Knowledge replaces fear.

Controlled Substances Record Keeping for Healthcare Practitioners in Illinois

By Glen D. Crick, Attorney at Law

Introduction

This article applies only to medical doctors, dentists, podiatrists, veterinarians, physicians' assistants, and advanced practice nurses who order, store, prescribe, administer, dispense, or "waste" controlled substances in Illinois. Although record keeping requirements found in the federal Controlled Substances Act apply to practitioners throughout the United States, there are specific requirements found under the Illinois Controlled Substances Act and Rules that may not apply in other states. The point of this article is to simplify controlled substances record keeping requirements for Illinois healthcare practitioners. The article does not address records required to be kept by manufacturers, distributors, drug treatment programs, methadone maintenance programs, hospitals, hospices, and pharmacies.

The opinions reflected herein are those of Glen D. Crick, an attorney licensed to practice in Illinois only, and are based on his twenty-five years of experience defending healthcare professionals subject to investigation and prosecution by regulatory and administrative agencies in Illinois and other states, and the federal Drug Enforcement Administration (DEA). Mr. Crick also draws on his previous ten years' experience investigating and directing investigations for the Illinois State Police and directing prosecutions and investigations for the agency now known as the Illinois Department of Financial and Professional Regulation (IDFPR).

It is important to note that federal and state laws that regulate controlled substances are constantly changing and, when in doubt, a practitioner is advised to check the current state of the law with DEA, Glen D. Crick , Ltd. or another attorney or law firm experienced in controlled substances regulatory matters.

The suggestions presented here are not to be considered to be "legal advice" and by reading this document, no attorney-client relationship is formed with Mr. Crick or Glen D. Crick, Ltd.

Laws Regulating Controlled Substances in Illinois

The importation, manufacture, distribution, use, and destruction of controlled substances in Illinois are regulated by the federal Controlled Substances Act, the Illinois Controlled Substances Act, and the Rules for the Illinois Controlled Substances Act. Both federal and state laws govern a healthcare practitioner's ability to order, store, prescribe, administer, dispense, and dispose of controlled substances in Illinois and they impose similar, but not identical, record keeping requirements. A practitioner is responsible for complying with **both** federal and state requirements.

Dual Registration

Every practitioner who orders, stores, prescribes, administers, dispenses, or destroys controlled substances in Illinois must register with both the federal government through the DEA and the state government through the Illinois Department of Financial and Professional Regulation (IDFPR). The federal government issues a registration number, commonly referred to as a "DEA number," to a qualified practitioner. At the state level, a practitioner is issued an Illinois Controlled Substance License.

Good Faith Requirement

Illinois law provides that controlled substances may only be prescribed, administered, or dispensed in "good faith." Good faith requires that a healthcare practitioner be acting in the regular course of treating a bona fide patient

who is under the practitioner's care for a pathology or condition, except when that condition is a physical or psychological dependence upon or addiction to controlled substances. An example of failing to meet the good faith requirement is a veterinarian prescribing a controlled substance (or any other drug) for use by a human being.

Doctor-Patient Relationship
To meet the good faith requirement, an established doctor-patient relationship must exist. The most common violation of the doctor-patient relationship occurs when a doctor prescribes or dispenses a controlled substance to a relative, friend, employee, or other person without examining that person or without making or keeping a record of his or her treatment. A practitioner **may** prescribe, administer, or dispense a controlled substance to a friend or relative. However, the practitioner would be held to the same standards as he or she would for any other patient and must maintain a complete record of examination, diagnosis, and treatment, including a health history, examination results, and notations of all patient contacts.

There is a growing belief that physicians should not treat family members because they cannot be dispassionate and objective, but that is not the standard of practice in Illinois.

Terms and Definitions

NOTE: Unless otherwise indicated, the definitions of terms in this section, indicated in italicized text, are reprinted from *Title 21 United States Code Controlled Substances Act*.

