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NEW JERSEY ADMINISTRATIVE CODE

TITLE 13

LAW AND PUBLIC SAFETY

CHAPTER 45A

ADMINISTRATIVE RULES OF THE DIVISION OF CONSUMER AFFAIRS

SUBCHAPTER 35

PRESCRIPTION MONITORING PROGRAM

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SUBCHAPTER 35. PRESCRIPTION MONITORING PROGRAM

13:45A-35.1 PURPOSE AND SCOPE

a) The rules in this subchapter implement the provisions of P.L. 2007, c. 244, as amended by P.L. 2015, c. 74 (N.J.S.A. 45:1-44 through 51), establishing a Prescription Monitoring Program (PMP) in the Division of Consumer Affairs.

b) The rules in this subchapter shall apply to the following:

1) A pharmacy filling prescriptions in New Jersey in an outpatient setting for a Schedule II, III, IV, or V controlled dangerous substance, for human growth hormone, or gabapentin.

i) For purposes of this subchapter, “human growth hormone” means somatrem, somatropin, or any analogue of either of them, consistent with 21 U.S.C. § 333(e)4;

2) An out-of-State pharmacy registered with the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20 that ships, mails, distributes, or delivers a Schedule II, III, IV, or V controlled

dangerous substance, human growth hormone, or gabapentin into New Jersey in an outpatient setting pursuant to a prescription;

3) A person authorized to receive PMP information from the Division under N.J.S.A. 45:1-46 and N.J.A.C. 13:45A-35.6;

4) A pharmacist employed by a current pharmacy permit holder;

5) A practitioner who has a current State Controlled Dangerous Substance (CDS) registration;

6) A licensed health care professional authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

7) A medical resident authorized by a faculty member of a medical teaching facility to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

8) A dental resident authorized by a faculty member of a dental teaching facility to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

9) A certified medical assistant authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

10) A registered dental assistant authorized by a licensed dentist to access the prescription monitoring information, subject to the limitations and requirements of this subchapter; and

11) A licensed mental health practitioner providing treatment for substance abuse to patients at a residential or outpatient substance abuse treatment center licensed by the Department of Health, subject to the limitations and requirements of this subchapter.

c) The reporting requirements of this subchapter shall not apply to the direct administration of a controlled dangerous substance, human growth hormone, or gabapentin to the body of

an ultimate user; or to the administration or dispensing of a controlled dangerous substance that is otherwise exempted as determined by the Secretary of Health and Human Services pursuant to the National All Schedules Prescription Electronic Reporting Act of 2005, Pub.L. 109-60.

d) The reporting requirements of this subchapter shall not apply to any prescriptions filled by a pharmacy for a Schedule II, III, IV, or V controlled dangerous substance, for human growth hormone, or gabapentin dispensed to an inpatient at a hospital, long-term care, or other facility in which the resident is provided with 24-hour nursing care.

13:45A-35.2 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise:

"Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state (high), to sustain opioid dependence (that is opioid addiction), or that is other than the purpose for which the medication was prescribed.

"Acute pain" means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma, or disease and is generally persistent for up to one month, but no more than three months.

"Acute trauma" means serious illness and traumatic injuries requiring immediate short-term medical care to relieve suffering and minimize morbidity and mortality risk.

"CDS registration" means registration with the Division of Consumer Affairs to manufacture, distribute, dispense, or conduct research with controlled dangerous substances issued pursuant to P.L. 1970, c. 226 § 11 (N.J.S.A. 24:21-11).

"Certified medical assistant" means a person who is a graduate of a post-secondary medical assisting educational program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), or its successor, the Accrediting Bureau of Health Education Schools (ABHES), or its successor, or any accrediting agency recognized by the U.S. Department of Education, which educational program includes, at a minimum, 600

clock-hours of instruction, and encompasses training in the administration of intramuscular and subcutaneous injections, as well as instruction and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique, including sterile technique; hazards and complications; and emergency procedures; and who maintains current certification or registration, as appropriate, from the Certifying Board of the American Association of Medical Assistants (AAMA), the National Center for Competency Testing (NCCT), the American Medical Technologists (AMT), or any other recognized certifying body approved by the Board of Medical Examiners. A "clock-hour" shall be calculated at the rate of one hour for every 50 minutes of in-class participation.

