Prescription Monitoring Program

Effective date: 8/27/13

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[.]; <u></u>

<u>(xv) species code; and</u>

<u>(xvi) name of animal, if applicable.</u>

* * *

Section 80.71 is hereby amended to read as follows:

§80.71 Practitioners, dispensing controlled substances.

* * *

(e) The practitioner shall submit dispensing information, for all controlled substances dispensed, electronically to the department utilizing a transmission format acceptable to the department, [by] not later than [the 15th day of the next month following the month in]<u>24 hours after</u> [which] the substance was delivered. <u>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</u>

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.

* * *

Section 80.107 is hereby amended to read as follows:

§80.107 Confidentiality.

* * *

(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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REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 3308(2) of the Public Health Law authorizes and empowers the Commissioner to make any regulations necessary to supplement the provisions of Article 33 of the Public Health Law in order to effectuate their purpose and intent. In addition, regulations with regard to the Prescription Monitoring Program Registry (PMP) are authorized by Public Health Law §3343-a(9). The Department proposes amendments to the regulations that would effectuate the changes in §3333 and §3371 of the Public Health Law and the addition of §3343-a to the Public Health Law resulting from Chapter 447 of the Laws of 2012.

Legislative Objectives:

Article 33 of the Public Health Law, officially known as the New York State Controlled Substances Act, was enacted in 1972 to govern and control the possession, prescribing, manufacturing, dispensing, administering and distribution of controlled substances within New York. The legislative purpose of Article 33 is to allow the legitimate use of controlled substances in health care, including palliative care, veterinary care, research and other uses authorized by the law while combating the illegal use of and trade in controlled substances. The proposed amendments are required by changes to Article 33 of the Public Health Law pursuant to Chapter 447 of the Laws of 2012.

Needs and Benefits:

These amendments are required to facilitate the changes and the additions to the Public Health Law enacted by Chapter 447 of the Laws of 2012 which, among other things, require

real-time reporting to the PMP by pharmacies and dispensing practitioners and add a duty to consult the PMP by practitioners who are prescribing controlled substances.

Benefits of the proposed amendments include ensuring that practitioners are aware of other prescriptions that their patients have recently received which could discourage "doctor shopping" and avoid over-prescribing of controlled substances, as well as assisting in avoiding harmful drug interactions. The proposed amendments will implement the recent changes to Article 33 of the Public Health Law made by Chapter 447 of the Laws of 2012. A more specific description of the benefits provided by the amendments follows.

The current regulations require prescription information from pharmacies and dispensing practitioners for certain controlled substances to be filed electronically with the New York State Department of Health on a monthly basis. The amendments specify the new "real time" reporting requirement added by Chapter 447 of the Laws of 2012 as "24 hours after the substance was delivered." The amendments also specify a new reporting time frame for mail or licensed express delivery services of "not later than 72 hours after the substance was shipped from the pharmacy" and a waiver process to allow pharmacies to make such filings within a longer period of time. Additionally, the amendments create a requirement for "zero reporting" when no controlled substances have been dispensed by a practitioner or pharmacy to ensure that at least every 14 days the Bureau of Narcotic Enforcement has been informed that no controlled substances have been dispensed. The amendments provide for a waiver of the zero reporting requirement when appropriate. Also, the amendments authorize pharmacists to access 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", as well as providing for the authorization of designees to access the PMP on the pharmacist's behalf.

New York State has collected controlled substance dispensing information since 1973. Since February of 2010, a portion of the data contained within the PMP has been made available to all DEA-licensed practitioners throughout New York State, free-of-charge. Although the PMP has been in existence for decades, practitioners have never been required to consult it, and very few have used it. From February of 2010 through March of 2013, out of approximately 115,000 practitioners, only about 4,400 had used the PMP for a total of approximately 407,000 searches. Pursuant to Chapter 447 of the Laws of 2012, and as specified in the amendments, practitioners will be required to consult the PMP "[p]rior to prescribing for or dispensing to a patient any controlled substance listed on schedule II, III, or IV…for the purpose of reviewing that patient's controlled substance history" and to use as a deciding factor regarding "whether or not to prescribe or dispense a controlled substance [to the patient.]" This consultation must occur "no more than 24 hours prior to the practitioner prescribing or dispensing any controlled substance to that patient." There are enumerated exceptions, as well as a waiver process from this duty to consult. There is also a provision for the authorization of designees to access the PMP on the practitioner's behalf.

