



SELECTED POINTS REGARDING THE LEGAL PRACTICE OF PHARMACY IN OHIO

[March 2016]

ORC – *Ohio Revised Code Laws*

USC – *United States Code Laws*

OAC – *Ohio Administrative Code Rules*

CFR – *Code of Federal Regulations*

This document is an abridged version of the *Drug Laws of Ohio*. It is intended only to be a quick guideline, with the law and rule numbers provided to direct you to the complete law or rule. This information is not intended to constitute legal advice and should not be relied upon in lieu of consultation with appropriate resources. Laws and rules change. It is your responsibility to stay current.

PHARMACISTS / PHARMACY INTERNS / PHARMACY TECHNICIANS

1. "Practice of pharmacy" means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. As used in this division, "pharmacist care" includes the following:
 - A. Interpreting prescriptions;
 - B. Dispensing drugs and drug therapy related devices;
 - C. Compounding drugs;
 - D. Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances;
 - E. Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs;
 - F. Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;
 - G. Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;
 - H. Acting pursuant to a consult agreement with a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established with the physician;
 - I. Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code, if the pharmacist has met the requirements of that section.

[ORC Sec. 4729.01(B)]

Before an initial license to practice as a pharmacist or pharmacy intern is issued by the Board, the applicant must submit fingerprint impressions to the Ohio Bureau of Criminal Identification and Investigation (BCI & I) for a Criminal Records Check. The results of a Criminal Records Check must consist of both a BCI & I criminal records check and an FBI (Federal Bureau of Investigation) criminal records check. The fingerprint impressions must be submitted via electronic means from a "WebCheck" provider agency located in Ohio. Additionally, a pharmacist or pharmacy intern who lets their license



lapse for more than three years will be required to submit to a criminal background check if requesting a pharmacist or pharmacy intern license.

[ORC Section 4729.071; OAC Rule 4729-5-12]

2. Identification cards for pharmacists and pharmacy interns shall be renewed annually on the fifteenth day of September. Each pharmacist and pharmacy intern shall sign the identification card (pocket license) and carry it while engaged in the practice of pharmacy.
[ORC Sec. 4729.12; OAC Rule 4729-5-02]
3. Each pharmacist and pharmacy intern shall display wall license (certificate of registration) in a conspicuous place in principal place of practice.
[ORC Sec. 4729.12]
4. Pharmacists and pharmacy interns shall notify the Board of Pharmacy within 60 days of any legal change of name and within 30 days of any change of address or place of employment.
[OAC Rules 4729-5-05 & 4729-5-06]
5. A pharmacy intern under the personal supervision of a pharmacist may compound, dispense, or sell dangerous drugs. In addition to assisting a pharmacy with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist:
 - A. The sale of schedule V controlled substances pursuant to Rule 4729-11-09 OAC;
 - B. The receipt of oral prescriptions pursuant to Rule 4729-5-30(D)(3) OAC;
 - C. The transfer of a non-controlled prescription copy pursuant to Rule 4729-5-24(G) OAC;
 - D. The act of patient counseling pursuant to Rule 4729-5-22 OAC;
 - E. Administer the same vaccines to the same age groups as the pharmacist:
 1. Administer all CDC-recommended vaccines to patients who are 13 years of age and older, without a prescription;
 2. Administer all CDC-recommended vaccines to patients who are 7 years of age or older and up to 12 years of age, with a prescription;
 3. Administer the flu vaccine to all patients who are 7 years of age or older, without a prescription;
 4. Administer the zoster vaccine according to the age criteria specified in the FDA approved labeling.
 - F. The documentation of informed consent to administer an immunization pursuant to Section 4729.41 ORC and Rule 4729-5-27(O) OAC.

[ORC Sec. 4729.28; OAC Rules 4729-5-08 & 4729-5-25(A)]
6. Pharmacists will be required to document sixty hours (6.0 C.E.U.s) of continuing pharmacy education every three years, of which three hours (0.3 C.E.U.s) must be in either ACPE or Board-approved jurisprudence and two hours (0.2C.E.U.s) must be in the area of patient safety/medication errors. Through the 2018 reporting cycle, C.E.U.s must be obtained on or after March first of the year that is three years prior to September 15th of the year in which evidence of the continuing education is required for identification card renewal. After 2018, C.E.U.s must be obtained within a period of time that is no more than three (3) years prior to September 15th of the year in which evidence of the continuing pharmacy education is required for pharmacist license renewal.

The state board of pharmacy may grant extension periods and waivers for the completion of license renewal and continuing education requirements for active military service members and their spouses.

If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the pharmacist or the pharmacist's spouse was on active duty. A pharmacist seeking an extension period or waiver must provide documentation to the board demonstrating active-duty service. [OAC Chapter 4729-7-02]

7. As an alternative to providing evidence of all of the required C.E.U.s of approved continuing education as required by OAC Rule 4729-7-02, except for the 0.3 C.E.U.s of Ohio state board of pharmacy approved jurisprudence, and 0.2 C.E.U.s of patient safety, a pharmacist may satisfy the continuing pharmacy education requirements by providing evidence at the time of renewal that he/she has met the requirements of and is currently certified by a board approved pharmacy practice specific specialty certification program. At a minimum, such pharmacy practice specific specialty certification programs shall consist of:
 1. Periodic recertification examinations;
 2. Documentation by the certification program that the pharmacist is currently certified by the program;
 3. Other requirements as determined by the board.

Pharmacists who choose an alternative method to meet their continuing pharmacy education requirements are still required to provide evidence of having completed at least 0.3 C.E.U.s of Ohio state board of pharmacy approved pharmacy felony jurisprudence and 0.2 C.E.U.s of patient safety related continuing pharmacy education. [OAC Rule 4729-7-08]

Qualified Pharmacy Technicians under the personal supervision of a pharmacist must:

1. be eighteen years of age or older,
2. possess a high school diploma or equivalence, or was employed as a pharmacy technician prior to April 7, 2009,
3. have passed an examination approved by the Ohio Board of Pharmacy, and
4. have submitted a criminal records check and the results do not show that the person previously has been convicted of or pleaded guilty to any felony in this state, any other state, or the United States.

[ORC Sec. 4729.42(A)]

No person who is not a pharmacy, pharmacy intern or qualified pharmacy technician shall do any of the following in a pharmacy or while performing a function of a pharmacy:

1. Engage in the compounding of any drug,
2. Package or label any drug,
3. Prepare or mix any intravenous drug to be injected into a human being. [ORC Sec. 4729.42(B)]

DANGEROUS DRUGS

8. "Dangerous drug" means any of the following:
 - A. Any drug to which either of the following applies:
 - (1) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear 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, or the drug _____ may be dispensed only upon a prescription;

- (2)** Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.
- B.** 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;
 - C.** Any drug intended for administration by injection into the human body other than through a natural orifice of the human body. [ORC Sec. 4729.01(F)]
- 9.** Insulin is a dangerous drug because it is administered by injection - keep out of self-service areas. [ORC Secs. 4729.01(F)(3) & 4729.51(C)(4)]
- 10.** "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. [ORC Sec. 4729.01(J)]
- 11.** "Wholesale sale" means any sale in which the purpose of the purchaser is to resell the article purchase or received by the purchaser. [ORC Sec. 4729.01(K)]
- 12.** Samples of dangerous drugs shall be furnished free of charge by manufacturers or their representatives to a prescriber and from a prescriber to their patient except that a terminal distributor licensed as a Charitable Pharmacy may accept samples of dangerous drugs from manufacturer, their representatives, or prescribers licensed as a terminal distributor of dangerous drugs to be dispensed from the Charitable Pharmacy to a patient pursuant to a patient specific prescription. [ORC Sec. 3719.81]
- 13.** A Charitable Pharmacy must hold a terminal distributor license, be exempt from federal taxation and not be a hospital. A sample drug must be in its original container and have been stored under the proper conditions. A Charitable Pharmacy may not accept any samples of controlled substances and must dispense the samples drugs free of charge. [ORC Sec. 3719.811]
- 14.** To prevent their use, adulterated drugs shall be stored in a separate area apart from the storage of drugs used for dispensing and administration. Adulterated drugs shall be stored no longer than one year from date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license and two years by those holding a wholesale distributor of dangerous drugs license only. [OAC Rule 4729-9-17]
- 15.** Out-dated dangerous drugs are adulterated and may not be dispensed. [ORC Secs. 3715.52(A) & 3715.521; OAC Rule 4729-9-01(B)]
- 16.** All solid oral dosage forms of dangerous drugs are misbranded unless they are imprinted with or bear markings that identify the drug and the manufacturer or distributor. [ORC Sec. 3715.64(A)(4)]
- 17.** A pharmacy may repackage and store drugs within the pharmacy prior to being dispensed if properly labeled by the pharmacy and appropriate records maintained for at least three years. The label must contain the name, strength, and dosage form of the drug, the identification of the repackager by name or the final six digits of their terminal distributor number, pharmacy control number and expiration or beyond-use date. In addition to the above, the record of repackaging must also include the

manufacturer's or distributor's name (if generic drug used), control number, expiration date and the positive identification of the pharmacist responsible for the repackaging to the drug.

