

51 N.J.R. 624(a)

VOLUME 51, ISSUE 9, MAY 6, 2019

RULE ADOPTIONS

Reporter

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*NJ - New Jersey Register > 2019 > MAY > MAY 6, 2019 > RULE ADOPTIONS
> LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS*

Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > OFFICE OF THE DIRECTOR

Administrative Code Citation

Adopted Amendments: N.J.A.C. 13:45A-35.1, 35.2, 35.3, 35.6, 35.7, 35.8, 35.9, and 35.11

Adopted New Rules: N.J.A.C. 13:45A-35.6A and 35.12

Text

Prescription Monitoring Program

Delegate Access: Athletic Trainers and Medical Scribes Employed by a Hospital's Emergency Department; Access to Prescription Monitoring Information: Electronic Health Record System; Requirements for Mandatory Look-Up; Patient Requests to Correct Inaccurate Information

Proposed: October 15, 2018, at 50 N.J.R. 2138(a).

Adopted: March 5, 2019, by Paul R. Rodriguez, Acting Director, Division of Consumer Affairs.

Filed: March 25, 2019, as R.2019 d.033, **without change**.

Authority: N.J.S.A. 45:1-45 et seq. (P.L. 2007, c. 244, as amended by P.L. 2015, c. 74 and P.L. 2017, c. 341).

Effective Date: May 6, 2019.

Expiration Date: January 16, 2026.

Summary of Public Comment and Agency Response:

The official comment period ended December 14, 2018. The Division of Consumer Affairs (Division) received one comment from Melinda R. Martinson, General Counsel, Medical Society of New Jersey.

1. COMMENT: The commenter expressed support for the process for patients to request the correction of inaccurate information in the program. The commenter is aware of a number of physicians who have had prescriptions inaccurately attributed to them as prescribers and the burden has been on the physician to seek the correction, which may or may not have involved a patient. The commenter urged the Division to support physicians' efforts to correct prescriptions inaccurately attributed to them and noted that patients, physicians, and society at large benefit from accurate prescribing information in the Prescription Drug Monitoring Program (PMP).

The commenter also expressed support for the new flexibility for physicians and other authorized individuals to access prescription monitoring information from electronic systems connecting hospital emergency departments, so long as appropriate security protections are in place. The commenter reiterated that flexibility and ease of access help to facilitate compliance with the program's requirements.

RESPONSE: The Division thanks the commenter for her support.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments and new rules are governed by N.J.S.A. 45:1-45 et seq. (P.L. 2007, c. 244, as amended by P.L. 2015, c. 74 and P.L. 2017, c. 341). However, in accordance with existing N.J.A.C. 13:45A-35.5(h), all persons authorized to access PMP prescription drug information, including licensed athletic trainers and medical scribes, must comply with the Federal Health Insurance Portability and Accountability Act of 1996 and the Federal health privacy rules set forth at 45 CFR Parts 160 and 164.

Regulations

Full text of the adoption follows:

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 and P.L. 2017, c.

341 (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.-9. (No change.)

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;

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;

12. A licensed athletic trainer authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter; and

13. A medical scribe authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter.

(c) - (d) (No change.)

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:

. . . .

"Certified medical assistant" means a person who is a graduate of a post-secondary medical assisting educational program accredited by the Commission 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, 330 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 National Healthcareer

Association (NHA), the American Medical Certification Association (AMCA), the National Certification Medical Association (NCMA), 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 or recurs for more than three months.

. . . .

"Licensed athletic trainer" means an individual who is licensed by the State Board of Medical Examiners to practice athletic training, pursuant to the Athletic Training Licensure Act, P.L. 1984, c. 203 (N.J.S.A. 45:9-37.35 et seq.).

. . . .

"Medical scribe" means an individual trained in medical documentation who assists a physician or other licensed health care professional by documenting the patient's encounter with the professional in the patient's medical record and gathering data for the professional, including, but not limited to, nursing notes, patient medical records, laboratory work, and radiology tests.

. . . .

[page=625] 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 for 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.-viii. (No change.)

ix. The source of payment for the drug dispensed;

x. Identifying information for any individual, other than the patient for whom the prescription was written, who picks up the prescription, if the pharmacist has a reasonable belief that the person picking up the

prescription may be seeking a controlled dangerous substance, in whole or in part, for any reason other than delivering the substance to the patient for the treatment of an existing medical condition.

(1) For purposes of this subparagraph, "identifying information" includes the individual's first and last name, relationship to the patient, and, if available, the type of, and identification number on, a state or Federal government identification; and

xi. (No change in text.)

2. (No change.)

13:45A-35.6 Access to prescription monitoring information; retention of information

(a) - (c) (No change.)

(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. Except as provided in (d)1 below, certification shall be completed online in the PMP system.

