

45 N.J.R. 46(a)

VOLUME 45, ISSUE 1

ISSUE DATE: **JANUARY 7, 2013**

RULE ADOPTIONS

**LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
CONTROLLED DANGEROUS SUBSTANCES**

Adopted Amendment: N.J.A.C. 13:45H-7.8

Adopted New Rule: N.J.A.C. 13:45H-7.20

Requirements of Prescriptions; Electronic Prescriptions

Proposed: August 20, 2012 at 44 N.J.R. 2101(b).

Adopted: October 26, 2012 by Eric T. Kanefsky, Acting Director, **Division of Consumer Affairs**.

Filed: December 10, 2012 as R.2013 d.007, **without change**.

Authority: N.J.S.A. 24:21-9 (P.L. 2007, c. 244).

Effective Date: January 7, 2013.

Expiration Date: February 15, 2015.

Summary of Public Comments and Agency Responses:

The official comment period ended October 19, 2012.

The Division received comments from:

Jay E. Bowen, D.O., President, Union County Medical Society of New Jersey

Lawrence Downs, JD., CEO & General Counsel, Medical Society of New Jersey

1. COMMENT: A commenter opined that conformity of the rules of the Drug Enforcement Agency (DEA) is a positive step, but controlled dangerous substances (CDS) duplicates the services of the DEA and should be eliminated.

RESPONSE: The Division is not clear about the import of the comment. The Division is responsible for administering and enforcing the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq. The Act creates the regulatory scheme. Every person who manufactures, distributes, or dispenses (defined in the Act to include prescribing) any CDS in the State is required to register with the Division. The Act authorizes the Division to promulgate rules relating to the control of dispensing CDS. The

rules include rules governing the issuance and filling of prescriptions. See N.J.A.C. 13:47H-7. The new rule permits the use of electronic prescriptions for CDS consistent with State rules and Federal law, eliminating the conflict between the CDS rules and the rules of the Board of Medical Examiners and the Board of Pharmacy and the possible confusion that may result.

It is not clear what the commenter means by duplication of services. Does the commenter object to the entire State regulatory scheme existing parallel to the Drug Enforcement Administration rules, to CDS registration and the registration fee, or to something else? The enforcement activities of the Division's Drug Control Unit (DCU) do not duplicate those of the DEA. While the DCU sometimes works with the DEA on certain cases, most of the time they do not. The DCU investigates lost or stolen CDS, triggered by reports that registrants are required to file; the DEA does not conduct such investigations. The DCU investigates incidents involving theft or counterfeiting of New Jersey Prescription Blanks (NJPBs), and forgery or alteration of NJPBs. The DCU also investigates reports of possible drug abuse or diversion by any of the 40,000 CDS registrants who are health care practitioners licensed by the Division's professional boards.

[page=47] P.L. 2007, c. 244 created New Jersey's Prescription Monitoring Program (NJPMP), a Statewide database that collects prescription data on CDS and Human Growth Hormone (HGH) dispensed in outpatient settings in New Jersey, and by out-of-State pharmacies dispensing into New Jersey. Patient information in the NJPMP is intended to supplement an evaluation of a patient, confirm a patient's drug history, or document compliance with a therapeutic regimen. When prescribers or pharmacists identify a patient as potentially having an issue of concern regarding drug use, they are encouraged to help the patient locate assistance and take any other action the prescriber or pharmacist deems appropriate.

The NJPMP is also an important component of the Division's effort, in partnership with law enforcement and healthcare partners at the local, State, and Federal levels, to halt the abuse and diversion of prescription drugs. The NJPMP serves as an effective tool for identifying those who fraudulently obtain prescription drugs or are otherwise involved in the criminal diversion of prescription medication.

CDS registration fees support the activities of the DCU and, to the extent not funded by grants, the NJPMP.

2. COMMENT: A commenter fully supports the Division's proposed rule.

RESPONSE: The Division thanks the commenter for its support.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment and new rule are governed by N.J.S.A. 24:21-9 (P.L. 2007, c. 244) and N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165). The Division notes, however, that the adopted amendment and new rule are subject to the Federal Drug Enforcement Administration Interim Final Rule set forth at 21 CFR 1300, 1304, 1306, and 1311. The DEA rules provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances dispensing. That the technology meets strict DEA security standards must be verified by a third-party audit of the application by a DEA-approved certification organization.

Full text of the adoption follows:

SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES

13: 45H-7.8 Requirements of prescriptions; schedule II

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in (d) and (e) below.

(b)-(d) (No change.)

(e) If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

(f) (No change in text.)

13: 45H-7.20 Electronic prescriptions

An individual practitioner may issue, and a pharmacist may accept for dispensing, an electronic prescription for a controlled dangerous substance, consistent with the requirements of this chapter and Federal law. For purposes of this section, "electronic prescription" means a prescription that is transmitted by a computer device in a secure manner, including computer-to-computer and computer-to-facsimile transmissions.