 1117-0014

NEW
APPLICATION FOR REGISTRATION UNDER CONTROLLED SUBSTANCES ACT OF 1970

Please PRINT or TYPE all entries.

No registration may be issued unless a completed application form has been received (21 CFR 1301.21).

DOE, JAMES C. M.D.
6522 SPRUCE STREET

CITY	STATE	ZIP CODE
ANYTOWN	MARYLAND	26103

RETAIN Copy 3. Mail Orig. and 1 copy with FEE to
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
P.O. Box 28083
CENTRAL STATION
WASHINGTON, D.C. 20005
For INFORMATION, Call: 202 254-8255
See "Privacy Act" Information on reverse

THIS BLOCK FOR DEA USE ONLY

REGISTRATION CLASSIFICATION: Submit Check or Money Order Payable to the DRUG ENFORCEMENT ADMINISTRATION in the Amount of $60.00.

1. BUSINESS ACTIVITY: (Check ONE only) (Specify Medical Degree, e.g., DDS, DO, DVM, MD, etc.)

● FEE MUST ACCOMPANY APPLICATION

A ☐ RETAIL PHARMACY B ☐ HOSPITAL/CLINIC C ☒ PRACTITIONER D ☐ TEACHING INSTITUTION (Instructional purposes only)

2. SCHEDULES: (Check all applicable schedules in which you intend to handle controlled substances. See Schedules on Reverse of Instruction Sheet.)

SCHEDULE II NARCOTIC	SCHEDULE II NONNARCOTIC	SCHEDULE III NARCOTIC	SCHEDULE III NONNARCOTIC	SCHEDULE IV	SCHEDULE V
☒	☒	☒	☒	☒	☒

3. ☒ CHECK HERE IF YOU REQUIRE ORDER FORMS.

4. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying, under the laws of the State or jurisdiction in which you are operating or propose to operate?
☒ YES - State License Number(s) 25-632586
☐ NOT APPLICABLE ☐ PENDING

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a DEA registration revoked, suspended or denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?
☐ YES ☐ NO

(c) If the applicant is a corporation, association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a DEA registration revoked, suspended or denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?
☐ YES ☐ NO ☐ NOT APPLICABLE

IF THE ANSWER TO QUESTIONS 4(b) or (c) is YES, include a statement using the space provided on the REVERSE of this part.

● ATTACH CHECK HERE

JAMES C. DOE, M.D. — Print or Type Name Here - Sign Below
301-123-4567 — Applicants Business Phone No.

SIGN HERE ▶ James C. Doe, M.D. — Signature of applicant or authorized individual
Jan 30, 1990

Title (If the applicant is a corporation, institution, or other entity, enter the TITLE of the person signing on behalf of the applicant (i.e., President, Dean, Procurement Officer, etc....))

5. CERTIFICATION FOR FEE EXEMPTION

☐ CHECK THIS BLOCK IF INDIVIDUAL NAMED HEREON IS A FEDERAL, STATE, OR LOCAL OFFICIAL.

The Undersigned hereby certifies that the applicant herein is an officer or employee of a Federal, State or local agency who, in the course of such employment, is authorized to obtain, dispense, or prescribe controlled substances or is authorized to conduct research, instructional activity or chemical analysis with controlled substances, and is exempt from the payment of this application fee.

Signature of Certifying Official — Date

Print or Type Name

Print or Type Title

Name of Institution or Agency

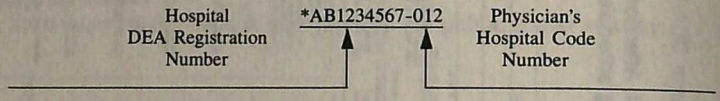
WARNING: SECTION 843(a)(4) OF TITLE 21, UNITED STATES CODE, STATES THAT ANY PERSON WHO KNOWINGLY OR INTENTIONALLY FURNISHES FALSE OR FRAUDULENT INFORMATION IN THIS APPLICATION IS SUBJECT TO IMPRISONMENT FOR NOT MORE THAN FOUR YEARS, A FINE OF NOT MORE THAN $30,000.00 OR BOTH.

Mail the Original and 1 copy with FEE to the above address. Retain 3rd copy for your records.

