

Controlled Substances Security Manual

**An Informational Outline of the
Controlled Substances Act of 1970**

United States Department Of Justice
Drug Enforcement Administration

**A SECURITY OUTLINE OF THE
CONTROLLED SUBSTANCES ACT OF 1970**

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This manual has been prepared by the Office of Diversion Control to assist drug handlers in their understanding of the Controlled Substances Act of 1970 and its implementing regulations pertaining to security.

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DRUG SECURITY MANUAL

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A MESSAGE FROM THE ADMINISTRATOR

The safeguarding of controlled substances is a problem confronting all manufacturers, distributors, pharmacies, and other drug handlers. Federal law limits the handling of these substances and by regulation requires that they be properly safeguarded at all times. The drug Enforcement Administration (DEA) is responsible for ensuring that effective security is maintained. The drug industry is responsible for establishing and maintaining effective controls and procedures to prevent diversion.

This manual outlines the steps needed to establish a competent security system which deters diversion and reduces accessibility for potential abusers. Further guidance may be obtained from one of DEA's Field Diversion (listed at the end of this manual) or from the Office of Diversion Control located at our Headquarters in Washington, D.C.

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PREFACE

Over 770,000 manufacturers, distributors, pharmacies, and other handlers of controlled substances are registered with DEA. The vast majority of this group complies with controlled substances laws and regulations in a responsible and law abiding manner, and has self-regulation programs consistent with the highest standards. DEA relies upon these programs and concentrates its resources on the more serious problems of both practitioner and non-practitioner diversion.

Handlers of controlled substances must be aware of the various diversion methods, which include illegal sale, falsified prescription orders, burglary, employee theft, loss in-transit, robbery, and customer/patient theft. However, willful and intentional diversion by manufacturers, distributors and dispensers is another source of diversion.

A critical first step in diversion prevention is employee screening; concern with personnel security must start before and employee is hired. Pre-employment screening to identify potential security problems is important when choosing new employees to work in or around areas where controlled substances are handled. The screening program should include a careful evaluation of the applicant's personal and previous employment references. Criminal background checks with local law enforcement authorities and with DEA are equally important. Similar precautionary measures should be taken before transferring established employees to new jobs in areas where controlled substances are manufactured, processed, stored, shipped, dispensed, or handled in any way.

The areas which must be protected against theft and diversion vary greatly depending on the type of business. Manufacturers must be alert for pilferage at every level of drug handling, from the receipt of raw material, through all phases of manufacturing and processing, to finished product storage and shipping. They must be watchful for pilferage of production rejects and of returned or damaged merchandise. They must be alert to the theft of dosage form drugs, bulk raw material, equipment, and even chemical precursors. They must be certain that all controlled substances are secure throughout the entire manufacturing and distribution process. Many of the concerns also apply to controlled substance distributors.

Security problems confronting a pharmacist are no less serious. The pharmacist must secure the controlled substances storage and prescription compounding areas. As in the case of larger drug handlers, a key factor in protecting against theft and diversion is limiting employee access. Access to all controlled substances should be restricted to the minimum number of employees needed to perform the tasks related to these drugs.

APPLICATION OF STATE AND FEDERAL LAWS

Nothing in this manual 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 manual may be construed as authorizing or permitting any person to do any act in violation 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, DC 20402. Proposed and finalized amendments to the regulations are published in the Federal Register.

In many cases state law is more stringent than Federal law and must be complied with in addition to Federal law. This manual is an informational outline of Federal law covering specific security situations as set forth in the Federal Regulations.

DRUG ENFORCEMENT ADMINISTRATION

DEA is the lead Federal law enforcement agency responsible for enforcing the Controlled Substances Act (CSA). Established in 1973, DEA was the product of a merger of the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic intelligence, elements of the Bureau of Customs, and those functions of the Office of Science and Technology which were drug enforcement-related. In carrying out its mission, DEA cooperates with other Federal agencies, state, local, and foreign governments, private industry, professional groups, and other organizations.

