

SUMMARY OF LAWS & RULES

DRUG SAMPLES

KEY:	ORC - <i>Ohio Revised Code</i> OAC - <i>Ohio Administrative Code</i> 21 USCA - <i>Title 21, United States Code Annotated</i> 21 CFR - <i>Title 21, Code of Federal Regulations</i>
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Section 3719.01 **Definitions.** (Controlled Substance Act) [ORC: 07/01/96]

As used in Chapter 3719. of the Revised Code:

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(E) "Dangerous drug" has the same meaning as in section 4729.02 of the Revised Code.

(F) "Dispense" means sell, leave with, give away, dispose of, or deliver.

* * *

(H) "Drug" has the same meaning as given that term in section 4729.02 of the Revised Code.

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(W) "Person" means any individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

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(AA) "Practitioner" means the following:

- (1) A person who is licensed pursuant to Chapter 4715., 4731., or 4741. of the Revised Code and authorized by law to write prescriptions for drugs or dangerous drugs;
- (2) An advanced practice nurse authorized under section 4723.56 of the Revised Code to prescribe drugs and therapeutic devices.

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(DD) "Sale" includes delivery, barter, exchange, transfer, or gift, or offer thereof, and each transaction of those natures made by any person, whether as principal, proprietor, agent, servant, or employee.

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Section 3719.011 **Definitions.** (Controlled Substance Act) [ORC: 07/01/76]

As used in the Revised Code:

- (A) "Drug of abuse" means any controlled substance as defined in section 3719.01 of the Revised Code, any harmful intoxicant as defined in section 2925.01 of the Revised Code, and any dangerous drug as defined in section 4729.02 of the Revised Code.

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Section 4729.02 Definitions. (Dangerous Drug Distribution Act) [ORC: 07/21/94]

As used in this chapter:

* * *

(C) "Drug" means:

- (1) Any article recognized in the official United States pharmacopeia, national formulary, or any supplement, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (3) Any article, other than food, intended to affect the structure or any function of the body of man or other animals;
- (4) Any article intended for use as a component of any article specified in division (C)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories.

(D) "Dangerous drug" means:

- (1) Any drug which, under the "Federal Food, Drug, and Cosmetic Act," or Chapter 3715. or 3719. of the Revised Code, may be dispensed only upon a prescription;
- (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code, or to which that chapter does not apply;
- (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

* * *

(J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.

(K) "Wholesale sale" and "sale at wholesale" means any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

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(O) "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of that person authorized by that person to engage in the sale of dangerous drugs at wholesale.

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- (S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

* * *

Section 3719.09 **Authorized possession of controlled substances.** [ORC: 07/01/96]

Possession or control of controlled substances is authorized in the following instances and subject to the following conditions:

- (A) Possession of controlled substances in the course of business by a manufacturer, wholesaler, practitioner, pharmacist, category III terminal distributor of dangerous drugs, or other person authorized to administer, dispense, or possess controlled substances under Chapter 3719. or 4729. of the Revised Code;

* * *

Section 4729.51 **Persons who may sell, deliver, distribute and possess dangerous drugs.**
[ORC: 11/06/96]

- (A) No person other than a registered wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs, except as follows:
- (1) A pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs may make occasional sales of dangerous drugs at wholesale;
 - (2) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or deliver dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or delivery.

* * *

- (C) (1) Except as provided in division (C)(4) of this section, no person shall sell, at retail, dangerous drugs.
- (2) Except as provided in division (C)(4) of this section, no person shall possess for sale, at retail, dangerous drugs.
- (3) Except as provided in division (C)(4) of this section, no person shall possess dangerous drugs.
- (4) Divisions (C)(1), (2), and (3) of this section do not apply to a registered wholesale distributor of dangerous drugs, a licensed terminal distributor of dangerous drugs, a practitioner, or a person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. of the Revised Code.

* * *

Section 4729.52 **Registration as wholesaler; fees.** [ORC: 06/30/95]

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(D) Each registration certificate and its application shall describe not more than one establishment or place where the registrant or applicant may engage in the sale of dangerous drugs at wholesale. No registration certificate shall authorize or permit the wholesale distributor of dangerous drugs named therein to engage in the sale of drugs at wholesale or to maintain possession, custody, or control of dangerous drugs for any purpose other than for the registrant's own use and consumption at any establishment or place other than that described in the certificate.

