§ 6802. Definitions. 1. "Pharmacy" means any place in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

3. "Formulary" means the latest edition of the official national formulary, and its supplement.

4. "Pharmacopeia", when not otherwise limited, means the latest edition of the official United States pharmacopeia, and its supplement.

5. "Homeopathic pharmacopeia" means the official homeopathic pharmacopeia of the United States, and its supplement.

6. "Official compendium" means the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, official national formulary, or their supplements.

7. "Drugs" means:

a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.

b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.

c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.

d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

8. "Cosmetics" means:

a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

b. Articles intended for use as a component of any such articles; except that the term shall not include soap.

9. "Poison", where not otherwise limited, means any drug, chemical or preparation likely to be destructive to adult human life in quantity of sixty grains or less.

10. "Label" means a display of written, printed or pictorial matter upon the immediate container of any drug, device or cosmetic. Any requirement made by or under authority of this article, that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there be any, of the retail package of such drug, device or cosmetic or is easily legible through the outside container or wrapper.

11. "Immediate container" does not include package liners.

12. "Labeling" means all labels and other written, printed or pictorial matter:

a. Upon any drug, device or cosmetic or any of its containers or wrappers, or

b. Accompanying such drug, device or cosmetic.

13. "Misbranding". If a drug, device or cosmetic is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof,

but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the drug, device, or cosmetic to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. No drug, device or cosmetic which is subject to, and complies with regulations promulgated under the provisions of the federal food, drug, and cosmetic act, relating to adulteration and misbranding shall be deemed to be adulterated or misbranded in violation of the provisions of this article because of its failure to comply with the board's regulations, or the rules of the state board of pharmacy, insofar as the regulations are in conflict with regulations relating to adulteration and misbranding under the federal food, drug and cosmetic act.

14. "Antiseptic". The representation of a drug, device or cosmetic in its labeling, as an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

15. "New drug" means:

a. Any drug not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested by the drug's labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to September first, nineteen hundred thirty-nine it was subject to the former federal food and drug act of June thirtieth, nineteen hundred six, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for

use under such conditions, has become recognized, but which has not otherwise than in such investigations been used to a material extent or for a material time under such conditions.

16. "Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:

a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or

b. To affect the structure or any function of the body of man or animals.

17. The term "Federal Food, Drug and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June twenty-fifth, nineteen hundred thirty-eight, officially cited as public document number seven hundred seventeen-seventy-fifth congress (chapter six hundred seventy-five--third session), and all its amendments now or hereafter enacted.

18. "Wholesaler" means a person who bottles, packs or purchases drugs, devices or cosmetics for the purpose of selling or reselling to pharmacies or to other channels as provided in this article.

19. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics.

20. "Controlled substance" means any drug defined as a controlled substance by article thirty-three of the public health law.

21. "Manufacturer" means a person who compounds, mixes, prepares, produces, and bottles or packs drugs, cosmetics or devices for the purpose of distributing or selling to pharmacies or to other channels of distribution.

22. "Administer", for the purpose of section sixty-eight hundred one of this article, means:

a. (1) the direct application of an immunizing agent to adults, whether by injection, ingestion, inhalation or any other means, pursuant to a patient specific order or non-patient specific regimen prescribed or ordered by a physician or certified nurse practitioner, for: immunizations to prevent influenza, pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria or pertussis disease and medications required for emergency treatment of anaphylaxis; and other immunizations for patients eighteen years of age or older if the commissioner of health in consultation with the commissioner determines that an immunization: (i)(A) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (B) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York state; or (ii) is a recommended immunization for such patients who: (A) meet age requirements, (B) lack documentation of such immunization, (C) lack evidence of past infection, or (D) have an additional risk factor or another indication. If the commissioner of health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