Between 1914 and 1970, Congress enacted more than 50 pieces of legislation relating to the control and diversion of drugs. Most of these diverse laws were gathered into one piece of legislation, the CSA, which became effective May 11, 1971. A key element of this law is to improve control over the manufacture, distribution, and dispensing of controlled substances by providing a "closed" system for legitimate handlers of these drugs. Such a closed system deters the diversion of these drugs out of legitimate channels into illicit markets.

The information presented here should acquaint drug handlers with security requirements set up under the CSA, the Diversion Control Amendments of the Comprehensive Crime Control Act 1984, and the Code of Federal Regulations.

The drugs and drug products, i.e. controlled substances, that come under the jurisdiction of the CSA are divided into five schedules. Some examples in each schedule are outline below. For a complete listing of controlled substances contact any DEA office listed at the end of this manual.

SCHEDULES OF CONTROLLED SUBSTANCES

The CSA places each controlled substance -- drug or other substance -- into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. The Act also allows substance to be added to or removed from a schedule to another, the basis upon which substance are placed into each of the five schedules is explained below, and examples of drugs' or other substances within the schedules are listed.

Schedule I (CI) Substance

The controlled substances in this schedule are those that have no accepted medical use in the U.S., are not accepted as safe for use under medical supervision, and have a high abuse potential. Some examples are heroin, marijuana, LSD, peyote, mescaline, psilocybin, MDA, MDMA, ketobemidone, acetylmethadol, fenethylline, tilidine, methaqualone, and certain fentanyl and meperidine analogs.

Schedule II (CII) Substances

The controlled substances in this schedule have a high abuse potential with severe psychological or physical dependence liability, but have accepted medical use in the U.S. CII controlled substances consist of certain narcotic, stimulant, and depressant drugs. Some examples of CII narcotics are: opium, morphine, codeine, hydromorphone (Dilaudid)¹, methadone, meperidine (Demerol), cocaine, oxycodone (Percodan), anileridine (Lertine), the immediate precursor phenylacetone (P-2-P), and oxymorphone (Numorphan). Also in CII are the stimulants amphetamine (Dexedrine), methamphetamine (Desoxyn), phenmetrazine (Preludine), and methylphenidate (Ritalin); the depressants amobarbital, pentobarbital, secobarbital; and fentanyl (Sublimaze), etorphine hydrochloride, and phencyclidine (PCP).

Schedule III (CIII) Substances

The controlled substances in this schedule have an abuse potential and dependence liability less than those in CI and CII, and have an accepted medical use in the U.S. They include preparations containing limited quantities of certain narcotic drugs, and other nonnarcotic drugs such as: derivatives of barbituric acid, except those that are listed in another schedule, glutethimide (Doriden), methyprylon (Noludar), nalorphine, benzphetamine, chlorphentermine, clortermine, and phendimetrazine.

Schedule IV (CIV) Substances

The controlled substances in this schedule have an abuse potential and dependence liability less than those listed in CIII and have an accepted medical use in the U.S. They include such drugs as: barbitol, phenobarbital, methylphenobarbital, chloral hydrate, ethchlorvynol (Placidyl),

¹ Examples of trademark products appear in parentheses. Scheduling applies to all similar drug products of all other pharmaceutical manufactures within each generic drug classification.

ethinamate, (Valmid), paraldehyde, methohexital, fenfluramine, diethylpropion, phentermine, chlordiazepoxide (Librium), diazepam (Valium), oxazepam (Serax), clorazepate (Tranxene), flurazepam (Dalmane), lorazepam (Ativan), alprazolam (Xanax), temazepam (Restoril), triazolam (Halcion), mebutamate, dextropropoxyphene (Darvon), and petazocine (Taiwin).

Schedule V (CV) Substances

The controlled substances in this schedule have an abuse potential and dependence liability less than those listed in CIV and have an accepted medical use in the U.S. They are often available without prescription, and include preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarrheal purpose. Buprenorphine is also a CV drug.

