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NEW YORK CODES, RULES, AND REGULATIONS RELATING TO THE REGULATION OF CONTROLLED SUBSTANCES

Part 80: Rules and Regulations on Controlled Substances

GENERAL PROVISIONS

§80.1 Definitions.

Except where different meanings are expressly specified, the terms used in this Part shall have the meanings set forth in Public Health Law, section 3302.

(a) Authorized practitioner and practitioner means practitioner as such term is defined in the Public Health Law (section 3302(28), and shall include certified nurse practitioners and licensed midwives certified by the Education Department to prescribe and administer drugs. The term shall also include registered physician's assistants certified by the Education Department.

(b) GSA means the United States General Services Administration.

(c) Department means the Department of Health of the State of New York.

(d) Commissioner means the Commissioner of Health of the State of New York.

(e) Bureau of Narcotic Enforcement means the Bureau of Narcotic Enforcement of the Department of Health of the State of New York.

(f) Drug Enforcement Administration registration number means such number assigned by the Drug Enforcement Administration, United State Department of Justice, or its successor agency, to a practitioner, authorized practitioner, or any person authorized to manufacture, distribute, sell, dispense or administer controlled substances.

(g) Automated dispensing system means a system approved by the Department that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of controlled substances, and which collects, controls, and maintains all transaction information.

(h) Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

(i) Electronic signature means the creation of an electronic identifier (i.e. 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.

(j) Written prescription, for the purposes of this Part, and issued in New York State, shall mean an official New York State prescription form.

(k) Compliance with the requirements of this Part does not alter the responsibilities of the practitioner, pharmacist or pharmacy to comply with any applicable federal law or regulation.

§80.6 Safeguarding controlled substances.

(a) Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the Drug Enforcement Administration and which is used in the ordering of the controlled substances, where they will be available for inspection by properly authorized officers, agents and employees of the New York State Department of Health, Bureau of Narcotic Enforcement.

(b) Access to controlled substances stocks shall be limited to the minimum number of employees actually required to efficiently handle the manufacture, distribution, custody, dispensing, administration or other handling of such substances.

(c) The administrative head of a licensee hospital, laboratory, dispensary, nursing home and health-related facility and the supervisor of a manufacturer or distributor is responsible for the proper safeguarding and handling of controlled substances within the hospital or other facility. An administrative head or supervisor is not relieved of his responsibility to detect and correct any diversion or mishandling of controlled substances by a delegation of responsibility.

(d) Persons operating pharmacies and supervising pharmacists of such pharmacies are responsible for the proper safeguarding and handling of controlled substances within the pharmacy. Persons operating pharmacies and supervising pharmacists are not relieved of their responsibility to detect and correct any diversion of mishandling of controlled substances by a delegation of responsibility.

PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES

§80.60 Ordering.

No practitioner shall obtain Schedule II controlled substances except by means of his or her official Federal written order forms. Schedules II, III, IV and V controlled substances shall be obtained from manufacturers or distributors licensed under article 33 of the Public Health Law and this Part.

§80.61 Personal use.

A person authorized by law to obtain controlled substances for professional use shall not use such drugs for the treatment of his own addiction, or habitual use.

§80.62 Use of controlled substances in treatment.

(a) Physicians and other authorized practitioners in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment, other than treatment for addiction to controlled substances, when the practitioner regulates the dosage and prescribes or administers a quantity of such drugs no greater than that ordinarily recognized by members of his profession as sufficient for proper treatment in a given case.

(b) Such practitioners shall maintain a written patient record of administration, dispensing and prescription of all controlled substances. The patient record shall contain sufficient information to justify the diagnosis and warrant the treatment. The record shall contain at least the following information: patient identification data; chief complaint; present illness; physical examination as indicated; diagnosis; other data which support the diagnosis or treatment; and the regimen including the amount, strength, and directions for use of the controlled substance. This subdivision shall not be construed to require a record distinct from the medical record of the patient.

§80.63 Prescribing.