[OAC Rule 4729-9-20]

DANGEROUS DRUG DISTRIBUTORS / PHARMACIES

- 18.** "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.
[ORC Sec. 4729.01(O)]
- 19.** "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.
[ORC Sec. 4729.01(Q)]
- 20.** Ohio's Dangerous Drug Distribution Act requires a licensed terminal distributor of dangerous drugs to purchase dangerous drugs for resale only from a registered wholesale distributor of dangerous drugs; except, a licensed terminal distributor may make an occasional purchase from another licensed terminal distributor, or a licensed terminal distributor having more than one establishment licensed may transfer or receive dangerous drugs between these licensed terminal distributors.
[ORC Sec. 4729.51(D)]
- 21.** Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser. Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall obtain from the seller the number of the seller's registration certificate to engage in the sale of dangerous drugs at wholesale.
[ORC Sec. 4729.60; OAC Rule 4729-9-12]
- 22.** A pharmacist who is a terminal distributor of dangerous drugs or pharmacist employed by a terminal distributor of dangerous drugs may make "occasional sales" at wholesale of a drug to another terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or a prescriber if the total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule does not exceed 5% of the total cost of dangerous drugs purchased by the pharmacy during the same calendar year.
[OAC Rule 4729-9-10]
- 23.** Each pharmacy shall employ a pharmacist to be in full and actual charge of such pharmacy. Only a pharmacist may be the responsible person for a terminal distributor license for a pharmacy.
[ORC Sec. 4729.27; OAC Rule 4729-5-11(A)]
- 24.** A pharmacist shall be the responsible person for no more than one pharmacy licensed as a terminal distributor of dangerous drugs, except upon written permission from the Board. A pharmacist who has signed as the responsible person for a pharmacy shall be physically present in the pharmacy a sufficient

amount of time to provide supervision and control of the dangerous drugs and to maintain all drug records required by state and federal law.

[OAC Rule 4729-5-11(A)(1)]

- 25.** The responsible pharmacist shall be responsible for the practice of the profession of pharmacy, including but not limited to "supervision and control" of dangerous drugs, "adequate safeguards" to prevent sale or other distribution of dangerous drugs by any person other than a pharmacist, and maintaining all drug records otherwise required.

[OAC Rule 4729-5-11(A)(2)]

- 26.** Sign and have readily available the dangerous drug distributor, terminal or wholesale, license if you are the responsible pharmacist.

[OAC Rules 4729-5-11(B)(2), 4729-9-18]

- 27.** When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person **within thirty days** on a board approved form. A complete inventory of the controlled substances on hand at a pharmacy shall be taken with the new responsible pharmacist who then becomes responsible for this inventory. Effective January 1, 2015, each prescriber or terminal distributor of dangerous drugs must take inventory of all stocks of controlled substances on hand **every year** following the date on which the initial inventory is taken.

[OAC Rule 4729-5-11(B)(3) & (4), 4729-9-14]

- 28.** In a pharmacy, there must be personal supervision by a pharmacist of the dangerous drugs at all times; except, whenever personal supervision is not provided by a pharmacist, there must be in place a physical or electronic barrier approved by the Board of Pharmacy.

- A.** All poisons, needles and syringes, and dangerous drugs, including filled prescriptions awaiting patient pick-up, exempt narcotics, and insulin, must be under the personal supervision of the pharmacist or within the approved barrier.
- B.** No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.
- C.** No person may be within the physical confines of the pharmacy department unless under the personal supervision of the pharmacist, except as provided in Chapter 4729-17 of the OAC. [OAC Rules 4729-9-05, 4729-9-11, & 4729-17-07]

- 29.** The pharmacist is responsible for the sale of exempt narcotics and hypodermic equipment to the extent of establishing identity of the customer and the use for a legitimate purpose, and:

- A.** Hypodermics may only be sold to authorized individuals and may not be stocked in self-service areas;

[ORC Sec. 3719.172]

- B.** Exempt narcotics shall only be sold to persons at least eighteen years of age with suitable identification and sales records must be complete and legible and maintained in a bound record book;

[CFR Sec. 1306.26; OAC Rule 4729-11-09]

- C.** Ephedrine and ephedrine-containing products are Schedule V controlled substances in Ohio, unless the drug product is excepted, or is a food product or a dietary supplement that meets the labeling requirements or is specifically excepted. (Currently, FDA has asked for a voluntary withdrawal of OTC ephedrine products due to safety reasons.)

[ORC Sec. 3719.44(K); OAC Chapter 4729-12]

- 30.** Any person may assist a pharmacist in the compounding and dispensing of drugs only in the following manner:
- A.** The person may not engage in any procedure requiring professional judgment, a pharmacist must control the system of drug distribution and must be accountable at every point in the system between receipt of the drug order and final delivery to the patient;
 - B.** The person may not engage in any procedure contrary to the intent of the statutes and rules regulating the compounding and/or dispensing of drugs;
 - C.** Such a person must not have any pending or prior charges or convictions of state or federal drug laws, be addicted to or abusing drugs, or be impaired physically or mentally so as to render him/her unfit.

[OAC Rule 4729-5-25(B)]

- 31.** Notify the Board of Pharmacy, by telephone, immediately upon discovery of any theft or significant loss of dangerous drugs, prescription blanks, and official DEA order forms. Notify the local law enforcement agency and the D.E.A. if appropriate, following the discovery of such theft or loss. [CFR Sec. 1301.76(b); ORC Sec. 2921.22; OAC Rule 4729-9-15]

PRESCRIPTIONS

- 32.** "Prescription" means a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs. It also includes a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or a written, electronic, or oral order for a drug to treat chlamydia, gonorrhea, or trichomoniasis issued to and in the name of a patient who is not the intended user of the drug but is the sexual partner of the intended user.
[ORC Sec. 4729.01(H)]
- 33.** "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.
[OAC Rule 4729-5-01(D)]
- 34.** "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system. [OAC Rule 4729-5-01(H)]
- 35.** "Prescriber" includes any health care professional authorized by their practice act to prescribe drugs.
[ORC Sec. 4729.01(I); OAC Rule 4729-5-01(M)]
- 36.** Limited prescribers such as podiatrists, dentists, veterinarians, advanced practice nurses, physician assistants, and optometrists are authorized to prescribe drugs only within the course of their professional practice and/or formulary.
[OAC Rule 4729-5-15]

- 37.** A pharmacist working in a pharmacy located in Ohio may dispense prescriptions issued by a nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state other than Ohio.
[OAC Rule 4729-5-15(C)]
- 38.** Accepted and prevailing standards of care presuppose a professional relationship between a patient and physician when the physician is utilizing controlled substances. By definition, a physician may never have such a relationship with himself or herself. Thus, a physician may not self-prescribe or self-administer controlled substances. [OAC Rule 4731-11-08(A)]
- 39.** Accepted and prevailing standards of care require that a physician maintain detached professional judgment when utilizing controlled substances in the treatment of family members. A physician shall utilize controlled substances when treating a family member only in an emergency situation which shall be documented in the patient's record. ("Family member" means a spouse, parent, child, sibling or other individual in relation to whom a physician's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions. [OAC Rules 4731-11-08(B) & (C)]
- 40.** An optometrist licensed under Chapter 4725. of the Ohio Revised Code, who has passed the general and ocular pharmacology examination, and is certified by the Optometry Board to do so, may purchase and administer certain topical ocular pharmaceutical agents. In addition, an optometrist who has obtained a "therapeutic pharmaceutical agents certificate" may prescribe dangerous drugs to their patients pursuant to Section 4725.01(C) of the Revised Code. [ORC Secs. 4725.01(A),(B) & (C) and 4729.01(I); OAC Rules 4725-16-01, 4725-16-02, & 4729-5-15(A)(2)]
- 41.** Oral transmission by the prescriber or prescriber's agent of an original prescription and refills authorized by a prescriber may be transmitted to a pharmacist, pharmacy intern approved by the pharmacist on duty supervising the pharmacy intern, or a recording device within the pharmacy if the pharmacist is not available. The prescriber's agent must provide his/her full name when transmitting an oral prescription. The pharmacist is responsible for assuring the validity of the source of the oral prescription. [OAC Rules 4729-5-21(D) & 4729-5-30(D)]
- 42.** A licensed pharmacy intern may receive telephone prescriptions if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.
- A.** The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order.
 - B.** The supervising pharmacist on duty is responsible for the accuracy of the prescription.
 - C.** The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.
- [OAC Rule 4729-5-21(D)(3)]
- 43.** Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy provided the facsimile of the prescription includes the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy, the original prescription signed by the prescriber

from which the facsimile is produced shall not be issued to the patient and remains with the patient's records at the prescriber's office or the institutional facility where it was issued, and the facsimile of the prescription must include header information identifying the origin of the facsimile. The facsimile shall only be valid as a prescription if the pharmacy has a system to maintain the facsimile as part of the prescription record including the origin of the prescription for at least three years from the date of the last transaction.

