Proposed Regulations
NEW YORK STATE DEPARTMENT OF HEALTH
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Proposed Rule Making:
Amendment of Part 80 of Title 10 NYCRR (Prescription Monitoring Program)

Publication Date: 06/19/2013 **Comment Period Expiration:** 08/05/2013
Proposed Text and Statements:

SUMMARY OF EXPRESS TERMS

Part 80 (10 NYCRR)

Pursuant to recent amendments to Article 33 of the Public Health Law, the proposed regulations set forth the duty of practitioners to consult the Prescription Monitoring Program Registry (PMP), the duty of pharmacies to update the PMP in real time, the ability of pharmacists to consult the PMP, and the ability of practitioners and pharmacists to appoint designees to access the PMP on their behalf, as well as exceptions to such duties.
These proposed regulations would require practitioners to consult the PMP for the purpose of reviewing a patient's controlled substance history prior to prescribing for or dispensing to that patient any controlled substance listed on schedule II, III, or IV. Such history would be required to be obtained from the PMP no more than 24 hours prior to the practitioner prescribing or dispensing any controlled substance to that patient. Confirmation of such consultation or the reason for failing to consult would be noted in the patient's medical chart by the practitioner.
The amendments include exceptions to the duty to consult:

1. veterinarians;

2. a practitioner dispensing pursuant to Public Health Law section 3351(3);

3. a practitioner administering a controlled substance;

4. a practitioner prescribing or ordering a controlled substance for a patient of an institutional dispenser for use on the premises of or an emergency transfer from the institutional dispenser;

5. 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;

6. a practitioner prescribing a controlled substance to a patient under the care of a hospice;

7. a practitioner when:

a. it is not reasonably possible for the practitioner to access the PMP in a timely manner;

b. no other practitioner or designee authorized to access the PMP 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;

8. a practitioner acting in circumstances under which consultation of the PMP would 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;

9. a situation where the PMP is not operational or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure; or

10. a practitioner to whom the commissioner has granted a waiver from the requirement to consult the PMP. A waiver could be issued by the commissioner based upon a showing by a practitioner that his or her ability to consult the PMP 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.

These proposed regulations also provide that a practitioner may authorize a designee to consult the PMP 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 PMP. A practitioner could only appoint a designee if:

1. such designee is located in the state of New York when accessing the PMP;
2. 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;
3. the practitioner takes reasonable steps to ensure or has actual knowledge that such designee is sufficiently competent in the use of the PMP and that such designee is aware of and conforms to all relevant federal and state privacy statutes;
4. the practitioner remains responsible for ensuring that access to the PMP by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the PMP, and remains responsible for any breach of confidentiality; and
5. the practitioner selects and maintains all active designees authorized to access the PMP.

Upon relinquishment or termination of employment or authorization as a designee, a designating practitioner would be required to immediately notify the Department of the revocation of the designee's authorization to access the PMP on the designating practitioner's behalf.

These proposed regulations would also allow a pharmacist to consult the PMP 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 would also be able to designate another pharmacist or a pharmacy intern to consult the PMP on the pharmacist's behalf, provided that:

1. such designee is located in the state of New York when accessing the PMP and is employed by the same pharmacy or is under contract with such pharmacy; and
2. the designating pharmacist selects and maintains all active designees authorized to access the PMP.

Upon relinquishment or termination of employment or authorization as a designee, a designating pharmacist would be required to immediately notify the Department of the revocation of the designee's authorization to access the PMP on the designating pharmacist's behalf.

The amendments would require real-time reporting of prescription information. Pharmacists and dispensing practitioners within New York State would be required to file information regarding controlled substances and the patient with the Department via the Bureau of Narcotic Enforcement within 24 hours of the substance being delivered. A waiver allowing such filings within a longer period of time could 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 practitioner; or other exceptional circumstance. Pharmacies delivering prescriptions by mail or licensed express delivery services would be required to file the prescription information not later than 72 hours after the substance was shipped from the pharmacy.

These proposed regulations would also require, when applicable, pharmacies and dispensing practitioners to file a zero report, which is a report that no controlled substances were dispensed by a pharmacy or dispensing practitioner during the relevant period of time. A zero report would be required 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. A waiver of the requirement to file a zero report could 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.