(a) A prescription as defined by the Public Health Law means:

(1) an official New York State prescription;

(2) an electronic prescription;

(3) an oral prescription; or

(4) an out-of-state prescription, which means a prescription issued in lieu of an official prescription by a practitioner in another state who is licensed by that state to prescribe controlled substances.

(b) The use of preprinted prescriptions which indicate the controlled substance or the strength, dosage and/or quantity of the controlled substance is prohibited. Such prohibition shall not apply to printed prescriptions generated by means of a computer or an electronic medical record system, provided such printed prescriptions are generated at the time a practitioner prescribes a controlled substance for a patient.

(c) (1) Prior to prescribing for or dispensing to a patient any controlled substance listed on schedule II, III, or IV of section 3306 of the public health law, every practitioner shall consult the prescription monitoring program registry for the purpose of reviewing that patient's controlled substance history. The patient's controlled substance history shall be obtained from the prescription monitoring program registry no more than 24 hours prior to the practitioner prescribing or dispensing any controlled substance to that patient. A practitioner shall document such consultation in the patient's medical chart or, if the practitioner does not consult the prescription monitoring program registry, the practitioner shall document in the patient's medical chart the reason such consultation was not performed. Such documentation shall include the specific exception listed in paragraph (2) of this Subdivision.

(i) When such consultation is not performed due to circumstances specified in subparagraph (2)(vii) of this Subdivision, the practitioner shall further document in the patient's medical chart the conditions, occurrences, or circumstances that caused such consultation in a timely manner to be unreasonable. Such documentation shall include a description of the barrier(s) to accessing the registry, and the efforts made by the practitioner to contact other designees.

(ii) When such consultation is not performed due to circumstances specified in subparagraph (2)(viii) of this Subdivision, the practitioner shall further document in the patient's medical chart a description of the circumstances supporting the practitioner's conclusion that consultation of the registry would adversely impact the patient's ability to obtain a prescription in a timely manner and the relationship between that delay and the patient's medical condition.

(2) The duty to consult the prescription monitoring program registry shall not apply to:

(i) veterinarians;

(ii) a practitioner dispensing pursuant to public health law section 3351(3);

(iii) a practitioner administering a controlled substance, as defined in public health law section 3302(2);

(iv) a practitioner prescribing or ordering a controlled substance pursuant to public health law section 3342(1) for a patient of an institutional dispenser as defined by public health law section 3302 for use on the premises of, or during an emergency transfer from, the institutional dispenser;

(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 public health law section 4002;

(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 public health law section 3343-a, 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 circumstances under which consultation of the registry would, as determined by the practitioner, result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient, provided that the quantity of the controlled substance does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(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 defined in Section 80.64 of this Part. In the instance of a temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control; or

(x) a practitioner to whom the commissioner has granted a waiver from the requirement to consult the registry. A waiver may be issued by the commissioner based upon a showing by a practitioner that his or her ability to consult the registry in accordance with this section is unduly burdened by:

(a) technological limitations that are not reasonably within the control of the practitioner; or

(b) other exceptional circumstance demonstrated by the practitioner.

The practitioner's showing shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination. As part of the application for a waiver, the practitioner shall also provide any information which would tend to negate the need for a waiver. A waiver shall be granted by the commissioner for a specified period of time, but in no event for more than one year. Subsequent waivers shall be applied for in the same manner and shall be subject to the same requirements as the original waiver. A practitioner who has been granted a waiver shall notify the department in writing within five business days upon gaining the capability to consult the prescription monitoring program registry. Without regard to the original expiration date, the waiver granted to the practitioner shall terminate within a reasonable period of time as determined by the department, allowing for the practitioner to make accommodations to begin consulting the prescription monitoring program registry.

(3) A practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that 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. A practitioner may only appoint a designee if:

(i) such designee is located in the state of New York when accessing the prescription monitoring program registry;

(ii) the designee is employed by the same professional practice or is under contract with such practice. For purposes of this subparagraph, professional practice shall include, but not be limited to, an institutional dispenser where the designating practitioner is employed, under contract, or otherwise has privileges or authorization to practice;

(iii) the practitioner takes reasonable steps to ensure or has actual knowledge that such designee is sufficiently competent in the use of the registry and that such designee is aware of and conforms to all relevant federal and state privacy statutes;

(iv) 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 the practitioner remains responsible for any breach of confidentiality; and

(v) the practitioner selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department. Upon a designee's relinquishment or termination of employment or authorization as a designee, a designating practitioner shall immediately notify the department, in a fashion deemed appropriate by the commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating practitioner's behalf.