Administer: *To directly apply a drug or medicine to the body of a patient or to have the patient, at the direction of and in the presence of the practitioner, apply it directly to himself or herself by injection, inhalation, ingestion, or any other means.*

Controlled Substances: *Drugs or other chemicals that have the potential to be addictive and/or habit-forming.* Controlled substances are divided into five schedules, based on their medical usefulness and potential to be habit-forming**.** Schedule I controlled substances have no currently accepted medical use in the United States and are not addressed in this article. Schedule II controlled substances are approved for medical use, despite their high potential for abuse. State and federal regulations are strictest when dealing with Schedule II controlled substances. Schedules III, IV, and V controlled substances have less potential for abuse and, consequently, less stringent record keeping requirements.

Dispense: *To deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner.*

Dosage Form: *The physical form of the medication as it is administered to or taken by a patient.* State and federal laws often use the terms "form," "dosage form," "finished form," and "finished dosage form" interchangeably. For the purpose of this article, the term "dosage form" includes the medium by which the controlled substance is delivered (i.e., tablets, ointments, gels, suppositories, etc.) and the "strength," which is a measurement of the amount of controlled substance within the form. Example: A practitioner must keep a record of all "5 mg hydrocodone tablets" received and a record of all "10 mg hydrocodone tablets" received, as opposed to a record that merely reflects "hydrocodone tablets" received.

The Illinois Controlled Substances Act and Rules differ from the federal Controlled Substances Act in that the terms "strength" and "dosage form" are found only in Illinois

laws. To minimize confusion while attempting to be accurate, the phrase **"dosage form (including strength)"** is used throughout this article when referring to record keeping practices required by Illinois law.

Legend Drugs: *Prescription drugs (including controlled substances) sometimes are referred to as "legend" drugs because they bear a specific FDA-assigned label or "legend", such as "Caution: Federal law prohibits dispensing without prescription."*

Patient Controlled Substances Record (definition reprinted from Title 77 Illinois Administrative Code 3100.510): *Illinois practitioners are required by the Rules for the Illinois Controlled Substances Act to keep a "Patient Controlled Substances Record" in which controlled substances administered and dispensed to patients are recorded.* The Patient Controlled Substances Record is described, in detail, later in this article. It is strongly recommended that an entry be made in the Patient Controlled Substances Record every time a Schedule II, III, IV, or V controlled substance is administered or dispensed to a patient.

Prescribe: *To issue an order (usually on a written form called a "prescription blank") for medication to be dispensed to a patient or to an ultimate user.* Issuing an order for medication to immediately be administered to a patient, such as when a physician orders medication to be administered to a patient in a hospital, is not considered to be "prescribing" under Illinois or federal law.

Prescription Drugs: *Drugs and medicines that may only be dispensed pursuant to a lawful prescription issued by an authorized practitioner.* All prescription drugs are **not** controlled substances, but **all** legitimately manufactured controlled substances are available only by prescription, hence, all controlled substances are prescription drugs. The requirements for dispensing prescription drugs found under the Illinois Medical Practice Act, Dental Practice Act, Nurse Practice Act, Podiatric Medical Practice Act, and Veterinary Medicine and Surgery Practice Act apply equally to controlled substances.

Ultimate User: *Patient who will take the medication or the parent of a child to whom the parent will administer the medication.* In the case of veterinarians, the ultimate user is the owner of the animal being treated.

General Record Keeping Requirements

Every practitioner must maintain a complete and accurate record of each controlled substance ordered, stored, administered, dispensed, destroyed, or otherwise disposed of. Separate records must be maintained for each practice location. Controlled substances record keeping requirements are generally more restrictive under Illinois law than under federal regulations; therefore, Illinois standards are the primary focus of this article.

Common Record Keeping Mistakes

Three common mistakes made by practitioners in their record keeping practices are addressed later in this article, in detail. They are:

- failure to record Schedule II controlled substances received on the right side of the practitioner's (blue and white) copy of DEA Form 222 used to order the controlled substances
- failure to perform an initial, annual, or biennial inventory of **all** controlled substances on hand
- failure to record controlled substances

administered and dispensed to patients in a Patient Controlled Substances Record

Ordering Controlled Substances

A practitioner is required by federal and state law to maintain a record of **all** controlled substances ordered. This record must include the name, address, and registration number of the manufacturer, distributor, or other entity from which the controlled substances were ordered.