Registration Regarding Interns, Residents and Foreign Physicians

Any physician who is an intern, resident, foreign physician or physician on the staff of a Veterans Administration facility (exempted from registration), may dispense, administer and prescribe controlled substances under the registration of the hospital or other institution in which the physician is employed provided that:

1. The dispensing, administering or prescribing is in the usual course of professional practice;
2. The physician is authorized or permitted to do so by the state where practicing;
3. The hospital or institution has verified that the physician is permitted to dispense, administer or prescribe drugs within the state;
4. The physician acts only within the scope of employment in the hospital or institution;
5. The hospital or other institution authorizes the physician to dispense or prescribe under its registration and assigns a specific internal code number for each physician so authorized. An example of a specific internal code number is as follows:



6. A current list of internal codes and the corresponding individual physicians is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for purpose of verifying the authority of the prescribing physician.

*DEA registration numbers for physicians generally start with the letter "A", "New" registrants have been assigned the letter "B" as a first character after October 1, 1985. There has been no change in the registration number for those physicians who already had the letter "A" as a first character.

Records

Physician Recordkeeping Requirements

It is necessary for manufacturers, wholesalers, pharmacies, hospitals and certain physicians, among others, to keep records of drugs purchased, distributed and dispensed. Having this closed system, a controlled substance can be traced from the time it is manufactured to the time it is dispensed to the ultimate user.

All controlled substance records must be filed in a readily retrievable manner from all other business documents, retained for two years and made available for inspection by DEA.

Controlled substance records maintained as part of the patient file will require that this file be made available for inspection by DEA.

The 1984 Diversion Control Amendments have mandated additional recordkeeping requirements on physicians for certain activities.

Prescribing

A physician who prescribes Schedule II, III, IV and V controlled substances in the lawful course of professional practice is not required to keep records of those transactions.

Dispensing

A physician who dispenses controlled substances is required to keep a record of each transaction.

Administering

A physician who regularly engages in administering controlled substances in Schedule II, III, IV and V is required to keep records if patients are charged for these drugs either separately or together with other professional services. When a physician dispenses a controlled substance and administers this substance occasionally or regularly from the same inventory, the physician must keep a record of all transactions.

A physician who occasionally administers a controlled substance and does not dispense the controlled substance from the same inventory is not required to keep records of these transactions.

Narcotic Treatment

Records are required for controlled substances prescribed, dispensed or administered for maintenance or detoxification treatment. A physician is required to be registered as a narcotic treatment program to conduct these activities.

Inventory Requirements

A physician who dispenses or regularly engages in administering controlled substances and is required to keep records as stated above must take an inventory every two years of all stocks of the substances on hand.

Initial Inventory

A physician who intends to conduct any controlled substance activities for which records are required to be maintained (See section on Records) must take an inventory of all stocks of controlled substances on hand on the date he/she first engages in such activities. In the event no controlled substances are on hand at the initial inventory, a zero inventory should be recorded.

The inventory record must:

1. List the name, address and DEA registration number of the registrant.
2. Indicate the date and time the inventory is taken, i.e., opening or close of business.
3. Be signed by the person or persons responsible for taking the inventory.
4. Be maintained at the location appearing on the registration certificate for at least two years.
5. Keep records of Schedule II drugs separate from all other controlled substance records.

Biennial Inventory

Every two years following the date of the initial inventory, a new inventory is required. The information required on the biennial inventory is the same as that for the initial inventory. The biennial inventory date can be changed to a more convenient date provided it is within six months of the required date and advance written notification is given to the nearest DEA field office of the date on which the physician desires to take the inventory. A physician must keep the biennial inventory record for two years and is not required to submit a copy to the DEA.

All inventories and records of controlled substances in Schedule II must be maintained separately from all other records of the physician. All inventories and records of controlled substances in Schedules III, IV and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary professional and business records of the physician.

All records pertaining to controlled substances shall be made available for inspection and copying by duly authorized officials of the Drug Enforcement Administration.

Order Forms

A physician who has need for controlled substances in Schedule II for use in the office or medical bag must obtain these drugs by the use of a triplicate order form. Order forms can be obtained by requesting them on the initial application form by checking block "3" of the Form DEA-224 or from the Drug Enforcement Administration, Registration Unit, P.O. Box 28083, Central Station, Washington, DC 20005. Once a registrant has obtained DEA order forms, a separate requisition form, DEA-222A, will be mailed to the registrant in order to request additional books. No charge is made for order forms.

