

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

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TITLE 1 – GENERAL PROVISIONS

3300 - Short Title

3300a- Legislative purposes

3301 - Applicability of this article to actions and matters occurring or arising before and after the effective date.

3302 - Definitions of terms of general use in this article

3304 - Prohibited acts

3305 - Exemptions

3306 - Schedules of controlled substances

3307 - Exception from schedules

3308 - Powers and duties of the commissioner

3309 - Opioid overdose prevention

3309a - Prescription pain medication awareness program

TITLE 2 – MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

3310 - Licenses for manufacture or distribution of controlled substances

3311 - Authority to issue initial licenses, amended licenses and to renew licenses

3312 - Application for initial license

3313 - Granting of initial license

3315 - Applications for renewal of licenses to manufacture or distribute controlled substances

3316 - Granting of renewal of licenses

3318 - Identification of controlled substances

3319 - Distribution of free samples

3320 - Authorization distribution

3321 - Exempt distribution

3322 - Reports and records

TITLE 2-A – OPIOID STEWARDSHIP ACT

3323 – Opioid stewardship fund

TITLE 3 – RESEARCH, INSTRUCTIONAL ACTIVITIES, AND CHEMICAL ANALYSIS RELATING TO CONTROLLED SUBSTANCES

3324 - Licenses to engage in research, instructional activities, and chemical analysis relating to controlled substances

3325 – Authority to issue licenses

3326 – Institutional research licenses

3327 – Procedure

3328 – Exemptions from title

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

3329 – Reports and records

TITLE 4 – DISPENSING TO ULTIMATE USERS

3330 - Schedule I substances

3331 - Scheduled substances administering and dispensing by practitioners

3332 - Making of official New York state prescriptions for scheduled substances

3333 - Dispensing upon official New York state prescription

3334 – Emergency oral prescriptions for schedule II drugs and certain other controlled substances

3335 - Dispensing by online dispensers of controlled substances

3337 - Oral prescriptions schedule III, I V, V substances

3338 - Official New York state prescription forms

3339 - Refilling of prescriptions for controlled substances

3341 - Institutional dispensers certificates of approval

3342 - Dispensing and administering by institutional dispenser

3343 - Reports and records

3343a- Prescription monitoring program registry

3343b – Safe disposal of unused controlled substances

3345 – Possession of controlled substances by ultimate users original container

TITLE 5 – DISPENSING TO ADDICTS AND HABITUAL USERS

3350 – Dispensing prohibition

3351 – Dispensing for medical use

3352 – Reports and records

TITLE 5A – MEDICAL USE OF MARIHUANA

3360 - Definitions

3361 - Certification of patients

3362 - Lawful medical use

3363 - Registry identification cards

3364 - Registered organizations

3365 - Registering of registered organizations

3365a - Expedited registration of registered organizations

3366 - Reports by registered organizations

3367 - Evaluation; research programs; report by department

3368 - Relation to other laws

3369 - Protections for the medical use of marihuana

3369a - Regulations

3369b - Effective date

3369c - Suspend; terminate

3369d - Pricing

3369e - Severability

TITLE 6 – RECORDS AND REPORTS

3370 - Preserving and inspection of records

3371 - Confidentiality of certain records, reports, and information

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- 3371a- Disclosure of certain records, reports, and information to another state
- 3372 - Practitioner patient reporting
- 3373 - Confidential communications
- 3374 - Notification by license

TITLE 7 -- OFFENSES, VIOLATIONS AND ENFORCEMENT

- 3380 - Inhalation of certain toxic vapors or fumes, and certain hazardous inhalants; sale of glue and hazardous inhalants in certain cases
- 3381 - Sale and possession of hypodermic syringes and hypodermic needles
- 3381a- Destruction of hypodermic syringes and needles
- 3383 - Imitation controlled substances
- 3384 - Information program for retailers
- 3385 - Enforcement
- 3385a - Access to criminal history information
- 3387 - Seizure and forfeiture of controlled substances, imitation controlled substances and official New York state prescription forms; disposition
- 3388 - Seizure and forfeiture of vehicles, vessels or aircraft unlawfully used to conceal, convey or transport controlled substances
- 3390 - Revocation of licenses and certificates of approval
- 3391 - Revocation and suspension of license or certificate of approval procedure
- 3393 - Formal hearings procedure
- 3394 - Judicial review
- 3396 - Violations; penalties
- 3397 - Fraud and deceit

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

TITLE 1 - GENERAL PROVISIONS

§ 3300. **Short title.** This article shall be known as the New York State Controlled Substances Act.

§ 3300-a. **Legislative purposes.** The purposes of this article are:

1. to combat illegal use of and trade in controlled substances; and
2. to allow legitimate use of controlled substances in health care, including palliative care; veterinary care; research and other uses authorized by this article or other law; under appropriate regulation and subject to this article, title eight of the education law, and other applicable law.

§ 3301. **Applicability of this article to actions and matters occurring**

or arising before and after the effective date. Unless otherwise expressly provided, or unless the context otherwise requires:

- (a) the provisions of this article shall govern and control the possession, manufacture, dispensing, administering, and distribution of controlled substances with respect to any matter, act or omission, arising or occurring on or after the effective date hereof;
- (b) the provisions of this article do not apply to or govern any matter, act, or omission arising or occurring prior to the effective date hereof. Such matters, acts, or omissions must be governed and construed according to provisions of law existing at the time such matter, act or omission arose or occurred in the same manner as if this article had not been enacted.

§ 3302. **Definitions of terms of general use in this article.** Except where different meanings are expressly specified in subsequent provisions of this article, the following terms have the following meanings:

1. "Addict" means a person who habitually uses a controlled substance for a non-legitimate or unlawful use, and who by reason of such use is dependent thereon.
2. "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.
3. "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. No person may be authorized to so act if under title VIII of the education law such person would not be permitted to engage in such conduct. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.
4. "Controlled substance" means a substance or substances listed in section thirty-three hundred six of this chapter.
5. "Commissioner" means commissioner of health of the state of New York.
6. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.
7. "Department" means the department of health of the state of New York.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

8. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by lawful means, including by means of the internet, and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.
9. "Distribute" means to deliver a controlled substance, including by means of the internet, other than by administering or dispensing.
10. "Distributor" means a person who distributes a controlled substance.
11. "Diversion" means manufacture, possession, delivery or use of a controlled substance by a person or in a manner not specifically authorized by law.
12. "Drug" means
 - (a) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;
 - (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; and
 - (c) substances (other than food) intended to affect the structure or a function of the body of man or animal. It does not include devices or their components, parts, or accessories.
13. "Federal agency" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.
14. "Federal controlled substances act" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, and any act or acts amendatory or supplemental thereto or regulations promulgated thereunder.
15. "Federal registration number" means such number assigned by the Federal agency to any person authorized to manufacture, distribute, sell, dispense or administer controlled substances.
16. "Habitual user" means any person who is, or by reason of repeated use of any controlled substance for non-legitimate or unlawful use is in danger of becoming, dependent upon such substance.
17. "Institutional dispenser" means a hospital, veterinary hospital, clinic, dispensary, maternity home, nursing home, mental hospital or similar facility approved and certified by the department as authorized to obtain controlled substances by distribution and to dispense and administer such substances pursuant to the order of a practitioner.
18. "License" means a written authorization issued by the department or the New York state department of education permitting persons to engage in a specified activity with respect to controlled substances.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

19. "Manufacture" means the production, preparation, propagation, compounding, cultivation, conversion or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging or labeling of a controlled substance:

(a) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(b) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale; or

(c) by a pharmacist as an incident to his dispensing of a controlled substance in the course of his professional practice.

20. "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(b) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (a), but not including the isoquinoline alkaloids of opium;

(c) opium poppy and poppy straw.

21. "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under section 3306 of this article, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

22. "Opium poppy" means the plant of the species *Papaver somniferum* L., except its seeds.

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

24. "Pharmacist" means any person licensed by the state department of education to practice pharmacy.

25. "Pharmacy" means any place registered as such by the New York state board of pharmacy and registered with the Federal agency pursuant to the federal controlled substances act.

26. "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

27. "Practitioner" means:

A physician, dentist, podiatrist, veterinarian, scientific investigator, or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice or research licensed pursuant to this article. Such person shall be deemed a "practitioner" only as to such substances, or conduct relating to such substances, as is permitted by his license, permit or otherwise permitted by law.

28. "Prescribe" means a direction or authorization, by prescription, permitting an ultimate user lawfully to obtain controlled substances from any person authorized by law to dispense such substances.

29. "Prescription" shall mean an official New York state prescription, an electronic prescription, an oral prescription or an out-of-state prescription.

30. "Sell" means to sell, exchange, give or dispose of to another, or offer or agree to do the same.

31. "Ultimate user" means a person who lawfully obtains and possesses a controlled substance for his own use or the use by a member of his household or for an animal owned by him or in his custody. It shall also mean and include a person designated, by a practitioner on a prescription, to obtain such substance on behalf of the patient for whom such substance is intended.

32. "Internet" means collectively computer and telecommunications facilities which comprise the worldwide network of networks that employ a set of industry standards and protocols, or any predecessor or successor protocol to such protocol, to exchange information of all kinds. "Internet," as used in this article, also includes other networks, whether private or public, used to transmit information by electronic means.

33. "By means of the internet" means any sale, delivery, distribution, or dispensing of a controlled substance that uses the internet, is initiated by use of the internet or causes the internet to be used.

34. "Online dispenser" means a practitioner, pharmacy, or person in the United States that sells, delivers or dispenses, or offers to sell, deliver, or dispense, a controlled substance by means of the internet.

35. "Electronic prescription" means a prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the commissioner and the commissioner of education and consistent with federal requirements. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and must be manually signed.

36. "Electronic" means of or relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities. "Electronic" shall not include facsimile.

37. "Electronic record" means a paperless record that is created, generated, transmitted, communicated, received or stored by means of electronic equipment and includes the preservation,

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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retrieval, use and disposition in accordance with regulations of the commissioner and the commissioner of education and in compliance with federal law and regulations.

38. "Electronic signature" means an electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record, in accordance with regulations of the commissioner and the commissioner of education.

39. "Registry" or "prescription monitoring program registry" means the prescription monitoring program registry established pursuant to section thirty-three hundred forty-three-a of this article.

40. "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.

41. "Outsourcing facility" means a facility that:

(a) is engaged in the compounding of sterile drugs as defined in section sixty-eight hundred two of the education law;

(b) is currently registered as an outsourcing facility pursuant to article one hundred thirty-seven of the education law; and

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

Notwithstanding any other provision of law to the contrary, when an outsourcing facility distributes or dispenses any drug to any person pursuant to a prescription, such outsourcing facility shall be deemed to be providing pharmacy services and shall be subject to all laws, rules and regulations governing pharmacies and pharmacy services.

* § 3304. Prohibited acts.

1. It shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.
2. It shall be unlawful for any person to possess or have under his control an official New York state prescription form except as expressly allowed by this article.

NB Separately amended -- cannot be put together

* § 3304. Prohibited acts. a. It shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.

b. It shall be unlawful for any physician practicing medicine as defined in section sixty-five hundred twenty-one of the education law to prescribe, dispense or administer any amphetamines or sympathomimetic amine drug or compound thereof, designated as a schedule II controlled substance

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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pursuant to section thirty-three hundred six of this article for the exclusive treatment of obesity, weight control or weight loss. A violation of the provisions of this subdivision shall not be grounds for prosecution under article two hundred twenty of the penal law.

*** NB Separately amended -- cannot be put together**

§ 3305. Exemptions.

1. The provisions of this article restricting the possession and control of controlled substances and official New York state prescription forms shall not apply:

(a) to common carriers or to warehousemen, while engaged in lawfully transporting or storing such substances, or to any employee of the same acting within the scope of his employment; or

(b) to public officers or their employees in the lawful performance of their official duties requiring possession or control of controlled substances; or

(c) to temporary incidental possession by employees or agents of persons lawfully entitled to possession, or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

(d) to a duly authorized agent of an incorporated society for the prevention of cruelty to animals or a municipal animal control facility for the limited purpose of buying, possessing, and dispensing to registered and certified personnel, ketamine hydrochloride to anesthetize animals and/or sodium pentobarbital to euthanize animals, including but not limited to dogs and cats. The department shall, consistent with the public interest, register such duly authorized agent and such agent shall file, on a quarterly basis, a report of purchase, possession, and use of ketamine hydrochloride and/or sodium pentobarbital, which report shall be certified by the society for the prevention of cruelty to animals or municipal animal control facility as to its accuracy and validity. This report shall be in addition to any other record keeping and reporting requirements of state and federal law and regulation. The department shall adopt rules and regulations providing for the registration and certification of any individual who, under the direction of the duly authorized and registered agent of an incorporated society for the prevention of cruelty to animals, or municipal animal control facility, uses ketamine hydrochloride to anesthetize animals and/or sodium pentobarbital to euthanize animals, including but not limited to dogs and cats. The department may also adopt such other rules and regulations as shall provide for the safe and efficient use of ketamine hydrochloride and/or sodium pentobarbital by incorporated societies for the prevention of cruelty to animals and animal control facilities. Nothing in this paragraph shall be deemed to waive any other requirement imposed on incorporated societies for the prevention of cruelty to animals and animal control facilities by state and federal law and regulation.

2. The commissioner may, by regulation, provide for the exemption from all or part of the requirements of this article the possession of substances in schedule III or IV and use thereof as part of an industrial process or manufacture of substances other than drugs. The commissioner may impose such conditions upon the granting of such exemption as may be necessary to protect against diversion or misuse of the controlled substance.

3. The commissioner is hereby authorized and empowered to make any rules, regulations and determinations permitting the following categories of persons to obtain, dispense and administer controlled substances under such conditions and in such manner as he shall prescribe:

(a) a person in the employ of the United States government or of any state, territory, district, county, municipal, or insular government, obtaining, possessing, dispensing and administering controlled substances by reason of his official duties;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(b) a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, or to a physician or surgeon duly licensed in any state, territory, or the District of Columbia to practice his profession, or to a retired commissioned medical officer of the United States army, navy, or public health service, employed upon such ship or aircraft, for the actual medical needs of persons on board such ship or aircraft when not in port.

(c) a person in a foreign country in compliance with the provisions of this article.

4. The provisions of this article with respect to the payment of fees and costs shall not apply to the state of New York or any political subdivision thereof or any agency or instrumentality of either.

§ 3306. Schedules of controlled substances. There are hereby established five schedules of controlled substances, to be known as schedules I, II, III, IV and V respectively. Such schedules shall consist of the following substances by whatever name or chemical designation known:

Schedule I. (a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of 3-methylfentanyl only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-alpha-methylfentanyl (N-{1-(-methyl-2-phenethyl) -4-piperidinyl} -N-phenylacetamide).

(2) Acetylmethadol.

(3) Allylprodine.

(4) Alphacetylmethadol (except levo- alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadylacetate or LAAM).

(5) Alphameprodine.

(6) Alphamethadol.

(7) Alpha-methylfentanyl (N-{1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl} propionanilide; 1-(1-methyl-2-phenylethyl) -4-(N-propanilido) piperidine).

(8) Alpha-methylthiofentanyl (N-{1-methyl-2)-2-thienyl) ethyl-4-piperidinyl} -N-phenylpropanamide).

(9) Beta-hydroxyfentanyl (N-{1-2 (2-hydroxy-2-phenethyl)- 4-piperidinyl} -N-phenylpropanamide).

(10) Beta-hydroxy-3-methylfentanyl (other name: N-{1(2-hydroxy-2-phenethyl) -3-methyl -4-piperidinyl} -N-phenylpropanamide).

(11) Benzethidine.

(12) Betacetylmethadol.

(13) Betameprodine.

(14) Betamethadol.

(15) Betaprodine.

(16) Clonitazene.

(17) Dextromoramide.

(18) Diampromide.

(19) Diethylthiambutene.

(20) Difenoxin.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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- (21) Dimenoxadol.
- (22) Dimepheptanol.
- (23) Dimethylthiambutene.
- (24) Dioxaphetyl butyrate.
- (25) Dipipanone.
- (26) Ethylmethylthiambutene.
- (27) Etonitazene.
- (28) Etoxadine.
- (29) Furethidine.
- (30) Hydroxypethidine.
- (31) Ketobemidone.
- (32) Levomoramide.
- (33) Levophenacymorphan.
- (34) 3-Methylfentanyl (N-{3-methyl-1-(2-phenylethyl)-4-piperidyl}-N-phenylpropanamide).
- (35) 3-Methylthiofentanyl (N-{3-methyl-1-(2-thienyl)ethyl}-4-piperidyl}-N-phenylpropanamide).
- (36) Morpheridine.
- (37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine).
- (38) Noracymethadol.
- (39) Norlevorphanol.
- (40) Normethadone.
- (41) Norpipanone.
- (42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-{1-(2-phenethyl)-4-piperidyl}-propanamide).
- (43) PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine).
- (44) Phenadoxone.
- (45) Phenampromide.
- (46) Phenomorphan.
- (47) Phenoperidine.
- (48) Piritramide.
- (49) Proheptazine.
- (50) Properidine.
- (51) Propiram.
- (52) Racemoramide.
- (53) Thiofentanyl (N-phenyl-N-{1-(2-thienyl)ethyl}-4-piperidyl}-propanamide).
- (54) Tilidine.
- (55) Trimeperidine.
- (56) 3,4-dichloro-N-{(1-dimethylamino)cyclohexylmethyl}benzamide. Some trade or other names: AH-7921.
- (57) N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Some trade or other names: Acetyl Fentanyl.
- (58) N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide. Other name: Butyryl Fentanyl.
- (59) N-{1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl}-N-phenylpropanamide. Other name: Beta-Hydroxythiofentanyl.
- (60) N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide. Other name: Furanyl Fentanyl.
- (61) 3,4-Dichloro-N-{2-(dimethylamino)cyclohexyl}-N-methylbenzamide. Other name: U-47700.
- (62) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide. Other names: Acryl Fentanyl or Acryloylfentanyl.
- (63) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide. Other names: 4-fluoroisobutyryl fentanyl, para-fluoroisobutyryl fentanyl.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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- (64) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide. Other names: ortho-fluorofentanyl or 2-fluorofentanyl.
- (65) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide. Other name: tetrahydrofuranfentanyl.
- (66) 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Other name: methoxyacetyl fentanyl.
- (67) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide. Other name: cyclopropyl fentanyl.
- (68) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide. Other name: para-fluorobutyrylfentanyl.
- (69) N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide. Other name: Oxycodone.
- (70) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine. Other name: MT-45.

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Acetorphine.
- (2) Acetyldihydrocodeine.
- (3) Benzylmorphine.
- (4) Codeine methylbromide.
- (5) Codeine-N-oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Drotebanol.
- (10) Etorphine (except hydrochloride salt).
- (11) Heroin.
- (12) Hydromorphanol.
- (13) Methyldesorphine.
- (14) Methyldihydromorphine.
- (15) Morphine methylbromide.
- (16) Morphine methylsulfonate.
- (17) Morphine-N-oxide.
- (18) Myrophine.
- (19) Nicocodeine.
- (20) Nicomorphine.
- (21) Normorphine.
- (22) Pholcodine.
- (23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers): (EXPLANATION--Within the following chemical designations, character

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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symbol substitutions were made from the original text: "@" = Greek alpha, "&" = Greek beta, "' = prime mark and "Δ" = triangle.)