(2) the direct application of an immunizing agent to children between the ages of two and eighteen years of age, whether by injection, ingestion, inhalation or any other means, pursuant to a patient specific order or non-patient specific regimen prescribed or ordered by a physician or certified nurse practitioner, for immunization to prevent influenza, COVID-19, and medications required for emergency treatment of anaphylaxis resulting from such immunization. If the commissioner of health determines that there is an outbreak of influenza or COVID-19, or that there is the imminent threat of an outbreak of influenza or COVID-19, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

b. The injection of medications for the treatment of mental health and

substance use disorder, as prescribed or ordered by a licensed prescriber, acting within the scope of their practice in this state and in accordance with regulations promulgated by the commissioner, in consultation with the department of health and any other state agencies as necessary, provided that:

(1) Such administration is conducted pursuant to a valid patient-specific prescription or patient-specific order that authorizes a pharmacist to administer medications approved by the U.S. Food and Drug Administration for the treatment of mental health and substance use disorder. The pharmacist shall notify the licensed prescriber that the administration is complete within five days and shall convey such information to the prescriber by making an entry into an interoperable electronic medical records system, an electronic prescribing technology or a pharmacy record, or by using facsimile, electronic transmission or other electronic means. If an electronic means described in this subparagraph is not available to the pharmacist at the time of communication, the pharmacist or pharmacist's designee may communicate the information by telephone. Notification shall also be required if a patient does not receive an administration or if the patient experiences any side effects or adverse reactions to the medications. Administration in a pharmacy shall not commence until after the patient has received the initial injection and is considered eligible for maintenance treatment by the licensed prescriber.

(2) Such prescription may be subject to reassessment at appropriate intervals, as determined by the licensed prescriber.

(3) Such activity is conducted in accordance with regulations, promulgated or adopted by the commissioner, in consultation with the department of health and any other state agencies, as necessary, which shall include requirements for the following:

(i) Maintaining continued competency regarding the populations served and medications administered.

(ii) Pre-administration patient consent and education regarding common side effects, drug interactions, injection site reactions and other information routinely provided to patients upon dispensing. If a patient is unable to provide consent, the pharmacist must obtain consent from a person legally responsible when the recipient is incapable of consenting.

(iii) When administering an injection in a pharmacy, the pharmacist shall provide an area for the injection that provides for the patient's privacy.

(iv) Ensuring that only U.S. Food and Drug Administration approved medications are administered.

23. "Electronic prescription" means a prescription created, recorded, or stored by electronic means; issued with an electronic signature; and transmitted by electronic means, in accordance with regulations of the commissioner and applicable regulations of the commissioner of health and federal regulations; provided, however, that an original hard copy prescription that is created electronically or otherwise may be transmitted from the prescriber to the pharmacist by facsimile and must be manually signed. "Electronic" means of or relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities. "Electronic signature" means an electronic sound, symbol, or process, attached to or logically associated with an electronic prescription and executed or adopted by a person with the intent to sign the prescription, in accordance with regulations of the commissioner and applicable regulations of the commissioner of health and federal regulations.

24. "Compounding" means the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug with respect to an outsourcing facility under section 503B of the Federal Food, Drug and Cosmetic Act and further defined in this section.

25. "Outsourcing facility" means a facility that:

(a) is engaged in the compounding of sterile drugs;

(b) is currently registered as an outsourcing facility with the Secretary of Health and Human Services; and

(c) complies with all applicable requirements of federal and state law, including the Federal Food, Drug and Cosmetic Act.

26. "Sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format,

or a drug that is required to be sterile under federal or state law.

27. "Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262(i).

28. "Interchangeable biological product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. Section 262(k)(4) as set forth in the latest edition or supplement of the United States Food and Drug Administration Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, sometimes referred to as the "Purple Book," or a biological product determined by the United States Food and Drug Administration to be therapeutically equivalent as set forth in the latest edition or supplement of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, sometimes referred to as the "Orange Book."

29. "Self-administered hormonal contraceptives", for the purpose of section sixty-eight hundred one of this article, means self-administered contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(30) "Shared pharmacy services" means a system that allows a registered pharmacist or a registered pharmacy, pursuant to a request from another registered pharmacist or pharmacy, to process or fill a prescription or order, pursuant to regulations promulgated by the commissioner.