The Federal Triplicate Order Forms should not be confused with the multiple-copy prescription blanks that are required by some states. The Federal order forms are to be used by a physician who has a need for a drug in Schedule II which is to be used in the office. For example, a physician must fill out a Triplicate Order Form in order to obtain Demerol or Morphine, etc. from the normal source of supply.

A common omission on DEA order forms is failure to complete the "number of packages" and "date received" section. It is important that persons responsible for executing Schedule II order forms verify the quantities received by dating and completing the right hand side of the order form.

Schedule III-V records: A physician receiving controlled substances in these schedules must maintain records of transactions by filing "supplier's" invoices or maintaining a log book. The date of controlled substance receipt and any differences from the quantities ordered should be noted on the invoice. These records generally contain the same information as order forms and are to be retained for a two year period.

Sample Order Form

Below is a sample format of a completed order form. For instructions on completing and executing order forms, see the reverse of the purchaser's copy of the order form. The physician is responsible for filling in the number of packages and date received in the section provided on the order form.

See Reverse of PURCHASER'S Copy for Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*: TOWNE WHOLESALE DRUS, INC.

STREET ADDRESS: 695 COMMERCIAL WAY

CITY and STATE: ANYTOWN, U.S.A.

DATE: MARCH 5, 1990

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	3	100	Sod. Pentobarbital Capsules 100 mg		3	3/25/90
2	2	100	Secobarbital Capsules 100 mg		2	3/25/90
3						
4						
5						
6						
7			*TEST FORM ONLY--VOID FOR OFFICIAL USE*			
8						
9						
10						

2 ◀ NO. OF LINES COMPLETED

SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT

Date Issued: 2/25/89

DEA Registration No.: AD0000000

Name and Address of Registrant:
DOE, JAMES C., M.D.
6522 SPRUCE STREET
ANYTOWN, MARYLAND 26103

Schedules: 2,2N,3,3N,4,5

Registered as a: PRACTITIONER

No. of this Order Form: 8901234567

DEA Form 222 (Jun. 1983)

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

34948145

Prescription Orders

Who May Issue

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

(1) Authorized to prescribe controlled substances by a jurisdiction in which the physician is licensed to practice his profession; and

(2) Either registered under the Controlled Substances Act or exempted from registration (military and Public Health Service physicians). See section on Registration Regarding Interns, Residents and Foreign Physicians.

Execution of Prescription Orders by Physicians

A prescription order for a controlled substance shall be dated as of and signed on the date when issued. The prescription must also bear the full name and address of the patient and the name, address and registration number of the physician. Where an oral order is not permitted, a prescription order must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner. The prescription order may be prepared by a nurse or secretary for the signature of the physician, but the prescribing physician is responsible if the prescription order does not conform in all essential respects to the law and regulations.

A written prescription order is required for substances in Schedule II and must be signed by the physician. The refilling of a Schedule II prescription order is prohibited.

A prescription order for substances in Schedules III and IV may be issued either orally or in writing to the pharmacist and may be refilled if so authorized on the prescription. However, the prescription order may only be refilled up to five times within six months after the date of issue. After five refills or after six months, a new prescription order is required either orally or in writing from the physician.

Emergency Telephone Prescription Order for Schedule II Controlled Substances

In the case of a bonafide emergency, a physician may telephone a prescription order to a pharmacist for a controlled substance in Schedule II. In such case, the drug prescribed must be limited to the amount needed to treat the patient during the emergency period. The physician must furnish, within 72 hours, a written, signed prescription order to the pharmacy for the controlled substance prescribed. The pharmacist is required by law to notify DEA if a written prescription order is not received within 72 hours.

"Emergency" means that the immediate administration of the drug is necessary for proper treatment, that no alternative treatment is available and it is

not possible for the physician to provide a written prescription order for the drug at that time.

Multiple Copy Prescriptions

A Multiple Copy Prescription Program (MCPP) is a state-administered information collection system designed to deter pharmaceutical diversion. A number of states have adopted the MCPP and it has proven to be an invaluable tool against the diversion of controlled substances. Multiple copy prescriptions are strongly endorsed by the DEA.