These proposed amendments promote the safe and effective use of prescription drugs while attempting to curb the diversion of such drugs. Requiring real-time updates of the PMP and consultation of the PMP by practitioners has the potential to minimize medication errors and reduce the possibility of "doctor shopping" and over-prescribing. This should lead to enhanced patient care and safety.

The use of data from the PMP will help practitioners make a more informed decision when deciding whether to prescribe a controlled substance to a patient. Similarly, a review of the PMP will serve to further inform pharmacists about their patient presenting a prescription for

a controlled substance. The use of the PMP will present a clearer picture of a person's controlled substance history to the practitioner or pharmacist before prescribing or dispensing controlled substances in schedules II through IV. Some members of the medical community and particular professional societies have expressed concerns with these new requirements. Some of the expressed concerns have been the impact to practitioners' work-flow and the expressed belief that practitioners, instead of checking the database, would choose to not treat a patient who might otherwise be an appropriate candidate for a controlled substance prescription. As noted above, these amendments contain exceptions which address those concerns, detailing circumstances when a waiver is appropriate and restating various patient safety exceptions.

The amendments also provide for the sharing of confidential patient information with other select entities including, the Deputy Attorney 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.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Pharmacies and dispensing practitioners may incur costs related to programming associated with the implementation of the more frequent reporting requirement of controlled substance data to the Department. As pharmacies and dispensing practitioners currently are required to report to the Department on a monthly basis, costs should be limited to initial programming changes related to the 24-hour reporting requirement. Most pharmacies are expected to use existing software applications and/or existing vendors to meet this requirement.

A survey of existing chain pharmacies and vendors that support independent pharmacies indicated programming costs associated with implementation of the reporting requirement could be up to approximately $15,000. Other vendors indicated that they are currently able to meet the requirement with minimal lead time and costs. Dispensing practitioners that currently utilize the existing online manual data reporting system will be able to continue to utilize this Department-supported reporting system with no additional costs anticipated. There is no fee, tax, or transactional cost associated with creating a Health Commerce System account or accessing the PMP. In addition, the amendments include a waiver process to allow pharmacies and practitioners to report within a longer period of time.

Costs to State and Local Government:

The proposed rule does not require local government to perform any additional tasks as governmental entities, but will result in additional administrative tasks by the Department of Health as discussed below. Therefore, it is not anticipated to have an adverse fiscal impact on local government, but the Department of Health anticipates increased administrative costs as discussed below. It should be noted that 95 pharmacies throughout the State are owned by government entities and costs will be incurred by those government-owned pharmacies in the same manner as independent and chain pharmacies. Real-time updates and consultation of the PMP with regard to controlled substances could reduce the number of incidents of diversion and will likely reduce the volume and negative impacts of over-prescribing and the associated costs to the State. Therefore, the regulations may have a positive fiscal impact in that regard.

Costs to the Department of Health:

The Department of Health staff time will be necessary to implement the amendments allowing practitioner designees to access the PMP, as well as pharmacists and their designees. The Department will need to review Health Commerce System account applications and create user accounts for these new designees and pharmacists. It is estimated that 40,000 practitioners and an unknown number of designees to approximately 90,000 practitioners will require user account set-up. In addition, while not mandated, the potential exists for approximately 22,000 pharmacists and an unknown number of their designees to request user accounts. In addition, computer program development is needed to implement these new functionalities, including linking a practitioner's/pharmacist's account to that of a designee. In addition, several computer programmers have been assigned to update the current data collection system and add additional functionalities to the PMP, allowing pharmacies to report information in "real-time" in a more secure and user-friendly fashion.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other specific district, except where pharmacies are owned by local governments as described above.

Paperwork:

There is paperwork and process associated with obtaining authorization to access the PMP. Each practitioner or pharmacist, if they wish to consult, will be required to obtain a Health Commerce System account, if they do not currently have one, and if the practitioner or

pharmacist chooses to appoint designees then that information will have to be entered into the system by the practitioner or pharmacist. It is anticipated that these activities will primarily occur initially upon implementation of the amendments.

Duplication:

The requirements of this proposed regulation do not duplicate any other state or federal requirement.