- (1) 4-bromo-2, 5-dimethoxy-amphetamine Some trade or other names: 4-bromo-2, 5-dimethoxy-@-methylphenethylamine; 4-bromo-2, 5-DMA.
- (2) 2, 5-dimethoxyamphetamine Some trade or other names: 2, 5-dimethoxy-@-methylphenethylamine; 2,5-DMA.
- (3) 4-methoxyamphetamine Some trade or other names: 4-methoxy-@-methylphenethylamine; paramethoxyamphetamine, PMA.
- (4) 5-methoxy-3, 4-methylenedioxy -amphetamine.
- (5) 4-methyl-2, 5-dimethoxy-amphetamine Some trade and other names: 4-methyl-2, 5-dimethoxy-@-methylphenethylamine; "DOM"; and "STP".
- (6) 3, 4-methylenedioxy amphetamine.
- (7) 3, 4, 5-trimethoxy amphetamine.
- (8) Bufotenine Some trade and other names: 3-(&-dimethylaminoethyl)-5 hydroxindole; 3-(2-dimethylaminoethyl)- 5-indolol; N, N-dimethylserotonin; -5-hydroxy-N, N-dimethyltryptamine; mappine.
- (9) Diethyltryptamine Some trade and other names: N, N-diethyltryptamine; DET.
- (10) Dimethyltryptamine Some trade or other names: DMT.
- (11) Ibogane Some trade and other names: 7-ethyl-6, 6&, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5h-pyrido {1',2':1,2} azepino {5,4-b} indole: tabernanthe iboga.
- (12) Lysergic acid diethylamide.
- (13) Mescaline.
- (14) Parahexyl. Some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetra hydro-6,6,9-trimethyl-6H-dibenfo {b,d} pyran.
- (15) Peyote. Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts.
- (16) N-ethyl-3-piperidyl benzilate.
- (17) N-methyl-3-piperidyl benzilate.
- (18) Psilocybin.
- (19) Psilocyn.
- (20) Tetrahydrocannabinols. Synthetic tetrahydrocannabinols not derived from the cannabis plant that are equivalents of the substances contained in the plant, or in the resinous extractives of cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
delta 1 cis or trans tetrahydrocannabinol, and their optical isomers
delta 6 cis or trans tetrahydrocannabinol, and their optical isomers
delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers (since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered). Any Federal Food and Drug Administration approved product containing tetrahydrocannabinol shall not be considered a synthetic tetrahydrocannabinol.
- (21) Ethylamine analog of phencyclidine. Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine cyclohexamine, PCE.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (22) Pyrrolidine analog of phencyclidine. Some trade or other names
1-(1-phenylcyclohexyl)-pyrrolidine; PCPy, PHP.
- (23) Thiophene analog of phencyclidine. Some trade or other names:
1-{1-(2-thienyl)-cyclohexyl}-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP.
- (24) 3,4-methylenedioxyamphetamine (MDMA).
- (25) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4
(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA.
- (26) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4
(methylenedioxy) phenethylamine, and N-hydroxy MDA.
- (27) 1-{1-(2-thienyl) cyclohexyl} pyrrolidine. Some other names: TCPY.
- (28) Alpha-ethyltryptamine. Some trade or other names: etryptamine; Monase;
Alpha-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; Alpha-ET or AET.
- (29) 2,5-dimethoxy-4-ethylamphetamine. Some trade or other names: DOET.
- (30) 4-Bromo-2,5-dimethoxyphenethylamine. Some trade or other names:
2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus.
- (31) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7), its optical isomers, salts and salts of
isomers.
- (33) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, also known as 25I-NBOMe;
2C-I-NBOMe; 25I; or Cimbi-5.
- (34) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, also known as 25
CNBOMe; 2C-C-NBOMe; 25C; or Cimbi-82.
- (35) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, also known as, 25
BNBOMe; 2C-B-NBOMe; Cimbi-36.
- (36) 5-methoxy-N,N-dimethyltryptamine.
- (37) Alpha-methyltryptamine. Some trade or other names: AMT.
- (38) 5-methoxy-N,N-diisopropyltryptamine. Some trade or other names: 5-MeO-DIPT.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Mecloqualone.
- (2) Methaqualone.
- (3) Phencyclidine.
- (4) Gamma hydroxybutyric acid, and salt, hydroxybutyric compound, derivative or preparation of gamma hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma hydroxybutyric acid, except gamma-butyrolactone, whenever the existence of such isomers, esters and ethers and salts is possible within the specific chemical.
- (5) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone;
2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide;
1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0) when any such substance is intended for human consumption.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(6) 1,4 butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glyco; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene Abstract Service number (110-63-4) when any such substance is intended for human consumption.

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Fenethylamine.

(2) N-ethylamphetamine.

(3) (+ -)cis-4-methylaminorex ((+ -)cis-4,5-dihydro-4-methyl -5-phenyl-2-oxazolamine).

(4) N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine).

(5) Methcathinone (some other names: 2-(methylamino) - propiophenone; alpha-(methylamino) propiophenone; 2-(methylamino) -1-phenylpropan-1-one; alpha-N- methylaminopropiophenone; monomethylpropion; ephedrone, N-methylcathinone, methylcathinone; AL-464; AL-422; AL-463 and UR1432), its salts, optical isomers and salts of optical isomers.

(6) Aminorex. Some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine.

(7) Cathinone. Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone.

(8) N-benzylpiperazine (some other names: BZP; 1-benzylpiperazine), its optical isomers, salts and salts of isomers.

(9) 4-methyl-N-methylcathinone or 4-Methylmethcathinone, also known as Mephedrone.

(10) 3,4-methylenedioxypropylamphetamine or Methylenedioxypropylamphetamine, also known as MDPV.

(11) 3,4-methylenedioxy-N-methylcathinone (some other names: methylone).

(12) 4-Methoxymethcathinone.

(13) 3-Fluoromethcathinone.

(14) 4-Fluoromethcathinone.

(15) Ethylpropion (Ethcathinone).

(16) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

(17) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

(18) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

(19) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

(20) 2-{4-(Ethylthio)-2,5-dimethoxyphenyl}ethanamine (2C-T-2).

(21) 2-{4-(Isopropylthio)-2,5-dimethoxyphenyl}ethanamine (2C-T-4).

(22) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).

(23) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).

(24) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(g) Synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following synthetic cannabinoid substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (1) (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone. Some trade or other names: UR-144.
- (2) {1-(5-fluoro-pentyl)-1H-indol-3-yl}(2,2,3,3-tetramethylcyclopropyl) methanone. Some trade names or other names: 5-fluoro-UR-144, XLR11.
- (3) N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide. Some trade or other names: APINACA, AKB48.
- (4) quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate. Some trade or other names: PB-22; QUPIC.
- (5) quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate. Some trade or other names: 5-fluoro-PB-22; 5F-PB-22.
- (6) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide. Some trade or other names: AB-FUBINACA.
- (7) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Some trade or other names: ADB-PINACA.
- (8) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide. Some trade or other names: AB-CHMINACA.
- (9) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Some trade or other names: AB-PINACA.
- (10) {1-(5-fluoropentyl)-1H-indazol-3-yl}(naphthalen-1-yl)methanone. Some trade or other names: THJ-2201.

(h) (1) Cannabimimetic agents. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation that is not approved by the federal food and drug administration (FDA) which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) As used in this subdivision, the term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

- (i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.
- (ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.
- (iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.
- (iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.
- (v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(3) Such term includes:

- (i) 5-(1,1-dimethylheptyl)-2-((1R,3S)-3-hydroxycyclohexyl)-phenol (CP-47,497);

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (ii) 5-(1,1-dimethyloctyl)-2-{{(1R,3S)-3-hydroxycyclohexyl}}-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);
- (iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);
- (iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);
- (v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);
- (vi) 1-{{2-(4-morpholinyl)ethyl}}-3-(1-naphthoyl)indole (JWH-200);
- (vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);
- (viii) 1-pentyl-3-{{1-(4-methoxynaphthoyl)}}indole (JWH-081);
- (ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
- (x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
- (xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);
- (xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);
- (xiii) 1-pentyl-3-{{(4-methoxy)-benzoyl}}indole (SR-19 and RCS-4);
- (xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and
- (xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

1. Raw opium.
2. Opium extracts.
3. Opium fluid.
4. Powdered opium.
5. Granulated opium.
6. Tincture of opium.
7. Codeine.
8. Ethylmorphine.
9. Etorphine hydrochloride.
10. Hydrocodone (also known as dihydrocodeinone).
11. Hydromorphone.
12. Metopon.
13. Morphine.
14. Oxycodone.
15. Oxymorphone.
16. Thebaine.
17. Dihydroetorphine.
18. Oripavine.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances including cocaine and ecgonine, their salts, isomers, and salts of isomers, except that the substances shall not include: (A) decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; or (B) {123I} ioflupane.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy).

(b-1) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than three hundred milligrams of dihydrocodeinone (hydrocodone) per one hundred milliliters or not more than fifteen milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than three hundred milligrams of dihydrocodeinone (hydrocodone) per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(c) Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

(1) Alfentanil.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (non-dosage forms).

(6) Carfentanil.

(7) Dihydrocodeine.

(8) Diphenoxylate.

(9) Fentanyl.

(10) Isomethadone.

(11) Levo-alpha-acetylmethadol (also known as levo-alpha-acetylmethadol, levomethadylacetate or LAAM).

(12) Levomethorphan.

(13) Levorphanol.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (14) Metazocine.
- (15) Methadone.
- (16) Methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
- (17) Moramide-intermediate, 2-methyl-3-morpholino-1, 1--diphenylpropane--carboxylic acid.
- (18) Pethidine (meperidine).
- (19) Pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
- (20) Pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
- (21) Pethidine-intermediate-C, 1--methyl--4-- phenylpiperidine--4--carboxylic acid.
- (22) Phenazocine.
- (23) Piminodine.
- (24) Racemethorphan.
- (25) Racemorphan.
- (26) Sufentanil.
- (27) Remifentanil.
- (28) Tapentadol.
- (29) Thiafentanil.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

- (1) Amphetamine.
- (2) Methamphetamine.
- (3) Phenmetrazine.
- (4) Methylphenidate.
- (5) Lisdexamfetamine.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Amobarbital.
- (2) Glutethimide.
- (3) Pentobarbital.
- (4) Secobarbital.

(f) Hallucinogenic substances.

Nabilone: Another name for nabilone: (+,-)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7, 8, 10, 10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo{b,d}pyran-9-one.

(g) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

- (1) Immediate precursor to amphetamine and methamphetamine:

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(i) Phenylacetone Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) Immediate precursors to phencyclidine(PCP):

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile (PCC).

(3) Immediate precursor to fentanyl:

(i) 4-anilino-N-phenethyl-4-piperidine (ANPP).

(h) Anabolic steroids. Unless specifically excepted or unless listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids and dehydroepiandrosterone) and includes:

(1) 3 β , 17-dihydroxy-5 α -androstane.

(2) 3 α , 17 β -dihydroxy-5 α -androstane.

(3) 5 α -androstane-3,17-dione.

(4) 1-androstenediol (3 β ,17 β -dihydroxy-5 α -androst-1-ene).

(5) 1-androstenediol (3 α ,17 β -dihydroxy-5 α -androst-1-ene).

(6) 4-androstenediol (3 β , 17 β -dihydroxy-androst-4-ene).

(7) 5-androstenediol (3 β , 17 β -dihydroxy-androst-5-ene).

(8) 1-androstenedione (5 α -androst-1-en-3,17-dione).

(9) 4-androstenedione (androst-4-en-3,17-dione).

(10) 5-androstenedione (androst-5-en-3,17-dione).

(11) Bolasterone (7 α ,17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one).

(12) Boldenone (17 β -hydroxyandrost-1, 4,diene-3-one).

(13) Boldione (androsta-1,4-diene-3,17-dione).

(14) Calusterone (7 β , 17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one).

(15) Clostebol (4-chloro-17 β -hydroxyandrost-4-en-3-one).

(16) Dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1, 4-dien-3-one).

(17) Δ^1 -dihydrotestosterone (a.k.a. '1-testosterone') (17 β -hydroxy-5 α -androst-1-en-3-one).

(18) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one).

(19) Drostanolone (17 β -hydroxy-2 α -methyl-5 α -androstane-3-one).

(20) Ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene).

(21) Fluoxymesterone (9-fluoro-17 α -methyl-11 β , 17 β -dihydroxyandrost-4-en-3-one).

(22) Formebolone (2-formyl-17 α -methyl-11 α ,17 β -dihydroxyandrost-1, 4-dien-3-one).

(23) Furazabol (17 α -methyl-17 β -hydroxyandrostano{2, 3-c}-furan).

(24) 13 β -ethyl-17 β -hydroxygon-4-en-3-one.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (25) 4-hydroxytestosterone (4, 17{beta}-dihydroxy-androst-4-en-3-one).
- (26) 4-hydroxy-19-nortestosterone (4,17{beta}-dihydroxy-estr-4-en-3-one).
- (27) desoxymethyltestosterone (17{alpha}-methyl-5{alpha}-androst-2-en-17{beta}-ol) (a.k.a., madol).
- (28) Mestanolone (17{alpha}-methyl-17{beta}-hydroxy-5-androstan-3-one).
- (29) Mesterolone (1{alpha} methyl-17{beta}-hydroxy-5{alpha}-androstan-3-one).
- (30) Methandienone (17{alpha}-methyl-17{beta}-hydroxyandrost-1,4-dien-3-one).
- (31) Methandriol (17{alpha}-methyl-3{beta}, 17{beta}-dihydroxyandrost-5-ene).
- (32) Methenolone (1-methyl-17{beta}-hydroxy-5{alpha}-androst-1-en-3-one).
- (33) 17{alpha}-methyl-3{beta},17{beta}-dihydroxy-5a-androstane.
- (34) 17{alpha}-methyl-3{alpha}, 17{beta}-dihydroxy- 5a-androstane.
- (35) 17{alpha}-methyl-3{beta}, 17{beta}-dihydroxyandrost-4-ene.
- (36) 17{alpha}-methyl-4-hydroxynandrolone
(17{alpha}-methyl-4-hydroxy-17{beta}-hydroxyestr-4-en-3-one).
- (37) Methyldienolone (17{alpha}-methyl-17{beta}-hydroxyestra-4,9(10)-dien-3-one).
- (38) Methyltrienolone (17{alpha}-methyl-17{beta}-hydroxyestra-4,9-11-trien-3-one).
- (39) Methyltestosterone (17{alpha}-methyl-17{beta}-hydroxyandrost-4-en-3-one).
- (40) Mibolerone (7{alpha},17{alpha}-dimethyl-17{beta}-hydroxyestr-4-en-3-one).
- (41) 17{alpha}-methyl-{\Delta}1
1-dihydrotestosterone(17b{beta}-hydroxy-17{alpha}-methyl-5{alpha}-androst-1-en-3-one) (a.k.a.
'17-{\alpha}-methyl-1-testosterone').
- (42) Nandrolone(17{beta}-hydroxyestr-4-en-3-one).
- (43) 19-nor-4-androstenediol (3{beta},17{beta}-dihydroxyestr -4-ene).
- (44) 19-nor-4-androstenediol (3{alpha},17{beta}-dihydroxyestr-4-ene).
- (45) 19-nor-5-androstenediol (3{beta},17{beta}-dihydroxyestr -5-ene).
- (46) 19-nor-5-androstenediol (3{alpha},17{beta}-dihydroxyestr-5-ene).
- (47) 19-nor-4,9(10)-androstadienedione(estra-4,9(10)-diene-3,17-dione).
- (48) 19-nor-4-androstenedione (estr-4-en-3,17-dione).
- (49) 19-nor-5-androstenedione (estr-5-en-3,17-dione).
- (50) Norbolethone (13{beta}, 17{alpha}-diethyl-17{beta}-hydroxygon-4-en-3-one).
- (51) Norclostebol (4-chloro-17{beta}-hydroxyestr-4-en-3-one).
- (52) Norethandrolone (17{alpha}-ethyl-17{beta}-hydroxyestr-4-en-3-one).
- (53) Normethandrolone (17{alpha}-methyl-17{beta}-hydroxyestr-4-en-3-one).
- (54) Oxandrolone (17{alpha}-methyl-17{beta}-hydroxy-2-oxa-5{alpha}-androstan-3-one).
- (55) Oxymesterone (17{alpha}-methyl-4, 17{beta}-dihydroxyandrost-4-en-3-one).
- (56) Oxymetholone (17{alpha}-methyl-2-hydroxymethylene-17{beta}-hydroxy-5{alpha}-androstan-3-one).
- (57) Stanozolol (17{alpha}-methyl-17{beta}-hydroxy-5{alpha}-androst-2-eno{3, 2-c}-pyrazole).
- (58) Stenbolone (17{beta}-hydroxy-2-methyl-5{alpha}-androst-1-en-3-one).
- (59) Testolactone (13-hydroxy-3-oxo-13, 17-secoandrosta-1, 4-dien-17-oic acid lactone).
- (60) Testosterone (17{beta}-hydroxyandrost-4-en-3-one).
- (61) Tetrahydrogestrinone (13{beta}, 17{alpha}-diethyl-17{beta}-hydroxygon-4, 9, 11-trien-3-one).
- (62) Trenbolone (17{beta}-hydroxyestr-4, 9, 11-trien-3-one).
- (63) Any salt, ester or ether of a drug or substance described or listed in this subdivision.

(i) Subdivision (h) of this section shall not include any substance containing anabolic steroids expressly intended for administration through implants to cattle or other nonhuman species and that

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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are approved by the federal food and drug administration solely for such use. Any individual who knowingly and willfully administers to himself or another person, prescribes, dispenses or distributes such substances for other than implantation to cattle or nonhuman species shall be subject to the same penalties as a practitioner who violates the provisions of this section or any other penalties prescribed by law.

Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August twenty-five, nineteen hundred seventy-one, as excepted compounds under title twenty-one, section 308.32 of the code of federal regulations and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Any compound, mixture or preparation containing: (i) Amobarbital; (ii) Secobarbital; (iii) Pentobarbital; or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing: (i) Amobarbital; (ii) Secobarbital; (iii) Pentobarbital; or any salt of any of these drugs and approved by the federal food and drug administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(11) Tiletamine and zolazepam or any salt thereof. Some trade or other names for tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-{3,4-e}{1,4}-diazepin-7(1H)-one, flupyrazapon.

(12) Gamma hydroxybutyric acid, and salt, hydroxybutyric compound, derivative or preparation of gamma hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma hydroxybutyric acid, contained in a drug product for which an application has been approved under section 505 of the federal food, drug and cosmetic act.

(13) Ketamine, its salts, isomers and salts of isomers (some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone).

(14) Embutramide.

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 1.8 grams of dihydrocodeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(4) Not more than three hundred milligrams of ethylmorphine per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than five hundred milligrams of opium per one hundred milliliters or per one hundred grams or not more than twenty-five milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than fifty milligrams of morphine per one hundred milliliters or per one hundred grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Buprenorphine in any quantities.

(f) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product.

Some other names for dronabinol include: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo{b,d}pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.

(g) Chorionic gonadotropin. (1) Unless specifically excepted or unless listed in another schedule any material, compound, mixture, or preparation which contains any amount of chorionic gonadotropin.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(2) Paragraph one of this subdivision shall not include any substance containing chorionic gonadotropin expressly intended for administration through implants or injection to cattle or other nonhuman species and that are approved by the federal food and drug administration solely for such use. Any individual who knowingly and willfully administers to himself or another person, prescribes, dispenses or distributes such substances for other than implantation or injection to cattle or nonhuman species shall be subject to the same penalties as a practitioner who violates the provisions of this section or any other penalties prescribed by law.

Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than one milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam.

(2) Barbitol.

(3) Bromazepam.

(4) Camazepam.

(5) Chloral betaine.

(6) Chloral hydrate.

(7) Chlordiazepoxide.

(8) Clobazam.

(9) Clonazepam.

(10) Clorazepate.

(11) Clotiazepam.

(12) Cloxazolam.

(13) Delorazepam.

(14) Diazepam.

(15) Estazolam.

(16) Ethchlorvynol.

(17) Ethinamate.

(18) Ethyl Loflazepate.

(19) Fludiazepam.

(20) Flunitrazepam.

(21) Flurazepam.

(22) Halazepam.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (23) Haloxazolam.
- (24) Ketazolam.
- (25) Loprazolam.
- (26) Lorazepam.
- (27) Lormetazepam.
- (28) Mebutamate.
- (29) Medazepam.
- (30) Meprobamate.
- (31) Methohexital.
- (32) Methylphenobarbital (mephobarbital).
- (33) Nimetazepam.
- (34) Nitrazepam.
- (35) Nordiazepam.
- (36) Oxazepam.
- (37) Oxazolam.
- (38) Paraldehyde.
- (39) Petrichoral.
- (40) Phenobarbital.
- (41) Pinazepam.
- (42) Prazepam.
- (43) Temazepam.
- (44) Tetrazepam.
- (45) Triazolam.
- (46) Midazolam.
- (47) Quazepam.
- (48) Zolpidem.
- (49) Dichloralphenazone.
- (50) Zaleplon.
- (51) Zopiclone (eszopiclone).
- (52) Fospropofol.
- (53) Carisoprodol.

* (d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible:

- (1) Fenfluramine.

* NB Repealed upon the removal of fenfluramine and its salts and isomers from Schedule IV of the federal Controlled Substances Act

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers:

- (1) Cathine ((+) - norpseudoephedrine).
- (2) Diethylpropion.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (3) Fencamfamin.
- (4) Fenproporex.
- (5) Mazindol.
- (6) Mefenorex.
- (7) Pemoline (including organometallic complexes and chelates thereof).
- (8) Phentermine.
- (9) Pipradrol.
- (10) SPA((-))-1-dimethylamino-1, 2-diphenylethane).
- (11) Modafinil.
- (12) Sibutramine.

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

- (1) Pentazocine.
- (2) Butorphanol (including its optical isomers).
- (3) Tramadol in any quantities.

Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

- (1) Not more than two hundred milligrams of codeine per one hundred milliliters or per one hundred grams.
- (2) Not more than one hundred milligrams of dihydrocodeine per one hundred milliliters or per one hundred grams.
- (3) Not more than one hundred milligrams of ethylmorphine per one hundred milliliters or per one hundred grams.
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than twenty-five micrograms of atropine sulfate per dosage unit.
- (5) Not more than one hundred milligrams of opium per one hundred milliliters or per one hundred grams.
- (6) Not more than 0.5 milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Pyrovalerone.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Ezogabine {N-{2-amino-4-(4-fluorobenzylamino)-phenyl}-carbamic acid ethyl ester}.

(2) Lacosamide {(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide}.

(3) Pregabalin {(S)-3-(aminomethyl)-5-methylhexanoic acid }.

§ 3307. Exception from schedules.