GENERAL SECURITY REQUIREMENTS

Substantial Compliance

The general security requirements set forth in the Code of Federal Regulations (CFR) require all registrants and applicants for registration to provide effective physical security controls and operating procedures to guard against theft and diversion of controlled substances. Substantial compliance with these requirements and standards set forth in Title 21 CFR Sections 1301.72-1301.76 may be deemed sufficient by DEA after evaluation of the overall security system and needs of the individual applicant or registrant considering the following factors:

1. Type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labelling, cooperative buying, etc.).
2. Type and form of controlled substances (e.g., bulk liquids or dosage units, usable powders or non-usable powders, etc.).
3. Quantity of controlled substances.
4. Location of premises/security needs (e.g., high vs. low crime areas, waterfront boundaries, adjacent/attached buildings, urban vs. suburban vs. rural areas, etc.).
5. Type of building construction/general characteristics (e.g., metal curtain, wood frame, masonry, number and type of doors, windows and other openings, etc.).
6. Types of safes/vaults/secure enclosures (e.g., automatic storage and retrieval, construction of vaults and cages, modular vaults, container weight and type, UL listing/GSA rating, etc.).
7. Type of closure (e.g., built-in combination locks, key locks, padlocks, self closing and locking day gates, vault doors and frames, etc.).
8. Key and lock control (e.g., adequacy, accountability, routine changing, issuance and control procedures, logging, central repository, combination security, etc.).
9. Alarm systems (e.g., adequacy of supervision, method of signal transmission, proprietary vs. central station vs. police connection, adequacy of standby power sources, maintenance and testing, signal and response time, etc.).
10. Public access/perimeter fencing (e.g., adequacy of gates and fencing, if any, control at entry/exit points, parking location and proximity to facility, extent of unsupervised public access to the facility, etc.).
11. Supervision of employees (e.g., access control to manufacturing and storage areas, identification media and systems, control of and accountability for identification, responsibilities of employees, etc.).

12. Guest/visitor procedures (e.g., access control, logging procedures, identification media, internal movement control, etc.).
13. Local police/security force (e.g., availability, legal obligation to respond, frequency of patrol, adequacy of training, alarm response time, size of force, etc.).
14. Adequacy of internal systems for monitoring controlled substances (e.g., storage security, common or contract carrier security, etc.).

Request for Review

Any applicant or registrant who wants to know whether or not a proposed security system substantially complies with DEA requirements as prescribed by the regulations may submit plans, blueprints or sketches of the proposed system to the appropriate DEA Field Office. Even with preliminary Field Office approval of the proposed system, final approval will only be given at the time the system is completed and can be inspected at the location where it is to be used.

Waiver

Physical security controls at locations registered and approved under the former Harrison Narcotic Act (HNA) or the former Narcotic Manufacturing Act (NMA) of 1960 as of April 30, 1971, are considered to be in compliance with present security regulations. However, new or modified facilities or work and storage areas which have not previously been approved by DEA (even if these facilities are similar to those previously approved by the Bureau of Narcotics and Dangerous Drugs) will not necessarily be deemed in compliance with the security regulations. Furthermore, any change in ownership or control after April 30, 1971 of locations registered and approved under the former HNA or the former NMA would negate this waiver.

Changes

It is important to note that physical security controls and procedures must be expanded and extended accordingly if existing systems become inadequate as a result of a controlled substance being transferred to a different schedule, being placed in a schedule, or if there is a significant increase in the quantity of controlled substances in the possession of a registrant during normal business operations.

SECURITY REQUIREMENTS FOR NON-PRACTITIONER

Non-practitioners include manufacturers, packagers, labelers, distributors, importers, exporters, narcotic treatment programs, and compounders for narcotic treatment programs.

Minimum Standards: Handlers of CI&II Controlled Substances

Small quantities of CI&II raw materials, bulk materials awaiting further processing, and finishing products must be stored in an Underwriters Lab (UL) listed burglary-resistant safe with a Group 1-R lock, or a GSA Class V rated security container, or the equivalent, which affords the following security protection:

1. 30 man minutes against surreptitious entry,
2. 10 man minutes against forced entry,
3. 20 man hours against lock manipulation,
4. 20 man hours against radiological attack.