Alternatives:

Changing the regulations was required by virtue of amendments to state statute. There were no significant alternatives to be considered during the regulatory process.

Federal Standards:

The regulatory amendments do not exceed any minimum standards of the federal government. There is no federal equivalent to the PMP nor are there any federal standards regarding state PMPs.

Compliance Schedule:

The proposed rule requires real-time reporting by pharmacies and consultation of the PMP by practitioners in compliance with Part A of Chapter 447 of the Laws of 2012 which will be effective August 27, 2013.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

This proposed rule will affect New York State practitioners who prescribe and dispense prescriptions for controlled substances and New York State pharmacies and pharmacists. Records retrieved from the Education Department's Office of the Professions show that as of January 7, 2013 there were a total of 115,032 practitioners (physicians, dentists, physician assistants, podiatrists, midwifes and nurse practitioners) registered in the State of New York. Records retrieved from the Education Department's Board of Pharmacy show that as of January 7, 2013, there were a total of 5,044 registered pharmacies and there were 18,958 registered pharmacists in the State of New York. Of these totals, approximately 2,573 represent small business establishments and 95 are owned by government entities, accounting for 51% and 1.9% respectively of the total number of pharmacies.

Compliance Requirements:

These amendments are required to facilitate the changes and the additions to the Public Health Law enacted by Chapter 447 of the Laws of 2012 which, among other things, require real-time reporting to the PMP by pharmacies and dispensing practitioners and add a duty to consult the PMP by practitioners who are prescribing controlled substances.

Under current regulations, pharmacies and dispensers are required to report controlled substance dispensing data to the Department on a monthly basis. The proposed amendments would require more frequent reporting of controlled substance dispensing data (i.e., within 24 hours after the substance was delivered). The proposed regulations also require a new reporting

time frame for mail or licensed express delivery services of “not later than 72 hours after the substance was shipped from the pharmacy.” Additionally, the amendments create a requirement for “zero reporting” when no controlled substances have been dispensed by a practitioner or pharmacy to ensure that at least every 14 days the Bureau of Narcotic Enforcement has been informed that no controlled substances have been dispensed. The amendments provide for waivers of these requirements when appropriate. These requirements may necessitate computer programming services initially.

Professional Services:

The proposed amendments would require pharmacies to report controlled substance dispensing information to the Department of Health within 24 hours of delivering the controlled substance. Previously, dispensers were required to report once a month. This change will likely require additional computer programming development by the dispenser or their contracted vendor. A survey of existing chain pharmacies and vendors that support independent pharmacies indicated programming costs associated with implementation of the reporting requirement could be up to approximately $15,000. Other vendors indicated that they are currently able to meet the requirement with minimal lead time and costs. Dispensing practitioners that currently utilize the existing online manual data reporting system will be able to continue to utilize this Department-supported reporting system with no additional costs anticipated. Practitioners will need to obtain a Health Commerce System account, as well as internet service for themselves and/or their designees.

Compliance Costs:

Costs to Private Regulated Parties:

For pharmacies and dispensers to meet the reporting requirements specified in this rule, an estimate of no cost to approximately $15,000 can be anticipated. These costs are reflective of associated computer programming necessitated by the more frequent reporting of controlled substance data to the Department. There is no fee, tax, or transactional cost associated with creating a Health Commerce System account or accessing the PMP.

Costs to State Government and Local Government:

The proposed rule does not require local government to perform any additional tasks as governmental entities, but will result in additional administrative tasks by the Department of Health as discussed below. Therefore, it is not anticipated to have an adverse fiscal impact on local government, but the Department of Health anticipates increased administrative costs as discussed below. It should be noted that 95 pharmacies throughout the State are owned by government entities and costs will be incurred by those government-owned pharmacies in the same manner as independent and chain pharmacies. Real-time updates and consultation of the PMP with regard to controlled substances could reduce the number of incidents of diversion and will likely reduce the volume and negative impacts of over-prescribing the associated costs to the State. Therefore, the regulations may have a positive fiscal impact in that regard.

A cure period is not required to be incorporated in the amendments pursuant to Chapter 524 of the Laws of 2011 insofar as the proposed amendments do not involve the establishment or modification of a violation or of penalties associated with a violation.