Ordering Schedule II Controlled Substances: DEA Form 222
A DEA Form 222 must be completed when Schedule II controlled substances are ordered from a manufacturer, distributor, or other source. Each DEA Form 222 is comprised of three attached pages. The first page is white with brown print, the second page is white with green print, and the third page is white with blue print. To order Schedule II controlled substances, a practitioner must complete the form and forward the top two copies (with carbon paper still attached) to the distributor. The practitioner keeps the blue and white copy on file. The distributor keeps the brown and white copy on file and forwards the green and white copy to the DEA.

Official copies of Form 222 only are available from the DEA. They may be ordered:

- by calling the DEA Headquarters Registration Unit at 800-882-9539
- through the nearest DEA Field Office
- on the Internet at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp

Forms usually are mailed within ten working days, and there is no charge for this service.

According to the FDA's *Title 21 Code of Federal Regulations*, a practitioner's copies of Form 222 must be maintained separately from other records and "kept available for inspection for a period of two years."

Ordering Schedules III, IV, and V Controlled Substances
No special form is required for ordering Schedules III, IV, or V controlled substances.

Receiving Controlled Substances

Federal and state law require a practitioner to maintain a record of all controlled substances received. This record must include the name, address, and registration number of the manufacturer, distributor, or other entity from which the controlled substances are ordered.

Receiving Schedule II Controlled Substances
When shipments of Schedule II controlled substances are received, the practitioner who placed the order is responsible for confirming that the contents of the shipment match the controlled substances ordered. **On the right side of the blue and white copy of Form 222 used to place the order, the practitioner is responsible for noting the date and what was received**. If there are any indications that shipped controlled substances were not received, a practitioner should immediately notify both the shipper and the DEA.

Failure to properly complete the blue and white copy of the form when a shipment of Schedule II controlled substances is received is a very common mistake.

Receiving Schedules III, IV, and V Controlled Substances

No special forms are required to be completed when Schedules III, IV, and V controlled substances are received. However, the recording requirements that follow **apply to all schedules of controlled substances**.

Recording Controlled Substances Received
Under *Title 77 Illinois Administrative Code 3100*, records for each controlled substance received must include:

- name of substance
- dosage form (including strength)
- number of commercial containers of each finished form received (such as 10 bottles of 100 10-milligram tablets)
- date of receipt
- Name, address, and federal (DEA) registration number of the entity from which the containers were received

Receiving Controlled Substances from Patients
A practitioner may not accept an unused portion of any controlled substance prescription from a patient if the practitioner did not originally dispense the controlled substance to the patient. A record of a controlled substance received from a patient to whom the controlled substance was dispensed should be kept in the same manner as records of other controlled substances received by the practitioner. A practitioner may also counsel patients to destroy unused or unneeded controlled substances themselves.

Samples
A healthcare practitioner must keep a record of all controlled substances that come in and go out, including samples. Records of controlled substance samples received, maintained, administered, dispensed, or destroyed must be kept in the same manner as records for other controlled substances.

Storing Controlled Substances

Controlled substances must be stored in a secure location that is inaccessible to the public or other unauthorized personnel. The FDA's *Title 21 Code of Federal Regulations (CFR),* requires practitioners to store controlled substances in a securely locked, substantially constructed cabinet. Steps should be taken to limit access and secure controlled substances even during the work day in a busy practice.

Inventory

Initial Inventory
The Illinois Controlled Substances Act requires every practitioner who administers or dispenses controlled substances to take an inventory of all supplies on hand on the date he or she first engages in administering or dispensing them. If a practitioner commences business with no controlled substances on hand, he or she must record this fact as the initial inventory.

Annual Inventory
After an initial inventory, the Illinois Controlled Substances Act requires a practitioner to take a new inventory at least once each year of all stocks of controlled substances on hand. The annual inventory may be taken on any date that is within one year of the previous inventory.

Biennial Inventory
The federal Controlled Substances Act requires practitioners to take a complete inventory of all controlled substances on hand, once during every two-year period.

Recommendation: Take a complete inventory annually, shortly after the beginning of each new year.

Separate Inventories
A practitioner is required to maintain inventories and records of Schedule II controlled substances separately from all other records. Inventories and records of Schedules III, IV, and V controlled substances must be maintained separately from other records or in such a manner that the information is **readily retrievable from the practitioner's ordinary business records**.

Inventory Records
Inventory records must be in written, typewritten, or printed form and maintained at the registered location for at least two years from the date that the inventory was taken.