This safe or security container must be bolted, strapped, or otherwise securely fastened to the floor or wall in such a way that it cannot be readily removed if it weighs less than 750 pounds. Depending upon the quantities and types of controlled substances stored, this safe or security container must be equipped with an alarm system which upon attempted unauthorized entry transmits a signal directly to a central protection company, a local or state police agency which has a legal obligation to respond, a 24-hour proprietary central station operated by the registrant, or such other protection as DEA may approve.

Large quantities of such controlled substances which do not permit storage in a safe or security container may be stored in a vault meeting the following specifications or equivalent, if constructed after September 1, 1971:

1. The walls, floor and ceiling are constructed of at least eight inches of reinforced concrete or other substantial masonry reinforced vertically and horizontally with #4 (half inch) steel rods tied six inches on center, or UL listed modular vault panels.
2. The door and frame unit are UL listed burglary-resistant, GSA Class V rated or equivalent, i.e., multiple position Group 1-R combination lock, relocking device, special metal alloy that resists carbide drilling, and in general affords the overall security protection set forth above for safes and security containers.
3. If operations require the vault/container to remain open to frequent access, the door is required to be equipped with a day gate which is self-closing and self-locking. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return it at night, and is always relocked immediately after use, a day gate is not required.
4. The walls or perimeter are equipped with an alarm system which upon attempted unauthorized entry must transmit an alarm directly to a central protection company, local or

state police agency which has a legal obligation to respond, a 24-hour proprietary central station operated by the registrant, or such other protection as DEA may approve. If necessary due to local condition or other problems, holdup buttons may be required to be placed at strategic points of entry or exit from the perimeter.

5. The door is equipped with a contact switch(es) and there is complete electrical lacing of the walls, floors and ceiling, sensitive ultrasonic or infrared sensors within, a sensitive sound accumulator system, or other such devices or equipment designed to detect unauthorized entry as may be approved by DEA.

Vaults constructed before or under construction on September 1, 1971 and approved by the Bureau of Narcotics and Dangerous Drugs or its predecessor agencies may be of substantial construction with a steel door, combination or key lock, and alarm system.

NOTE: DEA evaluates a registrant security system on an element-by-element and on an overall basis, measuring the system against the potential theft or diversion problem the registrant might encounter at the registered location. Thus, DEA may approve a security system although some of the specific standards are not met, e.g., a registrant who provides 24-hour guard surveillance may not need the full alarm protection as set forth in the regulations. A registrant who handles large quantities of in-process liquids running through a pipe system may not need vaults this form of controlled substances because of the difficulties in containing or diverting the liquids and their possible non-restrictability. The minimum standards and general security requirements set forth above and below are used by DEA as a basis for making decisions on the specific security needs of each registrant.

Minimum Standards: Handlers of CIII-V Controlled

Small quantities of C III-V controlled substances may be stored in a UL listed burglary-resistant safe or a GSA Class V rated security container or equivalent which complies with the requirements for storing C I& II substances. Large quantities of such controlled substances which do not permit storage in a safe or security container may be stored in:

- 1) A building or area within a building having perimeter security which limits access during working hours, provides adequate security after working hours, and has the following security controls:
 - a) An electronic alarm system as described above for C I&II controlled substances;
 - b) Substantially constructed self-closing and self-locking doors employing either multiple-position combination or key lock type locking mechanisms (NOTE: in lieu of self Blocking/closing doors, a door which is kept closed and locked at all times when not in use, and when in use is kept under direct observation of a responsible employee of the registrant is permitted); and
 - c) Requisite key control, combination limitations, and change procedures.