"Chronic pain" means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically.

"Controlled dangerous substance" means any substance that is listed in Schedules II, III, and IV of the schedules provided under the "New Jersey Controlled Dangerous Substances Act," P.L. 1970, c. 226 (N.J.S.A.24:21-1 et seq.). Controlled dangerous substance also means any substance that is listed in Schedule V under the "New Jersey Controlled Dangerous Substances Act" when the Director has determined that reporting Schedule V substances is required by Federal law, regulation, or funding eligibility, consistent with N.J.A.C. 13:45H.

"Current patient" means any person who is the recipient of a professional service rendered by the practitioner for purposes of diagnosis, treatment, or a consultation related to treatment.

"Data Collection Manual" means the New Jersey Prescription Monitoring Program Data Collection Manual, Version 2.1, incorporated herein by reference, as amended and supplemented, and available on the New Jersey Prescription Monitoring Program website at www.njconsumeraffairs.gov.

"Delegate" means a person authorized to access the PMP information of the practitioner's current or new patient on behalf of a practitioner who is an authorized user of the PMP.

"Dental resident" means a person who practices dentistry as a resident pursuant to N.J.S.A. 45:6-20 and, pursuant to N.J.A.C. 13:30-1.3, is a graduate of a dental school approved by the Commission on Dental Accreditation and has passed Part I and Part II of the National Board Dental examination and obtained a resident permit from the New Jersey Board of Dentistry.

“Director” means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

“Diversion” means the redirection of a prescription drug from its lawful purpose for illicit use.

“Division” means the Division of Consumer Affairs in the Department of Law and Public Safety.

“Emergency department of a general hospital” means an emergency department of a hospital (approved general) licensed and regulated by the Department of Health under N.J.A.C. 8:43G.

“Hospice” means a hospice as defined in N.J.A.C. 8:42C-1.2, which is licensed by the New Jersey State Department of Health.

“Licensed health care professional” means a registered nurse, licensed practical nurse, or dental hygienist licensed pursuant to Title 45 of the Revised Statutes. A “licensed health care professional” also means an advanced practice nurse or a physician assistant who access the PMP as a delegate.

“Medical resident” means a graduate physician who is authorized to practice medicine and surgery by means of a valid permit issued by the State Board of Medical Examiners to a person authorized to engage in the practice of medicine and surgery while in the second year or beyond of a graduate medical education program pursuant to N.J.A.C. 13:35-1.5. For purposes of this subchapter, a medical resident shall not include a licensed physician participating in a graduate medical education program.

“Mental health practitioner” means a clinical social worker, marriage and family therapist, clinical alcohol and drug counselor, professional counselor, psychologist, or psychoanalyst licensed or otherwise authorized to practice pursuant to Title 45 of the Revised Statutes.

“Misuse” means the use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs.

"New patient" means a person who for the first time seeks from or is rendered professional services by the practitioner for purposes of diagnosis, treatment, or a consultation related to a treatment.

"Pharmacy permit holder" means an individual or business entity that holds a permit to operate a pharmacy practice site pursuant to P.L. 2003, c. 280 (N.J.S.A. 45:14-40 et seq.).

"Practitioner" means an individual currently licensed, registered, or otherwise authorized by this State or another state to prescribe drugs in the course of professional practice.

"Registered dental assistant" is a person who has fulfilled the requirements for registration established by the Dental Auxiliaries Act, P.L. 1979, c. 46 (N.J.S.A. 45:6-48 et seq.), as set forth in N.J.A.C. 13:30-2.2, and works under the direct supervision of a licensed dentist.

13:45A-35.3 PHARMACY REPORTING REQUIREMENTS; ELECTRONIC FORMAT

a) A pharmacy filling a prescription for a Schedule II, III, IV, or V controlled dangerous substance, for human growth hormone, as defined in N.J.A.C. 13:45A-35.1, or gabapentin, in an outpatient setting, shall collect and electronically transmit to the Division's PMP vendor on a daily basis information for each prescription, as specified in the New Jersey PMP Data Collection Manual.