Security

A physician who has controlled substances stored in an office or clinic must keep these drugs in a securely locked, substantially constructed cabinet or safe.

It is recommended that the controlled substance stock be kept to a minimum. Should it be necessary to have a substantial quantity of controlled substances stored in the office, DEA encourages having security which exceeds the minimum requirements, such as a safe and alarm system. Access to the controlled substance storage area should be restricted to the absolute minimum number of employees.

Controlled Substance Theft

A physician involved in the loss of controlled substances must notify the nearest DEA field office of the theft or significant loss upon discovery. The field office will provide information on what reports are required of the physician. The physician must make a report regarding the loss or theft by completing DEA Form 106. Also, the physician is required to notify the local police department of the theft.

Discontinuance of Practice by a Physician

The Registration Certificate and any unused order forms must be returned by a physician to the nearest DEA field office upon discontinuance of practice. It is advisable that the physician write the word "VOID" across the face of the order form prior to forwarding to DEA. Information concerning the disposal of controlled substances in the possession of a physician at the time of discontinuance of practice should be obtained from the nearest DEA field office and from the responsible state agencies.

Controlled Substance Registrant Protection Act of 1984

On May 31, 1984, Congress approved the Controlled Substance Registrant Protection Act of 1984. Robberies, burglaries and assaults perpetrated on pharmacists and other registrants are a serious problem in the United States. These crimes result in property loss and sometimes serious injury to professionals and innocent bystanders. The proceeds from thefts and robberies serve to fuel the drug abuse problem.

The Controlled Substance Registrant Protection Act of 1984 mandates Federal investigation if any of the following conditions are met:

1. Replacement cost of the controlled substances taken is $500 or more.
2. A registrant or other person is killed or suffers "significant" bodily injury during the commission of the controlled substance robbery or theft.
3. Interstate or foreign commerce is involved in planning or executing the crime.

The perpetrator convicted of violating the Act's provisions is subject to the following penalties:

1. Conviction for commission of burglary or robbery can result in a maximum $25,000 fine and/or 20 years imprisonment.
2 Conviction for use of a dangerous weapon in the commission of the crime can result in a maximum $35,000 fine and/or 25 years imprisonment.
3. If death results from the crime, the convicted person can receive a maximum $50,000 fine and/or life imprisonment.

Narcotic Treatment Programs (Methadone Clinics)

The Narcotic Addict Treatment Act of 1974 (PL 93-281) was signed into law on May 14, 1974. The Act designates which government agencies have responsibility for narcotic treatment programs. The Act further defines the terms "maintenance" and "detoxification" and explains who has to register to treat patients for drug dependence.

The DEA regulations regarding narcotic treatment programs were published on October 25, 1974 and became effective on November 15, 1974. These regulations state in detail DEA's requirements regarding narcotic treatment programs.

Record keeping and security requirements are very similar to those required of a pharmaceutical distributor or manufacturer.

Order forms are required for all Schedule II narcotic transactions between the supplier and the narcotic treatment programs. This includes the transfer of Schedule II narcotics from the manufacturer or distributor to the dispensing location. A narcotic treatment program can obtain six (6) books of order forms (DEA-222) from DEA at any one time.

A narcotic treatment program registered with DEA can handle only the narcotic substances applied for on their DEA Form 363 (registration application) and that are approved for use in maintenance or detoxification. Controlled substances for treatment of conditions other than narcotic addiction cannot be administered, dispensed or stored on the premises of a narcotic treatment program unless the program possesses a practitioner registration at the program location.

Following is a list of definitions regarding narcotic treatment programs:

Maintenance Treatment

The dispensing for a period in excess of 180 days of a narcotic substance in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Detoxification Treatment

Short-term detoxification treatment is the dispensing for a period not in excess of 30 days of a narcotic substance in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug. This treatment is to be used as a method of bringing the individual to a narcotic drug-free state within such period. Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

Compounder

A program engaging in maintenance or detoxification treatment which also changes the dosage form of a narcotic substance for use in maintenance or detoxification treatment at other locations.