* * *

Section 4729.99 Penalties. (Chapter 4729.) [ORC: 07/01/96]

* * *

(E) (1) Whoever violates section 4729.37, division (C)(2) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code is guilty of a felony of the fifth degree. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter or a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fourth degree.

(2) If an offender is convicted of or pleads guilty to a violation of section 4729.37, division (C) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code, if the violation involves the sale, offer to sell, or possession of a schedule I or II controlled substance, with the exception of marihuana, and if the offender, as a result of the violation, is a major drug offender, as defined in section 2929.01 of the Revised Code, the court that sentences the offender, in lieu of the prison term authorized or required by division (E)(1) of this section and sections 2929.13 and 2929.14 of the Revised Code and in addition to any other sanction imposed for the offense under sections 2929.11 to 2929.18 of the Revised Code, shall impose upon the offender, in accordance with division (D)(3)(a) of section 2929.14 of the Revised Code, the mandatory prison term specified in that division and may impose an additional prison term under division (D)(3)(b) of that section.

(3) * * *

(F) * * *

(G) Whoever violates division (C)(1) of section 4729.51 of the Revised Code is guilty of a felony of the fourth degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the third degree.

(H) Whoever violates division (C)(3) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fifth degree.

Section 3719.81 Illegal use and distribution of drug samples; exceptions. [ORC: 07/01/76]

(A) A person may furnish another a sample of any drug of abuse, or of any drug or pharmaceutical preparation which would be hazardous to health or safety if used without the supervision of a practitioner, if all of the following apply:

(1) The sample is furnished by a manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals to a practitioner, or is furnished by a practitioner to a patient for use as medication;

- (2) The drug is in the original container in which it was placed by the manufacturer, and such container is plainly marked as a sample;
 - (3) Prior to its being furnished, the drug sample has been stored under the proper conditions to prevent its deterioration or contamination;
 - (4) If the drug is of a type which deteriorates with time, the sample container is plainly marked with the date beyond which the drug sample is unsafe to use, and such date has not expired on the sample furnished. Compliance with the labeling requirements of the Federal Food, Drug, and Cosmetics Act shall be deemed compliance with this section;
 - (5) The drug is distributed, stored, or discarded in such a way that the drug sample may not be acquired or used by any unauthorized person, or by any person, including a child, for whom it may present a health or safety hazard.
- (B) Division (A) of this section does not apply to restrict the furnishing of any sample of a non-narcotic substance if such substance may, under the "Federal Food, Drug, and Cosmetic Act", as defined in division (D)(1) of section 4729.02 of the Revised Code, and under the laws of this state, otherwise be lawfully sold over the counter without a prescription.
- (C) The state board of pharmacy shall, pursuant to sections 119.01 to 119.13 of the Revised Code, adopt regulations necessary to give effect to this section.

Section 3719.31 Prohibition against careless distribution of samples containing drug or poison. [ORC: 10/01/53]

No person shall leave, throw, or deposit upon the doorstep or premises owned or occupied by another, or hand, give, or deliver to any person, except in a place where it is kept for sale, a patent or proprietary medicine, preparation, pill, tablet, powder, cosmetic, disinfectant, or antiseptic, or a drug or medicine that contains poison or any ingredient that is deleterious to health, as a sample or for the purpose of advertising.

As used in this section "drug," "medicine," "patent or proprietary medicine," "pill," "tablet," "powder," "cosmetic," "disinfectant," or "antiseptic" includes all remedies for internal or external use.

Section 3719.07 Records of controlled substances handled. [ORC: 06/29/94]

- (A) Every practitioner, or other person who is authorized to administer or use controlled substances, shall keep a record of all such drugs received by him, and a record of all such drugs administered, dispensed, or used by him, otherwise than by prescription in accordance with the provisions of division (E) of this section. The keeping of a record of the quantity, character, and potency of solutions or other preparations purchased or made up by a practitioner or other person using small quantities of solutions or other preparations of controlled substances for local application, and of the dates when purchased or made up, without keeping a record of the amount of such solution or other preparation applied by him to individual patients is a sufficient compliance with this division.