1) For purposes of this section, in accordance with N.J.S.A. 45:1-45 and as specified in the Data Collection Manual, the following information shall be collected and transmitted to the Division:

i) The surname, first name, and date of birth of the patient for whom the medication is intended;

ii) The street address and telephone number of the patient;

iii) The date that the medication is dispensed;

iv) The number or designation identifying the prescription and the National Drug Code of the drug dispensed;

v) The pharmacy permit number of the dispensing pharmacy;

vi) The prescribing practitioner's name and Drug Enforcement Administration registration number;

vii) The name, strength, and quantity of the drug dispensed, the number of refills ordered, and whether the drug was dispensed as a refill or a new prescription;

viii) The date that the prescription was issued by the practitioner;

ix) The source of payment for the drug dispensed; and

x) Such other information, not inconsistent with Federal law, regulation, or funding eligibility requirements, as the Director determines necessary and that is set forth in the Data Collection Manual.

2) Consistent with the requirements of N.J.S.A. 45:1-47.a, information for gabapentin prescriptions shall be collected and electronically transmitted until May 7, 2019, a one-year period from the effective date of this regulation. At the conclusion of this one-year period, the Division shall determine and make public the decision whether the inclusion of gabapentin in the PMP shall be permanent.

13:45A-35.4 REQUESTS FOR EXEMPTION OR WAIVER

a) A pharmacy that does not dispense Schedule II, III, IV, or V controlled dangerous substances, human growth hormone, or gabapentin, or that dispenses Schedule II, III, IV, or V controlled dangerous substances, human growth hormone, or gabapentin only to inpatients in a hospital, long-term or other facility in which the residents are provided with 24-hour nursing care, shall apply to the Division for an exemption from the PMP on a form supplied by the Division and available at www.njconsumeraffairs.gov.

b) A pharmacy may apply for a waiver of the PMP electronic reporting requirements contained in this subchapter or in the Data Collection Manual for good cause, such as technological limitations or financial hardship, by filing a written application for waiver with the Division on a form supplied by the Division and available at www.njconsumeraffairs.gov. The application for waiver shall document the reasons for the pharmacy's inability to comply

with the electronic submission requirement and shall specify the format the pharmacy proposes to use to submit required information to the PMP vendor.

c) An application for exemption or waiver request granted pursuant to this section shall be valid until June 30 of the following year unless otherwise limited by the Division. If the conditions that necessitated the exemption or waiver are corrected or no longer exist, the pharmacy shall notify the Division, and the exemption or waiver shall become void. If the reasons necessitating the exemption or waiver persist, the pharmacy shall, by June 30 of each year as part of its pharmacy permit or out-of-State pharmacy registration annual renewal application, apply to the Division for a renewal of the exemption or waiver.

13:45A-35.5 FREQUENCY REQUIREMENTS FOR TRANSMITTING INFORMATION; CONFIDENTIALITY

a) A pharmacy shall transmit prescription information required by N.J.A.C. 13:45A-35.3 to the PMP vendor on a daily basis pursuant to the schedule established in the Data Collection Manual. Omissions and errors in the transmitted information shall be corrected and submitted as provided in the Data Collection Manual.

b) A pharmacy shall transmit the required prescription information in such a manner as to ensure the confidentiality of patient information in compliance with all Federal and State laws, rules, and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996 and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

13:45A-35.6 ACCESS TO PRESCRIPTION MONITORING INFORMATION; RETENTION OF INFORMATION

a) The Division shall provide online access to prescription monitoring information submitted to the PMP to the following:

1) A pharmacist who is employed by a current pharmacy permit holder and is authorized to dispense controlled dangerous substances, human growth hormone, or gabapentin who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient, or verifying information with respect to a prescriber;

2) A practitioner who has a current CDS registration and is authorized to prescribe, dispense, or administer controlled dangerous substances, human growth hormone, or gabapentin who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient of the practitioner, or verifying information with respect to a prescriber;

3) A delegate authorized by a practitioner to access the PMP information for the purpose of providing health care to a new or current patient of the delegating practitioner who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient of the delegating practitioner, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

4) A current medical resident of a medical teaching facility who is authorized to access PMP information and who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient at the medical teaching facility for whom the residency program has responsibility of care, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

5) A current dental resident of a dental teaching facility who is authorized to access PMP information and who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient at the medical teaching facility for whom the residency program has responsibility of care, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

