50 N.J.R. 1219(a)

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RULE ADOPTIONS

Reporter
50 N.J.R. 1219(a)

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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, 35.3, 35.4, and 35.6

Text

Prescription Monitoring Program

Purpose and Scope; Pharmacy Reporting Requirements; Electronic Format; Requests for Exemption or Waiver; Access to Prescription Monitoring Information; Retention of Information

Proposed: January 2, 2018, at 50 N.J.R. 9(a).

Adopted: March 27, 2018, by Sharon Joyce, Acting Director, Division of Consumer Affairs.

Filed: April 11, 2018, as R.2018 d.101, **with a non-substantial change** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-47.

Effective Date: May 7, 2018.

Expiration Date: December 14, 2018.

Summary of Public Comment and Agency Response:

The official comment period ended March 3, 2018. **No comments were received.**

Federal Standards Statement

A Federal standards analysis is not required because the amendments are not adopted under the authority of, or in order to implement, comply with, or participate in any program under Federal law. The adopted amendments are governed by N.J.S.A. 45:1-47.

Regulations

Full text of the adoption follows (addition to proposal indicated in boldface with asterisks ***thus***; deletion from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 35. PRESCRIPTION MONITORING PROGRAM

13:45A-35.1 Purpose and scope

(a) (No change.)

(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. (No change.)

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.-10. (No change.)

(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-35.3 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. (No change.)

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 *[(one year from the effective date of this amendment)]* ***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)-(c) (No change.)

[page=1220] 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.-5. (No change.)

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.-9. (No change.)

(b)-(i) (No change.)