Economic and Technological Feasibility:

There are expected to be initial costs to dispensers to meet the 24-hour reporting requirement. After initial programming is completed, it is expected that these changes will reduce the amount of time spent by employees reviewing and submitting controlled substance data to the Department.

The current PMP has been operating on-line for approximately three and a half years, and is currently available to all DEA-licensed practitioners within New York State. In an attempt to encourage use, the Department is investing resources in updating the current system to make it more user-friendly and to provide additional functions.

The technological requirements to access the PMP are minimal. Practitioners, pharmacists, and their designees will need access to the internet and a Health Commerce System account. The proposed amendments also provide for waivers of these requirements when appropriate. There is no fee, tax, or transactional cost associated with creating a Health Commerce System account or accessing the PMP.

Minimizing Adverse Impact:

To minimize any undue burden on a particular practitioner, the amendments provide for the use of a designee and PMP program functionalities to allow for multiple searches at one time to aid in potential work flow changes. The amendments also provide for a waiver process for practitioners to be exempted from the duty to consult the PMP based upon technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstance demonstrated by the practitioner. Additionally, the amendments provide for a reporting waiver process for pharmacies and practitioners.

Small Business and Local Government Participation:

During the drafting of these amendments, the Department consulted with the State Education Department's Board of Pharmacy. The Department also consulted with representatives from the Pharmaceutical Society of the State of New York, the membership of which consists of pharmacists and others who have an interest in the practice of pharmacy, including owners of small businesses, vendors, employees of pharmacies and employees of private and government institutions, and the New York Chapter of the American Society of Consultant Pharmacists, the membership of which consists of pharmacists who provide consulting services to private or government owned residential health care facilities. Issues and comments relevant to dispensing, record keeping, and consulting were discussed at open forums such as the New York State Pharmacy Conference meetings and the Pharmacy Advisory Committee (PAC) meetings. Pharmacy conferences are held quarterly for the purpose of sharing information among stakeholders in the practice of pharmacy, including representatives from the colleges of pharmacy in New York State, government agencies, regulatory agencies, and all pharmacy practice settings. The PAC acts as an advisory body to the Department of Health on pharmacy issues related to the Medicaid Program. The Department also consulted with the National Association of Chain Drug Stores, an organization dedicated to advancing the interests and objectives of the chain community pharmacy industry, and with various other pharmacy leaders and stakeholders. The amendments were drafted taking into consideration the pharmacy community's comments and suggestions with respect to the current laws and regulations and how the amendments would affect the overall dispensing process.

The Department consulted with the Medical Society of the State of New York, an organization dedicated to promoting and maintaining high standards in medical education and in

the practice of medicine in an effort to ensure that quality medical care is available to the public. The Department also consulted with the Greater New York Hospital Association and the New York City Health and Hospitals Corporation. Input was also received from the Office of Professional Medical Conduct, the New York Chapter of the American College of Physicians and the workgroup established under Public Health Law Section 3309-a to provide input related to the implementation of the PMP. Some practitioners and practitioner professional societies expressed concerns regarding the expected cost to practitioners as well as technological barriers facing technologically naïve practitioners. The Department is confident that the exceptions and waiver process provided for in the statute and the regulatory amendments address these concerns.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

The amendments apply uniformly throughout the state, including rural areas. Outside of major cities and metropolitan population centers, the majority of counties in New York contain rural areas. These can range in extent from small towns and villages and their surrounding areas, to locations that are sparsely populated. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. According to the Education Department's Board of Pharmacy, as of January 7, 2013, there are a total of 2,030 registered pharmacies and 8,651 registered pharmacists located in rural counties, which account for 45.6% of the pharmacists and 40.2% of the pharmacies registered in the State of New York. The total number of DEA registered practitioners in rural areas (i.e., those with the authority to write a controlled substance prescription) is 43,593, representing 61% of the total number of DEA registered prescribers. These practitioners include medical doctors, dentists, nurse practitioners, physician assistants, podiatrists and midwifes.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