6) A designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Optometrists, New Jersey State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this State or another state that regulates the practice of persons who are authorized to prescribe or dispense controlled dangerous substances, human growth hormone, or gabapentin, as applicable, who certifies that he or she is engaged in a bona fide specific investigation of a designated practitioner whose professional practice was or is regulated by that board;

7) A designated representative of a state Medicaid or other government program who certifies that he or she is engaged in a bona fide investigation of a designated practitioner, pharmacist, or patient;

8) The State Medical Examiner, a county medical examiner, a deputy or assistant county medical examiner, or a qualified designated assistant thereof, who certifies that the request is for the purpose of investigating a death pursuant to P.L. 1967, c. 234 (N.J.S.A. 52:17B-78 et seq.);

9) Effective after 30 days public notice in the New Jersey Register, a licensed mental health practitioner providing treatment for substance abuse to patients at a residential or outpatient substance abuse treatment center licensed by the Department of Health provided that the licensed mental health practitioner:

i) Certifies that the request is for the purpose of providing health care to a current patient at a residential or outpatient substance abuse treatment center licensed by the Department of Health, or verifying information with respect to a patient or practitioner; and

ii) Provides the Division with the written consent of the patient for the mental health practitioner to obtain prescription monitoring information about the patient.

(1) Patient consent shall be valid for the period of treatment by the mental health practitioner at the residential or outpatient substance abuse treatment center or for one year, whichever is less. After one year, the mental health practitioner shall re-obtain, and re-submit to the Division, the written consent of the patient; and

10) Authorized personnel, as determined by the Director of the Division, responsible for administration of the provisions of P.L. 1970, c. 226 (N.J.S.A. 24:21-1 et seq.).

b) The Division may provide prescription monitoring information submitted to the PMP to the following, consistent with the purpose certified to by the requester under the requirements of (c) below:

1) A properly convened grand jury pursuant to a subpoena properly issued for the records;

2) Authorized personnel, as determined by the Director of the Division or the PMP vendor responsible for establishing and maintaining the PMP;

3) A State, Federal, or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner, pharmacist, or patient; and

4) A prescription monitoring program in another state with which the Division has established an interoperability agreement, or which participates with the Division in a system that facilitates the secure sharing of information between states.

c) All persons authorized to have online access to PMP information shall, in accordance with N.J.A.C. 13:45A-35.7, register with the Division and shall receive a login ID and password. Such persons shall complete all forms and statements required by the Division.

1) All persons authorized to have online access to PMP information who become aware or suspect that their login ID and password to the PMP were compromised or used without authorization shall, within five business days of discovering the unauthorized access, notify the Division through the PMP and submit supporting documentation evidencing the unauthorized use.

d) All persons authorized to have online access to PMP information shall, in accordance with (a) above, prior to each look-up certify to the purpose for which the requested information will be used. The certification shall be completed online in the PMP system.

e) All persons granted access to PMP information, either through online access or by request, shall comply with all Federal and State laws, rules, and regulations concerning the confidentiality of patient information, including the Federal Health Insurance Portability and Accountability Act of 1996, specifically the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

1) A delegate shall share PMP information with only his or her delegating practitioner.

2) A person granted access to PMP information pursuant to N.J.A.C. 13:45A-35.6(a)6, 7, 8, or 9 may, in the performance of his or her professional duties, share information with personnel from his or her agency in accordance with agency policy and procedures.

3) In accordance with N.J.A.C. 13:45A-35.8(f), all persons granted online access to the PMP shall not share their PMP login ID and password with any other person or entity.

f) The Division may provide non-identifying PMP information to public or private entities for statistical, research, or educational purposes, provided that the confidentiality of patient information is not compromised.

g) Notwithstanding the provisions of this subchapter, the Division may obtain unsolicited automated reports from the PMP or disseminate such reports to pharmacists, practitioners, mental health practitioners, and other licensed health care professionals.

h) The Division shall maintain PMP information in such a manner as to ensure the privacy and confidentiality of patient information in compliance with all Federal and State laws, rules, and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164. The Division shall retain PMP information for a minimum of seven years.