No record need be kept of schedule V controlled substances administered, dispensed, or used in the treatment of any one person or animal, when the amount administered, dispensed, or used for that purpose does not exceed in any forty-eight consecutive hours:

- (1) One hundred twenty-five milligrams of opium;
- (2) Thirty milligrams of morphine or of any of its salts;
- (3) Two hundred fifty milligrams of codeine or any of its salts;
- (4) One hundred twenty-five milligrams of dihydrocodeine or any of its salts;

- (5) Thirty milligrams of ethylmorphine or any of its salts;
- (6) A quantity of any other schedule V controlled substances or any combination of schedule V controlled substances that does not exceed in pharmacologic potency any one of the drugs named above in the quantity stated.

* * *

- (E) Every practitioner or other person, except a pharmacist, manufacturer, or wholesaler, authorized to administer or use controlled substances shall keep a record of all controlled substances received, administered, dispensed, or used which shall contain:
 - (1) The description of all controlled substances received, the name and address of the person from whom received, and the date of receipt;
 - (2) The description of controlled substances administered, dispensed, or used, the date of administering, dispensing, or using, the name and address of the person to whom, or for whose use, or the owner and species of the animal for which the controlled substance was administered, dispensed, or used.

* * *

Every such record shall be kept for a period of two years and the date of the transaction recorded.

* * *

As used in this section, "description" means the dosage form, strength, and quantity, and the brand name, if any, or the generic name of a drug or controlled substance.

Rule 4729-9-14 Records. [OAC: 07/01/89]
(Amplifies 3719.07, 3719.28)

- (A) Each practitioner ... shall keep a record of all controlled substances received, administered, dispensed, or used.
 - (1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.
 - (2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom, or for whose use, or the owner and species of the animal for which the controlled substance was administered, dispensed, or used.
 - (3) Records of drugs administered which become a permanent part of the patient's medical record, shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.
- (B) Each practitioner ... shall maintain an inventory of all controlled substances as follows.
 - (1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken:
 - (a) The name of the substance.
 - (b) The total quantity of the substance.

- (i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter).
 - (ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).
 - (iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).
- (c) If the substance is listed in schedule I or II, the practitioner ... shall make an exact count or measure of the contents.
 - (d) If the substance is listed in schedule III, IV, or V, the practitioner ... shall make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.
- (2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the practitioner Each inventory for each place or establishment shall be kept at the place or establishment;
 - (3) An inventory of all stocks of controlled substances on hand on the date the practitioner ... first engages in the administering, dispensing, or use of controlled substances. In the event the practitioner ... commences business with no controlled substances on hand, he shall record this fact as his initial inventory;
 - (4) Each practitioner ... shall take a new inventory of all stocks of controlled substances on hand every two years following the date on which the initial inventory is taken;
 - (5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the board of pharmacy, each practitioner ... shall take an inventory of all stock of such substance on hand at that time.
 - (6) All records of receipt, distribution, administering, dispensing, in-ventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any practitioner ... intending to maintain such records at a location other than this place must first send notification to the board; if not contested by the board within sixty days, it will stand as approved.

Section 1304.03 Persons required to keep records and file reports. [21 CFR: 07/01/93]

(a) * * *

(b) A registered individual practitioner is required to keep records, as described in Section 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by pre-scribing or administering in the lawful course of professional practice.

* * *

Section 1304.04 Maintenance of records and inventories. [21 CFR: 02/13/86]

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to Section 1305.13 of this chapter) may be kept at a central location, rather than at the

registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.

All notifications must include:

- (1) The nature of the records to be kept centrally.
- (2) The exact location where the records will be kept.
- (3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.
- (4) Whether central records will be maintained in a manual, or computer readable form.