These amendments are required to facilitate the changes and the additions to the Public Health Law enacted by Chapter 447 of the Laws of 2012 which, among other things, require real-time reporting to the PMP by pharmacies and dispensing practitioners and add a duty to consult the PMP by practitioners who are prescribing controlled substances. Under current

regulations, pharmacies and dispensers are required to report controlled substance dispensing data to the Department on a monthly basis. The proposed amendments would require more frequent reporting of controlled substance dispensing data (i.e., within 24 hours after the substance was delivered). The proposed regulations also require a new reporting time frame for mail or licensed express delivery services of "not later than 72 hours after the substance was shipped from the pharmacy." Additionally, the amendments create a requirement for "zero reporting" when no controlled substances have been dispensed by a practitioner or pharmacy to ensure that at least every 14 days the Bureau of Narcotic Enforcement has been informed that no controlled substances have been dispensed. These requirements may necessitate computer programming services initially. The amendments provide for waivers of these reporting requirements when appropriate. The requirements are identical for both rural areas and non-rural areas of the State.

Costs:

For pharmacies and dispensers to meet the reporting requirements specified in this rule, an estimate of no cost to approximately $15,000 can be anticipated. These costs are reflective of associated computer programming necessitated by the more frequent reporting of controlled substance data to the Department. The proposed amendments also provide for waivers of these requirements for economic hardship, technological limitation that are not reasonably within the control of the pharmacy, or other demonstrated exceptional circumstances. There is no fee, tax, or transactional cost associated with creating a Health Commerce System account or accessing the PMP. Estimated costs are not anticipated to be different for rural areas versus non-rural areas of the State.

Minimizing Adverse Impact:

To minimize any undue burden on a particular practitioner, the amendments provide for a waiver process for practitioners to be exempted from the duty to consult the PMP based upon technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstance demonstrated by the practitioner. Additionally, the amendments provide for a reporting waiver process for pharmacies and practitioners. It is anticipated that these waiver categories will sufficiently address the burdens of rural providers.

Rural Area Participation:

During the drafting of these amendments, the Department consulted with various statewide groups whose constituencies include rural areas, e.g.: the State Education Department's Board of Pharmacy, the Pharmaceutical Society of the State of New York and the New York Chapter of the American Society of Consultant Pharmacists. Pharmacy conferences were also held quarterly for the purpose of sharing information among stakeholders in the practice of pharmacy, including representatives from the colleges of pharmacy in New York State, government agencies, regulatory agencies, and all pharmacy practice settings. The Department also consulted with the National Association of Chain Drug Stores, an organization dedicated to advancing the interests and objectives of the chain community pharmacy industry in rural and metropolitan areas, and with various other pharmacy leaders and stakeholders. Input was received from the workgroup established under Public Health Law Section 3309-a to provide guidance related to the implementation of the PMP. The amendments were drafted taking into consideration the pharmacy community's comments and suggestions with respect to

the current laws and regulations and how the amendments would affect the overall dispensing process.

The Department also consulted with the Medical Society of the State of New York and the Greater New York Hospital Association.

JOB IMPACT STATEMENT

A Job Impact Statement is not included because the Department has concluded that the proposed regulatory amendments will not have a substantial adverse effect on jobs given that the amendments are simply implementing an underlying requirement imposed by the legislature through the Public Health Law. The amendments provide for the duty of a practitioner to consult the PMP, as well as the real-time reporting of dispensed controlled substances by pharmacies and practitioners, and will not have a substantial adverse effect upon jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The Department of Health (DOH) received the following comments, which are summarized below with responses:

COMMENT: Many comments from practitioners, pharmacists and professional organizations were supportive of DOH's Prescription Monitoring Program Registry (PMP).

COMMENT: Several comments were received from the pharmacy community related to the 24-hour controlled substance reporting requirement. Requests were made to change the 24-hour reporting requirement to "within one business day". Operational details related to this requirement were also requested.

RESPONSE: Representatives of DOH met with pharmacy associations, representing both chain pharmacies and independent pharmacies, to assess the feasibility of 24-hour controlled substance reporting to the PMP. DOH representatives were assured that a 24-hour reporting period was feasible. In addition, the 24-hour reporting period was also suggested by the workgroup established by the Internet System for Tracking Over-Prescribing Act (I-STOP), Chapter 447 of the Laws of 2012. Operational requirements have been posted on the DOH, Bureau of Narcotic Enforcement's web site.

COMMENT: Several comments were received related to the zero controlled substance reporting requirements for pharmacies. A commenter stated that this requirement required a change in

software and requested an expanded time frame (six months) for implementation of the zero reporting requirement.