1) For purposes of retention in this subsection, “PMP information” shall not include data obtained from other states via an interoperability agreement.

i) The Division shall review the prescription monitoring information provided by a pharmacy permit holder pursuant to N.J.S.A. 45:1-45 et seq., and the rules of this subchapter. The review shall include, but not be limited to, a review to identify whether:

1) Any person is obtaining a prescription in a manner that may be indicative of misuse, abuse, or diversion of a controlled dangerous substance. When an evaluation of the information indicates that a person may be obtaining a prescription for the same or a similar controlled dangerous substance from multiple practitioners or pharmacies during the same period, the Division may provide prescription monitoring information about the person to practitioners and pharmacies; and

2) A violation of law or regulation or breach of the applicable standards of practice by any person may have occurred, including, but not limited to, diversion of a controlled dangerous substance. If the Division determines that such a violation or breach may have occurred, the Division shall notify the appropriate law enforcement agency or

professional licensing board, and provide the prescription monitoring information required for an investigation.

j) Pursuant to N.J.S.A. 45:1-46, the prescription monitoring information submitted to the Division shall be confidential and not be subject to public disclosure under the State Open Public Records Act, P.L. 1963, c. 73 (N.J.S.A. 47:1A-1 et seq.) or P.L. 2001, c. 404 (N.J.S.A. 47:1A-5 et seq.).

13:45A-35.7 REGISTRATION

a) All persons authorized to have online access to PMP information shall register with the Division. To register, all persons shall:

1) Provide the Division with a unique individual e-mail address.

2) Complete an online tutorial upon initial access to the PMP and as deemed necessary by the Director.

3) Submit all documentation required by the Division to verify the person's identity and credentials. The required documentation shall be listed on the New Jersey Prescription Monitoring Program website at www.njconsumeraffairs.gov.

b) The Division shall register a practitioner to have online access to PMP information upon issuance or renewal of the practitioner's CDS registration.

1) Practitioners may also register to access prescription monitoring information outside of their applicable CDS issuance or renewal time period.

13:45A-35.8 DELEGATES

a) A practitioner or a faculty member authorized by a medical or dental teaching facility may designate a delegate or delegates for the purpose of accessing PMP information for a new or current patient, or a prescriber, consistent with the requirements of this subchapter.

1) As set forth in this subsection, for each designated delegate, a practitioner or a faculty member authorized by a medical or dental teaching facility is responsible for the use or misuse of the PMP and the prescription monitoring information, ensuring compliance with

the recordkeeping requirements, conducting a bi-annual audit, and verifying the education, training, and licensure or certification requirements for each delegate.

2) A delegate may be an authorized delegate for more than one practitioner.

b) The director of the medical or dental residency program shall designate the faculty members who are authorized to designate medical or dental residents, as applicable, as delegates. The director of the medical or dental residency program shall comply with the recordkeeping provisions of N.J.A.C. 13:45A-35.10.

c) Delegates may be designated as follows:

1) A practitioner may designate as a delegate a licensed health care professional or a certified medical assistant who is employed at the practice setting at which the practitioner practices.

i) An individual who is no longer employed at the practice setting at which the practitioner practices is no longer authorized to be a delegate or to access the PMP on behalf of that practitioner.

2) A licensed dentist may designate as a delegate a registered dental assistant who is employed at the practice setting at which the licensed dentist practices dentistry.

i) An individual who is no longer employed at the practice setting at which the licensed dentist practices dentistry is no longer authorized to be a delegate or to access the PMP on behalf of that dentist.

3) A faculty member authorized by a medical teaching facility, in accordance with (b) above, may designate as a delegate a medical resident.

i) An individual who is terminated or withdraws from, or completes the graduate medical education program is no longer authorized to be a delegate or to access the PMP.

ii) A medical resident whose program includes training outside the medical teaching facility shall not be designated as a delegate in that setting unless the

delegating practitioner has been designated as an authorized faculty member pursuant to (b) above and the residency program retains responsibility of care for the patient for whom healthcare is provided or information is requested.

4) A faculty member authorized by a dental teaching facility may designate as a delegate a dental resident.

i) An individual who is terminated or withdraws from, or completes the graduate dental education program is no longer authorized to be a delegate or to access the PMP.

d) Prior to designating a delegate, a practitioner or an authorized faculty member of a medical or dental teaching facility shall confirm the education, training, and licensure or certification requirements of each delegate.