1. The commissioner may, by regulation, except any compound, mixture, or preparation containing any depressant substance in paragraph (a) of schedule III or in schedule IV from the application of all or any part of this article if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant effect on the central nervous system.
2. The commissioner may, by regulation, reclassify as a schedule III substance, any compound, mixture or preparation containing any stimulant substance listed in paragraph (c) of schedule II, if
 - (a) the compound, mixture or preparation contains one or more active medicinal ingredients not having a stimulant effect on the central nervous system; and
 - (b) such ingredients are included therein in such combinations, quantity, proportion or concentration as to vitiate the potential for abuse of the substances which do have a stimulant effect on the central nervous system.
3. The commissioner may, by regulation, except any compound, mixture or preparation containing a narcotic antagonist substance from the application of all or any part of this article if (1) such compound, mixture or preparation has no potential for abuse, and (2) such compound, mixture or preparation has been excepted or exempted from control under the Federal Controlled Substances Act.
4. The commissioner may by regulation exempt or reclassify any compound, mixture or preparation containing any substance listed in subdivision (h) or (j) of Schedule II of section three thousand three hundred six of this article as a Schedule III, IV or V substance if (a) the compound, mixture or preparation contains one or more active medicinal ingredients not found in subdivision (h) or (j) of Schedule II of section three thousand three hundred six of this article; and (b) such ingredients are included therein in such combinations, quantity, proportion or concentration as to substantially reduce the potential for abuse.
5. The commissioner may by regulation or emergency regulation, reclassify any compound, mixture or preparation containing any substance listed in Schedule I of section three thousand three hundred six of this title as a Schedule II, III, IV or V substance, or exempt it from this article, if

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

that same compound, mixture or preparation is redesignated or rescheduled other than under Schedule I under the federal Controlled Substances Act, or deleted as a controlled substance under the federal Controlled Substances Act. If the commissioner acts under this subdivision and does not exempt the compound, mixture or preparation from this article, he or she may only reclassify it to a newly created subdivision in the same numbered schedule or a higher numbered schedule than to which it is redesignated or rescheduled under the federal act.

6. The commissioner shall establish minimum standards for the storage, reporting, ordering and record keeping of controlled substances specified in subdivision (b-1) of schedule II of section thirty-three hundred six of this article by manufacturers and distributors as if such substances were set forth in schedule III of section thirty-three hundred six of this article.

§ 3308. Powers and duties of the commissioner.

1. The commissioner, and any representative authorized by him, shall have the power to administer oaths, compel the attendance of witnesses and the production of books, papers and records and to take proof and testimony concerning all matters within the jurisdiction of the department.
2. The commissioner is hereby authorized and empowered to make any rules, regulations and determinations which in his judgment may be necessary or proper to supplement the provisions of this article to effectuate the purposes and intent thereof or to clarify its provisions so as to provide the procedure or details to secure effective and proper enforcement of its provisions.
3. No rule or regulation hereunder shall become effective unless, at least twenty-one days prior to the proposed effective date, persons who have conveyed to the department in writing a request to be notified of proposed changes and additions to the department's rules and regulations under this article have been provided with the text of such proposed rules and regulations and have been given an opportunity to comment in writing thereon.
4. The rules, regulations and determinations, when made and promulgated by the commissioner, shall be the rules, regulations and determinations of the department and, until modified or rescinded, shall have the force and effect of law. It shall be the duty of the department, to enforce all of the provisions of this article and all of the rules, regulations and determinations made thereunder.
5. Notwithstanding any inconsistent provision of this article, the commissioner in consultation with the commissioner of education is hereby authorized to promulgate regulations regarding the prescribing, dispensing, use and transmission of electronic prescriptions, which may be prescribed and dispensed in lieu of an official New York state prescription.
6. The commissioner in consultation with the commissioner of education is hereby authorized to promulgate regulations regarding the dispensing of out-of-state prescriptions.

§ 3309. Opioid overdose prevention.

1. The commissioner is authorized to establish standards for approval of any opioid overdose prevention program, and opioid antagonist prescribing, dispensing, distribution, possession and administration pursuant to this section which may include, but not be limited to, standards for program directors, appropriate clinical oversight, training, record keeping and reporting.
2. Notwithstanding any inconsistent provisions of section sixty-five hundred twelve of the education law or any other law, the purchase, acquisition, possession or use of an opioid antagonist pursuant to this section shall not constitute the unlawful practice of a profession or other violation under title eight of the education law or this article.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

3. (a) As used in this section:

- (i) "Opioid antagonist" means a drug approved by the Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. "Opioid antagonist" shall be limited to naloxone and other medications approved by the department for such purpose.
 - (ii) "Health care professional" means a person licensed, registered or authorized pursuant to title eight of the education law to prescribe prescription drugs.
 - (iii) "Pharmacist" means a person licensed or authorized to practice pharmacy pursuant to article one hundred thirty-seven of the education law.
 - (iv) "Opioid antagonist recipient" or "recipient" means a person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioid-related overdose, or an organization registered as an opioid overdose prevention program pursuant to this section or any person or entity or any person employed by the person or entity.
 - (v) As used in this section, "entity" includes, but is not limited to, a school district, public library, board of cooperative educational services, county vocational education and extension board, charter school, non-public elementary or secondary school, restaurant, bar, retail store, shopping mall, barber shop, beauty parlor, theater, sporting or event center, inn, hotel or motel.
- (b)(i) A health care professional may prescribe by a patient-specific or non-patient-specific prescription, dispense or distribute, directly or indirectly, an opioid antagonist to an opioid antagonist recipient.
- (ii) A pharmacist may dispense an opioid antagonist, through a patient-specific or non-patient-specific prescription pursuant to this paragraph, to an opioid antagonist recipient.
 - (iii) An opioid antagonist recipient may possess an opioid antagonist obtained pursuant to this paragraph, may distribute such opioid antagonist to a recipient, and may administer such opioid antagonist to a person the recipient reasonably believes is experiencing an opioid overdose.
 - (iv) The provisions of this paragraph shall not be deemed to require a prescription for any opioid antagonist that does not otherwise require a prescription; nor shall it be deemed to limit the authority of a health care professional to prescribe, dispense or distribute, or of a pharmacist to dispense, an opioid antagonist under any other provision of law.
 - (v) Any pharmacy with twenty or more locations in the state, shall either: (1) pursue or maintain a non-patient-specific prescription with an authorized health care professional to dispense an opioid antagonist to a consumer upon request, as authorized by this section; or (2) register with the department as an opioid overdose prevention program.

3-a. Any distribution of opioid antagonists through this program shall include an informational card or sheet. The informational card or sheet shall include, at a minimum, information on:

- (a) how to recognize symptoms of an opioid overdose;
- (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders;
- (c) the number for the toll free office of alcoholism and substance abuse services HOPE line;
- (d) how to access the office of alcoholism and substance abuse services' website; and
- (e) the application of good samaritan protections provided in section three thousand-a of this chapter; and
- (f) any other information deemed relevant by the commissioner.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

The educational card shall be provided in languages other than English as deemed appropriate by the commissioner. The department shall make such informational cards available to the opioid overdose prevention programs.

4.(a) Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.

(b) A recipient, opioid overdose prevention program, person or entity, or any person employed by the person or entity, acting reasonably and in good faith in compliance with this section, shall not be subject to criminal, civil or administrative liability solely by reason of such action.

5. The commissioner shall publish findings on statewide opioid overdose data that reviews overdose death rates and other information to ascertain changes in the cause and rates of fatal opioid overdoses. The report may be part of existing state mortality reports issued by the department, and shall be submitted annually, on or before October first, to the governor, the temporary president of the senate, the speaker of the assembly and the chairs of the senate and assembly health committees, and shall be made public on the department's internet website. The report shall include, at a minimum, the following information on a county basis:

(a) information on opioid overdose deaths, including age, gender, ethnicity, and geographic location

(b) data on emergency room utilization for the treatment of opioid overdose;

(c) data on utilization of pre-hospital services;

(d) data on dispensing and utilization of opioid antagonists; and

(e) any other information necessary to ascertain the success of the program, areas of the state which are experiencing particularly high rates of overdoses, ways to determine if services, resources and responses in particular areas of the state are having a positive impact on reducing overdoses, and ways to further reduce overdoses.

* 6. The commissioner shall provide the current information and data specified by each type of drug included in the report required by subdivision five of this section to each county every three months. The office of addiction services and supports website shall include a hyperlink to such information and data may be utilized by a county or any combination thereof as it works to address the opioid epidemic.

* **NB Repealed March 31, 2027**

7. With the first prescription to a particular patient of an opioid of each year for use in a setting other than a general hospital or nursing home under article twenty-eight of this chapter or facility under article thirty-one of the mental hygiene law, or when a practitioner is prescribing a controlled substance to a patient under the care of hospice as defined by section four thousand two of this chapter, the prescriber shall prescribe an opioid antagonist when any of the following risk factors are present: (a) a history of substance use disorder; (b) high dose or cumulative prescriptions that result in ninety morphine milligram equivalents or higher per day; (c) concurrent use of opioids and benzodiazepine or nonbenzodiazepine sedative hypnotics.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3309-a. Prescription pain medication awareness program.

1. There is hereby established within the department a prescription pain medication awareness program to educate the public and health care practitioners about the risks associated with prescribing and taking controlled substance pain medications.

2. Within the amounts appropriated, the commissioner, in consultation with the commissioner of the office of alcoholism and substance abuse services, shall develop and conduct a public health education media campaign designed to alert youth, parents and the general population about the risks associated with prescription pain medications and the need to properly dispose of any unused medication. In developing this campaign, the commissioner shall consult with and use information provided by the work group established pursuant to subdivision four of this section and other relevant professional organizations. The campaign shall include an internet website providing information for parents, children and health care professionals on the risks associated with taking opioids and resources available to those needing assistance with prescription pain medication addiction. Such website shall also provide information regarding where individuals may properly dispose of controlled substances in their community and include active links to further information and resources. The campaign shall begin no later than September first, two thousand twelve.

3. Course work or training in pain management, palliative care and addiction.

(a) Every person licensed under title eight of the education law to treat humans, registered under the federal controlled substances act and in possession of a registration number from the drug enforcement administration, United States Department of Justice or its successor agency, and every medical resident who is prescribing under a facility registration number from the drug enforcement administration, United States Department of Justice or its successor agency, shall, on or before July first, two thousand seventeen and once within each three year period thereafter, complete three hours of course work or training in pain management, palliative care, and addiction approved by the department.

(b) Every person licensed on or after July first, two thousand seventeen under title eight of the education law to treat humans, registered under the federal controlled substances act and in possession of a registration number from the drug enforcement administration, United States Department of Justice or its successor agency, and every medical resident who begins prescribing under a facility registration number from the drug enforcement administration, United States Department of Justice or its successor agency on or after July first, two thousand seventeen, shall complete such course work or training within one year of such registration and once within each three year period thereafter.

(c) The commissioner, in consultation with the department of education and the office of alcoholism and substance abuse services, shall establish standards and review and approve course work or training in pain management, palliative care, and addiction and shall publish information related to such standards, course work or training on the department's website.

(d) Existing course work or training, including course work or training developed by a nationally recognized health care professional, specialty, or provider association, or nationally recognized pain management association, may be considered in implementing this subdivision.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(e) Nothing shall preclude course work or training that meets the requirements of paragraph (c) of this subdivision from counting toward this requirement if taken online.

(f) Course work or training shall include, but not be limited to: state and federal requirements for prescribing controlled substances; pain management; appropriate prescribing; managing acute pain; palliative medicine; prevention, screening and signs of addiction; responses to abuse and addiction; and end of life care.

(g) Each licensed person required by this subdivision to complete course work or training shall document to the department by attestation on a form prescribed by the commissioner that such licensed person has completed the course work or training required by this subdivision. For medical residents who are prescribing under a facility registration number from the drug enforcement administration, United States Department of Justice or its successor agency, such attestation shall be made by the facility.

(h) The department shall institute a procedure for application for an exemption from said requirement. The department may provide an exemption from the course work and training required by this subdivision to any such licensed person who: (i) clearly demonstrates to the department's satisfaction that there would be no need for him or her to complete such course work or training; or (ii) that he or she has completed course work or training deemed by the department to be equivalent to the course work or training approved by the department pursuant to this subdivision.

(i) Nothing herein shall preclude such course work or training in pain management, palliative care, and addiction from counting toward continuing education requirements under title eight of the education law to the extent provided in the regulations of the commissioner of education.

(j) Nothing herein shall preclude such course work or training in pain management, palliative care, and addiction from counting toward continuing education requirements of a nationally accredited medical board to the extent acceptable to such board.

4. Establish a work group, no later than June first, two thousand twelve, which shall be composed of experts in the fields of palliative and chronic care pain management and addiction medicine. Members of the work group shall receive no compensation for their services, but shall be allowed actual and necessary expenses in the performance of their duties pursuant to this section. The work group shall:

(a) Report to the commissioner regarding the development of recommendations and model courses for continuing medical education, refresher courses and other training materials for licensed health care professionals on appropriate use of prescription pain medication. Such recommendations, model courses and other training materials shall be submitted to the commissioner, who shall make such information available for the use in medical education, residency programs, fellowship programs, and for use in continuing medication education programs no later than January first, two thousand thirteen. Such recommendations also shall include recommendations on: (i) educational and continuing medical education requirements for practitioners appropriate to address prescription pain medication awareness among health care professionals;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(ii) continuing education requirements for pharmacists related to prescription pain medication awareness; and (iii) continuing education in palliative care as it relates to pain management, for which purpose the work group shall consult the New York state palliative care education and training council;

(b) No later than January first, two thousand thirteen, provide outreach and assistance to health care professional organizations to encourage and facilitate continuing medical education training programs for their members regarding appropriate prescribing practices for the best patient care and the risks associated with overprescribing and under prescribing pain medication;

(c) Provide information to the commissioner for use in the development and continued update of the public awareness campaign, including information, resources, and active web links that should be included on the website; and

(d) Consider other issues deemed relevant by the commissioner, including how to protect and promote the access of patients with a legitimate need for controlled substances, particularly medications needed for pain management by oncology patients, and whether and how to encourage or require the use or substitution of opioid drugs that employ tamper-resistance technology as a mechanism for reducing abuse and diversion of opioid drugs.

5. On or before September first, two thousand twelve, the commissioner, in consultation with the commissioner of the office of alcoholism and substance abuse services, the commissioner of education, and the executive secretary of the state board of pharmacy, shall add to the workgroup such additional members as appropriate so that the workgroup may provide guidance in furtherance of the implementation of the I-STOP act. For such purposes, the workgroup shall include but not be limited to consumer advisory organizations, health care practitioners and providers, oncologists, addiction treatment providers, practitioners with experience in pain management, pharmacists and pharmacies, and representatives of law enforcement agencies.

6. The commissioner shall report to the governor, the temporary president of the senate and the speaker of the assembly no later than March first, two thousand thirteen, and annually thereafter, on the work group's findings. The report shall include information on opioid overdose deaths, emergency room utilization for the treatment of opioid overdose, the utilization of pre-hospital addiction services and recommendations to reduce opioid addiction and the consequences thereof.

TITLE 2 - MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 3310. Licenses for manufacture or distribution of controlled substances.

1. No person shall manufacture or distribute a controlled substance in this state without first having obtained a license to do so from the department.
2. A license issued under this section shall be valid for two years from the date of issue, except that in order to facilitate the renewals of such licenses, the commissioner may upon the initial application for a license, issue some licenses which may remain valid for a period of time greater than two years but not exceeding an additional eleven months.
3. The fee for a license under this section shall be one thousand two hundred dollars; provided however, if the license is issued for a period greater than two years the fee shall be increased, pro rata, for each additional month of validity.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

4. Licenses issued under this section shall be effective only for and shall specify:

- (a) the name and address of the licensee;
- (b) the nature of the controlled substances, either by name or schedule, or both, which may be manufactured or distributed;
- (c) whether manufacture or distribution or both such activities are permitted by the license.

5. Upon application of a licensee, a license may be amended to allow the licensee to relocate within the state or to add a manufacturing or distributing activity or to add further substances or schedules to the manufacturing or distribution activity permitted thereunder. The fee for such amendment shall be two hundred fifty dollars.

§ 3311. Authority to issue initial licenses, amended licenses, and to renew licenses.

- 1. Subject to the provisions of this article the commissioner is authorized to issue licenses authorizing the manufacture or distribution of controlled substances.
- 2. An application for a license, amendment of a license, or renewal of a license which, if granted, would authorize the manufacture or distribution of a controlled substance which the applicant is not then authorized to manufacture or distribute shall, with respect to any such additional authorization, be treated as an application for an initial license.
- 3. An application for a license which, if granted, would authorize a licensee to continue to manufacture or distribute a controlled substance shall, with respect to such continued manufacture or distribution only, be treated as an application for renewal of a license.
- 4. A late-filed application for the renewal of a license may, in the discretion of the commissioner, be treated as an application for an initial license.

§ 3312. Application for initial license.

1. An applicant for an initial license to manufacture or distribute controlled substances shall furnish to the department such information as it shall require and evidence that the applicant:

- (a) and its managing officers are of good moral character;
- (b) possesses sufficient land, buildings and equipment to properly carry on the activity described in the application;
- (c) is able to maintain effective control against diversion of the controlled substances for which the license is sought;
- (d) is able to comply with all applicable state and federal laws and regulations relating to the manufacture or distribution of the controlled substances for which the license is sought.

2. The application shall include the name, residence address and title of each of the officers and directors and the name and residence address of any person having a ten per centum or greater proprietary, beneficial, equitable or credit interest in the applicant. Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the application setting forth:

- (a) any position of management or ownership during the preceding ten years of a ten per centum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs; and
- (b) whether such person or any such business has been convicted, fined, censured or had a license suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs; and

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(c) such other information as the commissioner may require.

3. The applicant shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application on any newly discovered or occurring fact or circumstance which is required to be included in the application.

§ 3313. Granting of initial license.

1. The commissioner shall grant an initial license or amendment to a license as to one or more of the substances or activities enumerated in the application if he is satisfied that:
 - (a) the applicant will be able to maintain effective control against diversion of controlled substances;
 - (b) the applicant will be able to comply with all applicable state and federal laws;
 - (c) the applicant and its officers are ready, willing and able to properly carry on the manufacturing or distributing activity for which a license is sought;
 - (d) the applicant possesses sufficient land, buildings and equipment to properly carry on the activity described in the application;
 - (e) it is in the public interest that such license be granted; and
 - (f) the applicant and its managing officers are of good moral character.

2. If the commissioner is not satisfied that the applicant should be issued an initial license, he shall notify the applicant in writing of those factors upon which further evidence is required. Within thirty days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing or both.

§ 3315. Applications for renewal of licenses to manufacture or distribute controlled substances.

1. An application for the renewal of any license issued pursuant to this title shall be filed with the department not more than six months nor less than four months prior to the expiration thereof.
2. The application for renewal shall include such information prepared in such manner and detail as the commissioner may require, including but not limited to:
 - (a) any material change in the circumstances or factors listed in section thirty-three hundred twelve of this article;
 - (b) every known charge or investigation, pending or concluded during the period of the license, by any governmental agency with respect to:
 - (i) each incident or alleged incident involving the theft, loss, or possible diversion of controlled substances manufactured or distributed by the applicant; and
 - (ii) compliance by the applicant with the requirements of the federal controlled substances act, or the laws of any state with respect to any substance listed in section thirty-three hundred six of this article.
3. An applicant for renewal shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.
4. If the commissioner is not satisfied that the applicant is entitled to a renewal of such license, he shall within forty-five days after the filing of the application serve upon the applicant or his attorney of record in person or by registered or certified mail an order directing the applicant to show cause

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

why his application for renewal should not be denied. Such order shall specify in detail the respects in which the applicant has not satisfied the commissioner that the license should be renewed.

5. Within thirty days of service of such order, the applicant may either submit additional material to the commissioner or demand a hearing or both. If a hearing is demanded the commissioner shall fix a date for hearing not sooner than fifteen days nor later than thirty days after receipt of the demand, unless such time limitation is waived by the applicant.

§ 3316. Granting of renewal of licenses.

1. The commissioner shall renew a license unless he determines and finds that the applicant:

(a) is unlikely to maintain or be able to maintain effective control against diversion; or
(b) is unlikely to comply with all federal and state laws applicable to the manufacture or distribution of the controlled substance or substances for which the license is sought.

* (c) is unlikely during the period of his or her license to complete the reports or to pay the ratable share required by title two-A of this article on or before the required date. Prior evidence of non-compliance shall constitute substantial evidence of such.

* NB Repealed June 30, 2024

2. For purposes of this section, proof that a licensee, during the period of his license, has failed to maintain effective control against diversion or has knowingly or negligently failed to comply with applicable federal or state laws relating to the manufacture or distribution of controlled substances, shall constitute substantial evidence that the applicant will be unlikely to maintain effective control against diversion or be unlikely to comply with the applicable federal or state statutes during the period of proposed renewal.

§ 3318. Identification of controlled substances.

1. No controlled substance may be manufactured or delivered within this state in solid or capsule form unless it has clearly marked or imprinted upon each such capsule or solid:

(a) an individual symbol or number assigned to the person who manufactured the controlled substance in such form, and
(b) a code number or symbol assigned by the commissioner identifying such substance or combination of substances.

2. No controlled substance contained within a bottle, vial, carton or other container, or in any way affixed or appended to or enclosed within a package of any kind, and designed or intended for delivery in such container or package to an ultimate consumer, shall be manufactured or distributed within this state unless such container or package has clearly and permanently marked or imprinted upon it:

(a) an individual symbol or number assigned to the person who packaged the controlled substance in such form; and
(b) a code number or symbol assigned by the commissioner identifying such substance or combination of substances.

3. The commissioner shall assign a code number or symbol to each controlled substance, and in his discretion for combinations of substances, so as to provide ready identification of such substance. Upon application by a manufacturer of controlled substances, the commissioner shall assign to such manufacturer an identifying number or symbol. Wherever

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

possible and practical, the commissioner shall assign code numbers which conform to the national drug code system.

§ 3319. Distribution of free samples. It shall be unlawful to distribute free samples of controlled substances, except to persons licensed pursuant to title III of this article.

§ 3320. Authorized distribution.

1. Controlled substances may be lawfully distributed within this state only to licensed distributors or manufacturers, practitioners, pharmacists, pharmacies, institutional dispensers, registered outsourcing facilities, and laboratory, research or instructional facilities authorized by law to possess the particular substance distributed.
2. A person authorized to obtain a controlled substance by distribution may lawfully receive such substance only from a distributor licensed pursuant to this article.

