Article - Health Occupations

§12–101.

(a) In this title the following words have the meanings indicated.

(b) "Authorized prescriber" means any licensed dentist, licensed dental hygienist with prescriptive authority under § 4–206.4 of this article, licensed physician, licensed podiatrist, licensed veterinarian, advanced practice registered nurse with prescriptive authority under Title 8 of this article, licensed nurse anesthetist, or other individual authorized by law to prescribe prescription or nonprescription drugs or devices.

(c) "Biological product" has the meaning stated in 42 U.S.C. § 262.

(d) "Board" means the State Board of Pharmacy.

(d–1) "Compounded nonsterile preparations" means products compounded in accordance with USP 795.

(e) "Compounded sterile preparations" means biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be compounded using aseptic techniques.

(f) (1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

(2) "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(g) (1) "Delegated pharmacy act" means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under this title and regulations adopted by the Board.

(2) "Delegated pharmacy act" does not include:

(i) An act within the parameters of a therapy management contract as provided under Subtitle 6A of this title;

(ii) Except as provided in § 12–6B–06 of this title, the administration of a vaccination in accordance with § 12–508 of this title;

(iii) The delegation of a pharmacy act by a registered pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with § 12–301(b) of this title;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy in accordance with regulations adopted by the Board;

(vi) A decision–making task that requires the professional judgment of a pharmacist; and

(vii) The performance of other functions prohibited in regulations adopted by the Board.

(h) (1) "Device" means a device used in the diagnosis, treatment, or prevention of disease.

(2) "Device" does not include any:

(i) Surgical or dental instrument;

(ii) Physical therapy equipment;

(iii) X–ray apparatus; or

(iv) Component part or accessory of any of these items.

(i) "Direct supervision" means that a licensed pharmacist is physically available, notwithstanding appropriate breaks, on–site and in the prescription area or in an area where pharmacy services are provided to supervise the practice of pharmacy and delegated pharmacy acts.

(j) "Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(1) Interpretation of an authorized prescriber's prescription for a drug or device;

(2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

(k) (1) "Distribute" means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under this article, prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

(2) "Distribute" does not include the operations of a person who holds a permit issued under § 12–6C–03 of this title.

(l) "Drug" has the meaning stated in § 21–101 of the Health – General Article.

(l–1) "Injectable medication for treatment of a sexually transmitted infection" means a medication that:

(1) Is administered by injection other than intravenously;

(2) Treats a sexually transmitted infection; and

(3) Is not a vaccine.

(m) "Interchangeable biological product" means a biological product that is:

(1) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

(2) Determined to be therapeutically equivalent as stated in the latest edition of or supplement to the United States Food and Drug Administration's approved drug products with therapeutic equivalence evaluations (the "Orange Book").

(n) "License" means, unless the context requires otherwise, a license issued to a pharmacist by the Board to practice pharmacy.

(o) "Licensed pharmacist" means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

(o–1) (1) "Maintenance injectable medication" means a medication that:

(i) Is administered by injection other than intravenously; and

(ii) Treats a chronic need, condition, or disorder.

(2) "Maintenance injectable medication" includes a medication for the treatment of a psychiatric disorder or substance use disorder, contraception, and vitamins.

(o–2) "Nicotine replacement therapy medication" means a drug or product, regardless of whether it is available over the counter, that:

(1) Delivers nicotine to an individual; and

(2) Is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation.

(p) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and regulations of this State and the federal government.

(q) "Nonresident pharmacy" means a pharmacy located outside this State that, in the normal course of business, as determined by the Board, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.

(r) "Pharmaceutical care" means the provision of a patient's drug regimen for the purpose of achieving definite outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and which may include patient counseling and providing information to licensed and certified health care providers.

(s) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(t) "Pharmacy" means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

(u) "Pharmacy permit" means a permit issued by the Board to establish and operate a pharmacy.

(v) "Pharmacy student" means an individual who is enrolled as a student in a school or college of pharmacy approved by the Board or accredited by the Accreditation Council for Pharmacy Education.

(w) "Pharmacy technician trainee" means an individual engaged in a Board approved pharmacy technician training program.

(x) (1) "Practice pharmacy" means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;

(viii) Administering vaccinations in accordance with § 12–508 of this title or self–administered drugs or maintenance injectable medications in accordance with § 12–509 of this title;

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(xi) Providing drug therapy management in accordance with § 19–713.6 of the Health – General Article;

(xii) Prescribing and dispensing contraceptive medications and self–administered contraceptive devices approved by the U.S. Food and Drug Administration; or

(xiii) Prescribing and dispensing nicotine replacement therapy medications.

(2) "Practice pharmacy" does not include the operations of a person who holds a permit issued under § 12–6C–03 of this title.

(y) "Registered pharmacy intern" means an individual who is registered with the Board to practice pharmacy under the direct supervision of a pharmacist.

(z) "Registered pharmacy technician" means an individual who is registered with the Board to perform delegated pharmacy acts.

(z–1) "Registration" means, unless the context requires otherwise, a registration issued by the Board to perform delegated pharmacy acts under the supervision of a licensed pharmacist.

(z–2) (1) "Self–administered drug" means a drug that is regularly administered by the patient for whom the drug is prescribed or by an individual who is not otherwise authorized to administer drugs under this article.

(2) "Self–administered drug" includes:

(i) Eyedrops; and

(ii) A drug that is administered by an intramuscular injection or a subcutaneous injection.

(aa) "Supervision" means reviewing the work, guiding and directing the activities, and monitoring the performance of an individual.

(bb) "USP–NF" means the United States Pharmacopeia and the National Formulary.

(cc) "USP 795" means the standards set forth in the United States Pharmacopeia, General Chapter 795, "Pharmaceutical Compounding – Nonsterile Preparations".

(dd) "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations".