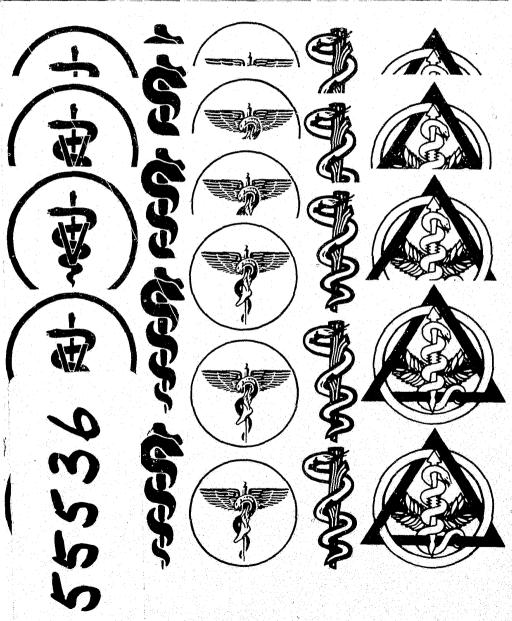


Manual

Physician's United States Department of Justice Drug Enforcement Administration

An Informational Outline of the Controlled Substances Act of 1970





This booklet has been reviewed and endorsed by the DEA/Practitioners Working Committee. The Committee represents six national health professional organizations:

American Dental Association,

American Medical Association,

American Nurses Association,

American Osteopathic Association,

American Podiatry Association,

and American Veterinary Medical Association.

This booklet was printed and distributed by the Office of Public Affairs. It has been prepared by the Office of Compliance and Regulatory Affairs as part of DEA's Voluntary Compliance Program to assist physicians in their understanding of the Controlled Substances Act of 1970 and its implementing regulations as they pretain to medical practitioners,

Revised April 1978

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Application of State Law and Federal Law



Nothing in this pamphlet shall be construed as authorizing or permitting any person to do any act which he is not authorized or permitted to do 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 he 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 will not allow you to do things that you would be authorized under Federal law. This pamphlet is an example of Federal law covering specific situations as outlined in the Federal regulations.

Drug Enforcement Administration

The Drug Enforcement Administration is the lead Federal law enforcement agency charged with the responsibility of combating drug abuse. 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 for 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 drugs 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, as they affect various classes of practitioners.

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 drugs, contact any Regional Office of the Drug Enforcement Administration. The addresses are listed in the back portion of this outline.

NOTE: The "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 Drugs



The drugs that come under jurisdiction of the Controlled Substances Act are divided into five schedules. They are as follows:

Schedule I Substances

The drugs 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, peyote, mescaline, psilocybin, tetrahydrocannabinols, ketobemidone, levomoramide, racemoramide, benzylmorphine, dihydromorphine, morphine methylsulfonate, nicocodeine, nicomorphine, and others.

Schedule II Substances

The drugs 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 (Dolophine), pantopon, meperdine (Demerol), cocaine, oxycodone (Percodan), anileridine (Leritine), and oxymorphone (Numorphan). Also in Schedule II are amphetamine (Benzedrine, Dexedrine), methamphetamine (Desoxyn), phenmetrazine (Preludin), methylphenidate (Ritalin), amobarbital, pentobarbital, secobarbital, methaqualone, etorphine hydrochloride, diphenoxylate, and phencyclidine.

Schedule III Substances

The drugs 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), methyprylon (Noludar), chlorhexadol, sulfondiethylmethane, sulfonmethane, nalorphine, benzphetamine, chlorphentermine, clortermine, mazindol, phendimetrazine, and paregoric. Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital is in this schedule.

Schedule IV Substances

The drugs in this schedule have an abuse potential less than those listed in Schedule III and include such drugs as: barbital, phenobarbital, methylphenobarbital, chloral betaine (Beta Chlor), 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), lorazepam (Ativan), mebutamate, and dextropropoxyphene (Darvon).

Schedule V Substances

The d ugs 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 drugs generally for antitussive and antidiarrheal purposes.

Registration

Every physician who administers, prescribes, or dispenses any of the drugs listed in the five schedules 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 controlled substances in some type of bottle, box, or other container to the patient. (Under the Act, the definition of "dispense" also includes the administering of controlled substances).

Physicians are required to register with the Drug Enforcement Administration, Registration Section, 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 Section or from any DEA Regional Office. Complete instructions accompany the form.

The registration must be renewed annually and the certificate of registration must be maintained at the registered location and kept available for official inspection. Every physician will receive a re-registration application approximately 60 days before the expiration date of his registration each year. If a registered physician does not receive such forms within 45 days before the expiration date of his registration, he must give notice of such fact and request the re-registration forms by writing to the Registration Section of the Drug Enforcement Administration.

