PRESCRIPTION MONITORING PROGRAM STATE PROFILES – NEW YORK

Research current through July 2014.

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NEW YORK

http://www.health.state.ny.us/professionals/narcotic/
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- Status of Program –operational
- Housing Entity – Department of Health
- Advisory Commission – yes
- Funding – public and private grants
- Drugs Monitored – Schedules II – V
- Who's Required to Report Dispensing Information – dispensing practitioner; pharmacies; practitioners include physicians, dentists, podiatrists, veterinarians, scientific investigators, or other persons licensed or otherwise permitted to dispense, administer, or conduct research with regard to a controlled substance
- Exemptions from Reporting – none
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – yes
- Data Collection Interval – real time (has been interpreted in regulation to mean within 24 hours)
- Notice to Consumers – no
- Interstate Sharing – with other PMPs and authorized users in other states
- Persons Authorized to Receive Information – medical examiner or coroner; Department of Health; law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; agency or department of government (includes Medicaid); patient or parent of minor child; health care agent; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – no
- Unsolicited Reports – to prescribers, pharmacists, law enforcement, and licensing boards
- Training Required – no
- Mandatory Enrollment – no
- Mandatory Access – yes; a practitioner shall consult the PMP prior to prescribing or dispensing a Schedule II, III, or IV controlled substance unless one of ten exemptions applies

McKinney's Consolidated Laws of New York Annotated (2014)
Public Health Law
Chapter 45. Of the Consolidated Laws
Article 33. Controlled Substances
Title I. General Provisions

§ 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:

(a) 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 (b) 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.

(b) 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:

(i) 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: (A) educational and continuing medical education requirements for practitioners appropriate to address prescription pain medication awareness among health care professionals; (B) continuing education requirements for pharmacists related to prescription pain medication awareness; and (C) 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;

(ii) 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 underprescribing pain medication;

(iii) 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

(iv) 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.

3. 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.

4. 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. The report shall also include a recommendation as to whether subdivision two of section thirty-three hundred forty-three-a of this article should be amended to require practitioners prescribing or dispensing certain identified schedule V controlled substances to comply with the consultation requirements of such subdivision.

McKinney's Consolidated Laws of New York Annotated (2014)
Public Health Law
Chapter 45. Of the Consolidated Laws
Article 33. Controlled Substances
Title IV. Dispensing to Ultimate Users

§ 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;

(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;

(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 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 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.

McKinney's Consolidated Laws of New York Annotated (2014)
Public Health Law
Chapter 45. Of the Consolidated Laws
Article 33. Controlled Substances
Title VI. Records and Reports

§ 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;

(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 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.

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

McKinney's Consolidated Laws of New York Annotated (2014)
Public Health Law
Chapter 45. Of the Consolidated Laws
Article 33. Controlled Substances
Title VI. Records and Reports

§ 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.

Compilation of Codes, Rules and Regulations of the State of New York (2014)
Title 10. Department of Health
Chapter II. Administrative Rules and Regulations
Subchapter K. Controlled Substances
Part 80. Rules and Regulations on Controlled Substances
Prescribing and Dispensing Controlled Substances. (Refs & Annos)

Section 80.71. Practitioners, 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 sections 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.

Compilation of Codes, Rules and Regulations of the State of New York (2014)
Title 10. Department of Health
Chapter II. Administrative Rules and Regulations
Subchapter K. Controlled Substances
Part 80. Rules and Regulations on Controlled Substances
Prescribing and Dispensing Controlled Substances. (Refs & Annos)

Section 80.73. Pharmacists; dispensing schedule II substances and certain other controlled substances

(a) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6806 of the Education Law and regulations thereunder in a registered pharmacy, may, in good faith and in the course of his/her professional practice, sell and dispense to an ultimate user schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part, provided they are dispensed pursuant to an official New York State prescription, an out-of-state prescription or an electronic prescription delivered within 30 days of the date such prescription was signed by the authorized practitioner or an oral prescription where permitted.

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

(1) 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 having custody of such animal;

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

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

(4) the name of the prescribing practitioner;

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

(6) the number of the prescription under which it is recorded in the pharmacy prescription file;

(7) the date of filling; and

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

(c) A licensed, registered pharmacist in a registered pharmacy may, in good faith and in the course of his/her professional practice, sell and dispense, to an ultimate user, controlled substances upon the delivery to such pharmacist, within 30 days of the date such prescription was issued by an authorized practitioner, an official New York State prescription or an out-of-state written prescription transmitted by facsimile in accordance with section 80.67(e) or (f) of this Part.

(d) The pharmacist filling the prescription shall endorse upon the prescription his/her signature, the date of filling, and the number of the prescription under which it is recorded in the pharmacy prescription file.

(e) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

(f)

(1) The endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years. The prescription information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than 24 hours after the substance was delivered. A waiver allowing a pharmacy 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 pharmacy, or other exceptional circumstance demonstrated by the pharmacy. 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. Pharmacies delivering prescriptions by mail or licensed express delivery services shall file the prescription information with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than 72 hours after the substance was shipped from the pharmacy. The information filed with the department shall include but not be limited to:

(i) pharmacy prescription number;

(ii) pharmacy's national identification number;

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

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

(v) patient date of birth;

(vi) patient's sex;

(vii) date prescription filled;

(viii) metric quantity;

(ix) national drug code number of the drug;

(x) number of days supply;

(xi) prescriber's Drug Enforcement Administration number;

(xii) date prescription issued;

(xiii) serial number of official prescription form, or an identifier designated by the department;

(xiv) payment method;

(xv) number of refills authorized;

(xvi) refill number;

(xvii) species code; and

(xviii) name of animal, if applicable.