§ 3321. Exempt distribution.

1. The commissioner by regulation or ruling may exempt from the licensing requirements of this title:
 - (a) the return of controlled substances to a manufacturer, registered outsourcing facility or distributor by a practitioner or pharmacy;
 - (b) the sale of controlled substances by a pharmacy or practitioner to a pharmacy or practitioner for the immediate needs of the pharmacy or practitioner receiving such substances; and
 - (c) the disposition of controlled substances by a person in lawful possession thereof who, not in the ordinary course of business, wishes to discontinue such possession.
2. Records of such transactions shall be prepared and maintained and reports filed in such manner as the commissioner shall require.

§ 3322. Reports and records.

1. Persons licensed under this title or operating a registered outsourcing facility shall maintain records of all controlled substances manufactured, compounded, received, disposed of, delivered or distributed by them. The record shall show the date of receipt or delivery, the name and address, and registration number of the person from whom received or to whom delivered or distributed, the kind and quantity of substance received and delivered or distributed, the kind and quantity of substance produced or removed from the process of manufacture and the date thereof.
2. Any person licensed under this title or operating a registered outsourcing facility shall prepare and maintain a biennial report setting forth the current inventory of controlled substances, the quantities of controlled substances manufactured, compounded, delivered or distributed within the state during the period covered by the report and such other information as the commissioner shall by regulation prescribe. Maintaining for inspection a biennial inventory of controlled substances prepared and maintained in compliance with federal statutes and regulations shall be deemed in compliance with this section.
3. Any person licensed under this title or operating a registered outsourcing facility shall forthwith notify the department of any incident involving the theft, loss or possible diversion of controlled substances manufactured, compounded, delivered or distributed by the licensee or operator.
4. The records and reports required by this section shall be prepared, preserved, or filed in such manner and detail as the commissioner shall by regulation prescribe.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

*TITLE 2A – OPIOID STEWARDSHIP ACT

***§ 3323. Opioid Stewardship Fund**

1. Definitions:

(a) "Opioid stewardship payment" shall mean the total amount to be paid into the opioid stewardship fund for each state fiscal year as set forth in subdivision two of this section.

(b) "Ratable share" shall mean the individual portion of the opioid stewardship payment to be paid by each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York.

(c) Notwithstanding any inconsistent provision of law to the contrary, "distribute" shall mean to deliver a controlled substance other than by administering or dispensing to the ultimate user, including intra-company transfers between any division, affiliate, subsidiary, parent or other entity under complete common ownership and control. For purposes of this section, "distribute" shall not include controlled substances surrendered to reverse distributors, or donated to recipient entities or third-party intermediaries pursuant to the unused prescription drug donation and redispensing program of section two hundred eighty-b of this chapter.

2. Opioid stewardship payment imposed on manufacturers and distributors. All manufacturers and distributors licensed under this article (hereinafter referred to as "licensees"), that sell or distribute opioids in the state of New York shall be required to pay an opioid stewardship payment. On an annual basis, the commissioner shall certify to the state comptroller the amount of all revenues collected from opioid stewardship payments and any penalties imposed. The amount of revenues so certified shall be deposited quarterly into the opioid stewardship fund established pursuant to section ninety-seven-aaaaa of the state finance law. No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section.

3. Determination of opioid stewardship payment. The total opioid stewardship payment amount shall be one hundred million dollars annually, subject to downward adjustments pursuant to subdivision nine of this section.

4. Reports and records. Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall provide to the commissioner a report detailing all opioids sold or distributed by such manufacturer or distributor in the state of New York. Such report shall include:

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (a) the manufacturer's or distributor's name, address, phone number, federal Drug Enforcement Agency (DEA) registration number and controlled substance license number issued by the department;
- (b) the name, address and DEA registration number of the entity to whom the opioid was sold or distributed;
- (c) the date of the sale or distribution of the opioid;
- (d) the gross receipt total, in dollars, of all opioids sold or distributed;
- (e) the name and National Drug Code (NDC) of the opioid sold or distributed;
- (f) the number of containers and the strength and metric quantity of controlled substance in each container of the opioid sold or distributed;
- (g) the total number of morphine milligram equivalents (MMEs) sold or distributed; and
- (h) any other elements as deemed necessary by the commissioner.

4-a. Initial and future reports. (a) Such information shall be reported annually to the department in such form as defined by the commissioner, provided however that the initial report provided pursuant to subdivision four shall consist of all opioids sold or distributed in the state of New York for the two thousand seventeen calendar year, and must be submitted by August 1, 2018. Subsequent annual reports shall be submitted on April first of each year based on the actual opioid sales and distributions of the prior calendar year.

(b) For the purpose of such annual reporting, MMEs shall be determined pursuant to a formulation to be issued by the department and updated as the department deems appropriate.

5. Determination of ratable share. Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall pay a portion of the total opioid stewardship payment amount. The ratable share shall be calculated as follows:

(a) The total amount of MMEs sold or distributed in the state of New York by the licensee for the preceding calendar year, as reported by the licensee pursuant to subdivision four of this section, shall be divided by the total amount of MME sold in the state of New York by all licensees pursuant to this article to determine the licensee payment percentage. The licensee payment percentage shall be multiplied by the total opioid stewardship payment. The product of such calculation shall be the licensee's ratable share. The department shall have the authority to adjust the total number of a licensee's MMEs to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee, when making such determination and adjust the ratable share accordingly.

(b) The licensee's total amount of MME sold or distributed, as well as the total amount of MME sold or distributed by all licensees under this article, used in the calculation of the ratable share shall not include the MME of those opioids which are: (i) manufactured in New York state, but whose final point of delivery or sale is outside of New York state; (ii) sold or distributed to entities certified to operate pursuant to article thirty-two of the mental hygiene law, or article forty of the public health law; or (iii) the MMEs attributable to buprenorphine, methadone or morphine.

(c) The department shall provide to the licensee, in writing, on or before October fifteenth, two thousand eighteen, the licensee's ratable share for the two thousand seventeen calendar year. Thereafter, the department shall notify the licensee in writing annually on or before October fifteenth of each year based on the opioids sold or distributed for the prior calendar year.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

6. Payment of ratable share. The licensee shall make payments quarterly to the department with the first payment of the ratable share, provided that the amount due on January first, two thousand nineteen shall be for the full amount of the first annual payment, with additional payments to be due and owing on the first day of every quarter thereafter.
7. Rebate of ratable share. In any year for which the commissioner determines that a licensee failed to report required information as required by this section, those licensees complying with this section shall receive a reduced assessment of their ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period.
8. Licensee opportunity to appeal. A licensee shall be afforded an opportunity to submit information to the department to justify why the ratable share provided to the licensee, pursuant to paragraph (c) of subdivision five of this section, or amounts paid thereunder are in error or otherwise not warranted. If the department determines thereafter that all or a portion of such ratable share, as determined by the commissioner pursuant to subdivision five of this section, is not warranted, the department may: (a) adjust the ratable share; (b) adjust the assessment of the ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period; or © refund amounts paid in error.
9. Department annual review. The department shall annually review the amount of state operating funds spent in the office of alcoholism and substance abuse services (OASAS) budget for opioid prevention, treatment and recovery. The commissioner of OASAS shall certify to the department the amount of annual spending for such services, utilizing available information on patient demographics and the actual cost of services delivered by the state and by state-funded providers. The certification of such spending shall begin in state fiscal year two thousand eighteen-nineteen, and continue annually thereafter. The total amount of such spending shall be provided to the department by the commissioner of OASAS no later than June thirtieth of each year. There shall be no stewardship fund payments beginning on July first in the event state operating funds spent in the OASAS budget for opioid prevention, treatment and recovery in the most recently reported year is equal to or less than state operating funds spent for such purposes in state fiscal year two thousand nine-ten.
10. Penalties. (a) The department may assess a civil penalty in an amount not to exceed one thousand dollars per day against any licensee that fails to comply with subdivisions four and four-a of this section.
(b) In addition to any other civil or criminal penalty provided by law, where a licensee has failed to pay its ratable share in accordance with subdivision six of this section, the department may also assess a penalty of no less than ten percent and no greater than three hundred percent of the ratable share due from such licensee.
(c) Where the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.

* NB Repealed June 30, 2024

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

TITLE 3 - RESEARCH, INSTRUCTIONAL ACTIVITIES, AND CHEMICAL ANALYSIS RELATING TO CONTROLLED SUBSTANCES

§ 3324. Licenses to engage in research, instructional activities, and chemical analysis relating to controlled substances:

1. No person within this state shall manufacture, obtain, possess, administer or dispense a controlled substance for purposes of scientific research, instruction or chemical analysis without having first obtained a license to do so from the department.
2. A license issued under this title shall be valid for two years from the date of issue.
3. The fee for a license under this title shall be forty dollars.
4. Licenses issued under this title shall be effective only for and shall specify:
 - (a) the name and address of the licensee;
 - (b) the nature of the project or projects permitted by the license;
 - (c) the nature of the controlled substance or substances to be used in the project, by name if in schedule I, and by name or schedule or both if in any other schedule;
 - (d) whether dispensing to human subjects is permitted by the license.
5. Upon application of a person licensed pursuant to this title, a license may be amended to add a further activity or to add further substances or schedules to the project permitted thereunder. The fee for such amendment shall be twenty dollars.

§ 3325. Authority to issue licenses; applications.

1. Subject to the provisions of this title, the commissioner is authorized to license a person to manufacture, obtain and possess, dispense, and administer controlled substances for purposes of scientific research, chemical analysis or instruction.
2. A license or amendment of a license shall be issued by the department unless the applicant therefor has failed to furnish a satisfactory protocol pursuant to subdivision three of this section, or a satisfactory statement pursuant to section 3326, and proof that the applicant:
 - (a) and its managing officers are of good moral character;
 - (b) possesses or is capable of acquiring facilities, staff and equipment sufficient to carry on properly the proposed project detailed in the protocol or statement accompanying the application;
 - (c) is able to maintain effective control against diversion of the controlled substances for which the license is sought;
 - (d) is able to comply with all applicable state and federal laws and regulations relating to the controlled substances for which the license is sought.
3. An application for a license or for an amendment to a license shall be accompanied by a detailed protocol setting forth:
 - (a) the nature of the proposed project;
 - (b) the proposed quantity or quantities of each controlled substance involved;
 - (c) the qualifications and competence of the applicant to engage in such project;
 - (d) specific provisions for the safe administration or dispensing of controlled substances to humans, if such is contemplated, and the proposed method of selecting humans;
 - (e) such other additional information as the commissioner may require.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

4. The application for a license pursuant to this title shall include copies of all papers filed with the Bureau, the Federal Food and Drug Administration and any other governmental agency, whether state or federal, in connection with the applicant's proposed project.

§ 3326. Institutional research licenses.

1. Subject to the provisions of this title, the commissioner is authorized to license an institution, which regularly engages in research, to approve specific projects conducted under its immediate auspices.
2. An institution seeking a license pursuant to this section shall make application in the same manner as an applicant for a license pursuant to section 3325. However, such institution shall submit, in lieu of a detailed protocol of a specific project, a statement including:
 - (a) the qualifications and such other data as the commissioner may require regarding each member of the committee within the institution which will approve specific projects;
 - (b) a description of the system within the institution for approving, supervising and evaluating such projects.
3. Upon approval of each specific project, such institution shall forward to the commissioner a description of the project, the names and qualifications of the individuals working thereon and of those individuals designated to supervise the project. If administration or dispensing to human subjects is contemplated, there shall also be included a description of the provisions for safe administration or dispensing.
4. Such institution shall forward to the commissioner periodic progress reports and evaluations of, as well as amendments to each project, in such manner and in such detail as the commissioner may prescribe.

§ 3327. Procedure.

1. A license or amendment to a license shall be issued or refused by the department within ninety days from the date of filing of a completed application.
2. Within thirty days of notification of such refusal, the applicant may either submit additional material to the commissioner or demand a hearing or both. If a hearing is demanded the commissioner shall fix a date for hearing not sooner than fifteen days nor later than thirty days after receipt of the demand, unless such time limitation is waived by the applicant.

§ 3328. Exemptions from title. The following persons engaging in the following activities shall be exempt from the provisions of this title:

1. A practitioner lawfully administering, dispensing, or prescribing a controlled substance in the course of his professional practice to an ultimate user for a recognized medical purpose;
2. A licensed manufacturer engaged in research upon non-human subjects or chemical analysis conducted on the premises specified in the manufacturer's license;
3. A licensed distributor engaged in quality control analysis at the premises specified in his license.
4. A practitioner or patient participating in a clinical research program on the therapeutic use of marijuana or tetrahydrocannabinols. (a) Each such clinical research program shall have received protocol approval from the United States Food and Drug Administration, shall possess an effective investigational new drug application and shall have been registered by the Drug

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

Enforcement Administration, United States Department of Justice. (b) Each such clinical research program authorized under the provisions of article thirty-three-A of this chapter.

§ 3329. Reports and records.

1. Persons licensed under this title shall keep records showing the receipt, administration, dispensing, or destruction of all controlled substances and maintain the records in such manner and detail as the commissioner, by regulation, shall require.
2. Persons licensed under this title shall submit reports to the department summarizing the activity conducted under the license. Included in such report shall be a detailed inventory of controlled substances, and an accounting for all such substances received or disposed of during the period covered by the report and such other information as the commissioner shall, by regulation, require. Such reports shall be filed with the department at such times as the commissioner may require.

TITLE 4 - DISPENSING TO ULTIMATE USERS

§ 3330. Schedule I substances. No prescription may be made or filled for any controlled substance in schedule I nor may such substance be possessed, distributed, dispensed or administered except pursuant to title III of this article.

§ 3331. Scheduled substances administering and dispensing by practitioners.

1. Except as provided in titles III or V of this article, no substance in schedules II, III, IV, or V may be prescribed for or dispensed or administered to an addict or habitual user.
2. A practitioner, in good faith, and in the course of his or her professional practice only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V, or he or she may cause the same to be administered by a designated agent under his or her direction and supervision.
3. A veterinarian, in good faith, and in the course of the practice of veterinary medicine only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V or he may cause them to be administered by a designated agent under his direction and supervision.
4. No such substance may be dispensed unless it is enclosed within a suitable and durable container, and:
 - (a) Affixed to such container is a label upon which is indelibly typed, printed or otherwise legibly written the following:
 - (i) the name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person in custody of such animal;
 - (ii) the name, address, and telephone number of the dispensing practitioner;
 - (iii) specific directions for use, including but not limited to the dosage and frequency of dosage, and the maximum daily dosage;
 - (iv) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";
 - (v) the date of dispensing;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (vi) either the name of the substance or such code number assigned by the department for the particular substance pursuant to section thirty-three hundred eighteen of this article;
- (b) Such container shall be identified as a controlled substance by either:
 - (i) an orange label;
 - (ii) a label of another color over which is superimposed an orange transparent adhesive tape; or
 - (iii) an auxiliary orange label affixed to the front of such container and bearing the legend, prominently marked or printed "Controlled Substance, Dangerous Unless Used As Directed";
- (c) Any label, transparency, or auxiliary label shall be applied in a manner which would inhibit its removal.

5. (a) No more than a thirty-day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time.

(b) Notwithstanding the provisions of paragraph (a) of this subdivision, a practitioner, within the scope of his or her professional opinion or discretion, may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with paragraph (a) of this subdivision, any appropriate renewal, refill, or new prescription for the opioid or any other drug.

(c) For the purposes of this subdivision, "acute pain" shall mean pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. Such term shall not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices.

6. A practitioner dispensing a controlled substance shall file information pursuant to such dispensing with the department by electronic means in such manner and detail as the commissioner shall, by regulation, require. This requirement shall not apply to the dispensing by a practitioner pursuant to subdivision five of section thirty-three hundred fifty-one of this article.

7. A practitioner may not administer, prescribe or dispense any substance referred to in subdivision (h) of Schedule II, and subdivision (g) of Schedule III, of section three thousand three hundred six of this article for other than therapeutic purposes. A practitioner may not administer, prescribe or dispense any such substance to any individual without first obtaining the informed consent of such individual, or where the individual lacks capacity to give such consent, a person legally authorized to consent on his or her behalf.

8. No opioids shall be prescribed to a patient initiating or being maintained on opioid treatment for pain which has lasted more than three months or past the time of normal tissue healing, unless the medical record contains a written treatment plan that follows generally accepted national professional or governmental guidelines. The requirements of this paragraph shall not apply in the case of patients who are being treated for cancer that is not in remission, who are in hospice or other end-of-life care, or whose pain is being treated as part of palliative care practices.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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§ 3332. Making of official New York state prescriptions or electronic prescriptions for scheduled substances.

1. No controlled substance may be prescribed by a practitioner except on an official New York state prescription or on an electronic prescription, and in good faith and in the course of his or her professional practice only.

2. Such prescription shall be prepared on an official New York state prescription form, written with ink, indelible pencil or, apart from the practitioner's signature, typewriter or electronic printer, or to the extent authorized by federal requirements, on an electronic prescription. The original official New York state prescription or the electronic prescription must contain the following:

- (a) the name, address, and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person having custody of such animal;
- (b) the name, address, Federal registration number, telephone number, and handwritten signature of the prescribing practitioner, except that an electronic prescription must contain the electronic signature of the prescribing practitioner;
- (c) specific directions for use, including but not limited to the dosage and frequency of dosage and the maximum daily dosage;
- (d) the date upon which such prescription was actually signed by the prescribing practitioner.

3. No such prescription shall be made for a quantity of controlled substances which would exceed a thirty day supply if the controlled substance were used in accordance with the directions for use specified on the prescription. A practitioner may, however, issue a prescription for up to a three month supply of a controlled substance provided that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of greater than a thirty day supply of a controlled substance and that the practitioner specifies the condition on the face of the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within thirty days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided by any previously issued prescription. A practitioner may, however, issue a prescription for up to a six month supply of any substance listed in subdivision (h) of Schedule II of section thirty-three hundred six of this article provided that such substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of a six month supply and that the practitioner specifies the condition on the prescription or on the electronic prescription.

4. The practitioner shall deliver the original official New York state prescription to the ultimate user or shall transmit the electronic prescription to the pharmacy.

§ 3333. Dispensing upon official New York state prescription or electronic prescription.

1. A licensed pharmacist may, in good faith and in the course of his or her professional practice, sell and dispense to an ultimate user controlled substances only upon the delivery of an official New York state prescription or the receipt of an electronic prescription to such pharmacist, within thirty days of the date such prescription was signed by an authorized practitioner; provided, however, a pharmacist may dispense a part or portion of such prescription in accordance with regulations of the commissioner in consultation with the commissioner of education. No pharmacy or pharmacist may sell or dispense greater than a thirty day supply of a controlled substance to an ultimate user unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided pursuant to any previously issued prescription, except that a pharmacy or pharmacist may

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo
sell or dispense up to a three month supply of a controlled substance if there appears, on the official New York state prescription or electronic prescription, a statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a thirty day supply of a controlled substance. A pharmacy or pharmacist may sell or dispense up to a six month supply of any substance listed in subdivision (h) of Schedule II of section thirty-three hundred six of this article if there appears, on the official New York state prescription or on an electronic prescription, a statement that the substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of a specified greater supply.

2. No controlled substance may be so dispensed or sold unless it is enclosed within a suitable container, and: (a) Affixed to such container is a label upon which is indelibly typed, printed, or otherwise legibly written the following:

(i) the name and address of the ultimate user for whom the substance is intended, or if intended for use upon an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(ii) the name, address, and telephone number of the pharmacy from which such substance is dispensed;

(iii) specific directions for use as stated on the prescription;

(iv) the name of the prescribing practitioner;

(v) the legend, prominently marked or printed in either boldface or upper case lettering:

"CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(vi) the number of the prescription under which it is recorded in the pharmacist's prescription file;

(vii) such code number assigned by the department for the particular substance pursuant to section thirty-three hundred eighteen of this article, or when requested by the practitioner, the name of such substance;

(b) Such container shall be identified as a controlled substance by either:

(i) an orange label;

(ii) a label of another color over which is superimposed an orange transparent adhesive tape; or

(iii) an auxiliary orange label affixed to the front of such container and bearing the legend, prominently marked or printed "Controlled Substance, Dangerous Unless Used As Directed";

(c) Any label, transparency, or auxiliary label shall be applied in a manner which would inhibit its removal.

3. The pharmacist filling the controlled substance prescription shall endorse upon the original official New York state prescription the date of delivery and his or her signature or, if an electronic prescription, his or her electronic signature.

4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The proprietor of the pharmacy shall file or cause to be filed such prescription information with the department by electronic means on a real time basis as the commissioner in consultation with the commissioner of education shall, by regulation, require; provided, however, that the commissioner may, pursuant to a process established in regulation, grant a waiver allowing a pharmacy to make such filings within a longer period of time if and to the extent that the commissioner finds it warranted, in his or her discretion, due to economic hardship, technological limitations that are not reasonably within the control of the pharmacy, or other exceptional circumstance demonstrated by the pharmacy; and provided, further, however, that such regulations shall specify the manner in which such requirements shall apply to the delivery of controlled substances to individuals in this state by means of mail or licensed express delivery services.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

5. When filing prescription information electronically pursuant to subdivision four of this section, the proprietor of the pharmacy shall dispose of any electronically recorded prescription information in such manner as the commissioner shall by regulation require.

§ 3334. Emergency oral prescriptions for schedule II drugs and certain other controlled substances.