* * *

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

- (1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and
- (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

* * *

Section 1304.17 Inventories of dispensers and researchers. [21 CFR: 09/24/73]

Each person registered or authorized ... to dispense or conduct research with controlled substances and required to keep records pursuant to Section 1304.03 shall include in his inventory the same information required of manufacturers pursuant to Section 1304.15(c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

- (a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the contents; and
- (b) If the substance is listed in Schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

Section 1304.21 General requirements for continuing records. [21 CFR: 09/24/73]

- (a) On and after May 1, 1971, every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.
- (b) Separate records shall be maintained by a registrant for each registered location except as provided in Section 1304.04(a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.
- (c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in Sections 1304.25 and 1304.26.
- (d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

Section 1304.24 **Records for dispensers and researchers.** [21 CFR: 09/24/73]

Each person registered or authorized ... to dispense or conduct research with controlled substances and required to keep records pursuant to Section 1304.03 shall maintain records with the following information for each controlled substance:

- (a) The name of the substance;
- (b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- (c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;
- (d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and
- (e) The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

Section 3719.08 **Labeling.** [ORC: 07/01/76]

- (A) * * *
- (B) Whenever ... a practitioner dispenses any controlled substance [*including a drug sample which is a controlled substance*] in the course of his practice, he shall affix to the container in which such controlled substance is dispensed, a label showing:
 - (1) His own name and address, ...;
 - (2) The name of the patient for whom the controlled substance is prescribed or, if the patient is an animal, the name of the owner and the species of the animal;

- (3) The name of the practitioner ... by whom the drug was dispensed;
- (4) Such directions as ... provided by the practitioner on usage of the drug;
- (5) The date ... filled or refilled, whichever date is later.

* * *

(C) No person shall alter, deface, or remove any label so affixed as long as any of the original contents remain.

(D) Every label for a schedule II, III, or IV drug shall contain the following warning:

"Caution: federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Rule 4729-9-01 Definitions. (Dangerous Drugs) [OAC: 07/01/92]
(Amplifies 4729.02, 4729.26, 4729.56, 4729.57, 4729.66)

(A) "Dangerous drug," as defined in division (D)(1) of section 4729.02 of the Revised Code, means any drug or drug product the commercial package of which bears a label containing the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian" or any similar restrictive statement.

(B) A dangerous drug is adulterated if beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirement of the federal act as indicated in the product labeling.

* * *

Rule 4729-9-13 Distributor of dangerous drug samples. [OAC: 09/10/76]
(Amplifies 3719.28, 3719.81, 4729.51, 4729.66)

No manufacturer, manufacturer's representative or wholesale dealer in pharmaceuticals may furnish a sample of a drug of abuse to a practitioner unless requested by the practitioner and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy.

Section 2925.01 Definitions. (Drug Offenses) [ORC: 07/01/96]

* * *

(L) "Sample drug" means a drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a practitioner, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

* * *

Section 2925.36 Illegal dispensing of drug samples. [ORC: 07/01/96]

(A) No person shall knowingly furnish another a sample drug.

- (B) Division (A) of this section does not apply to manufacturers, wholesalers, pharmacists, owners of pharmacies, dentists, doctors of medicine and surgery, doctors of osteopathic medicine and surgery, doctors of podiatry, veterinarians, and other persons whose conduct is in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. of the Revised Code, or to optometrists whose conduct is in accordance with a valid therapeutic pharmaceutical agents certificate issued under Chapter 4725. of the Revised Code.
- (C) (1) Whoever violates this section is guilty of illegal dispensing of drug samples.
- (2) If the drug involved in the offense is a compound, mixture, preparation, or substance included in schedule I or II, with the exception of marihuana, the penalty for the offense shall be determined as follows:
- (a) Except as otherwise provided in division (C)(2)(b) of this section, illegal dispensing of drug samples is a felony of the fifth degree, and, subject to division (E) of this section, division (C) of section 2929.13 of the Revised Code applies in determining whether to impose a prison term on the offender.
- (b) If the offense was committed in the vicinity of a school or in the vicinity of a juvenile, illegal dispensing of drug samples is a felony of the fourth degree, and, subject to division (E) of this section, division (C) of section 2929.13 of the Revised Code applies in determining whether to impose a prison term on the offender.
- (3) If the drug involved in the offense is a dangerous drug or a compound, mixture, preparation, or substance included in schedule III, IV, or V, or is marihuana, the penalty for the offense shall be determined as follows:
- (a) Except as otherwise provided in division (C)(3)(b) of this section, illegal dispensing of drug samples is a misdemeanor of the second degree.
- (b) If the offense was committed in the vicinity of a school or in the vicinity of a juvenile, illegal dispensing of drug samples is a misdemeanor of the first degree.
- (D) In addition to any prison term authorized or required by division (C) or (E) of this section and sections 2929.13 and 2929.14 of the Revised Code and in addition to any other sanction imposed for the offense under this section or sections 2929.11 to 2929.18 of the Revised Code, the court that sentences an offender who is convicted of or pleads guilty to a violation of division (A) of this section shall do both of the following:
- (1) The court shall suspend for not less than six months or more than five years the driver's or commercial driver's license or permit of any person who is convicted of or has pleaded guilty to a violation of this section.
- (2) If the offender is a professionally licensed person or a person who has been admitted to the bar by order of the supreme court in compliance with its prescribed and published rules, in addition to any other sanction imposed for a violation of this section, the court forthwith shall comply with section 2925.38 of the Revised Code.