If a physician has more than one office in which he administers and/or dispenses any of the drugs listed in the five schedules, he then is required to register at each office. However, if a physician only administers and/or dispenses at his principal office and only writes prescription orders at the other office or offices, he then is only required to register at his principal office where he administers and/or dispenses, provided each office is within the same state. Certificates of registration are not transferrable from state to state. A physician who moves his place of practice within the same state should request modification of his registration.

The registration fee is \$5.00 annually for each place of registration.

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.

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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, or foreign physician may dispense, administer, and prescribe controlled drugs under the registration of a hospital or other institution which is registered and by whom the physician is employed, provided that:

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

DEA Registration	AB1234567-012	Hospital Code
Number	A A	Number

6. A current list of internal codes and the corresponding individual practitioners 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 the purpose of verifying the authority of the prescribing physician.

Records

In order for the Drug Enforcement Administration to curtail the diversion of controlled drugs, 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 drug can be traced from the time it was manufactured to the time it was dispensed to the ultimate user.

Narcotic Drugs

A physician who prescribes and/or administers narcotic drugs in the lawful course of his professional practice is not required to keep records of those transactions. If a physician dispenses a narcotic drug to a patient, he is required to keep a record of such dispensing.

Non-Narcotic Drugs

A physician who regularly engages in dispensing any of the nonnarcotic drugs listed in the schedules to his patients as a regular part of his professional practice, and for which he charges his patients either separately or together with other professional services, must keep records of all such drugs received and dispensed. The records must be kept for a period of two years and are subject to inspection by the Drug Enforcement Administration. (Dispensed as used above includes administering.)

Inventory

A physician who regularly engages in dispensing drugs and is required to keep records as stated above must take an inventory every two years of all stocks of controlled drugs on hand. A physician who plans to dispense drugs regularly, is requested to take the initial inventory when he first engages in dispensing. A physician must keep this 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 drugs in Schedule II for use in his 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 4 of the Form DEA-224 or from the Drug Enforcement Administration, Registration Section, P.O. Box 28083, Central Station, Washington, D.C. 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 triplicate prescription blanks that are required by some states. The Federal order forms are to be used by a physician when he has a need for a drug in Schedule II which is to be used in his office. For example, a physician must fill out a Triplicate Order Form in order to obtain Demerol or Morphine, etc. from his normal source of supply.

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 Book, The physician is responsible for filling in the number of packages and date received in the section provided on the order form.

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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 the jurisdiction in which he 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).

Execution of Prescription Orders by Physicians

All prescription orders for controlled substances shall be dated as of, and signed on, the date when issued and must 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, prescription orders must be written in ink or indelible pencil or typewriter and must be manually signed by the practitioner. The prescription orders may be prepared by a nurse or secretary for the signature of the physician, but the prescribing physician is responsible in case the prescription order does not conform in all essential respects to the law and regulations.

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

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

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

Discontinuance of Practice by a Physician



A physician who discontinues his practice must return his Registration Certificate and any unused order forms to the nearest office of the DEA. A physician having controlled substances in his possession at the time of discontinuing practice should obtain information from the Regional Office of the DEA in his area and from the responsible state agency on how to dispose of these drugs.

Security

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

Drug Theft

A physician involved in the loss of controlled substances must notify the DEA Regional Office in his area of the theft or significant loss upon discovery. The Regional 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. The physician should also notify his local police department of such theft.

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 control over narcotic treatment programs and the basic requirements of each. The Act further defines the terms "maintenance" and "detoxification" and explains who has to register to treat patients for drug dependence.

In the October 25, 1974 issue of the Federal Register, DEA regulations regarding narcotic treatment programs were published in final form. They became effective as part of Title 21, Code of Federal Regulations, Chapter 1300, on November 15, 1974. These regulations state in detail DEA's requirements regarding narcotic treatment programs.

Recordkeeping 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 manufacturing or distributor sites to the dispensing location.

At the present time, a narcotic treatment program can obtain six (6) books of order forms (DEA Form 222) from DEA at any one time.

Narcotic treatment programs registered with DEA can handle only the narcotics that they apply for on their DEA Form 363 (registration application) and are approved for use for maintenance in 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 at any time, unless the program possesses a practitioner registration at the location of the narcotic treatment program.

Below is a list of definitions regarding narcotic treatment programs:

Maintenance Treatment

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

Detoxification Treatment

The dispensing for a period not in excess of twenty-one days, of a narcotic drug 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, as a method of bringing the individual to a narcotic drug-free state within such period.