(2)

(i) When applicable, pharmacies and dispensing practitioners shall file a zero report with the Bureau of Narcotic Enforcement in a format acceptable to the department. For the purposes of this Part, a zero report shall be a report that no controlled substances were dispensed by a pharmacy or dispensing practitioner during the relevant period of time. A zero report shall be submitted no later than 14 days following the most recent previously reported dispensing of a controlled substance, the submission of a prior zero report, or the termination of a waiver of the requirement to file a zero report.

(ii) A waiver of the requirement to file a zero report may be issued by the commissioner based upon a showing that a pharmacy or practitioner does not dispense controlled substances within the state of New York. The request for a waiver 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 well as any information which would tend to negate the need for a waiver. A waiver granted by the commissioner shall be for a specified period of time, but in no event for more than two years. Subsequent waivers shall be applied for in the same manner and shall be subject to the same requirements set forth above. A pharmacy or practitioner who has been granted a waiver shall notify the department in writing within five business days of any change in circumstances that would result in the possible dispensing of a controlled substance. The waiver granted to the

pharmacy or practitioner shall be terminated effective the date of notification, and the pharmacy or practitioner shall comply with all reporting requirements of this Part until or unless a subsequent waiver is granted.

(g) Emergency oral prescriptions for schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part may be dispensed by a pharmacist to an ultimate user in an emergency situation, provided the pharmacist shall:

(1) contemporaneously reduce such prescriptions to written memoranda or, to the extent authorized by federal requirements, to an electronic record and shall indicate on such memoranda the name and address of the prescriber and his/her Drug Enforcement Administration registration number, name and address of the ultimate user, date on which it is ordered, name and quantity of drugs prescribed, directions for use and the fact that it is a telephone order. The memoranda or electronic record for such emergency oral prescription shall be filed in the same manner as is otherwise required for such prescription. The pharmacist filling such oral orders shall indicate on the face of such telephone order his/her signature, the date filled and the number of the prescription under which it is recorded in the pharmacy prescription file;

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

(3) make a good-faith effort to verify the identity of both the practitioner and the ultimate user;

(4) no emergency 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; and

(5) within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written or an electronic prescription. Such prescription shall, in addition to the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing" If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(h) Within 72 hours after transmitting a prescription to a pharmacist by facsimile in accordance with section 80.67(e) or (f) of this Part, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or an original out-of-state written prescription. Such original prescription shall be attached to any prescription transmitted by facsimile. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(i) Such prescriptions shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions. The follow-up prescriptions shall be attached to, or otherwise associated with, the corresponding memoranda of oral orders or to prescriptions transmitted by

facsimile. The information required in section 80.68(d)(2) of this Part shall be filed electronically with the New York State Department of Health, not later than 24 hours after the substance was delivered. The pharmacy must submit this information electronically to the department utilizing a transmission format acceptable to the department. A waiver allowing a pharmacy 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 pharmacy, or other exceptional circumstance demonstrated by the pharmacy. 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.

(j) A pharmacist may partially fill a prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part provided that:

(1) the pharmacist does not have a sufficient quantity to fill a prescription and he/she makes a notation of the quantity supplied on the prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription;

(2) the patient is a resident in a residential health care facility ("RHCF" which is licensed or approved by the department; or

(3) the patient has been diagnosed as being terminally ill.

(4) when such prescription is partially filled in accordance with paragraph (2) or (3) of this subdivision, the pharmacist shall:

(i) record on the prescription whether the patient is "terminally ill" or is a "RHCF patient" and

(ii) record on the prescription the date of the partial filling, quantity dispensed, quantity remaining and the signature of the dispensing pharmacist.

(5) the prescription shall be valid for a period not to exceed 30 days from the date the prescription was issued by the practitioner unless terminated sooner upon notification from the practitioner of the discontinuance of medication. All partial fillings filled under subdivision (1) of this section must occur within 30 days from the date the prescription was issued, except that partial fillings of prescriptions issued for more than a 30 day supply for patients residing in a residential healthcare facility or for patients enrolled in a hospice program that is licensed or approved by the department must occur within 60 days from the date the prescription was issued.

(6) the date of filling on the prescription shall be the date when the prescription has been filled to completion or the date when the pharmacy is notified by the practitioner that the prescription has been discontinued.

(k) 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.

(l) 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, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(m) When a pharmacist fills a prescription in a manner that would require, under subdivision (k) or subdivision (l) of this section, 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.

(n) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall conduct a reasonable search of the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

(o) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically to a separate pharmacy, the pharmacist shall confer with the separate pharmacy to determine if the separate pharmacy received that prescription and if the separate pharmacy dispensed upon that electronic prescription. If the separate pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy shall mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy receiving the written or oral version shall not dispense the prescription and shall mark it as void.

(p) A pharmacist shall use a pharmacy computer application that meets federal security requirements to process electronic controlled substance prescriptions and shall register such pharmacy computer application with the New York State Department of Health, Bureau of Narcotic Enforcement.