- 2) A cage within a building on the premises meeting the following specifications:
 - a) Walls constructed of not less than ten gauge steel fabric mounted on steel posts which are:
 - i) At least one inch in diameter;
 - ii) Set in concrete or installed with lag bolts which are pinned or brazed; and
 - iii) Placed no more than ten feet apart with horizontal one and one half-inch reinforcement every 60 inches.
 - b) Mesh construction with openings not more than two and one half inches across the square;
 - c) A ceiling constructed of the same material or walls extending to and firmly attached to the structural ceiling;
 - d) A door constructed of the same gauge steel fabric on a metal door frame in a metal door flange; and
 - e) An alarm system protecting the perimeter and interior as described above.
- 3) An enclosure of masonry or other such materials or secure storage area which has been approved by DEA.

Collocating CIII-V with CI&II Substances

Schedule III-V controlled substances may be stored with CI&II substances under the security measures required for those substances. CIII-V substances may be stored in the vault provided access to the area is not substantially increased and that permission for such storage is obtained in advance from the appropriate DEA Field Office.

Multiple Storage Areas

On occasion it may be necessary for non-practitioner registrants to handle several classes of controlled substances separately. Some examples of these special circumstances are damaged goods, returned goods, goods in processing, etc. In these circumstances, controlled substances may be stored apart from the main stock of controlled substances, provided that each storage area complies with the security requirement set forth in the previously described minimum standards.

Accessibility to Storage Areas

In order to minimize the possibility of diversion, the registrant must limit access to the storage areas for controlled substances to a minimum number of authorized employees. Although not specifically required, it may be necessary to institute some type of security pass system if the size, type, or other characteristics the firm dictate the need. Where it is necessary for employee or non-employee maintenance personnel, business guests, or other visitors to have access to or to pass through a controlled substances storage area, the registrant needs to provide authorization to those individuals. The authorization should be in writing, and the specially authorized individuals should be held under adequate observation during the time they are in the storage area.

Manufacturing and Compounding Areas

Manufacturing activities (include processing, packaging, and labelling) involving controlled substances listed in any schedule, and all compounders, must implement the following security controls:

1. All in-process substances must be returned to the controlled substances storage area at the termination of the process. If the process is not completed at the end of the work day, the processing area or tanks, vessels, bins, or bulk containers holding controlled substances must be securely locked inside an area or building which affords adequate security.
2. Manufacturing activities with controlled substances must be conducted in an area(s) with limited access and must be kept under surveillance by an employee(s) designated in writing by management to be responsible for the area. The designated employee(s) must be able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without the designated employee's knowledge. Access may be limited by the use of physical dividers such as walls or partitions, by traffic control lines, or restricted space designations.
3. During controlled substances production, the manufacturing areas should be accessible only to those employees necessary for efficient operation. If it becomes necessary for employee or non-employee maintenance personnel, business guests, or visitors to be present or to pass through manufacturing areas during production, it is in the best interest of the registrant to have an employee designated in writing as being responsible for providing adequate surveillance of the area.

Public Warehouses

Registrants who store controlled substances in public warehouses are responsible for selecting a facility that will provide adequate security to guard against losses and thefts. Whenever possible, the registrant should select a storage warehouse or terminal which meets the physical security requirement and controls set forth above and below, with the knowledge that it is the registrant, not the warehouseman, who is responsible for the security of the controlled substances. Other aspects of warehouse or terminal security which the registrant might consider are:

1. Adequacy of fencing, lighting, electronic security, checkpoints, and other perimeter controls;
2. Type of order tracking or tracing system in use, if any;
3. Personnel screening, hiring, and control programs;
4. Hours of operation;
5. Use of contract or proprietary guards;
6. Procedures and systems in use to control inbound and outbound tractors, trailers, containers, etc.;
7. Yard control of drivers, tractors, trailers, containers, etc.