(4) 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. A pharmacist may designate another pharmacist or a pharmacy intern as defined by section sixty-eight hundred six of the education law to consult the prescription monitoring program registry on the pharmacist's behalf, provided that:

(i) such designee is located in the state of New York when accessing the prescription monitoring program registry and is employed by the same pharmacy or is under contract with such pharmacy; and

(ii) the designating pharmacist selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department.

Upon relinquishment or termination of employment or authorization as a designee, a designating pharmacist shall immediately notify the department, in a fashion deemed appropriate by the commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating pharmacist's behalf.

(d) (1) No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except as otherwise permitted by this subdivision.

(2) Once the initial examination has been completed, the frequency and necessity for future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner: (i) had direct access to the patient's medical records and such records warrant continued controlled substance prescribing, or (ii) had direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for his or her own record and shall transmit to the initial prescriber the prescription information. The initial prescriber shall include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if: (i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient; and (ii) an emergency exists; and (iii) the prescription does not exceed a 5 day supply as determined by the directions for use. An emergency means that the immediate administration of the drug is necessary for the proper treatment of the patient and that no alternative treatment is available. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of section 80.68 and section 80.70 of this Part.

§80.67 Schedule II and certain other substances.

(a) Prescriptions shall not be refilled for schedule II substances and:

- Alprazolam
- Bromazepam
- Camazepam
- Chlordiazepoxide
- Clobazam
- Clonazepam
- Clorazepate
- Clotiazepam
- Cloxazolam
- Delorazepam
- Diazepam
- Estazolam
- Ethyl Loflazepate
- Fludiazepam
- Flunitrazepam
- Flurazepam
- Halazepam

- Haloxazolam
- Ketazolam
- Loprazolam
- Lorazepam
- Lormetazepam
- Medazepam
- Midazolam
- Nimetazepam
- Nitrazepam
- Nordiazepam
- Oxazepam
- Oxazolam
- Pinazepam
- Prazepam
- Quazepam
- Temazepam
- Tetrazepam
- Triazolam

(b) Such prescription shall be written with ink, indelible pencil, typewriter, or by other electronic means approved by the department, and shall be signed by the practitioner. Electronic prescriptions may be created, signed, and transmitted electronically provided the practitioner complies with all other requirements for issuing a prescription for a controlled substance in this Part and with federal requirements for electronic prescribing of controlled substances. The prescription shall contain the following:

(1) name, sex, 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 in custody of such animal;

(2) the printed name, address, Drug Enforcement Administration registration number, telephone number and handwritten signature of the prescribing practitioner. The printed name of the prescriber who has signed the prescription shall be imprinted or stamped legibly and conspicuously on the prescription, shall appear in an appropriate location on the prescription form and shall not be entered in or upon the space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be a substitute for or fulfill any legal requirement otherwise mandating that the prescription be signed by the prescriber;

(3) specific directions for use, including, but not limited to the dosage and frequency of dosage and the maximum daily dosage; and

(4) the date upon which such prescription was prepared and actually signed by the prescribing practitioner. A prescription shall be dated as of, and signed on, the date it is issued.

(5) the quantity of dosage units prescribed. On an official New York State prescription, the quantity of dosage units prescribed shall be indicated in both numerical and written word form.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(7) A prescription generated on an electronic system and printed out or transmitted via facsimile is not an electronic prescription and shall be manually signed.