There are six (6) registration categories (business activities) of Narcotic Treatment Programs:

1. Maintenance Program Only
2. Detoxification Program Only
3. Maintenance and Detoxification Program
4. Compounder with a Maintenance Program
5. Compounder with a Detoxification Program
6. Compounder with both a Maintenance and Detoxification Program

A program must register under the category which applies to its business activity.

A program may register for detoxification and/or maintenance or compounder with detoxification and/or maintenance. The program must register as a compounder if they compound narcotics on the premises for use at a program on-site and off-site. If compounding or distribution for other programs occurs at a location where no program exists, the compounding location must register with DEA as a manufacturer and/or distributor.

Problems have arisen regarding narcotic prescription orders (primarily in methadone). A physician may prescribe methadone or any other narcotic for analgesic purposes only. A patient who is to be or is being maintained or detoxified cannot receive a narcotic prescription order for this purpose. The individual must receive the necessary narcotics at a registered narcotic treatment program. In this case, the narcotics can be dispensed or administered but not prescribed.

Only four specific individuals employed by the narcotic treatment program can dispense or administer narcotics to a patient: (1) the licensed physician, (2) a registered nurse under the direction of the licensed physician, (3) a licensed practical nurse under the direction of the licensed physician or (4) a pharmacist under the direction of the licensed physician. This regulation is to prohibit the receptionist or counselor or another untrained individual (in some cases even a patient) from administering narcotics to the patient.

A physician who is not part of a narcotic treatment program may administer narcotic substances to an addicted individual to relieve that individual's acute withdrawal symptoms while the physician makes arrangements to refer the individual to a narcotic treatment program. Not more than one (1) day's medication may be administered at one time. This treatment cannot last more than three (3) days and may not be renewed or extended.

A hospital that has no program on the premises or a physician who is not part of a treatment program may administer narcotics to a drug dependent individual for either detoxification or maintenance purposes if the individual is

being treated for a condition other than the addiction. It is assumed that the physician or hospital staff will not take advantage of this situation and detoxify or maintain a drug dependent person who has sustained a very minor injury or illness which will not prevent him from going to a registered program.

Questions regarding any part of the Narcotic Addict Treatment Act of 1974 or any part of the regulations pertaining to the Act, should be directed to the nearest office of the Drug Enforcement Administration or Food and Drug Administration.

Narcotics for Patients With Terminal Illnesses or Chronic Disorders

Controlled substances and, in particular, narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or chronic disorder. These drugs have a legitimate clinical use and the physician should not hesitate to prescribe, dispense or administer them when they are indicated for a legitimate medical purpose. It is the position of the Drug Enforcement Administration that these controlled substances should be prescribed, dispensed or administered when there is a legitimate medical need.

Tips for Prescribers of Controlled Substances

1. Keep all prescription blanks in a safe place where they can't be stolen easily. Minimize the number of prescription pads in use.
2. Write a prescription order for Schedule II controlled substances in ink or indelible pencil or use a typewriter. The order must be signed by the physician.
3. Write out the actual amount prescribed in addition to giving an Arabic number or Roman numeral—to discourage alterations of the prescription order.
4. Avoid writing a prescription order for a large quantity of controlled substances unless it is absolutely determined that such a quantity is necessary.
5. Maintain only a minimum stock of controlled substances in the medical bag.
6. The medical bag should be taken by the physician while away from the automobile or locked in the trunk.
7. Be cautious when a patient mentions that another physician had been prescribing a controlled substance for him/her. Consult the physician or the hospital records—or else examine the patient thoroughly and decide if a controlled drug product should be prescribed.
8. A prescription blank should only be used for writing a prescription order—and not for notes or memos. A drug abuser could easily erase the message and use the blank to forge a prescription order.
9. Never sign prescription blanks in advance.
10. Maintain an accurate record of controlled substance products dispensed—as required by the Controlled Substances Act and its regulations.
11. Assist the pharmacist when he/she telephones to verify information about a prescription order. A corresponding responsibility rests with the pharmacist who dispenses the prescription order.
12. Phone the nearest DEA field office to obtain or to furnish information. The call will be held in the strictest confidence.