Each inventory record must contain the following information:

- date inventory taken
- whether inventory was taken at the start or end of the business day
- names of all controlled substances on hand
- dosage forms (including strength)
- number of units of dosage form in a commercial container (such as a 100-tablet bottle)
- number of commercial containers of each dosage form (such as four 100-tablet bottles)

As previously mentioned, controlled substance samples must be included in inventory records, according to the 2006 *DEA Practitioner's Manual*.

Prescribing Controlled Substances

A written prescription for a controlled substance must:

- be signed by the practitioner issuing the prescription
- bear the date the prescription is issued
- be written in ink or indelible pencil or typewritten

The prescription must include the:

- patient's full name and address or, for veterinarians, the species and the owner's full name and address
- practitioner's full name, address, and DEA registration number
- controlled substance name
- dosage form (including strength)
- quantity prescribed
- directions for use
- number of refills authorized, if any (2006 *DEA Practitioner's Manual*)

Record Keeping Requirements
Whenever a controlled substance is prescribed to a patient, the prescriber should make an entry in the patient's medical record, indicating the:

- date prescription was written
- brand or generic name of substance prescribed
- form
- dosage form (including strength)

A photocopy of the prescription placed in the patient's medical record is sufficient.

Prescribing Prohibitions
Under *Title 77 Illinois Administrative Code 3100*, while a practitioner may allow a secretary or nurse to prepare a prescription for the practitioner's signature, in no event may that person sign the practitioner's name on the prescription, or use a signature stamp.

Additionally, a prescription may not be written

in the name of the practitioner or an office staff member to obtain controlled substances for the purpose of general dispensing to patients.

The following activities are prohibited when prescribing controlled substances.

- Under the Illinois Controlled Substances Act, a practitioner may not have prescription forms preprinted to indicate the prescription of a particular controlled substance prior to the prescription being issued to a patient.
- Under *Title 77 Illinois Administrative Code 3100*, a practitioner may not pre-sign a blank prescription form for later use.
- Also under *Title 77 Illinois Administrative Code 3100*, a prescription for a controlled substance may not be issued for the purpose of continuing a patient's drug addiction or dependency.

Telefaxing Prescriptions
Prescriptions for Schedule II controlled substances may not be transmitted to a pharmacy by fax. However, both state and federal laws allow practitioners to send prescriptions for Schedules III, IV, and V controlled substances by fax. The fax must bear the signature of the prescriber. The pharmacy that fills the prescription must keep the fax on file for not less than two years, according to the Illinois Controlled Substances Act.

Oral Prescriptions
In lieu of a written prescription, a pharmacist may dispense Schedules III, IV, or V controlled substances upon receiving an oral prescription from a practitioner. Along with information about the controlled substance to be dispensed, under the Illinois Controlled Substances Act, an oral prescription must contain:

- full name and address of the patient or ultimate user to whom the controlled substance is to be dispensed
- full name, address, and registry number (DEA number) of the practitioner prescribing the controlled substance

The Illinois Controlled Substances Act also requires a pharmacist to promptly reduce the oral prescription to writing. The written memorandum must be dated as of the day the oral prescription was received, and must include the date the prescription was filled and the pharmacist's signature. Memoranda of oral prescriptions are required to be kept on file by the owner of the pharmacy for not less than two years.

There are some rare circumstances (epidemic, unforeseen accident, etc.) under which a practitioner may issue a valid oral prescription for a Schedule II controlled substance. In such instances, the Illinois Controlled Substances Act requires a prescriber to send a written copy of the emergency prescription to the dispensing pharmacist within seven days.

The Patient Controlled Substances Record

In addition to other records required by federal and state law, the Rules for the Illinois Controlled Substances Act require a practitioner to maintain a "Patient Controlled Substances Record."

Background
A number of years ago, Illinois had in place a "triplicate prescription" program, requiring a prescription to be filled out "in triplicate" whenever a Schedule II controlled substance

was dispensed. The program no longer is in use, but the Rules for administering the Illinois Controlled Substances Act have not been modified to reflect the change. *Title 77 Illinois Administrative Code 3100* Rules still refer to "triplicate" recording requirements.