Compounder

An entity engaging in maintenance treatment or detoxification treatment which also changes the dosage form of a narcotic drug for use in maintenance treatment 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

Every program must register under the category(ies) which applies to their business activity(ies).

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, then the compounding location must register with DEA as a manufacturer and/or distributor.

Problems have arisen regarding narcotic prescription orders (primarily in methadone). According to DEA regulations, a physician may prescribe methadone or any other narcotic for a patient for analgesic purposes only. A patient who is to be or is being maintained or detoxified cannot receive a narcotic prescrip-

tion order for this purpose. He must receive the necessary narcotics at a registered narcotic treatment program. In this case, the narcotics can be dispensed or administered to him, but not prescribed.

Furthermore, the regulations state that only four specific individuals employed by the narcotic treatment program can dispense or administer narcotics to the patients: (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. Incarcerated patients who are legitimately enrolled in narcotic treatment programs have caused considerable problems in certain areas. If this is the case, the program should attempt to make arrangements with FDA and possibly with TRIPS (Treatment Referral, Information and Placement Services) for another program in the area of the prison to assume responsibility for this individual. It must be remembered, however, that even though DEA allows dispensing to the patient on a daily basis by the proper program representative, final authority rests with the prison officials who may not allow this type of activity.

Section 1306.07(b) and (c) of Title 21, CFR have also raised several questions regarding Narcotic Treatment Programs:

A physician who is not part of a narcotic treatment program may administer narcotic drugs to an addicted individual on a daily basis for not more than a three (3) day period to relieve that individual's acute withdrawal symptoms while the physician makes arrangements to enroll the individual in a narcotic treatment program. 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. Also, a physician is allowed to exercise his medical judgment and to dispense or administer narcotics to an individual for extended periods for the purpose of relieving intractable pain in which no other relief or cure is known. An example of this would be terminal cancer patients or patients with painful chronic disorders.

Questions regarding any part of the Narcotics Addict Treatment 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 the Food and Drug Administration.

DEA Domestic Regional Offices

Region I—Boston
JFK Federal Building, Room G-64
Boston, Massachusetts 02203
(617) 223-2170
(Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont)

*Region II—New York 555 West 57th Street Suite 1900 New York, New York 10019 (212) 399-5131 (New York, New Jersey)

Region III—Philadelphia
William J. Green Federal Building
600 Arch Street
Room 10224
Philadelphia, Pennsylvania 19106
(215) 597-9540
(Delaware, District of Columbia,
Maryland, North Carolina, Pennsylvania, Virginia, West Virginia)

*Region V—Miami 8400 N.W. 53rd Street Miami, Florida 33166 (305) 591-4880 (Florida, Georgia, South Carolina, Puerto Rico) Region VI—Detroit 357 Federal Building and U.S. Courthouse 231 West Lafayette Detroit, Michigan 48226 (313) 226-6725 (Kentucky, Michigan, Ohio)

*Region VII—Chicago 1800 Dirksen Federal Bunding 219 South Dearborn Street Chicago, Illinois 60604 (312) 353-1234 (Illinois, Indiana, Wisconsin)

Region VIII—New Orleans 1001 Howard Avenue Suite 1800 Plaza Tower New Orleans, Louisiana 70113 (504) 589-2785 (Alabama, Arkansas, Louisiana, Mississippi, Tennessee)

There is no Region IX. Region IV merged with Region III effective August 1, 1977. Region X—Kansas City
U.S. Courthouse
1150 Grand Avenue, Room 400
Kansas City, Missouri 64106
(816) 374-2631
(Minnesota, North Dakota,
South Dakota, Iowa, Kansas,
Missouri, Nebraska)

*Region XI—Dallas 1880 Regal Flow Dallas, Texas 75235 (214) 767-7188 (Oklahoma, Texas)

Region XII—Denver U.S. Courthouse Room 336, P.O. Box 1860 Denver, Colorado 80201 (303) 837-3951 (Arizona, Colorado, New Mexico, Utah, Wyoming)

Region XIII—Seattle 221 First Avenue West Room 200 Seattle, Washington 98119 (206) 442-5996 (Alaska, Idaho, Montana, Oregon, Washington) *Region XIV—Los Angeles Los Angeles World Trade Center 350 South Figueroa, Suite 800 Los Angeles, California 90017 (213) 688-3494 (California, Hawaii, Nevada)