Guidelines for Prescribers of Controlled Substances

A Joint Statement of the Drug Enforcement Administration and the DEA/Practitioners Working Committee

Preface

The following represents the recommendations of the DEA Practitioners Working Committee. First formed in 1974, this committee has provided a forum for DEA officials, association executives and practitioners to meet voluntarily to discuss items, issues and subjects of mutual interest, areas of practical concern and generally maintain an open and responsive attitude among the various members. Having no intrinsic authority and seeking none, the DEA Practitioners Working Committee believes it has played a significant role in promoting the generally harmonious relationships which exist between its national organizations and their respective members. It is against this background of shared experience and knowledge that participants in the work of this committee offer these "Guidelines for Prescribers of Controlled Substances" to members of the professions throughout the country.

Purpose

The purpose of this joint statement and the presentation of guidelines is to provide and establish acceptable professional responses to the demands of the Controlled Substances Act. The guidelines provide a common sense approach to encourage voluntary compliance by the prescribing professions.

General Statement

The principles expressed in these guidelines constitute neither a pronouncement of law nor a code of ethics and are not intended to in any way supersede or be in conflict with statutes or ethical concepts governing the conduct of the various practitioners in their respective practices or in their respective professional organizations. Accountability is the responsibility of each discipline.

Application of State and Federal Law

Separate laws relating to the distribution of controlled substances have been enacted in most states. In many cases State law is much more stringent than Federal law and will not allow certain practices which may be authorized under Federal law. The guidelines are an example of good practices which should be encouraged under both Federal and State laws and regulations. Close cooperation and understanding between law enforcement and medicine will ensure that legitimate drugs remain in legitimate channels.

Communication

Recognizing that members of each profession have special competencies and knowledge concerning drugs and related therapeutic agents, a free exchange of information on these matters is encouraged among the professions at all levels.

General Guidelines

- Controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well-being of patients.
- Prescribing controlled substances for legitimate medical uses requires special caution because of their potential for abuse and dependence.
- Exercise good judgment in administering and prescribing controlled substances so that diversion to illicit use is avoided and the development of drug dependence is minimized or prevented.
- Guard against contributing to drug abuse through injudicious prescription writing practices or by acquiescence to unwarranted demands of some patients.
- Each prescriber is asked to examine his/her individual prescribing practices to ensure that all prescription orders for controlled substances are written with caution.
- Make specific effort to ensure that multiple prescription orders are not being obtained by the patient from different prescribers.

Prescription Orders

The prescriber is granted through legal authority the right to prescribe medications that are necessary for the proper treatment of his/her patients. Prescribing is governed by laws and regulations which set minimum standards and requirements. These guidelines tempered with good moral and ethical considerations, give guidance to going beyond the minimum requirements.

- The prescription order must be signed by the prescriber when it is written. The prescriber's name, address and DEA registration number and full name and address of the patient must be given when prescribing controlled substances.
- The written prescription order should be precise and distinctly legible to enhance exact and effective communications between prescriber and dispenser.

- The prescription order should indicate whether or not it may be refilled and, if so, the number of times or the duration such refill is authorized.

A prescription order for a drug in Schedules III, IV or V may be issued either orally or in writing and may be refilled if so authorized on the prescription order. However, for drugs in Schedules III and IV the prescription order may only be refilled up to five times within six months after the date of issue.

A written prescription order is required for drugs in Schedule II. The refilling of a Schedule II prescription order is prohibited. Only in an emergency situation may an oral order for a Schedule II drug be accepted by a dispenser. Such an oral order must be followed up by a written order within 72 hours.

Controlled substances which are prescribed without indication for refill cannot be refilled without authorization by the prescriber.

- Prescribe no greater quantity of a controlled substance than is needed until the next check-up.
- Try to make a prescription order alteration-proof.

When prescribing a controlled substance, write out the actual amount in addition to giving an Arabic number or Roman numeral in order to discourage alterations in written prescription orders.

The prescriber is encouraged to consider placing a number of check-off boxes on the prescription blanks which show amounts within which the prescribed amount falls, i.e., 1-25, 26-50, 51-100, over 100.

- Use a separate prescription blank for each controlled substance prescribed.
- The use of a prescription blank which is preprinted with the name of a proprietary preparation should be discouraged.
- When an institutional prescription blank is used, the prescriber should print his/her name, address and DEA registration number on the blank.