As a result, the Rules **only** require that the following information be recorded in the Patient Controlled Substances Record:

- Schedule II controlled substances **administered**
- Schedule II controlled substances that are not designated products **dispensed** (although the term "designated product" is used in the Rules, it is not defined in the Illinois Controlled Substances Act or the Rules)
- Schedules III, IV, and V controlled substances **dispensed**

Recommendation: Because both the federal and the Illinois Controlled Substances acts provide that every practitioner must maintain a record of all controlled substances administered, dispensed, or professionally used other than by prescription, and that this information be kept in a "readily accessible" format, to be on the safe side and for the sake of simplicity, make an entry in the Patient Controlled Substances Record **any time a controlled substance is administered or dispensed.**

The Patient Controlled Substances Record Requirements

The Patient Controlled Substances Record must be arranged alphabetically by drug or substance, with a separate page or pages for each dosage form (including strength). Both the federal and the Illinois Controlled Substances acts also require that entries made in this record must include:

- date controlled substance was dispensed or administered
- name of patient
- quantity (number of units or volume) dispensed or administered
- name or initials of the individual who dispensed or administered the controlled substance

Administering Controlled Substances

Record Keeping Requirements

When a healthcare practitioner administers a controlled substance to a patient, he or she should enter in the patient's individual medical record the following information:

- date
- controlled substance name
- dosage form (including strength)
- quantity administered

As noted previously in the "The Patient Controlled Substances Record" state law requires that every time a healthcare practitioner administers a Schedule II controlled substance, he or she must also make an entry in the Patient Controlled Substances Record. Again, it is recommended that an entry be made in the Patient Controlled Substances Record **any time any controlled substance is administered**.

Hospital and Nursing Home Exception

Controlled substances administered in hospitals or institutions licensed under the Illinois Hospital Licensing Act that come from the facilities' supplies are exempt from this requirement, but controlled substances ordered by a physician must:

- be in writing in the patient's record
- be signed and dated by the prescriber
- have the name and quantity of controlled substances ordered
- reflect the quantity of the controlled substance actually administered

Under *Title 77 Illinois Administrative Code* 3100, such records must be maintained for two years.

Dispensing Controlled Substances

A healthcare practitioner (other than a pharmacist) only may dispense controlled substances for patients under his or her care.

Record Keeping Requirements
A healthcare practitioner who dispenses a controlled substance should make an entry in the patient's individual medical record indicating:

- date controlled substance dispensed
- name of controlled substance
- dosage form (including strength)
- quantity
- number of refills authorized, if any

Recommendation: *Title 77 Illinois Administrative Code 3100* also requires that all Schedules II, III, IV, and V controlled substances dispensed be recorded in the practitioner's Patient Controlled Substances Record.

Labels on Containers of Controlled Substances Dispensed
Under Illinois law, the label on a container of any controlled substance dispensed must be written in ink or indelible pencil, and must indicate the date the controlled substance was dispensed.

The label must also include:

- patient's full name and address or, for veterinarians, the species and owner's full name and address
- practitioner's full name, address, and DEA registration number
- controlled substance name
- dosage form (including strength)
- quantity prescribed
- directions for use
- number of refills (if any) that are authorized

Transferring Controlled Substances

Controlled substances may be transferred among facilities and locations owned by a common practitioner or business entity. However, records of all such transfers must be maintained **both at the transferring and receiving locations** in the same manner as required for controlled substances shipped by and received from manufacturers and distributors. A practitioner is required to use DEA Form 222 to transfer Schedule II controlled substances and to keep detailed records of Schedules III, IV, and V controlled substances transferred.

Disposing of Controlled Substances

Returning Controlled Substances
A practitioner must keep records of all outdated or unused controlled substances returned to a distributor or manufacturer.

Reverse Distributors
Damaged, expired, or otherwise unusable or unwanted controlled substances, including samples, may be disposed of by transferring them to an entity authorized to receive such controlled substances ("reverse distributor").

Contact the local DEA field office for a list of authorized Reverse Distributors in your area. A practitioner is required to use DEA Form 222 to transfer Schedule II controlled substances to a reverse distributor and to keep a detailed record of all Schedules III, IV, and V controlled substances transferred. A practitioner also must maintain copies of records documenting all transfers of controlled substances for a period of two years. For a list of reverse distributors by state, see www.pharmacy.state.or.us/Pharmacy/Imports/Compliance/Reverse_Distributors_by_State12.07.pdf and similar websites.