Common or Contract Carriers

Registrants are also responsible for selecting common or contract carriers that will provide adequate security against in-transit losses or thefts. If the registrant has substantial quantities of controlled substances lost or stolen in transit when using a particular common or contract carrier, steps should be taken to obtain another secure carrier or means of transport. When evaluating common or contract carriers, in addition to evaluating warehouses or terminal security, the registrant might consider the following:

- 1) Physical security of the vehicles, e.g.:
 - a) Adequate vehicle and trailer locks subject to proper key control, and locking of vehicles at all times when unattended;
 - b) Vehicular alarm systems in use at all times when vehicles and trailers are unattended;
 - c) Fuel lock alarm devices;
 - d) Page alert alarm system carried by drivers when away from vehicles and trailer to alert them to unauthorized opening of doors, hood, etc.
- 2) Route variations to avoid patterns
- 3) Vehicles equipped with CB's or other radios to communicate with local law enforcement agencies or the company warehouse or terminal in the event of an emergency or other duress condition.
- 4) Special code numbers or symbols painted on or otherwise affixed to the roof.
- 5) Driver screening, hiring and control programs.
- 6) Overall priority and security afforded controlled substances shipments.
- 7) Use of subcontracted carriers.

These security aspects and procedures are also applicable when delivering and picking up controlled substances using company-owned or leased vehicles operated by company employees. Although not required, precautions such as securely wrapping and sealing packages containing controlled substances and using unmarked or coded boxes or shipping containers are strongly recommended for guarding against in-transit losses.

Theft or Loss

Registrants must notify the appropriate DEA field office of theft or significant loss of any controlled substance. Furthermore, the supplier is responsible for reporting in-transit losses of controlled substances by a common or contract carrier. The registrant must then promptly complete and submit the DEA Form 106 regarding such losses or thefts. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties identified and action taken against them.

Other Security Controls

Good Faith Inquiry. Before distributing a controlled substance to any person whom the registrant does not know to be registered to possess the controlled substance, the registrant must make a good faith inquiry either to DEA or to the appropriate state controlled substances licensing or registration agency, if any, to determine that the person or company may lawfully possess the controlled substances.

Suspicious Orders. The registrant must design and operate a system to disclose suspicious orders of controlled substances. The registrant must inform the appropriate DEA Field Office of suspicious orders immediately upon discovery. Such orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Controlled Substance Samples. Complimentary samples of any controlled substance may not be distributed unless the following conditions are met:

1. The distributor has a prior written request from the registrant which includes the customer's name, address, registration number, and name and quantity of the specified controlled substance;
2. The controlled substance is to be used to meet the legitimate medical needs of patients; and
3. Reasonable quantities are requested.

Distributing Through Agents. When controlled substances are distributed by agents (i.e., detailmen), the registrant is responsible for providing adequate security to guard against theft or diversion while the controlled substances are being stored or handled by the agents.

Employees

Screening. In order to fairly assess the likelihood of an employee committing a drug security breach, it is essential that non-practitioner registrants carefully screen individuals before hiring them. Of the utmost importance is a determination of convictions for crimes and unauthorized use of controlled substances. To this end, DEA recommends that the following two questions become a part of an employer's comprehensive screening program:

1. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor, or are you presently charged (formally) with committing a criminal offence? Do not include any traffic violations, juvenile offences on military convictions, except by general court-martial. If the answer is yes, furnish details of conviction, offense location, date, and sentence.
2. In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, Other than those prescribed to you by a physician? If the answer is yes, furnish details.

DEA also recommends that an authorization, in writing, be completed by a person who is allowed to or is considered for work in a controlled substances area. This authorization should permit inquiries to be made of courts and law enforcement agencies concerning pending charges or convictions. Information on employees' criminal records should then be used as follows:

1. Locally by name, date and place of birth, and other identifying information, inquire at local courts and law enforcement agencies for records of pending charges and convictions; and
2. Nationally by the same identifying information make and inquiry at the appropriate DEA Field Office.

In addition, pre-employment screening should be by written application which covers such areas as credit checks, residences, educational background, military history, character, reputation, and past employment. All applications should strongly warn that any falsification will result in dismissal and that data will be verified.