[OAC Rules 4729-5-21(E) & 4729-5-30(E)]

- 44.** Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for a resident of a long term care facility, a narcotic substance issued for a patient enrolled in a hospice, and a compounded sterile product prescription for a narcotic substance.

[CFR Sec. 1306.11, OAC Sec. 4729-5-30(E)(3)]

- 45.** A prescription may be transmitted by a Board approved electronic prescription transmission system provided that the system requires positive identification of the prescriber, the full name of any authorized agent of the prescriber who transmits the prescription, and the computer data is retained for a period of three years at the prescriber's office.

[OAC Sec. 4729-5-30(F)]

- 46.** A pharmacist considering filling a prescription must remember: A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

Pharmacists may document the administration of an immunization or the dispensing of naloxone on a prescription form in order to allow the pharmacy to bill an individual's health insurance.

[CFR Sec. 1306.04(a); OAC Rules 4729-5-21(A), 4729-5-30(A), 4729-5-39(F)]

- 47.** All prescriptions issued by a prescriber shall be dated on the day when issued, bear the manually printed, typewritten, or preprinted full name and address of the prescriber, and indicate a telephone number where the prescriber can be personally contacted during normal business hours.

[OAC Rule 4729-5-30(B)(1), (2), & (3)]

- 48.** All prescriptions issued by a prescriber and given to a patient or faxed to a pharmacy shall be manually signed by the prescriber in the same manner as he/she would sign a check or legal document.

[OAC Rule 4729-5-30(B)(14)(a)]

- 49.** For a controlled substance prescription, the prescriber must indicate the drug enforcement administration (DEA) registration number of the prescriber pursuant to Title 21 CFR 1306.05.

[OAC Rule 4729-5-30(B)(15)]

- 50.** For prescriptions issued by an advance practice nurse (APN) with prescriptive authority (clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner), the nurse prescriber must indicate the nurse prescriber's number (CTP number) as found on the certificate to prescribe as issued by the state board of nursing.

[OAC Rule 4729-5-30(B)(16)]

- 51.** Limit authorized refills of Schedule III and IV controlled substance prescriptions to five times and for a period not exceeding six months from the date the prescription is issued by the prescriber.
[CFR Sec. 1306.22(a); ORC Sec. 3719.05(A)(5)]
- 52.** The term "dispense", as used in the Ohio Revised and Administrative Codes, means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
[OAC Rule 4729-5-01(B)]
- 53.** No prescription may be dispensed for the first time beyond six months from the date it was issued nor refilled beyond one year from the date that it was issued.
[OAC Rules 4729-5-21(G) & 4729-5-30(B)(11)]
- 54.** All prescriptions must specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
[OAC Rule 4729-5-30(B)(8)]
- 55.** Do not dispense a quantity of drugs greater than that prescribed by the prescriber without authorization from a prescriber. The pharmacist shall document on the original prescription the name of the prescriber or prescriber's agent, the quantity, and the date the authorization was obtained.
[OAC Rule 4729-5-21(H)]
- 56.** All pharmacies are required to maintain patient profiles which shall provide for immediate retrieval of information regarding those patients who have received prescription from that pharmacy. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain the required information.
[OAC Rule 4729-5-18]
- 57.** Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying, in part, over-utilization or under-utilization, therapeutic duplication, drug-drug interactions, incorrect drug dosage, drug-allergy interactions, abuse/misuse, or inappropriate duration of drug treatment. Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem, including consultation with the prescriber and/or consulting with the patient. [OAC Rule 4729-5-20]
- 58.** A pharmacist or the pharmacist's designee shall personally offer to provide the service of counseling to the patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. When counseling is refused, the pharmacist shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document and shall accompany the prescription.
[OAC Rule 4729-5-22]

59. A pharmacist may dispense or sell a dangerous drug, other than a Schedule II controlled substance, without a written or oral prescription from a licensed health professional authorized to prescribe drugs if the pharmacy has a record of the patient's prescription with no refills available, the pharmacist is unable to obtain authorization to refill the prescription from a prescriber responsible for the patient's care, and in the pharmacist's professional judgment, the drug is essential to sustain the life of the patient, continue therapy for a chronic condition, or failure to dispense the drug to the patient could result in harm to the health of the patient. The pharmacist must notify the prescriber within seventy-two hours of the transaction, may not dispense or sell an amount of drug that exceeds a seventy-two hours supply, and may only dispense or sell the drug once for each prescription described.
[ORC Sec. 4729.281]

60. "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

- A.** Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;
- B.** Pursuant to the modification of a prescription made in accordance with a consult agreement;
- C.** As an incident to research, teaching activities, or chemical analysis;
- D.** In anticipation of prescription drug orders based on routine, regularly observed dispensing patterns,
- E.** Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:
 - (1)** At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.
 - (2)** A limited quantity of the drug is compounded and provided to the professional.
 - (3)** The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

[ORC Sec. 4729.01(C)]

61. For all compounded prescriptions, the pharmacist shall inspect and approve the compounding process, perform the final check of the finished product and be responsible for all compounding records and the proper maintenance, cleanliness, and use of all equipment used in compounding. Effective January 1, 2015, drugs compounded in a pharmacy must adhere to U.S. Pharmacopeial Convention (USP) Chapters 797 for sterile compounded and 795 for non-sterile compounded drugs. Additionally, all compounded prescriptions must also adhere to section 503A of the Federal Food, Drug and Cosmetic Act.
[OAC Rule 4729-9-21(C), & (D)]

62. A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
[OAC Rule 4729-9-21(F)]

The Board of Pharmacy recognizes and enforces Federal law that compounding is performed by a pharmacist in a pharmacy and pursuant to a patient specific prescription. [21 U.S. CODE § 353A - PHARMACY COMPOUNDING]

- You may not compound FDA approved drugs that are commercially available.

- Effective July 9, 2012, President Obama signed into law the FDA Safety and Innovation Act which in part grants permission for hospitals and health systems to repack and share drugs, not controlled substances, in short supply during an FDA published shortage plus 60 days after the drug is taken off the list. This is only within the same health system.
[<http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactFDCAct>]

- 63.** A pharmacist may compound a drug pursuant to a request made by a prescriber, or by an agent of the prescriber, for a drug to be used by the prescriber for the purpose of the direct administration to patients in the course of the prescriber's practice if the drug is compounded and provided to a prescriber by a pharmacy as an occasional exception to the normal practice of dispensing drugs pursuant to patient specific prescriptions. The pharmacy shall only provide those compounded preparations where the total value of those compounded preparations does not exceed five percent of the pharmacy's total dollar amount of sales of patient specific compounded prescriptions within the past twelve months, the preparations are not commercially available to a prescriber, and the preparations are used to treat an emergency situation, an unanticipated procedure for which a time delay would negatively affect a patient outcome, or for diagnostic purposes.
[OAC Rule 4729-9-25(A)]
- 64.** When a pharmacy compounds a drug for use within a physician's office, the pharmacy shall not supply more than a seventy-two hour supply of a compounded drug to a prescriber. A prescriber shall not have more than a seventy-two hour supply of a compounded drug on hand at any given time. The seventy-two hour supply provided to the prescriber shall be determined by previous administration patterns provided by a prescriber to the pharmacist. The limitation of a seventy-two hour supply shall not apply to compounded non-sterile drug preparations for topical administration supplied to a prescriber in a single container in which the quantity does not exceed sixty grams or sixty milliliters, or intended to treat an emergency situation in a quantity required to sufficiently treat individuals in the event of an emergency situation.
[OAC Rule. 4729-9-25(B)]
- 65.** A pharmacy shall not sell a compounded drug to another pharmacy or wholesaler and a prescriber shall only administer a requested compounded drug directly to their own patients. Prescribers shall not dispense a compounded drug to a patient, sell a compounded drug to another prescriber or pharmacy, or return a compounded drug to the supplying pharmacy.
[OAC Rule 4729-9-25(C) & (D)]
- 66.** When a pharmacy compounds a drug for use within a physician's office, these compounded drug preparations shall be assigned beyond use dates based on acceptable practice standards for stability and sterility for sterile compounded drug preparations and stability for non-sterile compounded drug preparations.
[OAC Rule 4729-9-25(E)]
- 67.** When a pharmacy compounds a drug for use within a physician's office, the compounded drug preparation must bear a complete label including the statements "For direct patient administration only" and "Not for resale". Compounded drug preparation containers that are too small to bear a complete label must bear a label that contains at least "Not for resale", drug name(s), strength, beyond use date, route of administration, pharmacy control number and the pharmacy name. In all cases, a complete label meeting the requirements of paragraph (F) of this rule must be applied to the outside container in which such compounded preparation is supplied. [OAC Rule 4729-9-25(F) & (G)]