Donating Controlled Substances
For information about Food and Drug Administration regulations for donating controlled substances to such entities as free clinics, see http://www.fda.gov/cder/guidance/5519fnl.htm on line. When controlled substances are donated, records must be kept in the same manner as for transferred controlled substances.

Wasted and Destroyed Controlled Substances
A practitioner must maintain a detailed record of all controlled substances wasted. In some instances, a practitioner may destroy unused controlled substances. Prior to destroying a controlled substance, it is strongly suggested that a practitioner contact the nearest DEA field office and request instructions about how to legally destroy it. (For a list of DEA field offices, visit http://www.justice.gov/dea/contactinfo.htm on line.) It also is suggested to maintain a record of when the call was placed, with whom the practitioner or someone calling on his or her behalf spoke, and the instructions received.

General Recommendations for Handling Controlled Substances

Depending on the size of the practice, a practitioner may wish to develop and implement written policies and procedures for dealing with controlled substances in his or her practice. Written procedures may include:

- entering every instance of prescribing, dispensing, or administering a controlled substance directly in each patient's chart
- maintaining a separate log of all controlled substance prescriptions telephoned to pharmacies
- checking patients' charts for refill timeliness before authorizing a prescription refill
- regularly reviewing all controlled substance record keeping practices to verify security and compliance

Additional Precautions
It is further suggested that a practitioner:

- minimize the number of prescription pads in use
- keep all prescription blanks in a safe place
- include the number of doses in both written and numeric forms when filling out prescription blanks to discourage prescription order alterations
- use prescription blanks only for writing prescription orders, and never for writing notes
- never sign prescription blanks in advance
- use tamper-resistant prescription pads
- make time to assist any pharmacist who calls to verify information about a prescription order
- contact the nearest DEA field office to obtain or provide information about suspicious prescription activities

Inspections and Audits

Investigators and agents of the Federal Drug Enforcement Administration (DEA) and investigators of the Illinois Department of Financial and Professional Regulation (IDFPR) may seek to inspect premises in Illinois where controlled substances are maintained and audit controlled substances records required to be kept. Often, DEA diversion investigators and IDFPR controlled substances investigators together will inspect and/or audit locations where controlled substances are stored.

A Practitioner's Legal Rights
A practitioner is not required by either federal or Illinois law to immediately submit to questioning by a DEA or an IDFPR investigator (refer to the article, "What to Do When Investigated," available on line at www.cricklaw.com). Rather than refuse to be interviewed, a practitioner may tell an investigator that he or she first wishes to consult with legal counsel.

In the normal course of business, an inspection and/or audit may **only** be conducted **with the voluntary consent of the practitioner**, or pursuant to the terms of an **Administrative Inspection Warrant**. Such a warrant may be issued by a state or federal judge or federal magistrate upon a showing that there is probable cause to believe a violation of federal or state controlled substances law has occurred or is occurring.

Unannounced Visits
The failure of an investigator to call ahead and schedule an appointment is not an oversight. It is a calculated move to catch a practitioner off guard. Further, investigators are not always subtle when identifying themselves in front of a waiting room of patients. They usually present their credentials to front desk staff, then ask to see the practitioner right away. If staff says the practitioner is with a patient or unavailable, then investigators may become demanding and intimidating.

Insisting that a practitioner stop seeing patients so that he or she may be interviewed is an attempt to coerce the practitioner into "cooperating." Investigators count on a practitioner's desire to avoid confrontation and return to work as soon as possible.

Notice of Inspection
In most instances, a DEA investigator will present the practitioner with a "Notice of Inspection of Controlled Premises" (DEA Form 82). This notice sets forth the practitioner's rights, including the **right to refuse to allow the inspection without an Administrative Inspection Warrant**. This form also states that any evidence found during the inspection may be used against the practitioner during a criminal prosecution.

An IDFPR investigator or controlled substances inspector will not present a Notice of Inspection, because no such IDFPR form exists. An IDFPR investigator may also neglect to inform a practitioner about his or her right to insist that an Administrative Inspection Warrant be obtained before any inspection and/or audit is conducted.