Post-employment screening is also very important. Events in employees' lives can change their reliability and integrity. Employees and supervisors should be encouraged to be on the lookout for troubled employees. Payroll and personnel offices should advise security officers of inquiries by creditors or attempted garnishment of wages. When employees are considered for promotion to positions of greater responsibility, additional comprehensive screening may be appropriate.

Responsibility to Report Drug Diversion. A necessary part of an overall employee security program is the reporting of employee drug theft or diversion in the workplace. It is also in the public interest. Employees who have knowledge of drug theft or diversion from their employer have an obligation to report such information to a responsible security official of the employer. Employers have a responsibility to treat such information as confidential and to take all reasonable steps to protect the confidentiality of the information and the identity of employees

furnishing information. Failure to report drug theft or diversion information should be a critical factor in determining an employee's continued employment in a drug security area.

Illicit Activities. Employees who possess, sell, use or divert controlled substances not only subject themselves to state or Federal prosecution for any illicit activity, but should also become the subject of independent action regarding their continued employment. Employers must assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to take other action against the employee.

NARCOTIC TREATMENT PROGRAMS

Only a licensed practitioner employed at a Narcotic Treatment Program (NTP) or other authorized individual designated in writing may accept delivery of narcotic substances. Excluded from authorization to accept delivery are any persons currently or previously dependent on narcotics. At the time of delivery, the licensed practitioner or other authorized individual designated in writing must sign for the narcotics and place his or her specific title (if any) on the invoice. Copies of these signed invoices must be kept by the distributor.

Narcotics may only be dispensed or administered at an NTP directly to the patient by either:

1. The licensed practitioner;
2. A registered nurse or a licensed practical nurse under the direction of the licensed practitioner;
3. A pharmacist under the direction of the licensed practitioner.

Persons enrolled at an NTP must wait in an area which is physically separated from the narcotic storage and dispensing area.

DEA may exercise discretion regarding the degree of security required in NTP's based upon such factors as the location of a program, the number of patients, the number of physicians, staff members and security guards, etc. These factors will be taken into consideration when evaluating existing security or requiring new security at an NTP.

SECURITY REQUIREMENTS FOR PRACTITIONERS

Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies, or other persons registered to do research, to dispense, or to use in teaching or chemical analysis a controlled substance in the course of professional practice.

Minimum security standards for practitioners are set forth in the regulations (Title 21 CFR 1300-end) and are to be used in evaluating security. They may not necessarily be acceptable for providing effective controls and operating procedures to prevent diversion or theft of controlled substances. For example, a hospital that keeps large quantities of controlled substances on hand may need a safe or vault similar to the requirements for a distributor. The same reasoning also applies to other practitioners.

A practitioner's overall security controls will be evaluated to determine if they meet the intent of the law and regulations to prevent theft or diversion.

Minimum Standards for Practitioners' Handling of Controlled Substances

Controlled substances must be stored in a securely locked cabinet of substantial construction. Pharmacies have the option of storing controlled substances as set forth above, or concealing them by dispersal throughout their stock of non-controlled substances.

Even though the Federal regulations do not specifically define locked cabinet construction, the intent of the law is that controlled substances must be adequately safeguarded. Therefore, depending on other security measures, a wooden cabinet may or may not be considered adequate. In an area with a high crime rate, a strong metal cabinet or safe may be required.

Some of the factors considered when evaluating a practitioner's controlled substances security include:

1. The number of employees, customers and/or patients who have access to the controlled substances.
2. The location of the registrant (high or low crime area).
3. Use of an effective alarm system.
4. Quantity of controlled substances to be kept on hand.
5. Prior history of theft or diversion.

Again, an overall evaluation of the practitioner's security will be made by DEA using the general and minimum security requirements as outlined in this manual to assure that the controlled substances are stored securely.

Other Security Controls for Practitioners

In order to minimize the opportunities for theft or diversion of controlled substances, practitioners have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm system where necessary.

Employee or Agent. A practitioner must not employ an agent or individual who has had his application for registration with DEA denied or revoked at any time, and who, as a result of his employment, will have access to controlled substances.