* * *

Section 2925.38 Convictions of professionally licensed persons. [ORC: 07/01/96]

If a person who is convicted of or pleads guilty to a violation of section ... 2925.36, ... of the Revised Code is a professionally licensed person, in addition to any other sanctions imposed for the violation, the court forthwith shall transmit a certified copy of the judgment entry of conviction to the regulatory or licensing board or agency that has the administrative authority to suspend or revoke

the offender's professional license. If a person who is convicted of or pleads guilty to a violation of any section listed in this section is a person who has been admitted to the bar by order of the supreme court in compliance with its prescribed and published rules, in addition to any other sanctions imposed for the violation, the court forthwith shall transmit a certified copy of the judgment entry of conviction to the secretary of the board of commissioners on grievances and discipline of the supreme court and to either the disciplinary counsel or the president, secretary, and chairman of each certified grievance committee.

Section 353 Exemptions and consideration for certain drugs, devices, and biological products. [21
USCA: 08/26/92]

* * *

(c) Sales restrictions.

- (1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.
- (2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section (b).
- (3) (A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug--
 - (i) which is subject to subsection (b), and
 - (ii) (I) which was purchased by a public or private hospital or other health care entity, or
 - (II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

* * *

(d) Distribution of drug samples.

- (1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a--
 - (A) practitioner licensed to prescribe such drug,
 - (B) health care professional acting at the direction and under the supervision of such a practitioner, or
 - (C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

- (2) (A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made--
- (i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and
 - (ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.
- (B) A written request for a drug sample required by subparagraph (A)(i) shall contain--
- (i) the name, address, professional designation, and signature of the practitioner making the request,
 - (ii) the identity of the drug sample requested and the quantity requested,
 - (iii) the name of the manufacturer of the drug sample requested, and
 - (iv) the date of the request.
- (C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.
- (3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:
- (A) Drug samples may only be distributed--
- (i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or
 - (ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities. A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.
- (B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

- (C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.
- (D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.
- (E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.
- (F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

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Section 331 Prohibited acts. [21 USCA: 10/25/94]

The following acts and the causing thereof are prohibited:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.
- (e) The refusal to permit access to or copying of any record as required by section 350a or 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 355(i) or (k), 357(d) or (g), 360b(j), (l), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.
- (f) The refusal to permit entry or inspection as authorized by section 374 of this title.

* * *

- (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

- (t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, or the distribution of drugs in violation of section 353(e) of this title or the failure to otherwise comply with the requirements of section 353(e) of this title.

Section 333 Penalties. [21 USCA: 09/13/94]

- (a) Violation of section 331 of this title; second violation; intent to defraud or mislead
 - (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.
 - (2) Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.
- (b) Prescription drug marketing violations
 - (1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by--
 - (A) knowingly importing a drug in violation of section 381(d)(1), of this title
 - (B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,
 - (C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or
 - (D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.
 - (2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:
 - (A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.
 - (B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

- (3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than \$100,000.
- (4)
 - (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).
 - (B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence--
 - (i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or
 - (ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation, the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).
- (5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

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(11/01/96)