- 68.** The sale of a compounded drug preparation to a prescriber is considered a wholesale sale and the pharmacy is required to follow the record keeping requirements for wholesale sales.
[OAC Rule 4729-9-25(H)]
- 69.** Except as provided in rule 4729-5-14 of the Administrative Code:
- A.** No pharmacist shall dispense dangerous drugs pursuant to a written outpatient prescription unless the following conditions are met:
 - (1)** The prescription is issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2)** If handwritten or typewritten, there are no more than three non-controlled substance prescription orders per prescription form.
 - (3)** If preprinted with multiple drug names or strength combinations:
 - (a)** There are no controlled substances among the choices;
 - (b)** There is only one prescription order selected per form.
 - B.** No prescriber shall write and no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:
 - (1)** The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2)** The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, or preprinted.
 - (3)** The quantity has been written both numerically and alphabetically.
 - (4)** If preprinted, there is only one drug and strength combination printed on the form.
 - C.** A prescription for a controlled substance issued by a medical intern, resident, or fellow as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
 - D.** A prescription for a controlled substance issued by a staff prescriber of a hospital may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
 - E.** If a board approved electronic prescription transmission system is used to fax a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The faxed order must comply with rule 4729-5-30 of the Administrative Code and must be filed in the most restrictive file according to rule 4729-5-09 of the Administrative Code. [OAC Rule 4729-5-13]
- 70.** Generically equivalent drugs contain identical amounts of the identical active ingredients that meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency, and where applicable, content uniformity, disintegration times, or dissolution rates and have not been listed by the FDA as having proven bioequivalence problems.
[ORC Sec. 3715.01(A)(16)]
- 71.** A pharmacist may dispense a generically equivalent drug in lieu of the prescribed brand name if the prescriber has not written, in his/her own handwriting, "Dispense As Written" or "D.A.W." on the prescription or has not indicated when giving an oral prescription that the prescribed drug is medically indicated. Also, the price to the patient of the generic drug is less than or equal to the prescribed drug,

the patient is informed that a generically equivalent drug is available and the patient is informed of his/her right to refuse the dispensing of a generically equivalent drug.

[ORC Sec. 4729.38(A); OAC Rule 4729-5-30(G)]

- 72.** A pharmacist dispensing a generically equivalent drug in lieu of the prescribed brand name drug is required to indicate on the prescription container or its label that a generic substitution was made. [ORC Sec. 4729.38(B)]
- 73.** No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:
- A.** The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license unless it is filled pursuant to a Board-approved central filling operation, in which case the label shall bear the name and address of the originating pharmacy as it appears on the terminal distributor of dangerous drugs license;
 - B.** The name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and identification of the animal;
 - C.** The name of the prescriber;
 - D.** Directions for use of the drug;
 - E.** The date of dispensing;
 - F.** Any cautions which may be required by federal or state law;
 - G.** The serial number of the prescription;
 - H.** The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed; and the strength if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription or verbally in the case of an orally transmitted prescription;
 - I.** The quantity of drug dispensed;
 - J.** If filled as part of a Board-approved central filling operation, an identification of the pharmacy providing the drugs for the dispensing operation.

[OAC Rule 4729-5-16(A)]

- 74.** All prescription labels must include the brand name of the drug dispensed or the generic name and the distributor of the finished dosage form unless the prescriber has indicated on the prescription that he/she does not want the drug identified.

[ORC Secs. 3715.64(B) & 4729.38(B); OAC Rule 4729-5-16(A)(8)]

- 75.** At least the prescription number and patient name must be placed on all prescription containers too small to bear a complete prescription label, unless the small label would impair the function of the product, and must be dispensed in a container bearing a complete prescription label.

[OAC Rule 4729-5-16(C)]

- 76.** An original prescription (for other than a Schedule II controlled substance) may be transmitted to a pharmacist by the use of a facsimile machine only by a prescriber or his/her agent. Such a facsimile shall be a valid prescription for dispensing a drug only if a system is in place that will allow the pharmacist to positively identify that the prescriber originated the facsimile. The signed written prescription from which the facsimile is produced shall not be issued to the patient and must be maintained with the patient's record. A facsimile of a prescription received in any manner other than from a prescriber or his/her agent or another pharmacist transferring a copy shall not be considered a valid prescription.

Schedule II faxes are permitted for nursing home patients, hospice patients' narcotic prescriptions, and patients on compounded home parenteral pain therapy.

[CFR Sec. 1306.11; OAC Rules 4729-5-30(E), 4729-17-09, 4729-19-02, & 4729-31-02]

- 77.** Observe child-proof and compendial packaging requirements when dispensing dangerous drugs. [Title 15, USC 1473(b) and CFR Part 1700]
- 78.** Partial dispensing of Schedule II drugs for LTCF and Terminally Ill patients is permitted. Required records and documentation of computer records are similar to the federal regulations. All partial dispensing must be noted on the original prescription.
[CFR Sec. 1306.13; OAC Rule 4729-5-26]
- 79.** A pharmacist may transfer a copy of a prescription and another pharmacist may refill a copy of a prescription provided such actions are in accordance with Rule 4729-5-24 of the Ohio Administrative Code.
- A.** Copies of prescriptions shall be transferred only between pharmacists except as provided by paragraph (G) of this rule;
 - B.** Copies of prescriptions for controlled substances shall be transferred only one time unless the pharmacies electronically share a real time, online database in which case a controlled substances prescription may be transferred up to the maximum number of refills permitted by law and the prescriber's authorization;
 - C.** The copy transferred shall be an exact duplicate of the original prescription except that it shall also include the serial prescription number assigned, the name and address of the pharmacy transferring the prescription, date of issuance and original date of dispensing, original number of refills and number of refills remaining, date of last refill, and full name of transferring pharmacist.
 - D.** The pharmacist transferring the a copy of a prescription must cancel the original prescription by writing "void" on the face of the prescription without destroying any of the original information on the prescription and document on the reverse side of the original written prescription the date of transfer, his or her signature, and the name and address of, and full name of the pharmacist at, the receiving pharmacy.
 - E.** If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site. The prescription record must contain the date of transfer, name of pharmacist making the transfer, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required.

[OAC Rule 4729-5-24(A)]

- 80.**
- A.** Prescription copies may be transferred between two pharmacies accessing the same prescription records in a centralized database or linked in any other manner provided the computerized systems satisfy all information requirements in paragraphs (A)(2) and (A)(4)(c) of 4729-5-24;
 - B.** (B) Prescription copies may be transferred between two pharmacists by use of a facsimile machine and this facsimile may be considered a copy of a prescription if all information requirements of paragraph (A) of 4729-5-24 are met.

[OAC Rules 4729-5-24(B) & (C)]

81.

- A.** Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.
 - (1)** In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon request of the patient, transfer the prescription information to the pharmacy designated by the patient.
 - (2)** No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drugs therapy is not interrupted.
- B.** Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy if:
 - (1)** The complete prescription information has been entered into the computer system;
 - (2)** The information is displayed on the patient's profile;
 - (3)** There is positive identification, either in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;
 - (4)** The original prescription is filed in accordance with rule 4729-5-09 of the Administrative Code;
 - (5)** All requirements of this rule are met for the transfer of the prescription.
- C.** Transfer of prescription information between two pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a Board-approved central filling operation shall not be considered a prescription copy and, therefore, is not subject to the requirements of this rule.

[OAC Rule 4729-5-24(D), (E), & (F)]

82. A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:

- A.** The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.
- B.** The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.
- C.** The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.
- D.** The intern may not send or receive a prescription copy for a controlled substance.
- E.** The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.
- F.** The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.