Administrative Inspection Warrant
Under federal law, officers of the Attorney General of the United States may conduct inspections of premises where controlled substances are maintained. Such premises are referred to as "controlled" premises. An Administrative Inspection Warrant authorizing inspections of controlled premises **is required, unless**:

- the owner **freely consents** to inspection

without a warrant
- a situation presents imminent danger to health or safety
- a situation involves inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impractical to obtain a warrant
- there is an emergency situation in which time or the opportunity to apply for a warrant is lacking
- any other situation for which a warrant is not constitutionally required

Any federal judge or magistrate or judge of a state court of record may, upon taking the proper oath or affirmation showing probable cause, issue a warrant for the purpose of conducting an inspection of a controlled premises. Inspections conducted pursuant to an Administrative Inspection Warrant are limited to:

- inspection of records, reports, or other documents required by law to be maintained
- inspection of the controlled premises and all pertinent equipment, substances, or materials found therein
- inventory of any stock of any controlled substance

Under Illinois law, IDFPR controlled substances inspectors and Illinois State Police investigators are authorized to inspect controlled premises **with the consent of the practitioner** or **pursuant to an Administrative Warrant**. A circuit court judge may issue an inspection warrant upon determining that there is probable cause.[42] Such warrant must identify the:

- premises to be inspected
- purpose of the inspection
- type of property to be seized

Unless otherwise stated on the warrant, an agent of the IDFPR or the State Police has the right to inspect:

- and copy any records, reports, or other documents required by state law to be maintained
- controlled premises and all pertinent equipment, substances, or materials found therein
- inventory of any controlled substances stock

An inspection warrant issued by a federal judge or magistrate or a state court judge does not extend to financial, sales, and pricing data, unless the owner of the controlled premises provides written consent allowing access to such information.

Deciding Whether to Consent to the Inspection

When presented with a Notice of Inspection (DEA Form 82), when otherwise requested to consent to an inspection, or when notified that an investigator intends to conduct such an inspection, it is up to the practitioner **to decide whether to voluntarily consent** to the inspection of the premises and records. The principal advantage of requiring a warrant be obtained is that the investigator will be required to state, in writing, and testify under oath to the circumstances he or she believes support issuance of the warrant. A federal judge or magistrate or state court judge determine whether probable cause exists. A judge or magistrate may not find probable cause and may refuse to issue the warrant. Even in instances when warrants **are** issued, there is an advantage because the affidavit and testimony will be a matter of record, and such a

record could prove valuable when defending the practitioner, should formal charges be filed.

Requiring a warrant to be obtained will also allow the practitioner time to locate and organize his or her files, and to ensure that any expired controlled substances are segregated from working stock.

Note of Caution: Under no circumstances should a practitioner create new records or falsify existing records. Practitioners also have been known to instruct staff to alter records. That is an even graver mistake. When an inspection reveals a problem, then staff is interviewed. During the interview, staff is asked about record keeping procedures, putting them in the position of providing information that will incriminate the practitioner or of committing a federal felony by lying to a federal officer.

Finally, it is ill-advised to consent to an inspection out of fear that requiring a warrant will anger an investigator. If an investigator is so unprofessional that a request to follow the law causes him or her to treat the practitioner under investigation unfairly, then it is unlikely that investigator will treat the practitioner fairly under **any** circumstance.

As noted in the article "What to Do When Investigated," available on line at www.cricklaw.com, **the investigator is not your friend**, and deciding on a course of action merely to placate the investigator is not a good idea.

What Will Be Inspected
During a typical inspection, the entire premises is inspected, with particular attention to areas where controlled substances are stored and where they are maintained during normal business hours. As previously noted, controlled substances must be stored in a securely locked, substantially constructed cabinet. A physical inventory of all controlled substances on hand will be conducted and recorded. Tablets will be counted and liquid amounts estimated.

Records that Will Be Audited
Though the sequence of documents reviewed may vary, investigators generally will review:

- initial, annual, and biennial inventories
- DEA Forms 222
- records of Schedules III, IV, V Controlled substances ordered and received
- the patient controlled substances record
- logs of controlled substances wasted, returned, and destroyed

Initial, Annual, and Biennial Inventories: In most instances, the initial inventory will be reviewed only if the controlled premises has been registered for less than two years or if no annual or biennial inventory is available. DEA investigators will request and review the biennial inventory. Although it is required by Illinois law, practitioners seldom will be asked for the annual inventory.