An institution should discourage the use of an institutional prescription blank for prescribing controlled substances. The prescriber should use his/her own prescription blank in such instances.

Duty to Inform

The prescriber has the responsibility to inform the patient of the effects of the prescribed drugs consistent with good medical practice and professional judgment. The patient has a corresponding duty to comply with the prescriber's directions for use of the prescribed medication.

Each of the professional organizations and the Drug Enforcement Administration has a responsibility to educate and inform the public on proper handling and use of controlled substances. The professions represented on the DEA/Practitioners Working Committee recognize that they have responsibilities to themselves beyond legal minimum restraints.

These guidelines have been prepared under the auspices of the Drug Enforcement Administration and the DEA/Practitioners Working Committee. They have been approved by American Dental Association, American Medical Association, American Nurses Association, American Osteopathic Association, American Podiatric Medical Association, American Veterinary Medical Association, National Institute on Drug Abuse and the Drug Enforcement Administration.

Drug Enforcement Administration Field Offices With Assigned Diversion Investigator Personnel

Location	Jurisdiction
Albuquerque District Office Suite 100 4775 Indian School Road, N.E. Albuquerque, New Mexico 87110 (505) 262-6283	New Mexico
Atlanta Division 75 Spring Street, S.W. Room 740 Atlanta, Georgia 30303 (404) 331-7328	Georgia South Carolina
Baltimore District Office 955 Federal Building 31 Hopkins Plaza Baltimore, Maryland 21201 (301) 962-7850	Maryland
Boston Division 50 Staniford Street Suite 200 Boston, Massachusetts 02203 (617) 565-2800	Maine Massachusetts New Hampshire Rhode Island Vermont
Buffalo Resident Office Suite 300 28 Church Street Buffalo, New York 14202 (716) 846-4421	Western and Central New York
Camden Resident Office c/o DEA P.O. Box 1940 Cherry Hill, New Jersey 08034 (609) 757-5407	Southern New Jersey

Charleston Resident Office
22 Capitol Street
P.O. Box 1146
Charleston, West Virginia 25324
(304) 347-5209

West Virginia

Chicago Division
500 Dirksen Federal Bldg.
219 South Dearborn Street
Suite 500
Chicago, Illinois 60604
(312) 353-7875

Central and Northern Illinois

Cleveland Resident Office
601 Rockwell
Room 300
Cleveland, Ohio 44114
(216) 522-3705

Northern Ohio

Columbus Resident Office
78 East Chestnut St.
Room 409
Columbus, Ohio 43215
(614) 469-2595

Central and Southern Ohio

Dallas Division
1880 Regal Row
Dallas, Texas 75235
(214) 767-7250

Northern Texas

Denver Division
316 U.S. Customs House
P.O. Box 1860
Denver, Colorado 80201
(303) 844-3951

Colorado
Wyoming

Des Moines Resident Office
Room 667, Federal Building
210 Walnut Street
Des Moines, Iowa 50309
(515) 284-4700

Iowa

Detroit Division
357 Federal Bldg.
231 W. Lafayette
Detroit, Michigan 48226
(313) 226-7290

Michigan

Ft. Lauderdale Resident Office
1475 W. Cypress Creek Blvd.
Suite 301
Ft. Lauderdale, Florida 33309
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Southern Florida

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1260 M Street, Room 200
Fresno, California 93721
(209) 487-5402

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Greensboro Resident Office
2300 W. Meadowview Road
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North Carolina

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Harrisburg, Pennsylvania 17108-0557
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Hawaii
Trust Territories

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Room 290
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Kansas
Western Missouri

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10825 Financial Parkway
Suite 317
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Arkansas

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1 Huntington Quadrangle
Suite 1C-02
Melville, New York 11747
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Long Island, New York

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World Trade Center
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(213) 894-2650

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Milwaukee, Wisconsin 53202
(414) 297-3395

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Minnesota
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Omaha, Nebraska 68101
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Philadelphia, Pennsylvania 19106
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Western Pennsylvania

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Portland, Oregon 97204
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Richmond, Virginia 23240
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Sacramento, California 95821
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Salt Lake City, Utah 84138
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National City, California 90250
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