G. The approved intern and the supervising pharmacist must meet all the requirements of this rule.
[OAC Rule 4729-5-24(G)]

- 83.** Do not fill and file any controlled substance prescriptions that are not complete in the following details:
- A.** Full name and address of the patient;
 - B.** Full name, address, and Drug Enforcement Administration (D.E.A.) number of the prescriber;
 - C.** Schedule II prescriptions must be filed separately from other prescriptions;
 - D.** Schedule III, IV and V prescriptions must be filed separately from other prescriptions;
 - E.** The prescription contains the kind and quantity of controlled substance dispensed; and
 - F.** The date of dispensing the controlled substance.

[CFR Secs. 1306.11, 1306.21, & 1306.25; ORC Secs. 3719.05, 3719.06, & 3719.07; OAC Rules 4729-5-09, 4729-5-27, & 4729-5-30]

- 84.** Do not accept and dispense a Schedule II controlled substance on an oral prescription except in the case of an emergency and according to D.E.A. requirements:
- A.** Quantity of drugs prescribed sufficient for emergency period only;
 - B.** Reduce oral prescription to writing immediately (must contain all information required in a written prescription for a controlled substance);
 - C.** Attach the written "Authorization For Emergency Dispensing" received from the physician within 7 days to the written record of the oral prescription; and
 - D.** Notify the nearest office of the D.E.A. if you do not receive the written "Authorization For Emergency Dispensing" from the prescriber within 7 days. [CFR Sec. 1306.11(d); ORC Sec. 3719.05(A)(3)]

- 85.** When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.
[OAC Rules 4729-5-21(C)(2)]

- 86.** When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.
[OAC Rules 4729-5-21(C)(3)]

- 87.** A retail seller of dangerous drugs shall disclose price information regarding dangerous drugs to any person requesting such information. Price information disclosure shall be provided by means of verbal disclosure on the premises of the retail seller or by means of telephone to any person having a valid prescription that identifies himself and requests such information. Price information disclosure shall not be required for those schedule II controlled substances where lives or property could be endangered by such disclosure.
[ORC Sec. 4729.361]

88. Pharmacists practicing in Ohio should be aware of rules promulgated by the Medical Board affecting the use of controlled stimulants and drugs used to enhance athletic ability. Some important points of these rules are:

- A.** Cocaine Hydrochloride may only be used as a topical anesthetic for mucous membranes in surgical situations, or as a topical anesthetic where medically appropriate for injuries that do not involve mucous membranes, or as granted by the State Medical Board.

[OAC Rule 4731-11-06(A)]

- B.** Schedule II controlled stimulants may be used where medically appropriate for the treatment of closed head injuries.

[OAC Rule 4731-11-06(B)]

- C.** Schedule II controlled stimulants may NOT be used for the purpose of weight reduction or control.

[OAC Rule 4731-11-03(B)]

- D.** A physician shall NOT utilize a Schedule II controlled stimulant in treating a patient who he knows, or should know, is pregnant.

[OAC Rule 4731-11-03(C)(3)]

- E.** If the patient has a history or propensity for alcohol or drug abuse, or has consumed or disposed of a controlled stimulant other than in strict compliance with the physician's directions, the physician shall not initiate or shall discontinue the use of all controlled stimulants immediately.

[OAC Rule 4731-11-03(C)(4)]

- F.** A physician shall not utilize a Schedule III or IV controlled substance for purposes of weight reduction unless it has an FDA approved indication for this purpose and then only in accordance with all of the provisions of this rule.

[OAC Rule 4731-11-04(A)]

- G.** Before initiating treatment for weight reduction utilizing any Schedule III or IV controlled substance:

- (1)** The physician shall determine through review of the physician's own records of prior treatment, or through review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.
- (2)** The physician shall obtain a thorough history, perform a thorough physical examination of the patient, determine that the patient has a BMI of at least thirty, or at least twenty- seven with co-morbid factors, and rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized.
- (3)** The physician shall assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.

[OAC Rule 4731-11-04(B)]

- H.** A physician may utilize a Schedule III or IV controlled substance that bears appropriate F.D.A. approved labeling for weight loss or the maintenance of weight loss, in the treatment of obesity only as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:

- (1)** The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response

to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

- (2)** The controlled substance is prescribed strictly in accordance with the F.D.A. approved labeling;
 - (a)** If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for "a few weeks", the total course of treatment using that controlled substance shall not exceed twelve weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule; and
 - (b)** If the F.D.A. approved labeling of the controlled substance being utilized for weight loss states that it is indicated for use for maintenance of weight loss that use cannot exceed the time period indicated as effective as reported in the clinical studies' information contained in the F.D.A. approved labeling. That time period includes any interruption in treatment permitted under paragraph (C) (3) of this rule.
- (3)** A physician shall not initiate a course of treatment utilizing a controlled substance for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. However, the physician may resume utilizing a controlled substance following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:
 - (a)** Illness of or injury to the patient justifying a temporary cessation of treatment; or
 - (b)** Unavailability of the physician; or
 - (c)** Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability; or
 - (d)** If the physician utilizes a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" and based on sound medical judgment believes that an interruption of that treatment was medically indicated so long as its use is in accordance with paragraph (C) of this rule.
- (4)** After initiating treatment, the physician may elect to switch to a different controlled substance for weight loss based on sound medical judgment, but the total course of treatment for any combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.
- (5)** If the patient has continued to lose weight under the short term treatment, the physician may continue therapy utilizing a controlled substance that bears F.D.A. approved labeling for "weight loss and the maintenance of that weight loss" so long as its use is in accordance with paragraph (C) of this rule.
- (6)** The physician shall not initiate or shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:
 - (a)** That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient's use of drugs or alcohol; or
 - (b)** That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.

- (7) The physician shall not initiate or shall discontinue utilizing all Schedule III or IV controlled substances that do not bear F.D.A. approved labeling which permits long-term use immediately upon ascertaining or having reason to believe:
- (a) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days; or
 - (b) That the patient has repeatedly failed to comply with the physician's treatment recommendations.
- (8) The physician shall not utilize any Schedule III or IV controlled substance for purposes of weight reduction in the treatment of a patient the physician knows or should know is pregnant.

[OAC Rule 4731-11-04(C)]

- I. Drugs such as anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones shall not be utilized to enhance athletic ability. The prescribing of controlled substances in a manner that would not be in accordance with the Medical Board rules or the prescribing of the drugs to enhance athletic ability would violate Section 4731.22 of the Medical Practice Act. This would constitute "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes". A pharmacist filling such a prescription would also be in violation of the law. [OAC Rule 4731-11-05]

RECORD KEEPING

89. All prescriptions shall be preserved on file at the pharmacy for a period of three years, subject to inspection by the proper officers of the law. All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.
[ORC Sec. 4729.37; OAC Rule 4729-5-27(C)]
90. All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records.
[OAC Rule 4729-5-27(D)]
91. Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy by mail or facsimile. The state board of pharmacy office will send written notification of the approval or disapproval of the request. Only after receiving the notice of the board's approval may the records be placed in the new location.
[OAC Rule 4729-5-27(E)]

- 92.** There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:
- A.** Prescription information entered into the record keeping system;
 - B.** Prospective drug utilization review;
 - C.** Dispensing;
 - D.** Patient counseling;
 - E.** Administering immunizations;
 - F.** Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.

[OAC Rule 4729-5-27(A)]

- 93.** "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug
- A.** A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
 - (1)** A manual signature on a hard copy record;
 - (2)** A magnetic card reader;
 - (3)** A bar code reader;
 - (4)** A biometric method;
 - (5)** A proximity badge reader;
 - (6)** A board approved system of randomly generated personal questions;
 - (7)** A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or
 - (8)** Other effective methods for identifying individuals that have been approved by the board,
 - B.** A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system. [OAC Rule 4729-5-01(N)]

- 94.** Alternate record keeping systems include, but are not limited to, the following:
- A.** A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system would require the manual signature or initials of a pharmacist on a hard copy record as indicated in paragraph (I) of rule 4729-5-27 of the Administrative Code.
 - B.** A computerized system that documents the positive identification of the pharmacist responsible for the practice of pharmacy. If this method is used, it must be approved by the board and provide a daily backup.
 - C.** Any record keeping system approved by the board.