These proposed regulations also provide for the sharing of confidential patient information with other select entities including the deputy attorney general for the Medicaid fraud control unit or his or her designee, local health departments, medical examiners or coroners, and to an individual (to provide the individual his or her own controlled substance history) and law enforcement under certain circumstances.

Pursuant to the authority vested in the Commissioner of Health by Article 33 of the Public Health Law, Sections 80.63, 80.68, 80.71, 80.73, and 80.107 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register but no earlier than August 27, 2013, to read as follows:

Section 80.63 is hereby amended to read as follows:

§80.63 Prescribing.

*** * ***

(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.

[(c)] (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.

* * *

Section 80.68 is hereby amended to read as follows:

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

* * *

(d)(1) The pharmacist filling the prescription shall endorse upon the prescription the date of delivery, and his/her signature.

(2) 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 [the 15th day of the next month following the month in]24 hours after [which] 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. The information filed with the [D]department shall include but not be limited to:

(i) pharmacy prescription number;
(ii) pharmacy's [N]national [I]identification [N]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]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 (DEA) number;
(xii) date prescription written;
(xiii) serial number of official prescription form or an identifier designated by the department; [and]
(xiv) payment method[.];
(xv) species code; and
(xvi) name of animal, if applicable.

* * *

Section 80.71 is hereby amended to read as follows:

§80.71 Practitioners, dispensing controlled substances.

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(e) The practitioner shall submit dispensing information, for all controlled substances dispensed, electronically to the department, [by] not later than [the 15th day of the next month following the month in]24 hours after [which] 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; [and]

(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.

Section 80.73 is hereby amended to read as follows:

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

* * *

(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 [the 15th day of the next month following the month in]24 hours after [which] 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:

[(1)](i) pharmacy prescription number;
[(2)](ii) pharmacy's national identification number;
[(3)](iii) patient name, in the case of an animal, the patient name field shall be filled with the name of the animal’s owner;
[(4)](iv) patient address, including street, city, state, ZIP code;
[(5)](v) patient date of birth;
[(6)](vi) patient's sex;
[(7)](vii) date prescription filled;
[(8)](viii) metric quantity;
[(9)](ix) national drug code number of the drug;
[(10)](x) number of days supply;
[(11)](xi) prescriber's Drug Enforcement Administration number;
[(12)](xii) date prescription issued;
[(13)](xiii) serial number of official prescription form, or an identifier designated by the department;
[(14)](xiv) payment method;
[(15)](xv) number of refills authorized; [and]
[(16)](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.

* * *

(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) shall be filed electronically with the New York State Department of Health, not later than [the 15th day of the next month following the month in]24 hours after [which] 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.

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Section 80.107 is hereby amended to read as follows:

§80.107 Confidentiality.

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(d) to [a central]the prescription monitoring program registry [established pursuant to article 33 of the Public Health Law; or]and to authorized users of such registry as set forth in Public Health Law section 3371(2);

(e) to a practitioner to inform him or her that a person under his or her treatment with a controlled substance also may be under treatment with a controlled substance by another practitioner[.] for the purposes of Public Health Law section 3371(2), and to facilitate the department's review of individual challenges to the accuracy of controlled substance histories pursuant to Public Health Law section 3343-a(6);

(f) to a pharmacist to provide information regarding prescriptions for controlled substances presented to the pharmacist for the purposes of Public Health Law section 3371(2) and to facilitate the department's review of individual challenges to the accuracy of controlled substance histories pursuant to Public Health Law section 3343-a(6);

(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:

(1) pursuant to an agreement with the commissioner;

(2) when the release of such information is deemed appropriate by the commissioner;

(3) for use in accordance with measures required by the commissioner to ensure that the security and confidentiality of the data is protected; and

(4) 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;

(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 Public Health Law section 3343-a(6) or from a treating practitioner pursuant to Public Health Law section 3371(2)(a)(iv); and

(k) to appropriate law enforcement agencies, as reasonably appears to be necessary, for the purposes of providing relevant information about suspected criminal activity, including controlled substances prescribed or dispensed, where the department has reason to believe that a crime related to the diversion of controlled substances has been committed.

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