DEA Forms 222: All forms completed since the last audit was conducted will be reviewed, and the total number of Schedule II controlled substances that were ordered and received will be recorded.

Records of Schedules III, IV, and V Controlled Substances Ordered and Received: Invoices and other records reflecting the purchase and receipt of Schedules III, IV, and V controlled substances will also be reviewed, and totals ordered and received will be recorded.

Patient Controlled Substances Record: The

Patient Controlled Substances Record is required by the Rules for the Illinois Controlled Substances Act, and is not required by the federal Controlled Substances Act. However, federal law does require that records "be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant." DEA agents will often ask for a controlled substance log or to review any other records that reflect controlled substances administered and dispensed.

Recommendation: The practitioner and/or legal counsel should observe each and every aspect of an inspection and/or audit.

Reconciliation
After controlled substances records have been examined, the investigator or investigators will compare the total amount of each controlled substance ordered and received to the amount administered, dispensed, returned, destroyed, and wasted that are documented in the practitioner's records, and the number on hand. The end result should be a determination about whether any controlled substances are unaccounted for. Any controlled substances unaccounted for will be presumed to have been diverted.

When determining the total number of controlled substances ordered and received, DEA investigators will not depend solely on the practitioner's records. Records of distributors also will be reviewed.

Depending on the volume of controlled substances ordered and used in a practice, and the manner in which the controlled substances records are kept, the audit may be completed on site and the results discussed with the practitioner upon completion of the audit. If a large number of records require review, the audit may be completed at a later time.

Post-audit Interview
In most cases, after an audit has been completed, the investigators meet with the practitioner to discuss their findings. At that time, the practitioner is advised of the audit results. The practitioner also will be advised about any controlled substances unaccounted for. Depending on the results of the audit, a practitioner may be asked to surrender his or her DEA registration. As described in detail in the accompanying article, "The Request to Surrender a DEA Registration," available on line at www.cricklaw.com, the response should be "No."

A practitioner also should be aware that:

- he or she is not required to answer any questions at the time when he or she is told about the investigators' audit findings
- lying to a DEA agent is a federal felony
- if he or she dislikes the tone and tenor of a discussion with investigators, then he or she may simply stop answering questions and explain that he or she wishes to consult with legal counsel (see the accompanying article, "What to Do When Investigated," found on line at www.cricklaw.com)

Federal and State Resources

United States Drug Enforcement Administration (DEA)
General Questions: Call 202-307-1000.

Drug Registrant Information:
Drug Enforcement Administration
Office of Diversion Control
8701 Morrissette Drive
Springfield, Virginia 22152

Call 800-882-9539.

Web Site: http://www.justice.gov/dea/contactinfo.htm
List of DEA Field Offices: http://www.justice.gov/dea/contactinfo.htm.

IDFPR Enforcement
Illinois Department of Financial and Professional Regulation, Division of Professional Regulation
100 W. Randolph Street, 9th Floor
Chicago, Illinois 60601
312-814-4500

IDFPR Administration
Illinois Department of Financial and Professional Regulation. Division of Professional Regulation
320 W. Washington Street
Springfield, Illinois 62786
217-785-0800

References

Title 77 Illinois Administrative Code 3100: http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html

DEA Web site: http://www.deadiversion.usdoj.gov

DEA Practitioner's Manual (2006): http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Illinois Controlled Substances Act (720 ILCS): http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html

FDA's *Title 21 Code of Federal Regulations (CFR)*: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Title 21 United States Code (USC) Controlled Substances Act (CSA): http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html

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About the Author

Glen D. Crick is an attorney who, since 1987, has concentrated his practice in representing health care and other licensed professionals before the Illinois Department of Financial and Professional Regulation, and other governmental entities in Illinois and in other states. Mr. Crick served as Director of Enforcement for the Department from 1980 to 1987, and was responsible for overseeing all investigative and prosecutorial activities of the Department. Prior to that, he was the supervisor of the Northern Illinois Fraud Investigations Unit of the Illinois State Police, Financial Fraud and Forgery Bureau.

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