[OAC Rule 4729-5-27(F)]

- 95.** All computerized record keeping systems must be capable of providing immediate retrieval (via CRT display and hard copy printout or other mutually agreeable transfer medium) of patient profile

information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

- A.** The original prescription number;
- B.** Date of issuance of the original prescription order by the prescriber;
- C.** Date of dispensing by the pharmacist;
- D.** Full name and address of the patient;
- E.** Full name and address of the prescriber;
- F.** Directions for use;
- G.** The name, strength, dosage form, and quantity of the drug prescribed;
- H.** The quantity dispensed if different from the quantity prescribed;
- I.** If utilizing a board approved system pursuant to paragraph (F)(2) of rule 4729-5-27 of the Administrative Code, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing;
- J.** The total number of refills authorized by the prescriber;
- K.** The refill history of the prescription as defined in paragraph (H) of rule 4729-5-27 of the Administrative Code. [OAC Rule 4729-5-27(G)]

96. The refill history of the prescription must include, but is not limited to:

- A.** The prescription number;
- B.** The name and strength of the drug dispensed;
- C.** The date of refill;
- D.** The quantity dispensed;
- E.** If utilizing a board approved system pursuant to paragraph (F)(2) of rule 4729-5-27 of the Administrative Code, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill;
- F.** The total number of refills dispensed to date for that prescription order.

[OAC Rule 4729-5-27(H)]

97. Hard copy documentation as required pursuant to paragraph (F)(1) of rule 4729-5-27 of the Administrative Code must be provided by each individual pharmacist who makes use of such system by one of the following methods:

- A.** A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:
 - (a) Date of dispensing;
 - (b) Prescription number;
 - (c) Patient name;
 - (d) Name, strength (if applicable), and quantity of drug;
 - (e) Identification of pharmacy and pharmacist;
 - (f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

- B.** A tamper evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or
- C.** Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:
 - (1)** Date of dispensing;
 - (2)** Prescription number;
 - (3)** Patient name;
 - (4)** Name, strength (if applicable), and quantity of drug;
 - (5)** Identification of the pharmacist;
 - (6)** Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by him/her and is correct as shown.

[OAC Rule 4729-5-27(I)]

98. Any computerized record keeping system must have the capability of producing a printout by any data field which the user pharmacy is responsible for maintaining pursuant to federal and state laws and their implementing regulations and rules within three working days of a request being submitted by an individual authorized by law to access such records.

[OAC Rule 4729-5-27(J)]

99. In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

[OAC Rule 4729-5-27(K)]

100. A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via digital display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:

- A.** Pharmacy name and address;
- B.** Original prescription number;
- C.** Date of issuance of the original prescription order by the prescriber;
- D.** Date of original dispensing by the pharmacist;
- E.** Full name and address of the patient;
- F.** Full name and address of the prescriber;
- G.** Directions for use;
- H.** Name, strength, dosage form, and quantity of the drug prescribed;

- I. Quantity dispensed if different from the quantity prescribed;
- J. Total number of refills authorized by the prescriber;
- K. Total number of refills dispensed to date for that prescription order;
- L. Date of each refill;
- M. Name or initials of each individual dispensing pharmacist. [OAC Rule 4729-5-27(L)]

101. A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

- A. Date and time of change;
- B. Changes made;
- C. Pharmacist making the change. [OAC Rule 4729-5-27(M)]

102. Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

- A. The complete prescription information must be entered in the computer system;
- B. The information must appear in the patient's profile;
- C. There is positive identification, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;
- D. The original prescription is filed according to rule 4729-5-09 of the Administrative Code. [OAC Rule 4729-5-27(N)]

INSTITUTIONAL FACILITIES

103. Each institutional pharmacy shall be directed by a pharmacist who holds a current identification card to practice pharmacy in Ohio.

- A. The institutional pharmacy director or designated pharmacist shall:
 - (1) Be the pharmacist-in-charge and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility;
 - (2) Sign the terminal distributor of dangerous drugs license and shall maintain the license in a readily available place in the pharmacy;
 - (3) Be responsible for the practice of pharmacy performed within the institution;
 - (4) Develop, implement, supervise, and coordinate all services provided by the pharmacy;
 - (5) In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, assure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the State Board of Pharmacy;
 - (6) Be responsible for the security and control of all drugs within the institution;
 - (7) Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs.
- B. An institutional pharmacy director or designated pharmacist who ceases to be the pharmacist-in-charge and responsible pharmacist shall take an inventory of the controlled substances with the new or acting pharmacist-in-charge at the time he/she ceases to be the pharmacist-in-charge.

[OAC Rule 4729-17-02]

- 104.** In the absence of a licensed pharmacist, drugs ordered by a prescriber for patient treatment may be obtained in the following manner:
- A.** Drugs may be made available to licensed health care professionals by use of a contingency drug supplies stored in a locked cabinet or other enclosure constructed and located outside of the institutional pharmacy that is sufficiently secure to deny access, without obvious damage, to unauthorized persons.
 - B.** When a drug is not available from the contingency drug supply and such drug is required to treat the immediate needs of an inpatient or outpatient whose health would otherwise be jeopardized, such drug may be obtained from the institutional pharmacy pursuant to written policies and procedures that identify the personnel authorized to access the pharmacy, ensure a minimum of two employees, one of whom shall be a licensed health care professional authorized to administer drugs, and provide a written record of each access to the institutional pharmacy.

[OAC Rule 4729-17-03(A)]

- 105.** Supplies of dangerous drugs may be maintained in patient care areas according to written policies and procedures developed and implemented by the pharmacist-in-charge. The policies and procedures shall:
- A.** Provide for a limited quantity of dangerous drugs to be maintained at any one location;
 - B.** Provide for the proper storage and labeling of all such drugs;
 - C.** (Provide for storage in a secure area. If dangerous drugs cannot be stored in a secure area, they shall be stored in a container which is sealed with a tamper-evident seal that must be broken to gain access to the drugs;
 - D.** Provide for notification of the pharmacist-in-charge, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;
 - E.** Provide for replacement of the drugs used, and the dangerous drug supply to be re-sealed;
 - F.** Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond use date;
 - G.** Provide adequate record keeping procedures to document the disposition of drugs from the supply.

[OAC Rule 4729-17-03(B)]

- 106.** All drug records shall be maintained for a period of three years and must be readily retrievable within three working days, excluding holidays and weekends, of all drug transactions within the previous three years. Electronic drug record keeping systems, computerized record keeping systems, or subsequent storage of such records, must be readily retrievable via CRT display, hard copy printout, or other mutually agreeable transfer medium. The pharmacist-in-charge shall be responsible for maintaining records of all drugs purchased or received, drug orders and records relating to the practice of pharmacy, records of drugs dispensed, compounded or repackaged for use within the institution and records of drugs distributed to other areas of the institution for administrator or use. [OAC Rules 4729-17-04]

- 107.**
- A.** All controlled substances dispensed to inpatients in an institutional facility in quantities exceeding a seventy-two-hour supply shall be dispensed and maintained according to the following requirements:

- (1)** All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except multidose liquids and injectables where unit-of-use packaging is not available;
 - (2)** The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (3)** A proof-of-use sheet or other Board-approved record keeping system shall be maintained for each drug and shall include at least, but is not limited to, the following information:
 - (a)** Patient name,
 - (b)** Date and time of access,
 - (c)** Drug name, strength, and quantity obtained,
 - (d)** The positive identification of the person doing the administration, and, if applicable,
 - (e)** The positive identification of both the person and the witness who waste a partial dose of a controlled substance;
 - (4)** At every change of shift, a reconciliation must be conducted by both the leaving and arriving health care professional responsible for the security of these drugs in the area in which they are stored and must include at least the following:
 - (a)** A physical count and reconciliation of the controlled substances and proof-of-use sheets, if applicable, to ensure the accountability of all doses,
 - (b)** An inspection of the packaging to ensure its integrity,
 - (c)** The positive identification of the persons conducting the reconciliation, and
 - (d)** The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. A pharmacist at the pharmacy department responsible for the terminal distributor of dangerous drugs license must be one of those notified.
- B.** All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code shall meet the following requirements, unless they are stored in a secure, automated storage system that meets the requirements of paragraph (C) below:
- (1)** The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (2)** A proof-of-use sheet or other Board approved record keeping system shall be maintained for each drug and shall include at least, but is not limited to, the following information:
 - (a)** Patient name,
 - (b)** Date and time of access,
 - (c)** Drug name, strength, and quantity obtained,
 - (d)** The positive identification of the person doing the administration, and, if applicable,
 - (e)** The positive identification of both the person and the witness who waste a partial dose of a controlled substance;
 - (3)** At every change of shift, a reconciliation must be conducted by both the leaving and arriving health care professional responsible for the security of these drugs in the area in which they are stored and must include at least the following:
 - (a)** A physical count and reconciliation of the controlled substances and proof-of-use sheets, if applicable, to ensure the accountability of all doses,
 - (b)** An inspection of the packaging to ensure its integrity,

- (c) The positive identification of the persons conducting the reconciliation, and
 - (d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. The responsible person for the terminal distributor of dangerous drugs license must be one of those notified;
 - (4) All controlled substances shall be packaged in tamper-evident containers except multidose liquids and injectables where unit-of-use packaging is not available.
 - C. All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code that are stored in a secure, automated storage system shall be handled as in paragraph (B) above unless the automated storage system meets all of the following requirements:
 - (1) The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (2) The system shall document the positive identification of every person accessing the system and shall record the date and time of access;
 - (3) A record keeping system shall be maintained that shall include at least, but is not limited to, the following information:
 - (a) Patient name,
 - (b) Date and time of access,
 - (c) Drug name, strength, and quantity removed,
 - (d) The positive identification of the person removing the drug, and, if applicable,
 - (e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;
 - D. Periodically, the responsible person shall cause a reconciliation of the automated storage system to be conducted that must include at least the following:
 - (1) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses,
 - (2) An inspection of the packaging to ensure its integrity,
 - (3) The positive identification of the persons conducting the reconciliation, and
 - (4) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. The responsible person for the terminal distributor of dangerous drugs license must be one of those notified;
 - (5) Access to all controlled substances stored in the automated storage system shall be limited to one drug and strength at a time;
 - (6) All controlled substances stored in the automated storage system shall be packaged in tamper-evident containers, unless the system only allows access to one dose at a time.