*Region II—New York

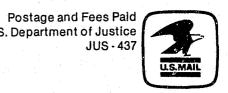
*Region V-Miami

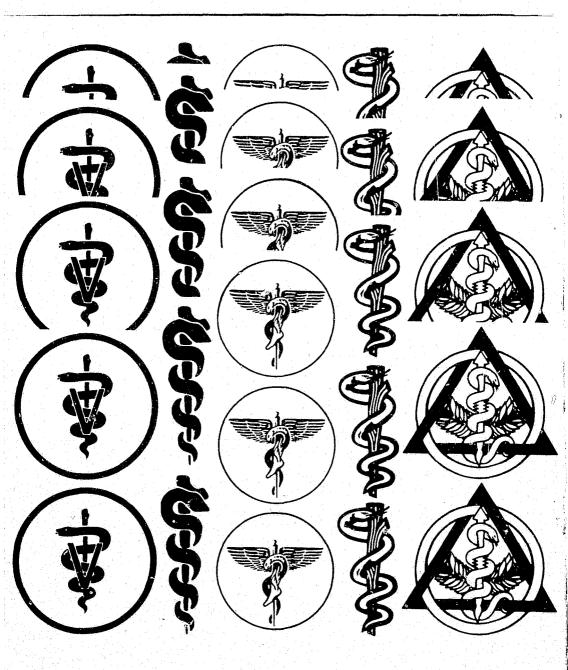
*Region VII—Chicago

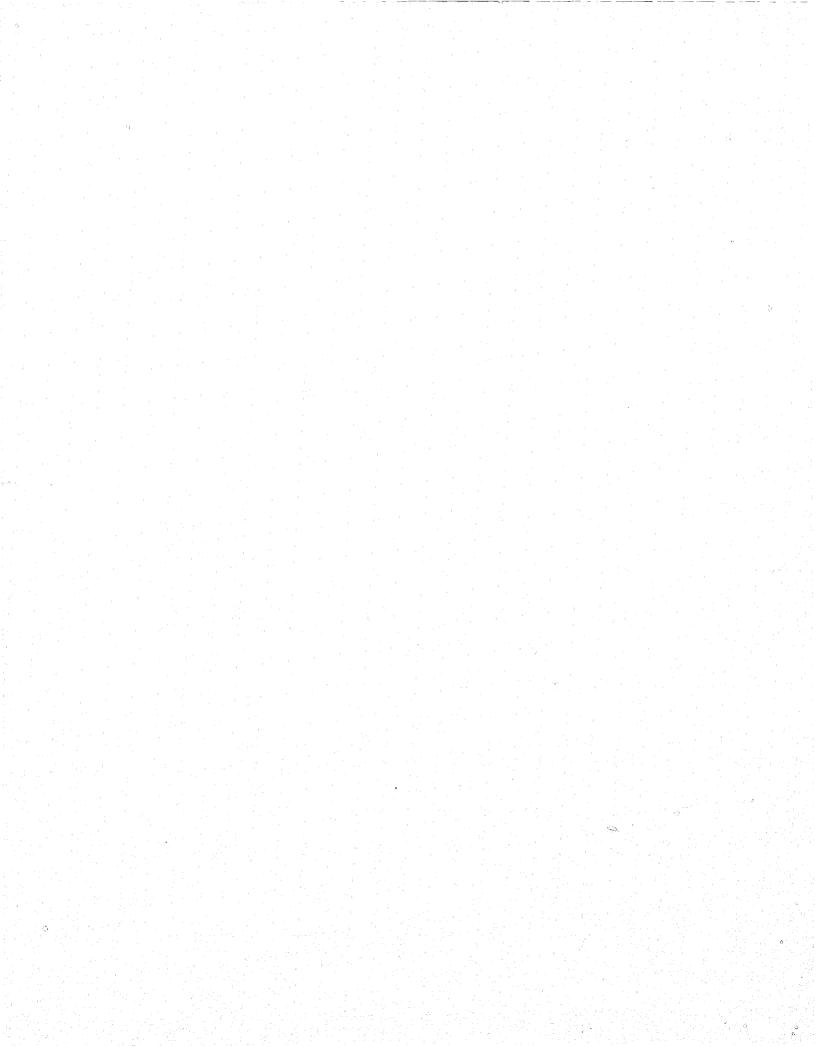
*Region XI—Dallas
*Region XIV—Los Angeles

Editor's Note: DEA Domestic Regional Offices will be reorganized from twelve to five offices effective October 1, 1978. The new offices are designated by an asterisk. The states will be realigned. Drug Enforcement Administraton U.S. Department of Justice Washington, D.C. 20537 Official Business

Postage and Fees Paid U.S. Department of Justice JUS - 437







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