(8) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and if the patient is limited English proficient, a specification of the preferred language indicated by the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(c) Except as provided for in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d) (1) A practitioner may issue a prescription for up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six month supply of an anabolic steroid if used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

(i) panic disorders, designated as code A;

(ii) attention deficit disorder, designated as code B;

(iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;

(iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;

(v) narcolepsy, designated as code E; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

(2) Such prescription shall specify the condition being treated on the face of the prescription. The practitioner issuing such prescription shall either:

(i) specify the name of such condition on the face of the prescription; or

(ii) specify a code on the prescription to denote the condition for which the prescription has been issued, in accordance with codes designated in paragraph (d)(1) of this section.

(3) Either the name of the condition or one of the designated codes shall fulfill the requirement in:

(i) section 3332(3) of the Public Health Law for the specific condition to be given on the face of the prescription; and

(ii) section 3333(1) of the Public Health Law for the 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 30 days' supply of a controlled substance.

(e) Such official New York State prescription or out-of-state written prescription for a patient enrolled in a hospice program or for a patient residing in a Residential Health Care Facility (RHCF) may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile, provided;

(1) The hospice program or RHCF is licensed or approved by the Department;

(2) The dispensing pharmacy has a written agreement or contract with the hospice program or "RHCF" to dispense controlled substances to a patient of such program or facility;

(3) The practitioner shall note on the prescription that the patient is a "hospice patient" or "RHCF patient"; and

(4) Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(f) An official New York State prescription or an out-of-state written prescription for a Schedule II narcotic substance or for those controlled substances listed in paragraph (a) of this Section to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile. Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(g) When an official New York State prescription or an out-of-state written prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(h) A practitioner may orally authorize a pharmacist to change information on an official New York State prescription or an out-of-state written prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, the reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(i) When a pharmacist fills a prescription under subdivision (g) or subdivision (h) of this section, in a manner that would require the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(j) When a practitioner is notified that an electronic prescription was not successfully delivered, the practitioner shall indicate on any written or oral prescription issued as a replacement of the original electronic prescription that the prescription was originally transmitted electronically, to which pharmacy the prescription was originally transmitted, and that the original transmission failed.

(k) If the content of any of the information required by this Part for a prescription is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

§80.71 Practitioner; dispensing controlled substances.

(a) Practitioners, in good faith and in the course of their professional practice only, and as limited in this Part may dispense controlled substances.

(b) Except as provided in subdivision (c) of this section, the quantity of substances dispensed may not exceed a 30-day supply if the substances were used in accordance with the directions for use. No additional dispensing of a controlled substance may be made by a practitioner to an ultimate user within 30 days of the date of the previous dispensing unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance previously dispensed.

(c) (1) A practitioner may dispense up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six month supply of an anabolic steroid if used in accordance with the directions for use, provided that such supply has been dispensed for the treatment of a condition specified in section 80.67(d) and 80.69(d) of this Part.

(d) No controlled substance shall be dispensed unless it is enclosed within a suitable and durable container upon which is indelibly typed, printed or otherwise legibly written upon an orange label affixed to such container, in a manner which would inhibit its removal, the following:

(1) 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 having custody of such animal;

(2) name, address and telephone number of the dispensing practitioner;

(3) specific directions for use, including but not limited to the dosage and frequency of dosage, and the maximum daily dosage;

(4) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(5) the date of dispensing; and

(6) either the name of the substance or such code number assigned by the department for the particular substance pursuant to section 80.24 of this Part.

(e) The practitioner shall submit dispensing information, for all controlled substances dispensed, electronically to the department utilizing a transmission format acceptable to the department, not later than 24 hours after the substance was delivered. A waiver allowing a practitioner to make such filings within a longer period of time may be issued by the commissioner based upon a showing of economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. Such waiver and any subsequent waiver shall be applied for in the same manner and shall be subject to the same requirements as specified in Section 80.63(c)(2)(x) of this Part and, if granted, such waiver shall not provide for a filing period longer than the 15th day of the next month following the month in which the substance was delivered. The information filed with the department shall include but not be limited to:

(1) dispenser identifier;

(2) patient name, in the case of an animal, the patient name field shall be filled with the name of the animal's owner;

(3) patient address, including street, city, state, ZIP code;

(4) patient date of birth;

(5) patient's sex;

(6) date controlled substance dispensed;

(7) metric quantity;

(8) national drug code number of the drug;

(9) number of days supply;

(10) prescriber's Drug Enforcement Administration (DEA) number;

(11) payment method;

(12) species code; and

(13) name of animal, if applicable.