[OAC Rule 4729-17-05]

108.

- A. Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient-specific order issued by a prescriber.
 - (1) Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

(2) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a facsimile machine to facsimile machine transfer shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacist receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacist shall maintain the facsimile showing the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.

(3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a State Board of Pharmacy approved paperless automated data processing system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals using positive identification. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order which shall be available in a readily retrievable fashion. With such a system, the institutional pharmacy director or responsible pharmacist shall have in place written policies and procedures allowing only authorized personnel in the pharmacy access to the drug orders.

B. All orders for drugs for inpatients shall include, but are not limited to, at least the following:

- (1)** Name of patient;
- (2)** Name, strength, and dosage form of drug;
- (3)** Directions for use, including route of administration if other than oral;
- (4)** Date prescribed; and
- (5)** Prescriber's positive identification.

[OAC Rule 4729-17-09]

109. Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient specific order issued by a prescriber.

[OAC Rule 4729-17-09(A)]

110. Drugs shall be dispensed for outpatients pursuant to an original order of a prescriber. All orders for the dispensing of drugs to outpatients shall, at a minimum, contain all of the items required by Rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with Rule 4729-5-16 of the Administrative Code, and records maintained in accordance with Rule 4729-5-27 of the Administrative Code.

[OAC Rule 4729-17-09(C)]

111.

A. All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

- (a)** The non-proprietary or proprietary name of the drug;
- (b)** The route of administration, if other than oral;
- (c)** The strength and volume, where appropriate, expressed in the metric system whenever possible;
- (d)** The control number and expiration date;

- (e) Identification of the manufacturer, packer or distributor, or if the repackager is the dispensing pharmacy identification of the repackager, shall be by name or by the final six digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label;
 - (f) Special storage conditions, if required.
- (2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:
 - (a) Identification of the dispensing pharmacy;
 - (b) The patient's name;
 - (c) The date of dispensing;
 - (d) The non-proprietary and/or proprietary name of the drug;
 - (e) The strength, expressed in the metric system whenever possible.
- (3) Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:
 - (a) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.
 - (b) The quantity dispensed may not be more than a thirty-one-day supply.
 - (c) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.
 - (d) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.
 - (e) Medications which have been packaged in multi-dose packaging may not be returned to stock or re-dispensed when returned to the pharmacy for any reason.
 - (f) When the drugs are not in the possession of the ultimate user and any one drug within each individual package has been discontinued, all drugs in the individual package are deemed adulterated and they may not be administered.
 - (g) The packaging is tamper-evident.
 - (h) Any pharmacist/pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:
 - (i) The U.S.P. monograph or official labeling requires dispensing in the original container;
 - (ii) The drugs or dosage forms are incompatible with packaging components or each other;
 - (iii) The drugs are therapeutically incompatible when administered simultaneously;
 - (iv) The drug products require special packaging.
- (4) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.
- B. All drugs dispensed to inpatients for self-administration shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code.
- C. Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
 - (1) The patient's name;

- (2) The name and amount of the parenteral solution;
- (3) The name and amount of the drug(s) added;
- (4) The expiration date or beyond-use date;
- (5) The name and address of the institutional facility pharmacy;
- (6) Cautionary statements, if required.

[OAC Rule 4729-17-10]

CONSULT AGREEMENTS

112. "Consult agreement" means an agreement to manage an individual's drug therapy that has been entered into by a pharmacist and a physician.

[ORC Sec. 4729.01(D)]

113. One or more pharmacists may enter into a consult agreement with one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. Under a consult agreement, a pharmacist is authorized to manage an individual's drug therapy, but only to the extent specified in the agreement, this section, and the rules adopted under this section.

[ORC Sec. 4729.39(A)]

114. Under a consult agreement, a pharmacist is authorized to do both of the following, but only to the extent specified in the agreement, this section, and the rules adopted under this section:

- a.** Manage drug therapy for treatment of specified diagnoses or diseases for each patient who is subject to the agreement, including all of the following:
 - 1.** Changing the duration of treatment for the current drug therapy;
 - 2.** Adjusting a drug's strength, dose, dosage form, frequency, administration, or route of administration;
 - 3.** Discontinuing the use of a drug;
 - 4.** Administering a drug;
 - 5.** Notwithstanding the definition of "licensed health professional authorized to prescribe drugs" in section [4729.01](#) of the Revised Code, adding a drug to the patient's drug therapy.
- b.** Order blood and urine tests and, in accordance with practice protocols that are part of the consult agreement, evaluate results related to the drug therapy being managed.
 - 1.** A pharmacist's authority to evaluate blood and urine tests under division (B)(1)(b)(i) of this section does not authorize the pharmacist to make a diagnosis.

115. The authority of a pharmacist to manage an individual's drug therapy under a consult agreement does not permit the pharmacist to manage drug therapy prescribed by any other physician.

[ORC Sec. 4729.39(B)]

116. For an individual who is a patient of a hospital, or a resident in a long term care facility, a pharmacist may enter into a consult agreement to manage the drug therapy of an individual provided that:

- A.** Before a consult agreement may be entered into and implemented, a hospital or long-term care facility shall adopt a policy for consult agreements. For any period of time during which a pharmacist or physician acting under a consult agreement is not physically present and available at the hospital or facility, the policy shall require that another pharmacist and physician be available at the hospital or facility.

- B.** The consult agreement shall be made in writing and shall comply with the hospital's or facility's policy on consult agreements.
- C.** The content of the consult agreement shall be communicated to the individual whose drug therapy will be managed in a manner consistent with the hospital's or facility's policy on consult agreements.
- D.** A pharmacist acting under a consult agreement shall maintain in the individual's medical record a record of each action taken under the agreement.
- E.** Communication between a pharmacist and physician acting under the consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement.
- F.** A consult agreement may be terminated by the individual, a person authorized to act on behalf of the individual, the primary physician acting under the agreement, or the primary pharmacist acting under the agreement. When a consult agreement is terminated, all parties to the agreement shall be notified and the termination shall be recorded in the individual's medical record.
- G.** The authority of a pharmacist acting under a consult agreement does not permit the pharmacist to act under the agreement in a hospital long-term care facility at which the pharmacist is not authorized to practice.

[ORC Sec. 4729.39(C)]

117. The State Board of Pharmacy and the State Medical Board shall consult with each other and adopt rules to be followed by pharmacists and physician that establish standards and procedures for entering into a consult agreement and managing an individual's drug therapy under a consult agreement. ORC Sec. 4729.39(D)]

- 118.** A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement and is:
- A.** Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.
 - B.** Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

[OAC Rule 4729-5-21(J)]

119. As used in section 4729.39 of the Revised Code, a "reasonable attempt to contact and confer" shall be deemed to have occurred if the pharmacist provides the physician with notification of the intended action to be taken pursuant to the consult agreement and provides the physician with the opportunity to respond in a timely manner. Such notification may include, but is not limited to, one of the following methods:

- A.** Personally meeting with the physician;
- B.** Telephone discussion with the physician;
- C.** Facsimile in a manner that confirms delivery;
- D.** Electronic mail that confirms delivery;
- E.** Any other method in writing that reaches the physician in a timely manner; or
- F.** Any other method of notification as outlined in the consult agreement between the pharmacist and physician that might reasonably be expected to allow for the notification of the physician prior to the implementation of the intended action.