1) Prior to designating a delegate, a practitioner or an authorized faculty member of a medical or dental teaching facility shall ensure that the delegate understands the limitations on disclosure of the prescription monitoring information, and the Federal and State laws, rules, and regulations concerning the confidentiality of patient information, including the Federal Health Insurance Portability and Accountability Act of 1996, specifically the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

2) Prior to designating a certified medical assistant as a delegate, a practitioner shall confirm that that the certified medical assistant has completed a minimum of 600 clock-hours of instruction, and which encompasses training in the administration of intramuscular and subcutaneous injections, as well as instruction and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique, including sterile technique; hazards and complications; and emergency procedures.

e) A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate is responsible for the use or misuse by his or her delegate of the PMP and the prescription monitoring information. A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate shall:

1) Terminate the delegate's access to the PMP when a delegate, for any reason, is no longer authorized to be a delegate.

2) Terminate the delegate's access and notify the PMP when a practitioner or an authorized faculty member of a medical or dental teaching facility learns of any potential unauthorized use by a delegate of the PMP or prescription monitoring information.

i) The practitioner or authorized faculty member of a medical or dental teaching facility shall, within five business days of discovering the unauthorized access, notify the Division through the PMP and submit supporting documentation evidencing the unauthorized use.

3) Conduct, at least once every six months, audits of the delegate's use of the PMP to monitor for potential misuse of the PMP or prescription monitoring information.

4) Ensure that the delegate follows the recordkeeping procedures established by the practitioner as set forth in N.J.A.C. 13:45A-35.10(a).

f) All persons authorized to have online access to PMP information shall not share access to the PMP with any other person or entity.

1) All persons granted access to the PMP shall access the PMP using their own unique user login ID and password. The login ID and password shall not be shared with any other person or entity.

2) All delegates shall identify the practitioner on whose behalf they are accessing the prescription monitoring information.

3) All persons authorized to have online access to PMP information may share such information as set forth in N.J.A.C. 13:45A-35.6.

13:45A-35.9 MANDATORY LOOK-UP

a) Except as provided in (c) below, a practitioner or the practitioner's delegate shall access prescription monitoring information for a new or current patient consistent with the following:

1) The first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient for acute or chronic pain;

i) When the practitioner or the practitioner's delegate accesses the prescription monitoring information for a new patient in advance of the scheduled appointment, the practitioner or delegate shall document the new patient's request for professional services; and

2) On a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain.

i) For purposes of this paragraph, "quarterly" means every three months from the date the initial prescription is issued.

b) Except as provided in (c) below, if the pharmacist has a reasonable belief that the person may be seeking a controlled dangerous substance, in whole or in part, for any purpose other than the treatment of an existing medical condition, such as for purposes of misuse, abuse, or diversion, a pharmacist shall not dispense a Schedule II controlled dangerous substance to any person without first accessing the prescription monitoring information to determine if the person has received other prescriptions that indicate misuse, abuse, or diversion.

c) The provisions of (a) and (b) above, as applicable, shall not apply to:

1) A veterinarian;

2) A practitioner or the practitioner's agent administering methadone as interim treatment for a patient on a waiting list for admission to an authorized substance abuse treatment program;

3) A practitioner administering a controlled dangerous substance directly to a patient;

4) A practitioner prescribing a controlled dangerous substance to be dispensed by an institutional pharmacy, as defined in N.J.A.C. 13:39-9.2;

5) A practitioner prescribing a controlled dangerous substance in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a five-day supply of the substance;

6) A practitioner prescribing a controlled dangerous substance to a patient under the care of a hospice;

7) A situation in which it is not reasonably possible for the practitioner or pharmacist to access the PMP in a timely manner, no other individual authorized to access the PMP is reasonably available, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

8) A situation under which consultation of the PMP would result in a patient's inability to obtain a prescription in a timely manner, thereby, in the clinical judgment of the practitioner or pharmacist, adversely impacting the medical condition of the patient, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

9) A situation in which the PMP is not operational as determined by the Division or where it cannot be accessed by the practitioner or pharmacist due to a temporary technological or electrical failure and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

10) A pharmacist who is employed by a pharmacy that, in accordance with N.J.A.C. 13:45A-35.4, has been granted a waiver due to technological limitations that are not reasonably within the control of the pharmacist, or other exceptional circumstances demonstrated by the pharmacist; or

11) A practitioner who is prescribing less than a 30-day supply of a controlled dangerous substance to a patient immediately, but no more than 24 hours, after the patient has undergone an operation, procedure, or treatment for acute trauma, for which a controlled dangerous substance is recognized in the customary treatment of pain following such operation, procedure, or acute trauma.

i) For purposes of this paragraph, "procedure" means an invasive procedure that requires anesthesia.

d) Prescribing or dispensing of Schedule II CDS after accessing the prescription monitoring information in accordance with (a) or (b) above shall be undertaken if consistent with the practitioner's or pharmacist's professional practice as set forth in the rules of the individual's respective professional licensing board.