When applicable, the practitioner shall file a zero report with the department as specified in Section 80.73(f)(2)(i) of this Part, or a practitioner may apply for a waiver of the requirement to file a zero report as specific in Section 80.73(f)(2)(ii) of this Part.

DISPENSING TO ADDICTS AND HABITUAL USERS, AND TREATMENT PROGRAMS

§80.84 Physicians and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction.

Pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000 (106 P.L. 310, Div. B, Title XXXV, Section 3502(a)), an authorized physician may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

(a) An approved controlled substance shall mean the following controlled substance which has been approved by the Food and Drug Administration (FDA) and the New York State Department of Health for the treatment of narcotic addiction:

  (1) buprenorphine

(b) An authorized physician is a physician specifically registered with the Drug Enforcement Administration to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction, and approved for such purpose pursuant to the provisions of Article 32 of the Mental Hygiene Law.

  (1) The total number of such patients of an authorized physician at any one time shall not exceed 30.

  (2) An authorized physician prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing an official New York State prescription in accordance with Section 3332 of the Public Health Law and Section 80.69 of this Part, shall also include his/her unique DEA identification number on the prescription.

(c) A pharmacist may dispense an approved controlled substance for the treatment of narcotic addiction pursuant to a prescription issued by an authorized physician. Such dispensing shall be in accordance with Section 3333 of the Public Health Law and Section 80.74 of this Part.

§80.85 Administration of controlled substances to addicts and habitual users.

(a) The administration of controlled substances to narcotic addicts or habitual users of controlled substances is prohibited except as provided for in this Part.

(b) Controlled substances may be administered to narcotic addicts or habitual users of controlled substances upon the order of a person authorized by law to practice medicine or osteopathy in this State and who possesses a Federal registration by the Drug Enforcement Administration, United States Department of Justice, authorizing him to use controlled substances in connection with his professional practice as follows:

  (1) for bona fide patients suffering from disease known to be incurable, such as cancer, advanced tuberculosis, and other diseases well recognized as coming within this class;

  (2) for addicts who are aged and infirm, or severely ill and it is determined that withdrawal of controlled substances would be dangerous to life, provided that:

    (i) such determination has been confirmed by adequate consultation;

    (ii) complete records of treatment, administration or dispensing of controlled substances including patient's name, date and type and quantity of controlled substance administered or dispensed are kept;

    (iii) adequate safeguards have been taken against diversion of the controlled substances from the intended use; and

    (iv) the patient is carefully supervised;

  (3) to relieve acute withdrawal symptoms, except that:

    (i) only the amount of controlled substances essential for relief of such acute symptoms shall be administered; and

    (ii) administration shall be in an institutional or other setting reasonably certain to provide a drug-free environment;

  (4) for detoxification of an addict participating in an authorized treatment program approved pursuant to article 23 of the Mental Hygiene Law; and

  (5) for treatment of addicts participating in an authorized methadone or other controlled substances maintenance program approved pursuant to article 23 of the Mental Hygiene Law.

(c) In properly verified cases of severe illness, infirmity, or physical disability, a licensed physician, registered nurse, licensed practical nurse, or registered pharmacist may deliver medication to the patient.

REPORTS AND RECORDS

§80.105 Practitioners.

Every physician, dentist, podiatrist, veterinarian, or other authorized practitioner shall keep a record of all controlled substances purchased by him and a record of all such drugs dispensed or administered by him out of his own stock of such drugs.

(a) Records of controlled substances purchased shall include date of delivery, type and quantity of drugs and the name and address of the supplier of the drug. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to satisfy this record requirement for schedule III, IV, and V controlled substances provided it includes all required information and is retained in a separate file. In addition, duplicate copies of Federal order forms for schedule I and II controlled substances shall be retained.

(b) Records of disposition of controlled substances shall include date of dispensing or administering of such drug, name and address of patient, and type and quantity of drug.