[OAC Rule 4729-29-01]

- 120.** For the purpose of implementing any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician as the term agent is used in rule 4729-5-30 of the Administrative Code unless the physician has specified otherwise in the consult agreement. The pharmacist's copy of the signed consult agreement shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the pharmacist to act in this manner. [OAC Rule 4729-29-02]
- 121.** As required by section 4729.39 of the Revised Code, all consult agreements and the records of actions taken pursuant to such consult agreements shall be in writing. The pharmacist shall maintain these records in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the consult. Such consult agreements shall be considered confidential patient records and are therefore subject to the requirements of rule 4729-5-29 of the Administrative Code. [OAC Rule 4729-29-03]
- 122.** The requirements of section 4729.39 of the Revised Code do not apply within an institutional facility as defined in rule 4729-17-01 of the Administrative Code when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.
[OAC Rule 4729-29-04]

A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement is:

- A.** Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.
- B.** Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

DRUG REPOSITORY PROGRAM

- 123.** The state board of pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in section 3715.63 of the Revised Code. Subject to the limitation specified in this division, unused drugs dispensed for purposes of the Medicaid program may be accepted and dispensed under the drug repository program.
[ORC Sec. 3715.87(B)]
- 124.** Any person, including a drug manufacturer or any health care facility as defined in section 1337.11 of the Revised Code, may donate prescription drugs to the drug repository program. The drugs must be

donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the state board of pharmacy under section 3715.873 of the Revised Code. Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other section of the Revised Code requires a pharmacy, hospital, or nonprofit clinic to participate in the program.

[ORC Sec. 3715.871(A)]

125. A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this section to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, as defined in section 4729.01 of the Revised Code. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal laws and laws of this state dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the board under section 3715.873 of the Revised Code. Drugs donated to the repository may not be resold.

[ORC Sec. 3715.871(B)]

126. The state board of pharmacy; the director of health; any person, including a drug manufacturer, or government entity that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be subject to any of the following for matters related to donating, accepting, or dispensing drugs under the program: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action. A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

[ORC Sec. 3715.872(B)]

127. "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the federal food and drug administration, or from a pharmacy licensed as a terminal distributor of dangerous drug, and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

[OAC Rule 4729-35-01(G)]

128. Dangerous drugs that are eligible to be donated include all dangerous drugs, except controlled substances and drug samples, if they are in their original and tamper-evident unit dose packaging, the drugs have been in the possession of a licensed healthcare professional and stored according to FDA storage requirements, the expiration date is six months or greater, there is no signs of tampering or

adulteration, and all pharmacy identifiers and confidential patient information has been removed from the packaging.

[OAC Rule 4729-35-04]

- 129.** An eligible dangerous drug may be donated to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program from a licensed terminal distributor of dangerous drugs, a licensed wholesale distributor of dangerous drugs, or a person who was legally dispensed a dangerous drug pursuant to a patient-specific drug order provided the person has not taken custody of the drug prior to donation.

[OAC Rule 4729-35-03]

- 130.** A pharmacy, hospital, or nonprofit-clinic that elects to participate in the drug repository program must determine if a person is eligible to receive drugs. To be eligible to receive drugs, a person must be a resident of Ohio and have no active third party prescription drug reimbursement coverage for the drug prescribed or be a resident of Ohio and is a patient of a nonprofit clinic.

[OAC Rule 4729-35-05]

- 131.** Proper record keeping and documentation by the donor and the recipient of dangerous drugs must be maintained including the name of the donor and recipient, drug name, strength, quantity, and the date of the donation. These records must be kept for at least three years.

[OAC Rules 4729-35-06, 4729-35-07, & 4729-35-08]

- 132.** A pharmacy, a hospital, or a nonprofit clinic may charge the recipient of a donated drug a maximum of two hundred per cent of the Medicaid professional dispensing fee to cover restocking and dispensing costs.

[OAC Rule 4729-35-09]

PRESCRIPTION MONITORING PROGRAM (OARRS)

- 133.** The state board of pharmacy may establish and maintain a drug database to monitor the misuse and diversion of controlled substances and other dangerous drugs the board includes in the database pursuant to rules adopted by the board.

[ORC Sec. 4729.75]

- 134.** The board shall electronically collect information from each pharmacy licensed as a terminal distributor of dangerous drugs who dispenses controlled substances and dangerous drugs as required to residents of Ohio. Data must be submitted on a daily basis. This information shall include:

- A.** identification of the terminal distributor;
- B.** patient identification;
- C.** prescriber identification;
- D.** date prescription issued by prescriber;
- E.** date prescription was dispensed;
- F.** indication of whether prescription dispensed is new or a refill;
- G.** name, strength, and national drug code of drug dispensed;
- H.** quantity of drug dispensed;
- I.** Number of days' supply dispensed;
- J.** serial or prescription number assigned by terminal distributor;
- K.** source of payment for prescription.

- L. Pharmacy National Provider Identification (NPI) Number;
 - M. Prescriber's NPI number unless the prescriber is a veterinarian
- [ORC Sec. 4729.77] [OAC 4729-37-04, 4729-37-07]

- 135.** The board shall electronically collect information from each wholesale distributor of dangerous drugs that delivers drugs to prescribers in this state. This information shall include:
- A. purchaser identification;
 - B. identification of drug sold;
 - C. date of sale;
 - D. wholesale distributor's license number. [ORC Sec. 4729.78]
- 136.** The Board of Pharmacy may provide information from the drug database to;
- A. a prescriber, prescriber's delegate, pharmacist, or pharmacist's delegate provided that the purpose of the request is to provide medical or pharmaceutical treatment to the patient who is the subject of the request,
 - B. a government agency responsible for the licensure, regulation, or discipline of the prescriber relating to the prescriber who is the subject of an active investigation,
 - C. a grand jury subpoena regarding a person who is the subject of an investigation of the grand jury,
 - D. a federal, state, or local law enforcement officer regarding a person who is the subject of an active investigation by that government agency, or
 - E. to the individual seeking the individual's own database information. [ORC Sec. 4729.79]

MISCELLANEOUS

- 137.** Patient Confidentiality:
- A. Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:
 - (1) The patient for whom the prescription or medication order was issued.
 - (2) The prescriber who issued the prescription or medication order.
 - (3) Certified/licensed health care personnel who are responsible for the care of the patient.
 - (4) A member, inspector, agent, or investigator of the State Board of Pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.
 - (5) An agent of the State Medical Board when enforcing Chapter 4731. of the Revised Code.
 - (6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.
 - (7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

- (8) An agent who contracts with the pharmacy as a “business associate” in accordance with the regulations promulgated by the Secretary of the United States Department of Health and Human Services pursuant to the federal standards for privacy of individually identifiable health information.
- (9) An agent of the State Board of Nursing when enforcing Chapter 4723. of the Revised Code.
- (10) Any person, other than those listed in paragraphs (A)(1) to (A)(7) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient. In an emergency, the pharmacist may disclose the prescription information when, in the professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.
- B. Testimonial privilege is not waived for any communication between a physician, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.
- C. Records relating to the practice of pharmacy, the administration drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the State Board of Pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

 - (1) Prescription identification number; or, if an order for medication, the name of the patient;
 - (2) The drugs prescribed;
 - (3) Quantity of drugs prescribed and dispensed;
 - (4) Name of the prescriber;
 - (5) Date, name of agency, and signature of person removing the records.
- D. All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A) (8) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

[OAC Rule 4729-5-29]

138. Pharmacist Drug Administration:

- A. **(AFTER March 19, 2015):** A pharmacist or intern licensed by the Ohio Board who meets the requirements of 4729.41(B) may administer:

 - i. All CDC-ACIP recommended vaccines to patients who are 13 years of age and older, without a prescription;
 - ii. All CDC-ACIP recommended vaccines to patients who are 7 years of age or older and up to 12 years of age, with a prescription;
 - iii. The flu vaccine to all patients who are 7 years of age or older, without a prescription.
 - iv. The zoster vaccine according to the age criteria specified in the FDA approved labeling
 - v. The measles, mumps, and rubella (MMR) vaccine

- B.** To be authorized in the administration of immunizations, a pharmacist shall do all of the following:
- (1)** successfully completing a Board approved course in the administration of immunizations,
 - (2)** receive and maintain certification to perform basic life support procedures,
 - (3)** practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician and approved by the state board of pharmacy. The protocols shall include provisions for observation of the individual who receives the immunization, procedures to be followed for adverse reactions, notification of the individual's family physician or local board of health of immunizations other than influenza immunizations within thirty days after the immunization, and parental consent for individuals receiving influenza immunization between the ages of seven and seventeen years of age.

[ORC Sec. 4729.41, OAC Rules 4729-5-36, 4729-5-37, & 4729-5-38].

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