1. In an emergency situation, as defined by rule or regulation of the department, a practitioner may orally prescribe and a pharmacist may dispense to an ultimate user controlled substances in schedule II and those schedule III or schedule IV controlled substances as the commissioner may, by regulation, require; provided however the pharmacist shall:

(a) contemporaneously reduce such prescription to writing or to the extent authorized by federal requirements, to an electronic record;

(b) dispense the substance in conformity with the labeling requirements applicable to the type of prescription which would be required but for the emergency; and

(c) make a good faith effort to verify the practitioner's identity, if the practitioner is unknown to the pharmacist.

2. No oral prescription shall be filled for a quantity of controlled substances which would exceed a five day supply if the substance were used in accordance with the directions for use.

3. Within seventy-two hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist the original of an official New York state prescription or an electronic prescription. Such prescription shall, in addition to the information otherwise required, also have upon the official New York state prescription or upon the electronic prescription the words: "Authorization for emergency dispensing." If the pharmacist fails to receive such prescription he or she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

4. Such official New York state prescription or electronic prescription shall be endorsed, and retained and filed in the same manner as is otherwise required for such prescriptions.

§ 3335. Dispensing by online dispensers of controlled substances. A controlled substance may be sold, delivered, or dispensed by means of the internet but only in accordance with this article. An online dispenser shall file with the department by electronic means information concerning the dispensing by means of the internet, of any controlled substances in such manner as the commissioner by regulation shall require.

§ 3337. Oral prescriptions schedule III, IV and V substances.

1. Except as provided in section thirty-three hundred thirty-four of this title, a practitioner may orally prescribe and a pharmacist may dispense to an ultimate user controlled substances in schedules III, IV or V provided however the pharmacist shall:

(a) contemporaneously reduce such prescription to writing or, to the extent authorized by federal requirements, an electronic record;

(b) dispense the substance in conformity with the labeling requirements applicable to a prescription; and

(c) make a good faith effort to verify the practitioner's identity, if the practitioner is unknown to the pharmacist.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

2. No oral prescription shall be filled for a quantity of controlled substances which would exceed a five day supply if the controlled substance were used in accordance with the directions for use, except that with respect to a schedule IV substance such prescription shall not exceed a thirty-day supply or one hundred dosage units, whichever is less; provided, however, that this provision shall not apply to any schedule IV controlled substance limited to a five day supply by section thirty-three hundred thirty-four of this title.
3. Within seventy-two hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist an official New York state prescription or an electronic prescription. If the pharmacist fails to receive such prescription he or she shall make a record of such fact in such manner and detail as the commissioner in consultation with the commissioner of education, by regulation, shall require.
4. Such official New York state prescription or electronic prescription shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions.

§ 3338. Official New York state prescription forms.

1. Official New York state prescription forms shall be prepared and issued by the department in the manner and detail as the commissioner in consultation with the commissioner of education may, by regulation, require, and, each form shall be serialized. Such forms shall be furnished to practitioners authorized to write such prescriptions and to institutional dispensers. Such prescription blanks shall not be transferable.
2. Except as expressly authorized by section thirty-three hundred thirty-four or thirty-three hundred thirty-seven of this article, controlled substances may be prescribed or dispensed only upon an official New York state prescription or, pursuant to regulations, an electronic prescription or out-of-state prescription.
3. The commissioner in consultation with the commissioner of education is hereby authorized and empowered to make rules and regulations, not inconsistent with this article, with respect to the retention or filing of such official New York state prescription forms, electronic prescriptions and out-of-state prescriptions, including information required to be filed with the department, the maximum number of official prescription forms which may be issued at any one time, the manner in which such forms shall be issued, the period of time after issuance by the department that such form shall remain valid for use, and the manner in which practitioners associated with institutional dispensers may use such forms, or any other matter of procedure or detail necessary to effectuate or clarify the provisions of this section and to secure proper and effective enforcement of the provisions of this article.
4. Upon a finding by the commissioner that a person has willfully failed to comply with the provisions of this article, the commissioner may revoke, cancel or withhold official New York state prescription forms which have been issued or for which application has been made.

§ 3339. Refilling of prescriptions for controlled substances.

1. Prescriptions for a schedule II controlled substance and those schedule III or schedule IV controlled substances which the commissioner may require by regulation may not be refilled.
2. A prescription, except for a schedule II controlled substance or those schedule III or schedule IV controlled substances which the commissioner may require by regulation may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription, provided however no such authorization shall be effective for a period greater than six months from the date the prescription is signed. In the event that the prescription authorizes the dispensing of more than a thirty day supply of schedule III, schedule IV or schedule V substances

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, the prescription may be refilled only once.

3. Unless an earlier refilling is authorized by the prescriber, no prescription for a controlled substance may be refilled earlier than seven days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use.

§ 3341. Institutional dispensers certificates of approval.

1. No institutional dispenser as herein before defined, shall receive, possess or cause controlled substances to be administered or dispensed without first having been issued a certificate of approval authorizing such activity by the commissioner.
2. Upon application of an institutional dispenser for a certificate of approval, the commissioner shall issue such certificate if he is satisfied that:
 - (a) the applicant and its managing officers are of good moral character;
 - (b) the applicant possesses the necessary land, building, paraphernalia and staff to properly carry on the activities described in the application;
 - (c) the applicant will be able to maintain effective control against diversion of controlled substances; and
 - (d) the applicant will be able to comply with all applicable state and federal laws.
3. Institutional dispensers to whom such certificates have been issued shall thereafter register biennially with the department. The fee for such certificate and for each biennial registration shall be one hundred dollars.
4. Certificates and registrations issued under this section shall be effective only for and shall specify:
 - (a) the name and address of the institutional dispenser;
 - (b) the nature of the controlled substance, or substances, either by name or schedule, or both, for which the certificate or registration is issued.

§ 3342. Dispensing and administering by institutional dispensers. 1. An institutional dispenser may cause controlled substances to be administered or dispensed for use on its premises or for the immediate care or treatment of a patient lawfully being transferred in an emergency situation, as defined by rule or regulation of the commissioner, to an alternative medical facility only pursuant to a written order by a practitioner for medication. Such orders shall be made and preserved in the manner and form as the commissioner shall, by regulation, prescribe.

2. An institutional dispenser may dispense controlled substances for use off its premises only pursuant to a prescription, prepared and filed in conformity with this title, provided, however, that, in an emergency situation as defined by rule or regulation of the department, a practitioner in a hospital without a full-time pharmacy may dispense controlled substances to a patient in a hospital emergency room for use off the premises of the institutional dispenser for a period not to exceed twenty-four hours.

3. An institutional dispenser shall maintain records of all controlled substances dispensed and administered in such manner as the commissioner shall, by regulation, require.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3343. Reports and records.

1. Prescriptions and copies of prescriptions shall be preserved in the following manner:

(a) dispensing practitioners filing information electronically pursuant to subdivision six of section thirty-three hundred thirty-one of this article, shall dispose of any electronically recorded information in such manner as the commissioner in consultation with the commissioner of education shall by regulation require;

(b) pharmacists dispensing controlled substances upon prescription shall preserve such prescriptions in such manner as the commissioner in consultation with the commissioner of education shall, by regulation, require.

2. Practitioners and pharmacies shall maintain records of all controlled substances received and dispensed in such manner as the commissioner shall, by regulation, require.

§ 3343-a. Prescription monitoring program registry.

1. Establishment of system. (a) The commissioner shall, in accordance with the provisions of this section, establish and maintain an electronic system for collecting, monitoring and reporting information concerning the prescribing and dispensing of controlled substances, to be known as the prescription monitoring program registry. The registry shall include information reported by pharmacies on a real time basis, as set forth in subdivision four of section thirty-three hundred thirty-three of this article.

(b) The registry shall include, for each person to whom a prescription for controlled substances has been dispensed, all patient-specific information covering such period of time as is deemed appropriate and feasible by the commissioner, but no less than six months and no more than five years. Such patient-specific information shall be obtained from the prescription information reported by pharmacies pursuant to subdivision four of section thirty-three hundred thirty-three of this article and by practitioners who dispense pursuant to subdivision six of section thirty-three hundred thirty-one of this article, and shall be processed and included in the registry by the department without undue delay. For purposes of this article, "patient-specific information" means information pertaining to individual patients included in the registry, which shall include the following information and such other information as is required by the department in regulation:

(i) the patient's name;

(ii) the patient's residential address;

(iii) the patient's date of birth;

(iv) the patient's gender;

(v) the date on which the prescription was issued;

(vi) the date on which the controlled substance was dispensed;

(vii) the metric quantity of the controlled substance dispensed;

(viii) the number of days supply of the controlled substance dispensed;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (ix) the name of the prescriber;
- (x) the prescriber's identification number, as assigned by the drug enforcement administration;
- (xi) the name or identifier of the drug that was dispensed; and
- (xii) the payment method.

(c) The registry shall be secure, easily accessible by practitioners and pharmacists, and compatible with the electronic transmission of prescriptions for controlled substances, as required by section two hundred eighty-one of this chapter, and section sixty-eight hundred ten of the education law, and any regulations promulgated pursuant thereto. To the extent practicable, implementation of the electronic transmission of prescriptions for controlled substances shall serve to streamline consultation of the registry by practitioners and reporting of prescription information by pharmacists. The registry shall be interoperable with other similar registries operated by federal or state governments, to the extent deemed appropriate by the commissioner, and subject to the provisions of section thirty-three hundred seventy-one-a of this article.

(d) The department shall establish and implement such protocols as are reasonably necessary to ensure that information contained in the registry is maintained in a secure and confidential manner and is accessible only by practitioners, pharmacists or their designees for the purposes established in subdivisions two and three of this section, or as otherwise set forth in sections thirty-three hundred seventy-one and thirty-three hundred seventy-one-a of this article. Such protocols shall include a mechanism for the department to monitor and record access to the registry, which shall identify the authorized individual accessing and each controlled substance history accessed.

2. Duty to consult prescription monitoring program registry; practitioners. (a) Every practitioner shall consult the prescription monitoring program registry prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV of section thirty-three hundred six of this article, for the purpose of reviewing a patient's controlled substance history as set forth in such registry; provided, however, that nothing in this section shall preclude an authorized practitioner, other than a veterinarian, from consulting the registry at his or her option prior to prescribing or dispensing any controlled substance. The duty to consult the registry shall not apply to:

- (i) veterinarians;
- (ii) a practitioner dispensing pursuant to subdivision three of section thirty-three hundred fifty-one of this article;
- (iii) a practitioner administering a controlled substance;
- (iv) a practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser pursuant to section thirty-three hundred forty-two of this title;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(v) a practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of controlled substance prescribed does not exceed a five day supply if the controlled substance were used in accordance with the directions for use;

(vi) a practitioner prescribing a controlled substance to a patient under the care of a hospice, as defined by section four thousand two of this chapter;

(vii) a practitioner when:

(A) it is not reasonably possible for the practitioner to access the registry in a timely manner;

(B) no other practitioner or designee authorized to access the registry, pursuant to paragraph (b) of this subdivision, is reasonably available; and

(C) the quantity of controlled substance prescribed does not exceed a five day supply if the controlled substance were used in accordance with the directions for use;

(viii) a practitioner acting in compliance with regulations that may be promulgated by the commissioner as to circumstances under which consultation of the registry would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient;

(ix) a situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in regulation; or

(x) a practitioner who has been granted a waiver due to technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner, pursuant to a process established in regulation, and in the discretion of the commissioner.

(b) For purposes of this section, a practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that: (i) the designee so authorized is employed by the same professional practice or is under contract with such practice; (ii) the practitioner takes reasonable steps to ensure that such designee is sufficiently competent in the use of the registry; (iii) the practitioner remains responsible for ensuring that access to the registry by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the registry, and remains responsible for any breach of confidentiality; and (iv) the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner and is reasonably informed by the relevant controlled substance history information obtained from the registry. The commissioner shall establish in regulation reasonable parameters with regard to a practitioner's ability to authorize designees pursuant to this section, which shall include processes necessary to allow the department to: (A) grant access to the registry in a reasonably prompt manner to as many designees as are authorized by practitioners, up to the number deemed appropriate by the commissioner for particular professional practices or types of practices, taking into account the need to maintain security of the registry and the patient-specific information maintained therein, and the objective of minimizing burdens to practitioners to the extent

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

practicable; (B) require that practitioners notify the department upon terminating the authorization of any designee; and (C) establish a mechanism to prevent such terminated designees from accessing the registry in a reasonably prompt manner following such notification.

3. Authority to consult prescription monitoring program registry; pharmacists. (a) A pharmacist may consult the prescription monitoring program registry in order to review the controlled substance history of an individual for whom one or more prescriptions for controlled substances is presented to such pharmacist.

(b) For purposes of this section, a pharmacist may designate another pharmacist, a pharmacy intern, as defined by section sixty-eight hundred six of the education law, or other individual as may be permitted by the commissioner in regulation, to consult the prescription monitoring program registry on the pharmacist's behalf, provided that such designee is employed by the same pharmacy or is under contract with such pharmacy. The commissioner shall establish in regulation reasonable parameters with regard to a pharmacist's ability to authorize designees pursuant to this section, which shall include processes necessary to allow the department to: (A) grant access to the registry in a reasonably prompt manner to as many designees as are authorized by pharmacists, up to the number deemed appropriate by the commissioner for particular pharmacies, taking into account the need to maintain security of the registry and the patient-specific information maintained therein, and the objective of minimizing burdens to pharmacists to the extent practicable; (B) require that pharmacists notify the department upon terminating the authorization of any designee; and (C) establish a mechanism to prevent such terminated designees from accessing the registry in a reasonably prompt manner following such notification.

4. Immunity. No practitioner or pharmacist, and no person acting on behalf of such practitioner or pharmacist as permitted under this section, acting with reasonable care and in good faith shall be subject to civil liability arising from any false, incomplete or inaccurate information submitted to or reported by the registry or for any resulting failure of the system to accurately or timely report such information; provided, however, that nothing in this subdivision shall be deemed to alter the obligation to submit or report prescription information to the department as otherwise set forth in this article or in regulations promulgated pursuant thereto.

5. Guidance to practitioners and pharmacists. The commissioner shall, in consultation with the commissioner of education, provide guidance to practitioners, pharmacists, and pharmacies regarding the purposes and uses of the registry established by this section and the means by which practitioners and pharmacists can access the registry. Such guidance shall reference educational information available pursuant to the prescription pain medication awareness program established pursuant to section thirty-three hundred nine-a of this article.

6. Individual access to controlled substance histories. The commissioner shall establish procedures by which an individual may: (a) request and obtain his or her own controlled substances history consisting of patient-specific information or, in appropriate circumstances, that of a patient who lacks capacity to make health care decisions and for whom the individual has legal authority to make such decisions and would have legal access to the patient's health care records; or (b) seek review of any part of his or her controlled substances history or, in appropriate circumstances, that of a patient who lacks capacity to make health care decisions and for whom the individual has legal authority to make such decisions and would have legal access to the patient's health care records, that such individual

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

disputes. Such procedures shall require the department to promptly revise any information accessible through the registry that the department determines to be inaccurate. Such procedures shall be described on the department's website and included with the controlled substances history provided to an individual pursuant to a request made under this subdivision or under subparagraph (iv) of paragraph (a) of subdivision two of section thirty-three hundred seventy-one of this article.

7. Department analysis of data. The department shall periodically analyze data contained in the prescription monitoring program registry to identify information that indicates that a violation of law or breach of professional standards may have occurred and, as warranted, provide any relevant information to appropriate entities as permitted under section thirty-three hundred seventy-one of this article. The department shall keep a record of the information provided, including, but not limited to, the specific information provided and the agency to which such information was provided, including the name and title of the person to whom such information was provided and an attestation from such person that he or she has authority to receive such information.

8. Funding the prescription monitoring program registry. (a) The commissioner shall make reasonable efforts to apply for monies available from the federal government and other institutions, to the extent deemed appropriate by the commissioner, and use any monies so obtained to supplement any other monies made available for the purposes of this title.

(b) Operation of the registry established by this section shall not be funded, in whole or in part, by fees imposed specifically for such purposes upon practitioners, pharmacists, designees or patients subject to this section.

9. Rules and regulations. The commissioner shall promulgate such rules and regulations as are necessary to effectuate the provisions of this section, in consultation with the work group established pursuant to subdivision three of section thirty-three hundred nine-a of this article.

§ 3343-b. Safe disposal of unused controlled substances.

1. The department shall oversee a program for the safe disposal of unused controlled substances by consumers in accordance with federal law. Individual members of the public shall be authorized to voluntarily surrender controlled substances listed on schedule II, III, IV or V of section thirty-three hundred six of this article in a secure manner, without identifying themselves. Safe disposal methods shall be publicized consistent with the prescription pain medication awareness program established pursuant to section thirty-three hundred nine-a of this article and article two-B of this chapter.
2. The surrender of a controlled substance pursuant to the program established pursuant to this section shall not constitute the possession, transfer or sale of such controlled substance for purposes of this article or the penal law.
3. Except as provided in article two-B of this chapter, disposal sites shall be operated by law enforcement agencies, pharmacies and other Federal Drug Enforcement Administration authorized collectors on a voluntary basis, provided, however, that such disposal sites shall not be precluded from operating as part of a drug take back program established pursuant to article two-B of this chapter. Nothing in this section shall require any political subdivision of the state to participate in the program established in this section.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3345. Possession of controlled substances by ultimate users original container. Except for the purpose of current use by the person or animal for whom such substance was prescribed or dispensed, it shall be unlawful for an ultimate user of controlled substances to possess such substance outside of the original container in which it was dispensed.

Violation of this provision shall be an offense punishable by a fine of not more than fifty dollars.

TITLE 5 - DISPENSING TO ADDICTS AND HABITUAL USERS

§ 3350. Dispensing prohibition.

Controlled substances may not be prescribed for, or administered or dispensed to addicts or habitual users of controlled substances, except as provided by this title or title III.

§ 3351. Dispensing for medical use.

1. Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:

(a) during emergency medical treatment unrelated to abuse of controlled substances;

(b) who is a bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis;

(c) who is aged, infirm, or suffering from serious injury or illness and the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of such person.

2. Controlled substances may be ordered for use by an addict or habitual user by a practitioner and administered by a practitioner or registered nurse to relieve acute withdrawal symptoms. \

3. Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be ordered for use of an addict by a practitioner and dispensed or administered by a practitioner or his designated agent as interim treatment for an addict on a waiting list for admission to an authorized maintenance program.

4. Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be administered to an addict by a practitioner or by his designated agent acting under the direction and supervision of a practitioner, as part of a regime designed and intended to withdraw a patient from addiction to controlled substances.

5. Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be administered to an addict by a practitioner or by his designated agent acting under the direction and supervision of a practitioner, as part of a substance abuse or chemical dependence program approved pursuant to article twenty-three or thirty-two of the mental hygiene law.

§ 3352. Reports and records. Persons certified pursuant to article thirty-two of the mental hygiene law to operate methadone maintenance treatment programs shall keep records showing the receipt, administration, dispensing, or destruction of all controlled substances and documenting each incident or alleged incident involving the theft, loss or possible diversion of controlled substances and shall maintain the records in such manner and detail as the commissioner, by regulation, shall require.

A person certified to conduct a maintenance program shall immediately file a report with the department of each incident or alleged incident involving the theft, loss or possible diversion of controlled substances.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

*TITLE 5-A - MEDICAL USE OF MARIHUANA

§ 3360. Definitions. As used in this title, the following terms shall have the following meanings, unless the context clearly requires otherwise:

1. "Certified medical use" means the acquisition, possession, use, or, transportation of medical marihuana by a certified patient, or the acquisition, possession, delivery, transportation or administration of medical marihuana by a designated caregiver, for use as part of the treatment of the patient's serious condition, as authorized in a certification under this title including enabling the patient to tolerate treatment for the serious condition. A certified medical use does not include smoking.
2. "Caring for" means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition.
3. "Certified patient" means a patient who is a resident of New York state or receiving care and treatment in New York state as determined by the commissioner in regulation, and is certified under section thirty-three hundred sixty-one of this title.
4. "Certification" means a certification, made under section thirty-three hundred sixty-one of this title.
5. "Designated caregiver" means the individual designated by a certified patient in a registry application. A certified patient may designate up to two designated caregivers.
6. "Public place" means a public place as defined in regulation by the commissioner.
7. (a) "Serious condition" means:
 - (i) having one of the following severe debilitating or life-threatening conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, or as added by the commissioner; and
 - (ii) any of the following conditions where it is clinically associated with, or a complication of, a condition under this paragraph or its treatment: cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; severe or persistent muscle spasms; or such conditions as are added by the commissioner.
 - (b) No later than eighteen months from the effective date of this section, the commissioner shall determine whether to add the following serious conditions: Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder and rheumatoid arthritis.
8. "Medical marihuana" means marihuana as defined in subdivision twenty-one of section thirty-three hundred two of this article, intended for a certified medical use, as determined by the commissioner in his or her sole discretion. Any form of medical marihuana not approved by the commissioner is expressly prohibited.
9. "Registered organization" means a registered organization under sections thirty-three hundred sixty-four and thirty-three hundred sixty-five of this title.
10. "Registry application" means an application properly completed and filed with the department by a certified patient under section thirty-three hundred sixty-three of this title.
11. "Registry identification card" means a document that identifies a certified patient or designated caregiver, as provided under section thirty-three hundred sixty-three of this title.
12. "Practitioner" means a practitioner who (i) is a physician licensed by New York state and practicing within the state, (ii) who by training or experience is qualified to treat a serious

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo condition as defined in subdivision seven of this section; and (iii) has completed a two to four hour course as determined by the commissioner in regulation and registered with the department; provided however, a registration shall not be denied without cause. Such course may count toward board certification requirements. The commissioner shall consider the inclusion of nurse practitioners under this title based upon considerations including access and availability. After such consideration the commissioner is authorized to deem nurse practitioners as practitioners under this title.