Loss or Theft. A practitioner shall notify the nearest DEA Field Office of the theft or significant loss of any controlled substance upon discovery of such loss or theft. The practitioner shall promptly complete and submit DEA Form 106 regarding the theft or loss.

Blank prescriptions and DEA Order Forms. A practitioner should develop the practice of keeping blank prescription forms in locations which would preclude patients or casual visitors from stealing the forms for the purpose of falsification. Unused DEA Order Forms should also be kept in a secure location for the same reason.

Additional Security Measures

Although not specifically required by Federal law or regulation, the following additional security measures are recommended to enhance the overall security of non-practitioners as well as practitioners in some situations:

1. For large operations, designate a specific individual to act as a security manager or supervisor.
2. Routinely test alarm systems. At least annually, in the presence of the alarm contractor, conduct an on-site inspection and test of the entire alarm system to determine needed repairs and adjustments.
3. Ensure that all alarm systems have at least 24-hour battery or other standby power sources in the event of commercial power failure.
4. Use only balanced or biased magnetic contact switches and ensure motion detectors do not disclosed coverage by either by-pass or elimination of the walktest LEDs, if any.
5. In addition to balanced or biased contacts, install UL approved heat detectors on vault doors.
6. Ensure that all telephone junction boxes or rooms where alarm telephone circuits terminate are locked, tamper protected, and all labels or tags identifying these alarm circuits have been removed.
7. Do not permit vault, safe or premises openings other than at scheduled times. Instruct your alarm contractor that unscheduled or telephone request for openings other than by prior written request or other secure pre-arrangement should be treated as an alarm or duress condition.
8. Use UL approved locks and lock cylinders which are rated as Apick≡ or burglary resistant.
9. Change all lock combinations at least annually or upon termination of any employee with knowledge of the combination(s), regardless if the reason for the termination.
10. Use two supervisors to open all premises which are alarmed. One individual should remain a safe distance away from the premise entrance while the other enters and searches to be certain everything is alright, then signal by pre-arrangement to the other.
11. Meet periodically with local and state law enforcement officials to discuss alarm response, criminal activity statistics, patrol frequency, and other pertinent matters.
12. Develop robbery, hostage and kidnapping (extortion) contingency plans which are disseminated and made known to all employees from management on down.

13. Enclose shipping/receiving areas in steel or chain link fencing, install day gates on loading platform doors, and adequately harden and secure other doors and openings to isolate and restrict access to the warehouse or manufacturing areas by drivers and other unauthorized individuals.
14. Require that all shipping/receiving dock day gates are kept closed at all times when docks are not in use.
15. Install local alarms or hard-wired day annunciation contact switches on all fire exits and other perimeter doors not authorized for employee or visitor use.
16. If utilizing company-owned or leased vehicles for the pickup and delivery of controlled substances, do not mark them with the company name or other identification which would indicate the nature of your business.
17. Isolate and secure office entry foyers or reception areas to prevent unauthorized entry. Entry from these areas should be remotely controlled by electronic locks or other automatic access devices after positive identification.
18. Locate receptionists behind bullet resistant barriers which are equipped with a package receiver and telephone or intercom system for communications.
19. Leave application forms for employment in the secured entry foyers or reception areas unless a secure pass through mechanism has been installed.
20. Secure doors from office areas to warehouse, research, and/or manufacturing areas with key/combination locks, machine-aided manual access devices, or other suitable mechanisms.
21. For larger operations, use a photo badge identification system for all employees and require other visitors such as tradesmen, contractors, vendors, etc. to wear special identification badges at all times when on the premises.
22. Install closed circuit TV cameras to monitor vaults, shipping/receiving areas, manufacturing area, cages, etc. These need not be continuously monitored if video recording systems are employed.
23. Issue and require the wearing of pocketless coverall type uniforms in the manufacturing areas vulnerable to pilferage of dosage form pharmaceuticals. The uniforms can be color coded to signify specific manufacturing areas.

**Drug Enforcement Administration Field Offices
with Assigned Diversion Investigators Personnel**

For updated contact information

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