13:45A-35.10 RECORDKEEPING

a) Each practitioner and each authorized faculty member of a medical or dental teaching facility who designates a delegate shall establish, retain, and follow written procedures to document, as part of the patient record, the PMP look-up as required in N.J.A.C. 13:45A-35.9 and any PMP information accessed for the patient.

1) Each delegate shall follow the documentation procedures established by his or her delegating practitioner.

2) Examples of documentation include a summary notation of the information reviewed by the practitioner or the printed PMP report in the patient record.

3) Once PMP information is documented in the patient record, disclosure of such information is governed by applicable State laws, other than N.J.S.A. 45:1-45, and Federal laws, including the Federal Health Insurance Portability and Accountability Act of 1996 and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

b) A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate shall establish, retain, and follow written procedures to document:

1) Verification of each delegate's education, training, and licensure or certification requirements, as required in N.J.A.C. 13:45A-35.8(d); and

2) The bi-annual audit, as required in N.J.A.C. 13:45A-35.8(e)3.

c) The program director of the medical or dental residency program shall retain records of the faculty members authorized to designate a medical or dental resident, as applicable, as a delegate.

d) Each mental health practitioner shall retain in the patient record a copy of the patient consent, and any PMP information accessed for the patient.

e) All records required to be maintained in this subchapter shall be made available to the Division upon request.

13:45A-35.11 PROFESSIONAL MISCONDUCT

a) Noncompliance with the rules in this subchapter may be deemed professional misconduct and may subject the pharmacy permit holder, an out-of-State pharmacy that is subject to this subchapter, pharmacist, practitioner, licensed health care professional, registered dental assistant, or mental health practitioner to disciplinary action pursuant to the provisions of N.J.S.A. 45:1-21 and to the penalties set forth in N.J.S.A. 45:1-49.

b) Noncompliance with the rules in this subchapter by a delegate may be deemed professional misconduct by the practitioner and may subject the practitioner to disciplinary action pursuant to the provisions of N.J.S.A. 45:1-21 and to the penalties set forth in N.J.S.A. 45:1-49.

c) Noncompliance with the rules in this subchapter may provide a basis for the withdrawal of the authorization of a registered resident to engage in the practice of medicine or the practice of dentistry, as applicable. Upon receipt of the notice of proposed withdrawal, the registered resident may request a hearing, which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq.

d) Noncompliance with the rules in this subchapter may provide a basis for the withdrawal of the authorization to a certified medical assistant to access the PMP. Upon receipt of the notice of proposed withdrawal, the certified medical assistant shall have an opportunity to provide a written explanation for the noncompliance.

e) The Division shall refer noncompliance with the rules in this subchapter to the appropriate licensing board.

f) The Division shall refer to law enforcement, which may result in a criminal conviction and a civil penalty in accordance with N.J.S.A. 45:1-49 the following persons:

1) A person who is authorized to obtain prescription monitoring information from the PMP who knowingly discloses such information in violation of the provisions of N.J.S.A. 45:1-45 through 50.

i) The production of a patient record in response to a lawful request by the patient, an authorized representative of the patient, or pursuant to a subpoena or other court order shall not be deemed a knowing disclosure within the meaning of the statute;

2) A person who is authorized to obtain prescription monitoring information who uses this information in the course of committing, attempting to commit, or conspiring to commit any criminal offense; and

3) A person who is not authorized to obtain prescription monitoring information from the PMP who knowingly obtains or attempts to obtain such information in violation of the provisions of N.J.S.A. 45:1-45 through 50.

g) Notwithstanding the provisions of this subchapter and the person's CDS registration status or employment status, the Division shall retain the right to take action for noncompliance with the rules in this subchapter or violations of the provisions of N.J.S.A. 45:1-45 through 50.