13. "Terminally ill" means an individual has a medical prognosis that the individual's life expectancy is approximately one year or less if the illness runs its normal course.
14. "Labor peace agreement" means an agreement between an entity and a labor organization that, at a minimum, protects the state's proprietary interests by prohibiting labor organizations and members from engaging in picketing, work stoppages, boycotts, and any other economic interference with the registered organization's business.
15. "Individual dose" means a single measure of raw medical marihuana or non-infused concentrates to be determined and clearly identified by a patient's practitioner for the patient's specific certified condition. For ingestible or sub-lingual medical marihuana products, no individual dose may contain more than ten milligrams of tetrahydrocannabinol.
16. "Form of medical marihuana" means characteristics of the medical marihuana recommended or limited for a particular certified patient, including the method of consumption and any particular strain, variety, and quantity or percentage of marihuana or particular active ingredient.
17. "Applicant" means a for-profit entity or not-for-profit corporation and includes: board members, officers, managers, owners, partners, principal stakeholders and members who submit an application to become a registered organization.
18. "Special certification" means a special certification made under subdivision nine of section thirty-three hundred sixty-one of this title.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3361. Certification of patients.

1. A patient certification may only be issued if:
 - (a) a practitioner has been registered with the department to issue a certification as determined by the commissioner;
 - (b) the patient has a serious condition, which shall be specified in the patient's health care record;
 - (c) the practitioner by training or experience is qualified to treat the serious condition;
 - (d) the patient is under the practitioner's continuing care for the serious condition; and
 - (e) in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical use of marihuana for the serious condition.
2. The certification shall include (a) the name, date of birth and address of the patient; (b) a statement that the patient has a serious condition and the patient is under the practitioner's care for the serious condition; (c) a statement attesting that all requirements of subdivision one of this section have been satisfied; (d) the date; and (e) the name, address, federal registration number, telephone number, and the handwritten signature of the certifying practitioner. The commissioner may require by regulation that the certification shall be on a form provided by the department. The practitioner may state in the certification that, in the practitioner's professional opinion, the

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

patient would benefit from medical marijuana only until a specified date. The practitioner may state in the certification that, in the practitioner's professional opinion, the patient is terminally ill and that the certification shall not expire until the patient dies.

3. In making a certification, the practitioner shall consider the form of medical marijuana the patient should consume, including the method of consumption and any particular strain, variety, and quantity or percentage of marijuana or particular active ingredient, and appropriate dosage. The practitioner shall state in the certification any recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical marijuana and dosage.
4. Every practitioner shall consult the prescription monitoring drug program registry prior to making or issuing a certification, for the purpose of reviewing a patient's controlled substance history. For purposes of this section, a practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that such designation is in accordance with section thirty-three hundred forty-three-a of this article.
5. The practitioner shall give the certification to the certified patient, and place a copy in the patient's health care record.
6. No practitioner shall issue a certification under this section for himself or herself.
7. A registry identification card based on a certification shall expire one year after the date the certification is signed by the practitioner.
8. (a) If the practitioner states in the certification that, in the practitioner's professional opinion, the patient would benefit from medical marijuana only until a specified earlier date, then the registry identification card shall expire on that date;
(b) If the practitioner states in the certification that in the practitioner's professional opinion the patient is terminally ill and that the certification shall not expire until the patient dies, then the registry identification card shall state that the patient is terminally ill and that the registration card shall not expire until the patient dies;
(c) If the practitioner re-issues the certification to terminate the certification on an earlier date, then the registry identification card shall expire on that date and shall be promptly returned by the certified patient to the department;
(d) If the certification so provides, the registry identification card shall state any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient; and
(e) The commissioner shall make regulations to implement this subdivision.
9. (a) A certification may be a special certification if, in addition to the other requirements for a certification, the practitioner certifies in the certification that the patient's serious condition is progressive and degenerative or that delay in the patient's certified medical use of marijuana poses a serious risk to the patient's life or health.
(b) The department shall create the form to be used for a special certification and shall make that form available to be downloaded from the department's website.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3362. Lawful medical use. 1. The possession, acquisition, use, delivery, transfer, transportation, or administration of medical marihuana by a certified patient or designated caregiver possessing a valid registry identification card, for certified medical use, shall be lawful under this title; provided that:

(a) the marihuana that may be possessed by a certified patient shall not exceed a thirty-day supply of the dosage as determined by the practitioner, consistent with any guidance and regulations issued by the commissioner, provided that during the last seven days of any thirty-day period, the certified patient may also possess up to such amount for the next thirty-day period;

(b) the marihuana that may be possessed by designated caregivers does not exceed the quantities referred to in paragraph (a) of this subdivision for each certified patient for whom the caregiver possesses a valid registry identification card, up to five certified patients;

(c) the form or forms of medical marihuana that may be possessed by the certified patient or designated caregiver pursuant to a certification shall be in compliance with any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient in the certification; and

(d) the medical marihuana shall be kept in the original package in which it was dispensed under subdivision twelve of section thirty-three hundred sixty-four of this title, except for the portion removed for immediate consumption for certified medical use by the certified patient.

2. Notwithstanding subdivision one of this section:

(a) possession of medical marihuana shall not be lawful under this title if it is smoked, consumed, vaporized, or grown in a public place, regardless of the form of medical marihuana stated in the patient's certification.

(b) a person possessing medical marihuana under this title shall possess his or her registry identification card at all times when in immediate possession of medical marihuana.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3363. Registry identification cards.

1. Upon approval of the certification, the department shall issue registry identification cards for certified patients and designated caregivers. A registry identification card shall expire as provided in section thirty-three hundred sixty-one of this title or as otherwise provided in this section. The department shall begin issuing registry identification cards as soon as practicable after the certifications required by section thirty-three hundred sixty-nine-b are granted. The department may specify a form for a registry application, in which case the department shall provide the form on request, reproductions of the form may be used, and the form shall be available for downloading from the department's website.

2. To obtain, amend or renew a registry identification card, a certified patient or designated caregiver shall file a registry application with the department. The registry application or renewal application shall include:

(a) in the case of a certified patient:

(i) the patient's certification (a new written certification shall be provided with a renewal application);

(ii) the name, address, and date of birth of the patient;

(iii) the date of the certification;

(iv) if the patient has a registry identification card based on a current valid certification, the registry identification number and expiration date of that registry identification card;

(v) the specified date until which the patient would benefit from medical marihuana, if the

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo
certification states such a date;

- (vi) the name, address, federal registration number, and telephone number of the certifying practitioner;
- (vii) any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient; and
- (viii) other individual identifying information required by the department;
- (b) in the case of a certified patient, if the patient designates a designated caregiver, the name, address, and date of birth of the designated caregiver, and other individual identifying information required by the department;
- (c) in the case of a designated caregiver:
 - (i) the name, address, and date of birth of the designated caregiver;
 - (ii) if the designated caregiver has a registry identification card, the registry identification number and expiration date of that registry identification card; and
 - (iii) other individual identifying information required by the department;
- (d) a statement that a false statement made in the application is punishable under section 210.45 of the penal law;
- (e) the date of the application and the signature of the certified patient or designated caregiver, as the case may be;
- (f) a fifty-dollar application fee, provided, that the department may waive or reduce the fee in cases of financial hardship; and
- (g) any other requirements determined by the commissioner.

3. Where a certified patient is under the age of eighteen:

(a) The application for a registry identification card shall be made by an appropriate person over twenty-one years of age. The application shall state facts demonstrating that the person is appropriate.

(b) The designated caregiver shall be (i) a parent or legal guardian of the certified patient, (ii) a person designated by a parent or legal guardian, or (iii) an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

4. No person may be a designated caregiver if the person is under twenty-one years of age unless a sufficient showing is made to the department that the person should be permitted to serve as a designated caregiver. The requirements for such a showing shall be determined by the commissioner.

5. No person may be a designated caregiver for more than five certified patients at one time.

6. If a certified patient wishes to change or terminate his or her designated caregiver, for whatever reason, the certified patient shall notify the department as soon as practicable. The department shall issue a notification to the designated caregiver that their registration card is invalid and must be promptly returned to the department. The newly designated caregiver must comply with all requirements set forth in this section.

7. If the certification so provides, the registry identification card shall contain any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient.

8. The department shall issue separate registry identification cards for certified patients and designated caregivers as soon as reasonably practicable after receiving a complete application under this section, unless it determines that the application is incomplete or factually inaccurate, in which case it shall promptly notify the applicant.

9. If the application of a certified patient designates an individual as a designated caregiver who is not authorized to be a designated caregiver, that portion of the application shall be denied by the department but that shall not affect the approval of the balance of the application.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

10. Aregistry identification card shall:

- (a) contain the name of the certified patient or the designated caregiver as the case may be;
- (b) contain the date of issuance and expiration date of the registry identification card;
- (c) contain a registry identification number for the certified patient or designated caregiver, as the case may be and a registry identification number;
- (d) contain a photograph of the individual to whom the registry identification card is being issued, which shall be obtained by the department in a manner specified by the commissioner in regulations; provided, however, that if the department requires certified patients to submit photographs for this purpose, there shall be a reasonable accommodation of certified patients who are confined to their homes due to their medical conditions and may therefore have difficulty procuring photographs;
- (e) be a secure document as determined by the department;
- (f) plainly state any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and
- (g) any other requirements determined by the commissioner.

11. A certified patient or designated caregiver who has been issued a registry identification card shall notify the department of any change in his or her name or address or, with respect to the patient, if he or she ceases to have the serious condition noted on the certification within ten days of such change. The certified patient's or designated caregiver's registry identification card shall be deemed invalid and shall be returned promptly to the department.

12. If a certified patient or designated caregiver loses his or her registry identification card, he or she shall notify the department and submit a twenty-five dollar fee within ten days of losing the card to maintain the registration. The department may establish higher fees for issuing a new registry identification card for second and subsequent replacements for a lost card, provided, that the department may waive or reduce the fee in cases of financial hardship. The department shall issue a new registry identification card as soon as practicable, which may contain a new registry identification number, to the certified patient or designated caregiver, as the case may be. The certified patient or designated caregiver shall not be able to obtain medical marihuana until the certified patient receives a new card.

13. The department shall maintain a confidential list of the persons to whom it has issued registry identification cards. Individual identifying information obtained by the department under this title shall be confidential and exempt from disclosure under article six of the public officers law. Notwithstanding this subdivision, the department may notify any appropriate law enforcement agency of information relating to any violation or suspected violation of this title.

14. The department shall verify to law enforcement personnel in an appropriate case whether a registry identification card is valid.

15. If a certified patient or designated caregiver willfully violates any provision of this title as determined by the department, his or her registry identification card may be suspended or revoked. This is in addition to any other penalty that may apply.

16. The commissioner shall make regulations for special certifications, which shall include expedited procedures and which may require the applicant to submit additional documentation establishing the clinical basis for the special certification. If the department has not established and made available a form for a registry application or renewal application and determined the application fee if any, or established and made available a form for a registry application or renewal application and determined the application fee for a special certification, then in the case of a special certification, a registry application or renewal application that otherwise conforms with

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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the requirements of this section shall not require the use of a form or the payment of an application fee.

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§ 3364. Registered organizations.

1. A registered organization shall be a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing marihuana for certified medical use.
2. The acquiring, possession, manufacture, sale, delivery, transporting, distributing or dispensing of marihuana by a registered organization under this title in accordance with its registration under section thirty-three hundred sixty-five of this title or a renewal thereof shall be lawful under this title.
3. Each registered organization shall contract with an independent laboratory to test the medical marihuana produced by the registered organization. The commissioner shall approve the laboratory and require that the laboratory report testing results in a manner determined by the commissioner. The commissioner is authorized to issue regulation requiring the laboratory to perform certain tests and services.
4. (a) A registered organization may lawfully, in good faith, sell, deliver, distribute or dispense medical marihuana to a certified patient or designated caregiver upon presentation to the registered organization of a valid registry identification card for that certified patient or designated caregiver. When presented with the registry identification card, the registered organization shall provide to the certified patient or designated caregiver a receipt, which shall state: the name, address, and registry identification number of the registered organization; the name and registry identification number of the certified patient and the designated caregiver (if any); the date the marihuana was sold; any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and the form and the quantity of medical marihuana sold. The registered organization shall retain a copy of the registry identification card and the receipt for six years.

(b) The proprietor of a registered organization shall file or cause to be filed any receipt and certification information with the department by electronic means on a real time basis as the commissioner shall require by regulation. When filing receipt and certification information electronically pursuant to this paragraph, the proprietor of the registered organization shall dispose of any electronically recorded prescription information in such manner as the commissioner shall by regulation require.
5. (a) No registered organization may sell, deliver, distribute or dispense to any certified patient or designated caregiver a quantity of medical marihuana larger than that individual would be allowed to possess under this title.

(b) When dispensing medical marihuana to a certified patient or designated caregiver, the registered organization (i) shall not dispense an amount greater than a thirty day supply to a certified patient until the certified patient has exhausted all but a seven day supply provided pursuant to a previously issued certification, and (ii) shall verify the information in subparagraph

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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(i) of this paragraph by consulting the prescription monitoring program registry under section thirty-three hundred forty-three-a of this article.

(c) Medical marijuana dispensed to a certified patient or designated caregiver by a registered organization shall conform to any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient.

6. When a registered organization sells, delivers, distributes or dispenses medical marijuana to a certified patient or designated caregiver, it shall provide to that individual a safety insert, which will be developed and approved by the commissioner and include, but not be limited to, information on:

- (a) methods for administering medical marijuana in individual doses,
- (b) any potential dangers stemming from the use of medical marijuana,
- (c) how to recognize what may be problematic usage of medical marijuana and obtain appropriate services or treatment for problematic usage, and
- (d) other information as determined by the commissioner.

7. Registered organizations shall not be managed by or employ anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances provided that this subdivision only applies to (a) managers or employees who come into contact with or handle medical marijuana, and (b) a conviction less than ten years (not counting time spent in incarceration) prior to being employed, for which the person has not received a certificate of relief from disabilities or a certificate of good conduct under article twenty-three of the correction law.

8. Manufacturing of medical marijuana by a registered organization shall only be done in an indoor, enclosed, secure facility located in New York state, which may include a greenhouse. The commissioner shall promulgate regulations establishing requirements for such facilities.

9. Dispensing of medical marijuana by a registered organization shall only be done in an indoor, enclosed, secure facility located in New York state, which may include a greenhouse. The commissioner shall promulgate regulations establishing requirements for such facilities.

10. A registered organization shall determine the quality, safety, and clinical strength of medical marijuana manufactured or dispensed by the registered organization, and shall provide documentation of that quality, safety and clinical strength to the department and to any person or entity to which the medical marijuana is sold or dispensed.

11. A registered organization shall be deemed to be a "health care provider" for the purposes of title two-D of article two of this chapter.

12. Medical marijuana shall be dispensed to a certified patient or designated caregiver in a sealed and properly labeled package. The labeling shall contain: (a) the information required to be included in the receipt provided to the certified patient or designated caregiver by the registered organization; (b) the packaging date; (c) any applicable date by which the medical marijuana should be used; (d) a warning stating, "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying health care practitioner, and in the case of breastfeeding mothers, including the infant's pediatrician. This product might impair the ability to drive. Keep out of reach of children."; (e) the amount of individual doses contained within; and (f) a warning that the medical marijuana must be kept in the original container in which it was dispensed.

13. The commissioner is authorized to make rules and regulations restricting the advertising and marketing of medical marijuana, which shall be consistent with the federal regulations governing prescription drug advertising and marketing.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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§ 3365. Registering of registered organizations. 1. Application for initial registration. (a) An applicant for registration as a registered organization under section thirty-three hundred sixty-four of this title shall include such information prepared in such manner and detail as the commissioner may require, including but not limited to:

- (i) a description of the activities in which it intends to engage as a registered organization;
- (ii) that the applicant:
 - (A) is of good moral character;
 - (B) possesses or has the right to use sufficient land, buildings, and other premises (which shall be specified in the application) and equipment to properly carry on the activity described in the application, or in the alternative posts a bond of not less than two million dollars;
 - (C) is able to maintain effective security and control to prevent diversion, abuse, and other illegal conduct relating to the marihuana;
 - (D) is able to comply with all applicable state laws and regulations relating to the activities in which it intends to engage under the registration;
- (iii) that the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of certification.
- (iv) the applicant's status under subdivision one of section thirty-three hundred sixty-four of this title; and
- (v) the application shall include the name, residence address and title of each of the officers and directors and the name and residence address of any person or entity that is a member of the applicant. Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the application setting forth:
 - (A) any position of management or ownership during the preceding ten years of a ten per centum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs;
 - (B) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding; and
 - (C) such other information as the commissioner may reasonably require.

2. Duty to report. The applicant shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.

3. Granting of registration. (a) The commissioner shall grant a registration or amendment to a registration under this section if he or she is satisfied that:

- (i) the applicant will be able to maintain effective control against diversion of marihuana;
- (ii) the applicant will be able to comply with all applicable state laws;
- (iii) the applicant and its officers are ready, willing and able to properly carry on the manufacturing or distributing activity for which a registration is sought;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (iv) the applicant possesses or has the right to use sufficient land, buildings and equipment to properly carry on the activity described in the application;
 - (v) it is in the public interest that such registration be granted; the commissioner may consider whether the number of registered organizations in an area will be adequate or excessive to reasonably serve the area;
 - (vi) the applicant and its managing officers are of good moral character;
 - (vii) the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees; and
 - (viii) the applicant satisfies any other conditions as determined by the commissioner.
- (b) If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within thirty days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.
- (c) The fee for a registration under this section shall be a reasonable amount determined by the department in regulations; provided, however, if the registration is issued for a period greater than two years the fee shall be increased, pro rata, for each additional month of validity.
- (d) Registrations issued under this section shall be effective only for the registered organization and shall specify:
- (i) the name and address of the registered organization;
 - (ii) which activities of a registered organization are permitted by the registration;
 - (iii) the land, buildings and facilities that may be used for the permitted activities of the registered organization; and
 - (iv) such other information as the commissioner shall reasonably provide to assure compliance with this title.
- (e) Upon application of a registered organization, a registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The fee for such amendment shall be two hundred fifty dollars.
4. A registration issued under this section shall be valid for two years from the date of issue, except that in order to facilitate the renewals of such registrations, the commissioner may upon the initial application for a registration, issue some registrations which may remain valid for a period of time greater than two years but not exceeding an additional eleven months.
5. Applications for renewal of registrations. (a) An application for the renewal of any registration issued under this section shall be filed with the department not more than six months nor less than four months prior to the expiration thereof. A late-filed application for the renewal of a registration may, in the discretion of the commissioner, be treated as an application for an initial license.
- (b) The application for renewal shall include such information prepared in the manner and detail as the commissioner may require, including but not limited to:
- (i) any material change in the circumstances or factors listed in subdivision one of this section; and
 - (ii) every known charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:
 - (A) each incident or alleged incident involving the theft, loss, or possible diversion of marijuana manufactured or distributed by the applicant; and
 - (B) compliance by the applicant with the laws of the state with respect to any substance listed in section thirty-three hundred six of this article.
- (c) An applicant for renewal shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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(d) If the commissioner is not satisfied that the applicant is entitled to a renewal of the registration, he or she shall within a reasonably practicable time as determined by the commissioner, serve upon the applicant or his or her attorney of record in person or by registered or certified mail an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the commissioner that the registration should be renewed.

(e) Within a reasonably practicable time as determined by the commissioner of such order, the applicant may submit additional material to the commissioner or demand a hearing or both. If a hearing is demanded the commissioner shall fix a date as soon as reasonably practicable.

6. Granting of renewal of registrations. (a) The commissioner shall renew a registration unless he or she determines and finds that:

- (i) the applicant is unlikely to maintain or be able to maintain effective control against diversion; or
- (ii) the applicant is unlikely to comply with all state laws applicable to the activities in which it may engage under the registration; or
- (iii) it is not in the public interest to renew the registration because the number of registered organizations in an area is excessive to reasonably serve the area; or
- (iv) the applicant has either violated or terminated its labor peace agreement.

(b) For purposes of this section, proof that a registered organization, during the period of its registration, has failed to maintain effective control against diversion, violates any provision of this article, or has knowingly or negligently failed to comply with applicable state laws relating to the activities in which it engages under the registration, shall constitute grounds for suspension or termination of the registered organization's registration as determined by the commissioner. The registered organization shall also be under a continuing duty to report to the department any material change or fact or circumstance to the information provided in the registered organization's application.

7. The department may suspend or terminate the registration of a registered organization, on grounds and using procedures under this article relating to a license, to the extent consistent with this title. The department shall suspend or terminate the registration in the event that a registered organization violates or terminates the applicable labor peace agreement. Conduct in compliance with this title which may violate conflicting federal law, shall not be grounds to suspend or terminate a registration.

8. The department shall begin issuing registrations for registered organizations as soon as practicable after the certifications required by section thirty-three hundred sixty-nine-b of this title are given.