1. If the PMP information is being accessed using an electronic system authorized pursuant to N.J.A.C. 13:45A-35.6A(a), the certification may be furnished through the electronic system.

(e) - (j) (No change.)

13:45A-35.6A Access to prescription monitoring information: electronic health record system

(a) The Division may make prescription monitoring information available on electronic systems that collect and display health information, such as an electronic system that connects hospital emergency departments for the purpose of transmitting and obtaining patient health data from multiple sources, or an electronic system that notifies practitioners of information pertaining to the treatment of overdoses, provided that the Division determines that any such electronic system has appropriate security protections in place.

(b) Practitioners who are required to access prescription monitoring information pursuant to N.J.A.C. 13:45A-35.9, may discharge that responsibility by accessing one or more authorized electronic systems into which the prescription monitoring information maintained by the Division has been integrated.

13:45A-35.7 Registration

(a) (No change.)

(b) A practitioner shall register to have online access to PMP information upon initial application for, or renewal of, the practitioner's CDS registration.

1. (No change.)

13:45A-35.8 Delegates

(a) - (b) (No change.)

(c) Delegates may be designated as follows:

1.-4. (No change.)

5. A practitioner practicing in a hospital's emergency department may designate as a delegate, a medical scribe who is working in a hospital's emergency department.

i. An individual who is no longer employed at the hospital's emergency department at which the practitioner practices is no longer authorized to be a delegate or to access the PMP on behalf of that practitioner.

ii. For purposes of (c)5 above, the medical director of a hospital's emergency department may designate medical scribes working in the emergency department as delegates for a practitioner practicing in a hospital's emergency department. In such cases, the medical director shall be responsible for compliance with (d) and (e) below.

6. A practitioner may designate as a delegate, an athletic trainer who is employed at a clinical practice setting. For purposes of this paragraph, "clinical practice setting" shall mean the setting at which the supervising physician practices.

i. An individual who is no longer employed at the clinical 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.

(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. (No change.)

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 330 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) - (f) (No change.)

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 or any opioid 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;
2. The first time the practitioner prescribes a benzodiazepine drug that is a Schedule III or Schedule IV controlled dangerous substance;
3. If the practitioner 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, the first time the practitioner or other person prescribes a non-opioid drug other than a benzodiazepine drug that is a Schedule III or Schedule IV controlled dangerous substance;
4. Any time the practitioner prescribes a Schedule II controlled dangerous substance for acute or chronic pain to a patient receiving care or treatment in the emergency department of a general hospital;

5. On a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance or for an opioid drug for acute or chronic pain, or for a benzodiazepine that is a Schedule III or Schedule IV controlled dangerous substance.

i. (No change.)

(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, any opioid, or a benzodiazepine drug that is a Schedule III or Schedule IV 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.-4. (No change.)

5. (Reserved)

6.-10. (No change.)

[page=626] 11. A practitioner who is prescribing no more than a five-day supply of a controlled dangerous substance to a patient immediately, but no more than 24 hours, after the patient has undergone an operation or treatment for acute trauma, in a general hospital or a licensed ambulatory care facility, so long as that operation or treatment was not part of the care or treatment in the emergency department of a general hospital as provided in (a) above.

(d) (No change.)

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, mental health

practitioner, or licensed athletic trainer 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) - (c) (No change.)

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

(e) - (g) (No change.)

13:45A-35.12 Patient requests to correct inaccurate information

(a) A patient, or the parent or legal guardian of an unemancipated minor who is a patient, may request a pharmacy permit holder that submitted prescription monitoring information concerning a prescription for controlled dangerous substances for that patient or unemancipated minor to correct information that the person believes to have been inaccurately entered into that patient's or unemancipated child's prescription profile. The request shall be in writing using the process established by the pharmacy permit holder.

(b) A pharmacy permit holder shall have written policies and procedures for processing, evaluating, reviewing, and handling patient requests to correct information submitted to the prescription monitoring program. The policies and procedures shall include, at a minimum:

1. A statement explaining in detail the basis for the requested correction;
2. The precise change requested;
3. Documentation of the error and of the correct information; and
4. The requester's name, address, telephone number, and original signature.

(c) Upon receiving notice from a patient, or the parent or legal guardian of an unemancipated minor who is a patient, that the prescription monitoring data specific to that patient's prescription history is incorrect, the pharmacy permit holder shall:

1. Verify that the information is incorrect and, if so, correct the information in both the patient profile and the PMP within 14 days of the patient notification.
 - i. The pharmacy permit holder shall notify the patient when the information has been corrected in the PMP.
2. If the pharmacy permit holder determines that a correction is not appropriate or justified, within 14 days of the patient request, the pharmacy permit holder shall notify the patient, and advise the patient of the process for requesting the Board of Pharmacy to review the disputed request for correction.