RESPONSE: The zero reporting requirement utilizes the same reporting requirements currently in existence for the reporting of controlled substance data in NYS. DOH acknowledges that minimal changes in software may be necessary. This is not expected to impact the majority of pharmacies in NYS.

COMMENT: Comments were received related to the submission of dispensing data based on the date the prescription was delivered. Multiple comments suggested that this is a new standard. Commenters requested that DOH allow for the option to report to the PMP from "either…the date filled or from the point of sale" with an indication of which date was used or to change the requirement all together to the date filled.

RESPONSE: There was no change in the regulation related to the submission of data based on the date the controlled substance was delivered. The current regulation does not provide for information to be submitted based on date filled, and the change proposed in these regulations is only related to the time frame (i.e., 24 hours) in which reporting must occur. The definition of "deliver" in regard to controlled substances may be found in Article 33 of the Public Health Law, Section 3302.

COMMENT: Comments were received regarding the time frame for the submission of corrections of pharmacy data submissions.

RESPONSE: Time frames related to error correction reporting were not addressed in this regulation.

COMMENT: Comments were received related to unattended or automated reporting of pharmacy controlled substance data and requests were made to “have an unattended reporting tool for an automatic uploading of data to enable them to submit their daily information to the PMP.”

RESPONSE: Unattended reporting of pharmacy controlled substance data was not addressed in this regulation, and there is nothing in statute or regulation prohibiting it. Although it is not available yet, DOH is actively working on this tool for pharmacy data submissions.

COMMENT: Comments were received inquiring about access to the PMP by a health care plan pharmacist and whether or not a physician employed by a health care plan could access the PMP information and delegate the information to others.

RESPONSE: The proposed regulations only relate to each of these questions within the context of a customer presenting a valid prescription to a pharmacist or a patient being treated by a physician.

COMMENT: A comment was received requesting "state specific penalties for practitioners or pharmacists whose practices access a person's information when not done in the course of patient care."

RESPONSE: These regulations did not establish any new penalties. However, there are multiple statutes that provide penalties for willful violations of the NYS Public Health Law.

COMMENT: A number of comments were received that explained certain types of practices and scenarios that the commenters believed warranted specific exceptions to the duty to consult or report to the PMP, and one suggested that self-monitoring would be sufficient if practitioners were given access to the PMP. A comment was received asking why, in a pharmacy setting, access to the PMP as a designee is limited to pharmacists and pharmacy interns. A number of comments included fact-specific information regarding why consultation of the PMP or reporting (or zero reporting) to the PMP would be difficult, costly, or create negative unintended consequences and requesting that an exception be made or waiver granted.

RESPONSE: The issue that all of the types of comments have in common is that they are based on objections to requirements in I-STOP. While these requirements are included in the proposed regulations as well, they are statutory requirements that cannot be undone by regulation. Specific exceptions were included in I-STOP, and it must be presumed that the Legislature intended to provide exceptions only in those instances and that any group or scenario that was not specifically exempted by the Legislature in I-STOP was intended to comply with the statute and subsequent regulations. In the instances where specific facts regarding individual offices,

companies or practices were provided, the commenters may wish to request a waiver in compliance with the I-STOP regulations upon adoption of such regulations.

COMMENT: One comment was received requesting access to the PMP by out-of-state pharmacists filling prescriptions that were written in New York.

RESPONSE: That issue is not mandated in I-STOP and was not addressed in the proposed regulations.

COMMENT: A number of comments have requested grace periods for certain groups or in general and/or a delay in implementation of the proposed regulations. One comment, in particular, noted that the possibility of the proposed regulations becoming effective so close to the implementation date results in a "very narrow timeline [that] does not provide adequate time to develop and implement policies and procedures at the institution that will be sufficient to meet the requirements outlined in the final regulations."

RESPONSE: I-STOP does not provide for a grace period or any delay in implementation.

COMMENT: One comment asserted that the current PMP does not allow providers to identify designees, and that there will be a wait time of approximately two to three weeks after implementation before this becomes possible.

RESPONSE: This comment addresses concerns about implementation rather than concerns or suggestions regarding the proposed regulations. However, it should be noted that this assertion is inaccurate, and providers have been able to identify designees since July 8, 2013. There will be no wait time regarding the identification of designees on the PMP for providers who have the necessary Health Commerce System (HCS) account.