9. The commissioner shall register no more than five registered organizations that manufacture medical marijuana with no more than four dispensing sites wholly owned and operated by such registered organization. The commissioner shall ensure that such registered organizations and dispensing sites are geographically distributed across the state. The commission may register additional registered organizations.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3365-a. Expedited registration of registered organizations. 1. There is hereby established in the department an emergency medical marijuana access program (referred to in this section as the "program") under this section. The purpose of the program is to expedite the availability of medical marijuana to avoid suffering and loss of life, during the period before full implementation of and production under this title, especially in the case of patients whose serious condition is progressive

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

and degenerative or is such that delay in the patient's medical use of marijuana poses a serious risk to the patient's life or health. The commissioner shall implement the program as expeditiously as practicable, including by emergency regulation.

2. The department shall begin accepting and acting on applications under this section for registered organizations as soon as practicable after the effective date of this section.

3. For the purposes of this section, and for specified limited times, the commissioner may waive or modify the requirements of this article relating to registered organizations, consistent with the legislative intent and purpose of this title and this section. Where an entity seeking to be a registered organization under the program operates in a jurisdiction other than the state of New York, under licensure or other governmental recognition of that jurisdiction, and the laws of that jurisdiction are acceptable to the commissioner as consistent with the legislative intent and purpose of this title and this section, then the commissioner may accept that licensure or recognition as wholly or partially satisfying the requirements of this title, for purposes of the registration and operation of the registered organization under the program and this section.

4. In considering an application for registration as a registered organization under this section, the commissioner shall give preference to the following:

(a) an applicant that is currently producing or providing or has a history of producing or providing medical marijuana in another jurisdiction in full compliance with the laws of the jurisdiction;

(b) an applicant that is able and qualified to both produce, distribute, and dispense medical marijuana to patients expeditiously;

(c) an applicant that proposes a location or locations for dispensing by the registered organization, which ensure, to the greatest extent possible, that certified patients with a special certification have access to a registered organization.

5. The commissioner may make regulations under this section:

(a) limiting registered organizations registered under this section to serving patients with special certifications;

(b) limiting the allowable levels of cannabidiol and tetrahydrocannabinol that may be contained in medical marijuana authorized under the program, based on therapeutics and patient safety.

6. A registered organization under this section may apply under section thirty-three hundred sixty-five of this title to receive or renew registration.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3366. Reports by registered organizations. 1. The commissioner shall, by regulation, require each registered organization to file reports by the registered organization during a particular period. The commissioner shall determine the information to be reported and the forms, time, and manner of the reporting.

2. The commissioner shall, by regulation, require each registered organization to adopt and maintain security, tracking, record keeping, record retention and surveillance systems, relating to all medical marijuana at every stage of acquiring, possession, manufacture, sale, delivery, transporting, distributing, or dispensing by the registered organization, subject to regulations of the commissioner.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3367. Evaluation; research programs; report by department. 1. The commissioner may provide for the analysis and evaluation of the operation of this title. The commissioner may enter into agreements with one or more persons, not-for-profit corporations or other organizations, for the performance of an evaluation of the implementation and effectiveness of this title.

2. The department may develop, seek any necessary federal approval for, and carry out research programs relating to medical use of marihuana. Participation in any such research program shall be voluntary on the part of practitioners, patients, and designated caregivers.

3. The department shall report every two years, beginning two years after the effective date of this title, to the governor and the legislature on the medical use of marihuana under this title and make appropriate recommendations.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3368. Relation to other laws. 1. (a) The provisions of this article shall apply to this title, except that where a provision of this title conflicts with another provision of this article, this title shall apply.

(b) Medical marihuana shall not be deemed to be a "drug" for purposes of article one hundred thirty-seven of the education law.

2. Nothing in this title shall be construed to require an insurer or health plan under this chapter or the insurance law to provide coverage for medical marihuana. Nothing in this title shall be construed to require coverage for medical marihuana under article twenty-five of this chapter or article five of the social services law.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369. Protections for the medical use of marihuana. 1. Certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title.

2, Non-discrimination. Being a certified patient shall be deemed to be having a "disability" under article fifteen of the executive law (human rights law), section forty-c of the civil rights law, sections 240.00, 485.00, and 485.05 of the penal law, and section 200.50 of the criminal procedure law. This subdivision shall not bar the enforcement of a policy prohibiting an employee from performing his or her employment duties while impaired by a controlled substance. This subdivision shall not require any person or entity to do any act that would put the person or entity in violation of federal law or cause it to lose a federal contract or funding.

3. The fact that a person is a certified patient and/or acting in accordance with this title, shall not be a consideration in a proceeding pursuant to applicable sections of the domestic relations law, the social services law and the family court act.

4. (a) Certification applications, certification forms, any certified patient information contained within a database, and copies of registry identification cards shall be deemed exempt from public disclosure under sections eighty-seven and eighty-nine of the public officers law.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(b) The name, contact information, and other information relating to practitioners registered with the department under this title shall be public information and shall be maintained by the commissioner on the department's website accessible to the public in searchable form. However, if a practitioner notifies the department in writing that he or she does not want his or her name and other information disclosed, that practitioner's name and other information shall thereafter not be public information or maintained on the department's website, unless the practitioner cancels the request.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369-a. Regulations. The commissioner shall make regulations to implement this title.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369-b. Effective date. Registry identification cards or registered organization registrations shall be issued or become effective no later than eighteen months from signing or until such time as the commissioner and the superintendent of state police certify that this title can be implemented in accordance with public health and safety interests, whichever event comes later. Prior to making a general certification under this section, the commissioner and the superintendent of state police may make a certification limited to accommodating expedited access for patients with special certifications and for registered organizations under the emergency medical marijuana access program under section thirty-three hundred sixty-five-a of this title

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369-c. Suspend; terminate. Based upon the recommendation of the commissioner and/or the superintendent of state police that there is a risk to the public health or safety, the governor may immediately terminate all licenses issued to registered organizations.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369-d. Pricing. 1. Every sale of medical marijuana shall be at the price determined by the commissioner. Every charge made or demanded for medical marijuana not in accordance with the price determined by the commissioner, is prohibited.

2. The commissioner is hereby authorized to set the per dose price of each form of medical marijuana sold by any registered organization. In setting the per dose price of each form of medical marijuana, the commissioner shall consider the fixed and variable costs of producing the form of marijuana and any other factor the commissioner, in his or her discretion, deems relevant to determining the per dose price of each form of medical marijuana.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

§ 3369-e. Severability. If any clause, sentence, paragraph, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which the judgment shall have been rendered.

*** NB Repealed July 5, 2028 and Repealed 6 months after the full cannabis control board created by Article 2 of the cannabis law has been appointed**

TITLE 6 - RECORDS AND REPORTS

§ 3370. Preserving and inspection of records.

1. Any record, including prescriptions, required to be kept or maintained by this article shall be preserved for a period of at least five years following the date of the event or transaction recorded, unless a shorter period of time is specifically provided.
2. Such records shall be made available during business hours for inspection and copying by any officer or employee of the department who is charged with the enforcement of this article and to any officer or employee of this state charged with the duty of regulating or licensing of any person who by virtue of such license is authorized to obtain, distribute, dispense or administer controlled substances.
3. Every record, including prescriptions, required to be kept under this article shall be maintained at the premises where the licensed activity is conducted.
4. The department shall cause to be expunged or otherwise destroyed, within five years from the date of receipt thereof, any record of the name of any patient received by it pursuant to the filing requirements of subdivision six of section thirty-three hundred thirty-one, subdivision four of section thirty-three hundred thirty-three, and subdivision four of section thirty-three hundred thirty-four of this article.
5. Electronic prescription records shall be maintained and preserved in accordance with regulations of the commissioner.

§ 3371. Confidentiality of certain records, reports, and information.

1. No person, who has knowledge by virtue of his or her office of the identity of a particular patient or research subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:
 - (a) to another person employed by the department, for purposes of executing provisions of this article;
 - (b) pursuant to judicial subpoena or court order in a criminal investigation or proceeding;
 - (c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board;
 - (d) to the prescription monitoring program registry and to authorized users of such registry as set forth in subdivision two of this section;

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

- (e) to a practitioner to inform him or her that a patient may be under treatment with a controlled substance by another practitioner for the purposes of subdivision two of this section, and to facilitate the department's review of individual challenges to the accuracy of controlled substances histories pursuant to subdivision six of section thirty-three hundred forty-three-a of this article;
- (f) to a pharmacist to provide information regarding prescriptions for controlled substances presented to the pharmacist for the purposes of subdivision two of this section and to facilitate the department's review of individual challenges to the accuracy of controlled substances histories pursuant to subdivision six of section thirty-three hundred forty-three-a of this article;
- (g) to the deputy attorney general for medicaid fraud control, or his or her designee, in furtherance of an investigation of fraud, waste or abuse of the Medicaid program, pursuant to an agreement with the department;
- (h) to a local health department for the purpose of conducting public health research or education:
 - (i) pursuant to an agreement with the commissioner;
 - (ii) when the release of such information is deemed appropriate by the commissioner;
 - (iii) for use in accordance with measures required by the commissioner to ensure that the security and confidentiality of the data is protected; and (iv) provided that disclosure is restricted to individuals within the local health department who are engaged in the research or education;
- (i) to a medical examiner or coroner who is an officer of or employed by a state or local government, pursuant to his or her official duties; and
- (j) to an individual for the purpose of providing such individual with his or her own controlled substance history or, in appropriate circumstances, in the case of a patient who lacks capacity to make health care decisions, a person who has legal authority to make such decisions for the patient and who would have legal access to the patient's health care records, if requested from the department pursuant to subdivision six of section thirty-three hundred forty-three-a of this article or from a treating practitioner pursuant to subparagraph (iv) of paragraph (a) of subdivision two of this section.

*2. The prescription monitoring program registry may be accessed, under such terms and conditions as are established by the department for purposes of maintaining the security and confidentiality of the information contained in the registry, by:

- (a) a practitioner, or a designee authorized by such practitioner pursuant to paragraph (b) of subdivision two of section thirty-three hundred forty-three-a, section thirty-three hundred sixty-one of this article or section thirty of the cannabis law, for the purposes of: (i) informing the practitioner that a patient may be under treatment with a controlled substance by another practitioner; (ii) providing the practitioner with notifications of controlled substance activity as deemed relevant by the department, including but not limited to a notification made available on a monthly or other periodic basis through the registry of controlled substances activity pertaining to his or her patient; (iii) allowing the practitioner, through consultation of the prescription monitoring program registry, to review his or her patient's controlled substances history as required by section thirty-three hundred forty-three-a, section thirty-three hundred sixty-one of this article or section thirty of the cannabis law; and (iv) providing to his or her patient, or person authorized pursuant to paragraph (j) of subdivision one of this section, upon request, a copy of such patient's controlled substance history as is available to the practitioner through the prescription monitoring program registry; or
- (b) a pharmacist, pharmacy intern or other designee authorized by the pharmacist pursuant to paragraph (b) of subdivision three of section thirty-three hundred forty-three-a of this article, for the purposes of: (i) consulting the prescription monitoring program registry to review the controlled substances history of an individual for whom one or more prescriptions for controlled substances or certifications for cannabis is presented to the pharmacist, pursuant to section thirty-three hundred

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

forty-three-a of this article; and (ii) receiving from the department such notifications of controlled substance activity as are made available by the department; or

(c) an individual employed by a registered organization as defined in section three of the cannabis law, for the purpose of consulting the prescription monitoring program registry to review the controlled substances history of an individual for whom one or more certifications for cannabis is presented to that registered organization, pursuant to section thirty-three hundred sixty-four of this article or section thirty-four of the cannabis law. Unless otherwise authorized by this article or by the cannabis law, an individual employed by a registered organization will be provided access to the prescription monitoring program in the sole discretion of the commissioner.

*** NB Effective until July 5, 2028**

*2. The prescription monitoring program registry may be accessed, under such terms and conditions as are established by the department for purposes of maintaining the security and confidentiality of the information contained in the registry, by:

(a) a practitioner, or a designee authorized by such practitioner pursuant to paragraph (b) of subdivision two of section thirty-three hundred forty-three-a of this article, for the purposes of: (i) informing the practitioner that a patient may be under treatment with a controlled substance by another practitioner; (ii) providing the practitioner with notifications of controlled substance activity as deemed relevant by the department, including but not limited to a notification made available on a monthly or other periodic basis through the registry of controlled substances activity pertaining to his or her patient; (iii) allowing the practitioner, through consultation of the prescription monitoring program registry, to review his or her patient's controlled substances history as required by section thirty-three hundred forty-three-a of this article; and (iv) providing to his or her patient, or person authorized pursuant to paragraph (j) of subdivision one of this section, upon request, a copy of such patient's controlled substance history as is available to the practitioner through the prescription monitoring program registry; or

(b) a pharmacist, pharmacy intern or other designee authorized by the pharmacist pursuant to paragraph (b) of subdivision three of section thirty-three hundred forty-three-a of this article, for the purposes of: (i) consulting the prescription monitoring program registry to review the controlled substances history of an individual for whom one or more prescriptions for controlled substances is presented to the pharmacist, pursuant to section thirty-three hundred forty-three-a of this article; and (ii) receiving from the department such notifications of controlled substance activity as are made available by the department.

*** NB Effective until July 5, 2028**

3. Where it has reason to believe that a crime related to the diversion of controlled substances has been committed, the department may notify appropriate law enforcement agencies and provide relevant information about the suspected criminal activity, including controlled substances prescribed or dispensed, as reasonably appears to be necessary. The department shall keep a record of the information provided, including, but not limited to: the specific information provided and the agency to which such information was provided, including the name and title of the person to whom such information was provided and an attestation from such person that he or she has authority to receive such information.

4. In the course of any proceeding where such information is disclosed, except when necessary to effectuate the rights of a party to the proceeding, the court or presiding officer shall take such action

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

as is necessary to insure that such information, or record or report of such information is not made public.

§ 3371-a. Disclosure of certain records, reports, and information to another state.

1. The commissioner is authorized to disclose records, reports and information filed pursuant to sections thirty-three hundred thirty-one and thirty-three hundred thirty-three of this article:

(a) to another state's controlled substance monitoring program or other authorized agency with which the department has established an interoperability agreement, pursuant to judicial subpoena or court order in a criminal investigation or proceeding in that state;

(b) to another state's agency, department, or board with which the department has established an interoperability agreement and which is authorized to regulate, license, register or otherwise supervise a person who is authorized by law to deal in controlled substances, in the course of any investigation or proceeding by or before such agency, department or board;

(c) to another state's controlled substance monitoring program or other authorized agency with which the department has established an interoperability agreement to inform a practitioner in another state that a patient may be under treatment with a controlled substance by another practitioner; or

(d) to another state's controlled substance monitoring program or other authorized agency with which the department has established an interoperability agreement to inform a pharmacy in another state that a person who presents or has presented a prescription for one or more controlled substances at the pharmacy may have also obtained controlled substances at another pharmacy where the circumstances indicate a possibility of drug abuse or diversion, potential harm to the person, or similar grounds under regulations of the commissioner.

2. Records, reports, and information disclosed under the provisions of this section shall be in accordance with regulations promulgated by the commissioner and shall include, but not be limited to:

(a) the authentication of the person requesting such information;

(b) an attestation from the person requesting the information that he or she has authority to request and receive such information, and that such information will only be used consistent with the purpose of the request for such information;

(c) a statement of the purpose of the request for such information; and

(d) ensuring that such information is, or will be, transmitted in a secure manner.

3. Every agreement under subdivision one of this section shall:

(a) require reciprocity with the department on the part of every other party to the agreement;

(b) guarantee protection for the confidentiality of information disclosed at least as strong as the protections that would apply to the information when in the possession of the department, including remedies for breaches of confidentiality; and

(c) be subject to renewal not less frequently than every two years.

§ 3372. Practitioner patient reporting. It shall be the duty of every attending practitioner and every consulting practitioner to report promptly to the commissioner, or his duly designated agent, the name and, if possible, the address of, and such other data as may be required by the commissioner with respect to, any person under treatment if he finds that such person is an addict or a habitual user of any narcotic drug. Such report shall be kept confidential and may be utilized only for statistical, epidemiological or research purposes, except that those reports which originate in the course of a

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

criminal proceeding other than under section 81.25 of the mental hygiene law shall be subject only to the confidentiality requirements of section thirty-three hundred seventy-one of this article.

§ 3373. Confidential communications. For the purposes of duties arising out of this article, no communication made to a practitioner shall be deemed confidential within the meaning of the civil practice law and rules relating to confidential communications between such practitioner and patient.

§ 3374. Notification by licensee. Persons licensed or certified pursuant to this article shall be under a continuing duty to promptly notify the department of:

1. Each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person;
2. Any charge or proceeding brought in any court or before any governmental agency, state or federal, in which it is alleged that the licensee, its employees, subsidiaries, managing officers, or directors has failed to comply with the provisions of the federal controlled substances act or the laws of any state relating to controlled substances.

TITLE 7 - OFFENSES, VIOLATIONS AND ENFORCEMENT

§ 3380. Inhalation of certain toxic vapors or fumes, and certain hazardous inhalants; sale of glue and hazardous inhalants in certain cases.

1. (a) As used in this section the phrase "glue containing a solvent having the property of releasing toxic vapors or fumes" shall mean and include any glue, cement, or other adhesive containing one or more of the following chemical compounds: acetone, cellulose acetate, benzene, butyl alcohol, ethyl alcohol, ethylene dichloride, ethylene trichloride, isopropyl alcohol, methyl alcohol, methyl ethyl ketone, pentachlorophenol, petroleum ether, toluene or such other similar material as the commissioner shall by regulation prescribe.

(b) As used in this section hazardous inhalants shall mean and include any of the preparations of compounds containing one or more of the chemical compounds; amyl nitrite, isoamyl nitrite, butyl nitrite, isobutyl nitrite, pentyl nitrite or any other alkyl nitrite compound that is either designed to be used, or commonly used, as an inhalant.

2. No person shall, for the purpose of causing a condition of intoxication, inebriation, excitement, stupefaction, or the dulling of his brain or nervous system, intentionally smell or inhale the fumes from any hazardous inhalants or from any glue containing a solvent having the property of releasing toxic vapors or fumes; provided, that nothing in this section shall be interpreted as applying to the inhalation of any anesthesia or inhalant for medical or dental purposes.

3. No person shall, for the purpose of violating subdivision two, use, or possess for the purpose of so using, any hazardous inhalants or any glue containing a solvent having the property of releasing toxic vapors or fumes.

4. No person shall sell, or offer to sell, to any other person any tube or other container of any hazardous inhalants or glue containing a solvent having the property of releasing toxic vapors or fumes:

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(a) if he has knowledge that the product sold, or offered for sale, will be used for the purpose set forth in subdivision two of this section; or

(b) unless there has been added to such glue a sufficient quantity of an additive, approved by the commission, which shall act as a deterrent to inhalation, and not be harmful or toxic to the human body. This provision shall not apply to hazardous inhalants or glue manufactured and sold for industrial use.

5. (a) No person shall use nitrous oxide for purposes of causing intoxication, inebriation, excitement, stupefaction or the dulling of the brain or nervous system of himself or another.

(b) No person shall sell any canister or other container of nitrous oxide unless granted an exemption pursuant to this subdivision. In no event shall any canister or other container of nitrous oxide be sold to a person under the age of twenty-one years.

(c) This subdivision shall not apply to the use of nitrous oxide in industrial, medical or dental applications, or to specific products which must use nitrous oxide as a propellant provided such products shall in no event be sold at retail to the public, as shall be determined by the commissioner pursuant to paragraph (d) of this subdivision.

(d) The commissioner is directed to promulgate regulations to exempt specific products which must use nitrous oxide, or a mixture of nitrous oxide with other gases, as a propellant from the provisions of this chapter provided such regulations shall prohibit the sale of such products at retail to the public.

(e) The provisions of this section shall not be deemed to prohibit the sale of food products containing nitrous oxide provided such products comply with the provisions of section sixteen-a of the agriculture and markets law.

(f) The commissioner may, upon the application of a manufacturer or seller of a product containing nitrous oxide and intended for sale at retail, authorize the sale of such a product if there is no evidence of substantial misuse of the product as defined by this subdivision and if the manufacturer or seller takes the following steps to:

(i) clearly indicate the legitimate purpose or use of the product on the package;

(ii) display prominently on the package in heavy type print language which warns of health dangers resulting from the misuse of nitrous oxide;

(iii) demonstrate that the product bears a distinctive feature or features enabling it to be clearly distinguished from the nitrous oxide products of other manufacturers;

(iv) educate wholesale and retail businesses which sell the product of the dangers of nitrous oxide and the need to monitor its sale; and

(v) prevent their sale of the product to any person, firm or corporation who or which sells drug-related paraphernalia as such term is defined by subdivision two of section eight hundred fifty of the general business law.

6. (a) Any person who violates any provision of subdivision two or three of this section shall be guilty of an offense and upon conviction thereof shall be punished by a fine of not more than fifty dollars or by imprisonment for not more than five days, or by both such fine and imprisonment.

(b) Any person who violates any provision of subdivision four or five of this section shall be guilty of a class A misdemeanor.

§ 3381. Sale and possession of hypodermic syringes and hypodermic needles. 1. It shall be unlawful for any person to sell or furnish to another person or persons, a hypodermic syringe or hypodermic needle except:

(a) pursuant to a prescription of a practitioner, which for the purposes of this section shall include a patient specific prescription form as provided for in the education law; or

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(b) to persons who have been authorized by the commissioner to obtain and possess such instruments; or

(c) by a pharmacy licensed under article one hundred thirty-seven of the education law, health care facility licensed under article twenty-eight of this chapter or a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice; provided, however, that such sale or furnishing: (i) shall only be to a person eighteen years of age or older; and (ii) shall be in accordance with subdivision four of this section; or (d) under subdivision three of this section.

2. Any person selling or furnishing a hypodermic syringe or hypodermic needle pursuant to a prescription shall record upon the prescription, his or her signature or electronic signature, and the date of the sale or furnishing of the hypodermic syringe or hypodermic needle. Such prescription shall be retained on file for a period of five years and be readily accessible for inspection by any public officer or employee engaged in the enforcement of this section. Such prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription, provided however no such authorization shall be effective for a period greater than two years from the date the prescription is signed.

3. The commissioner shall, subject to subdivision four of this section, designate persons, or by regulation, classes of persons who may obtain hypodermic syringes and hypodermic needles without prescription and the manner in which such transactions may take place and the records thereof which shall be maintained.

4. (a) A person eighteen years of age or older may obtain and possess a hypodermic syringe or hypodermic needle pursuant to paragraph (c) of subdivision one of this section.

(b) Subject to regulations of the commissioner, a pharmacy licensed under article one hundred thirty-seven of the education law, a health care facility licensed under article twenty-eight of this chapter or a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice, may obtain and possess hypodermic needles or syringes for the purpose of selling or furnishing them pursuant to paragraph (c) of subdivision one of this section or for the purpose of disposing of them.

(c) Sale or furnishing of hypodermic syringes or hypodermic needles to direct consumers pursuant to this subdivision by a pharmacy, health care facility, or health care practitioner shall be accompanied by a safety insert. Such safety insert shall be developed or approved by the commissioner and shall include, but not be limited to, (i) information on the proper use of hypodermic syringes and hypodermic needles; (ii) the risk of blood borne diseases that may result from the use of hypodermic syringes and hypodermic needles; (iii) methods for preventing the transmission or contraction of blood borne diseases; (iv) proper hypodermic syringe and hypodermic needle disposal practices; (v) information on the dangers of injection drug use, and how to access drug treatment; (vi) a toll-free phone number for information on the human immunodeficiency virus; and (vii) information on the safe disposal of hypodermic syringes and hypodermic needles including the relevant provisions of the environmental conservation law relating to the unlawful release of regulated medical waste. The safety insert shall be attached to or included in the hypodermic syringe and hypodermic needle packaging, or shall be given to the purchaser at the point of sale or furnishing in brochure form.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(d) In addition to the requirements of paragraph (c) of subdivision one of this section, a pharmacy licensed under article one hundred thirty-seven of the education law may sell or furnish hypodermic needles or syringes only if such pharmacy stores such needles and syringes in a manner that makes them available only to authorized personnel and not openly available to customers.

(e) A pharmacy registered under article one hundred thirty-seven of the education law may offer counseling and referral services to customers purchasing hypodermic syringes for the purpose of: preventing injection drug abuse; the provision of drug treatment; preventing and treating hepatitis C; preventing drug overdose; testing for the human immunodeficiency virus; and providing pre-exposure prophylaxis and non-occupational post-exposure prophylaxis. The content of such counseling and referral shall be at the professional discretion of the pharmacist.

(f) The commissioner shall promulgate rules and regulations necessary to implement the provisions of this subdivision which shall include: (i) standards for advertising to the public the availability for retail sale or furnishing of hypodermic syringes or needles; and (ii) a requirement that such pharmacies, health care facilities and health care practitioners cooperate in a safe disposal of used hypodermic needles or syringes.

(g) The commissioner may, upon the finding of a violation of this section, suspend for a determinate period of time the sale or furnishing of syringes by a specific entity.

5. The provisions of this section shall not apply to farmers engaged in livestock production or to those persons supplying farmers engaged in livestock production, provided that:

(a) Hypodermic syringes and needles shall be stored in a secure, locked storage container.

(b) At any time the department may request a document outlining:

(i) the number of hypodermic needles and syringes purchased over the past calendar year;

(ii) a record of all hypodermic needles used over the past calendar year; and

(iii) a record of all hypodermic needles and syringes destroyed over the past calendar year.

(c) Hypodermic needles and syringes shall be destroyed in a manner consistent with the provisions set forth in section thirty-three hundred eighty-one-a of this article.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3381-a. Destruction of hypodermic syringes and needles. All hypodermic syringes, needles and disposable hypodermic units which are no longer usable or required shall be crushed, broken or otherwise rendered inoperable in the process of disposal.

The department may specify procedures for disposal of such hypodermic syringes, needles and disposable units as may be necessary to protect public health including, but not limited to, placement of such syringes, needles and units in a leak-proof, puncture resistant container prior to disposal.

§ 3383. Imitation controlled substances.

1. For purposes of this section, the following terms shall have the following meanings:
 - a. "Manufacture" means the production, preparation, compounding, tableting, processing, encapsulating, packaging, repackaging, labeling or relabeling of an imitation controlled substance.
 - b. "Markings" means a simulated trademark, trade name, imprinting or other mark, or likeness thereof, of the manufacturer, distributor or dispenser of a controlled substance or a simulated code number or symbol or likeness thereof identifying a controlled substance or combination of such substances.
 - c. "Imitation controlled substance" means a substance, other than a drug for which a prescription is required pursuant to article one hundred thirty-seven of the education law, that is not a controlled substance, which by dosage unit appearance, including color, shape and size and by a representation is represented to be a controlled substance, as defined in the penal law. Evidence of representations that the substance is a controlled substance may include but is not limited to oral or written representations by the manufacturer or seller, as the case may be, about the substance with regard to:
 - (i) its price, nature, use or effect as a controlled substance; or
 - (ii) its packaging in a manner normally used for illicit controlled substances; or
 - (iii) markings on the substance.
2. It shall be unlawful for any person to manufacture, sell or possess with the intent to sell, an imitation controlled substance.
3. It shall be unlawful for any person to possess or use any punch, die, plate, stone or any other equipment in order to print, imprint, or reproduce the trademark, trade name or other identifying

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

mark, imprint or device of another or any likeness of any of the foregoing upon any substance or container or labeling thereof with intent to manufacture an imitation controlled substance.

4. No liability shall be imposed by virtue of this section on any person licensed pursuant to article one hundred thirty-one of the education law or licensed under this article who manufactures, distributed, sells, prescribes, dispenses or possesses an imitation controlled substance for use as a placebo or for use in clinical research conducted pursuant to the federal food, drug and cosmetic act.

5. Nothing in this section shall apply to a noncontrolled substance that was initially introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate.

6. In any prosecution under this section it shall be necessary to prove that the imitation controlled substance was represented to be a controlled substance; however, it shall not be a defense to a prosecution under this section that the accused believed the imitation controlled substance to be a controlled substance.

7. A violation of subdivision two or three of this section shall be a class A misdemeanor. A violation of subdivision two or three of this section by a person previously convicted of a violation of this section within the preceding five years shall be a class E felony.

8. If any provision or part of this section or application thereof is held invalid, the invalidity shall not affect other provisions, parts or applications of this section which can be given effect without the invalid provisions or application, and to this end the provisions of this section are severable.

§ 3384. Information program for retailers. The department shall develop and maintain a program to inform retailers about the methamphetamine problem in New York state.

§ 3385. Enforcement.

1. (a) The department and its representatives shall have access during business hours to all orders, prescriptions or records required to be kept under this article.

(b) Orders, prescriptions and records required to be kept under this article shall be maintained at the premises where the licensed activity is conducted.

2. For the purposes of enforcing the provisions of this article, each employee of the department designated by the commissioner shall possess all of the powers of a peace officer as set forth in section 2.20 of the criminal procedure law.

§ 3385-a. Access to criminal history information. Upon such terms and conditions as the commissioner of the division of criminal justice services agrees, authorized employees of the department's bureau of narcotic enforcement, designated by the commissioner pursuant to subdivision two of section three thousand three hundred eighty-five of this title, may access criminal history information in the central data facility established pursuant to subdivision six of section eight hundred thirty-seven of the executive law upon request to the director of the bureau of narcotic enforcement demonstrating the necessity for such access as part of an identified, ongoing criminal investigation. Any information obtained as a result of such access shall not be disseminated to persons not authorized to access such criminal history information.

§ 3387. Seizure and forfeiture of controlled substances, imitation controlled substances and official New York state prescription forms; disposition.

1. Any controlled substance or imitation controlled substance which has been manufactured, distributed, dispensed or acquired in violation of this article, or the lawful possession of which

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

cannot be immediately ascertained, and any official New York state prescription form which has been printed, distributed or acquired in violation of this article or the lawful possession of which cannot be immediately ascertained are hereby declared to be public nuisances and may be seized by a peace officer, acting pursuant to his special duties, or a police officer and shall be forfeited, and disposed of as follows:

- (a) except as in this section otherwise provided, the commissioner, the court or magistrate having jurisdiction shall order such controlled substance or imitation controlled substance forfeited or destroyed. A record of the quantity and nature of the substance, of the place where said substance was seized, and of the time, place and manner of destruction, shall be kept, and a return under oath, reporting said destruction, shall be made to the person ordering such destruction by the officer who destroys them;
- (b) upon written application by the commissioner, the court or magistrate by whom the forfeiture of controlled substances or imitation controlled substances has been decreed may order the delivery of any of them, except substances listed in schedule I of section thirty-three hundred six, to such commissioner for distribution or destruction, as hereinafter provided;
- (c) upon application by any hospital within this state, not operated for private gain, the commissioner may in his discretion deliver any controlled substance or imitation controlled substance that has come into his custody by authority of this section to the applicants for medicinal use;
- (d) the commissioner may from time to time deliver excess stocks of controlled substances or imitation controlled substances to the Bureau or shall destroy the same;
- (e) controlled substances or imitation controlled substances which are excess or undesired by persons lawfully possessing the same may be disposed of in such manner as the commissioner shall by regulation require;
- (f) official New York state prescription forms which have been seized as provided by this section shall be disposed of by express prepaid shipment to the "State Department of Health, Bureau of Prescription Analysis, Albany, New York," or by delivery to an authorized narcotic control representative of the department.

2. The commissioner shall keep a full and complete record of all controlled substances or imitation controlled substances received and of all controlled substances or imitation controlled substances disposed of, showing the exact kinds, quantities and forms of such substances; the persons from whom received and to whom delivered; by whose authority received, delivered and destroyed; and the dates of the receipt, disposal or destruction. This record shall be open to inspection by all federal or state officers charged with the enforcement of federal and state laws relating to controlled substances or imitation controlled substances.

3. Any raw material product, container or equipment of any kind which is used, or intended for use, in manufacturing, distributing, dispensing or administering a controlled substance or imitation controlled substance in violation of this article shall be seized by any peace officer, acting pursuant to his special duties, or police officer and forfeited in the same manner as property subject to seizure and forfeiture pursuant to section thirty-three hundred eighty-eight of this article, except that such property shall not be retained for use by any official.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3388. Seizure and forfeiture of vehicles, vessels or aircraft unlawfully used to conceal, convey or transport controlled substances.

1. Except as authorized in this article, it shall be unlawful to:

(a) transport, carry, or convey any controlled substance in, upon, or by means of any vehicle, vessel or aircraft; or

(b) conceal or possess any controlled substance in or upon any vehicle, vessel or aircraft, or upon the person of anyone in or upon any vehicle, vessel or aircraft; or

(c) use any vehicle, vessel or aircraft to facilitate the transportation, carriage, conveyance, concealment, receipt, possession, purchase, or sale of any controlled substance.

2. Any vehicle, vessel or aircraft which has been or is being used in violation of subdivision one, except a vehicle, vessel or aircraft used by any person as a common carrier in the transaction of business as such common carrier shall be seized by any peace officer, acting pursuant to his special duties, or police officer, and forfeited as hereinafter in this section provided. A vehicle, vessel or aircraft is not subject to forfeiture unless used in connection with acts or conduct which would constitute a felony under article 220 of the penal law.

3. The seized property shall be delivered by the officer having made the seizure to the custody of the district attorney of the county wherein the seizure was made, except that in the cities of New York, Yonkers, Rochester and Buffalo the seized property shall be delivered to the custody of the police department of such cities and such property seized by a member or members of the state police shall be delivered to the custody of the superintendent of state police, together with a report of all the facts and circumstances of the seizure.

4. It shall be the duty of the attorney general in seizures by members of the state police, otherwise it shall be the duty of the district attorney of the county wherein the seizure is made, if elsewhere than in the cities of New York, Yonkers, Rochester or Buffalo, and where the seizure is made in such cities it shall be the duty of the corporation counsel of the city, to inquire into the facts of the seizure so reported to him and if it appears probable that a forfeiture has been incurred by reason of a violation of this section, for the determination of which the institution of proceedings in the supreme court is necessary, to cause the proper proceedings to be commenced and prosecuted, not later than twenty days after written demand by a person claiming ownership thereof, to declare such forfeiture, unless, upon inquiry and examination, such district attorney, attorney general or corporation counsel decides that such proceedings cannot probably be sustained or that the ends of public justice do not require that they should be instituted or prosecuted, in which case, the district attorney, the attorney general or corporation counsel shall cause such seized property to be returned to the owner thereof. The procedure for proceedings instituted under this section shall conform as much as possible to the procedure for attachment.

5. Notice of the institution of the forfeiture proceeding shall be served either:

(a) personally on the owners of the seized property; or

(b) by registered mail to the owners' last known address and by publication of the notice once a week for two successive weeks in a newspaper published or circulated in the county wherein the seizure was made.

6. Forfeiture shall not be adjudged where the owners establish by preponderance of the evidence that:

(a) the use of such seized property, in violation of subdivision one of this section, was not intentional on the part of any owner; or

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

(b) said seized property was used in violation of subdivision one of this section by any person other than an owner thereof, while such seized property was unlawfully in the possession of a person who acquired possession thereof in violation of the criminal laws of the United States, or of any state.

7. The district attorney, the superintendent of state police or the police department having custody of the seized property, after such judicial determination of forfeiture, shall, at their discretion, either retain such seized property for the official use of their office, division or department, or, by a public notice of at least five days, sell such forfeited property at public sale; provided, however, that where such property is subject to a perfected lien such property may not be retained for their official use unless all such liens on the property to be retained have been or will be satisfied. The net proceeds of any such sale, after deduction of the lawful expenses incurred, shall be paid into the general fund of the county wherein the seizure was made except that the net proceeds of the sale of property seized in the cities of New York, Yonkers, Rochester and Buffalo shall be paid into the respective general funds of such cities, and of the sale of property seized by the state police into the general fund of the state.

8. Whenever any person interested in any property which is seized and declared forfeited under the provisions of this section files with a justice of the supreme court a petition for the recovery of such forfeited property, the justice of the supreme court may restore said forfeited property upon such terms and conditions as he deems reasonable and just, if the petitioner establishes either of the affirmative defenses set forth in subdivision six of this section and that the petitioner was without personal or actual knowledge of the forfeiture proceeding. If the petition be filed after the sale of the forfeited property, any judgment in favor of the petitioner shall be limited to the net proceeds of such sale, after deduction of the lawful expenses and costs incurred by the district attorney, police department or corporation counsel.

9. No suit or action under this section for wrongful seizure shall be instituted unless such suit or action is commenced within two years after the time when the property was seized.

§ 3390. Revocation of licenses and certificates of approval. Any license or certificate of approval granted pursuant to this article may be revoked by the commissioner in whole or in part upon a finding that the licensee or certificate holder has:

1. falsified any application, report, or record required by this article;
2. wilfully failed to furnish the department with timely reports or information required to be filed with the department;
3. been convicted of an offense in any jurisdiction relating to any substance listed in this article as a controlled substance;
4. wilfully or negligently failed to comply with any of the provisions of the federal controlled substances act, this article, or the regulations promulgated thereunder;
5. failed to maintain effective control against diversion of controlled substances; or
6. wilfully and unreasonably refused to permit an inspection authorized by this article.

§ 3391. Revocation and suspension of license or certificate of approval procedure.

1. A proceeding to revoke a license or certificate of approval shall be commenced by a notice served personally or by registered or certified mail upon the licensee or holder of a certificate of approval directing him to show cause why his license or certificate should not be revoked. Such notice shall set forth in detail the grounds for the proposed revocation and shall fix a date for hearing not less than fifteen nor more than thirty days from the date of such notice.
2. Simultaneous with the commencement of a proceeding to revoke a license or certificate or during the course of such proceeding, the commissioner may in the case of a clear and imminent danger

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

to the public health or safety forthwith suspend without prior notice any license or certificate theretofore issued.

3. If the commissioner suspends or revokes a license or certificate, all controlled substances owned or possessed by the licensee or holder of a certificate of approval and in the state of New York at the time of the suspension or the effective date of the revocation and which such licensee or holder of a certificate of approval is no longer authorized to possess, shall be seized or placed under seal in the manner provided in this article.
4. In lieu of revocation of a license or certificate, the commissioner may impose a civil penalty not in excess of ten thousand dollars. Such penalty may be imposed in lieu of revocation only if the commissioner is satisfied that the imposition and payment of such penalty will serve as a sufficient deterrent to future violations.

§ 3393. Formal hearings procedure.

1. The commissioner or any person designated by him for this purpose, shall have the power to administer oaths, compel the attendance of witnesses and the production of books, records and documents and to take proof and testimony concerning all matters within the jurisdiction of the department.
2. Notice of hearing shall be served at least fifteen days prior to the date of the hearing, provided, however, whenever the commissioner has made a preliminary order suspending a license or directing the cessation of any activity pending the hearing, the commissioner shall provide the person affected thereby with an opportunity to be heard within five days.
3. At a hearing any person who is a party thereto may appear personally, shall have the right of counsel, and may cross-examine witnesses and produce evidence and witnesses in his own behalf.
4. Following a hearing, the commissioner shall make appropriate findings of fact and determinations and shall issue an order in accordance therewith.
5. The person conducting the hearing shall not be bound by the rules of evidence but any determination must be founded upon sufficient legal evidence to sustain it.
6. The commissioner may adopt such rules and regulations governing the procedures to be followed with respect to the hearings as may be consistent with the fair and effective administration of this article.
7. Any notice, application, order or other paper required to be served upon any party to a proceeding hereunder may be served in person, by registered mail or by certified mail upon either the party or an attorney who has appeared on his behalf.

§ 3394. Judicial review.

1. All orders or determinations hereunder shall be subject to judicial review as provided in article seventy-eight of the civil practice law and rules. In any such proceeding findings of fact made by the commissioner, if supported by substantial evidence, shall be conclusive.
2. Application for such review must be made within sixty days after service of the order or determination upon the person whose license, certificate, right or privilege is affected thereby or upon the attorney of record for such person.
3. An order, or the enforcement of an order revoking or suspending a license or revoking or canceling official forms issued by the department, if accompanied by a finding of a clear and imminent danger to the public health or safety, may not be temporarily stayed or restrained prior to a determination on the merits of the application for judicial review.

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

Provided as a courtesy of Pharmacy Law Newsletter, University at Buffalo

§ 3396. Violations; penalties.

1. In any civil, criminal or administrative action or proceeding brought for the enforcement of any provision of this article, it shall not be necessary to negate or disprove any exception, excuse, proviso or exemption contained in this article, and the burden of proof of any such exception, excuse, proviso, or exemption shall be upon the person claiming its benefit.
2. Violation of any provision of this article for which a penalty is specifically provided herein shall be punishable as provided herein. Violation of any provision of this article for which no penalty is provided herein shall be punishable as provided in section twelve-b of article one of this chapter or in the penal law.
3. No person shall be prosecuted for a violation of any provision of this article if such person has been acquitted or convicted under the federal controlled substances act, of the same act or omission which, it is alleged, constitutes a violation of this article.
4. Upon the conviction of any person for violating any provision of this article, a copy of the judgment and sentence, and of the opinion of the court or judge, if any opinion be filed, shall be sent by the clerk of the court, or by the judge, to the board or officer, if any, by whom the convicted defendant has been licensed or registered to practice his profession, or to carry on his business.
5. Upon the imposition of any penalty, warning, reprimand or other sanction against any person for violating any provision of this article, a copy of the order, finding or opinion, if any is made or rendered, shall be sent by the person authorized by law to make such determination, to the board or officer by whom the respondent is licensed or registered to practice a profession or to carry on a business.

§ 3397. Fraud and deceit.

1. No person shall:
 - (a) obtain or attempt to obtain a controlled substance, a prescription for a controlled substance or an official New York State prescription form,
 - (i) by fraud, deceit, misrepresentation or subterfuge; or
 - (ii) by the concealment of a material fact; or
 - (iii) by the use of a false name or the giving of a false address;
 - (b) wilfully make a false statement in any prescription, order, application, report or record required by this article;
 - (c) falsely assume the title of, or represent himself to be a licensed manufacturer, distributor, pharmacy, pharmacist, practitioner, researcher, approved institutional dispenser, owner or employee of a registered outsourcing facility or other authorized person, for the purpose of obtaining a controlled substance;
 - (d) make or utter any false or forged prescription or false or forged written order;
 - (e) affix any false or forged label to a package or receptacle containing controlled substances; or
 - (f) imprint on or affix to any controlled substance a false or forged code number or symbol.
2. Possession of a false or forged prescription for a controlled substance by any person other than a pharmacist in the lawful pursuance of his profession shall be presumptive evidence of his intent to use the same for the purpose of illegally obtaining a controlled substance.
3. Possession of a blank official New York state prescription form by any person to whom it was not lawfully issued shall be presumptive evidence of such person's intent to use the same for the purpose of illegally obtaining a controlled substance.
4. Any person who, in the course of treatment, is supplied with a controlled substance or a prescription therefor by one practitioner and who, without disclosing the fact, is supplied during

ARTICLE 33: NEW YORK STATE CONTROLLED SUBSTANCES ACT

As of July 29, 2022

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such treatment with a controlled substance or a prescription therefor by another practitioner shall be guilty of a violation of this article.

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