COMMENT: Additionally, one comment stated that when I-STOP is effective, many prescribers may not yet have obtained the required HCS account or have "obtained approval for designated support staff to facilitate the duty to consult the [PMP]."

RESPONSE: Practitioners have been authorized to access the PMP through an HCS account since February of 2010, and the upcoming duty to consult the PMP was specified in I-STOP, which was signed into law on August 27, 2012. The proposed regulations were not the initiator of a practitioner's need to access to the HCS system. Additionally, the only "approval" that is necessary to designate support staff is that of the practitioner, who exhibits his/her approval by signing into his/her HCS account, accessing the PMP, and adding the support staff member as a designee – no additional approval is required in I-STOP or the proposed regulations.

COMMENT: Comments were submitted requesting exceptions from the requirement to document in a patient's chart whether or not the PMP was consulted and, if not, the specific exception that would authorize the decision not to consult the PMP. The exceptions were being sought for instances such as where opioids are administered to inpatients, asserting that this

requirement would be burdensome, or when an exception would regularly apply such as physicians in emergency departments.

RESPONSE: I-STOP and the proposed regulations provide multiple exceptions to the duty to consult the PMP. The I-STOP workgroup recommended that practitioners document whether or not they have consulted the PMP and, if they have not consulted, the specific exception relied on by the practitioner in choosing not to consult the PMP. That recommendation was incorporated into the proposed regulation. This documentation could be as simple as a checkbox in the patient's chart – especially in instances where the exception is regularly utilized. This provision will serve to protect practitioners who will, undoubtedly, have instances where they will have to answer questions about their treatment of specific patients. Rather than having to rely on memory or reconstruct their thought process at a given time, practitioners will have documentation regarding their consultation of – or reason to not consult – the PMP.

COMMENT: A comment was submitted requesting "clarification permitting hospital-employed practitioners/prescribers to utilize hospital administrative personnel who work with their practices as designees."

RESPONSE: This issue is addressed in the proposed §80.63(c)(3)(ii), specifying that a practitioner may appoint a designee if "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".

Therefore, a practitioner who is not within the same practice, in the traditional sense, as a hospital's administrative personnel may still be authorized to designate such personnel to access the PMP on his/her behalf.

COMMENT: A number of commenters presented questions or suggestions specific to implementation. For example, questions about how to utilize the system, where and how often information must be uploaded and electronic prescribing (which is not the subject of these regulations). Also, comments were received suggesting that DOH continue to alert pharmacies of missing or incorrect data and allow them to send in corrections within a reasonable timeframe, as well as providing written guidance to hospice program directors.

RESPONSE: This is not the proper forum to address these implementation issues, and the commenters are encouraged to contact the Bureau of Narcotic Enforcement directly with any questions or concerns regarding implementation and the PMP system. Additionally, DOH will consider all suggestions that have been submitted whether or not they apply to the proposed regulations.

COMMENT: Comments were received requesting that practitioners be allowed to use PMP data obtained more than 24 hours before a prescription is issued. Citing practitioner's workflow, these requests included a 36-hour time frame or at the time of admission for a prescription issued to inpatients upon discharge.

RESPONSE: The 24-hour window allows practitioners or their designees to obtain a patient's history outside of patient hours, yet ensures the data is still timely. This timeframe was recommended by the I-STOP workgroup.

COMMENT: Multiple comments were received asking that residents be allowed direct access to the PMP rather than accessing it as designees of a practitioner.

RESPONSE: The definition of "practitioner" within Article 33 does not include unlicensed residents, therefore precluding them from having direct access to the PMP. Unlicensed residents may access PMP information as a designee, receive it from a supervising physician or colleague or from administrative staff, providing teaching institutions with multiple options for disseminating this information. Residents who are licensed through the State Education Department may independently access the PMP. Moreover, the proposed regulations are also consistent with the supervised and limited practice of medicine engaged in by residents.

COMMENT: Comments were received concerning a practitioner's responsibility when she/he cannot access the PMP due to various technological failures.

RESPONSE: These concerns were addressed in the proposed regulations. Proposed section 80.63(2)(ix) would exclude practitioners from the duty to consult the registry on an occasion "when [the] registry is not operational…or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure."