

RULE ADOPTIONS
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ISSUE DATE: JANUARY 3, 2012
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
CONTROLLED DANGEROUS SUBSTANCES

Adopted Amendment: N.J.A.C. 13:45H-7.5

Manner of Issuance of Prescriptions

Proposed: November 1, 2010 at 42 N.J.R. 2568(a).

Adopted: September 26, 2011 by Thomas R. Calcagni, Director, Division of Consumer Affairs.

Filed: October 31, 2011 as R.2012 d.001, **without change**.

Authority: N.J.S.A. 24:21-9 (P.L. 2007, c. 244) and 45:9-22.19 (P.L. 2009, c. 165).

Effective Date: January 3, 2012.

Expiration Date: February 15, 2015.

Agency Note: Effective March 17, 2011, the rules in N.J.A.C. 8:65 were recodified as N.J.A.C. 13:45H. Notice of this recodification appeared in the New Jersey Register on May 2, 2011 at 43 N.J.R. 1204(b). As a result of the recodification, references to N.J.A.C. 8:65-7.5 in this notice of adoption have been changed to refer to N.J.A.C. 13:45H-7.5.

Summary of Public Comments and Agency Responses:

The Division received comments on the notice of proposal from the following individuals:

1. Leonard Eng, M.D., Child and Adolescent Psychiatrist, Raritan Bat Mental Health Center;
2. Debra L. Wentz, Ph.D., Chief Executive Officer, New Jersey Association of Mental Health and Addiction Agencies, Inc.; and
3. Joanne Boyer, R.Ph., Executive Director, New Jersey Board of Pharmacy.

1. COMMENT: Dr. Eng expressed support for the proposed amendments. The commenter noted that the statutory change that precipitated the proposed amendments to N.J.A.C. 13:45H-7.5 has reduced the frequency of office visits by patients who need to obtain stimulant prescriptions, resulting in an increase in available appointment times for patients in general. The commenter expressed support for the proposed amendment because following the enactment of the statutory change, there was some confusion among pharmacists concerning the prescription format required to authorize the issuance of a 90-day supply of Schedule II controlled substances.

RESPONSE: The Division thanks the commenter for his support of the proposed amendments.

2. COMMENT: Dr. Wentz, on behalf of the New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA), expressed concern that the proposed amendments could increase the possibility of stolen or lost prescriptions, especially for individuals in outpatient rehabilitation and half-way housing programs because these individuals would be required to hold onto the second and third prescriptions until they could be filled. The commenter recommended that the rule be amended to require patients to present all three prescriptions to the pharmacist at one time, and that the pharmacy place the second and third prescriptions on hold until the date they can be filled. In addition, the commenter noted that the proposed amendments would likely have an economic impact upon some physicians because they would begin to see patients less frequently.

RESPONSE: The proposed amendments to N.J.A.C. 13:45H-7.5 permit patients to present all three prescriptions for

Schedule II controlled substances to the pharmacist at one time. The second and third prescriptions will be held by the pharmacist until the prescriptions can be filled, consistent with the requirements in N.J.A.C. 13:45H-7.5(a)1i(2). Therefore, patients are not required to hold onto the second and third prescriptions, as the commenter suggests. In addition, N.J.S.A. 45:9-22.19, which authorizes physicians to provide patients with up to a 90-day supply for a Schedule II substance, did not impose such a requirement, although the Legislature was clearly cognizant of the potential for diversion or abuse created by the issuance of multiple prescriptions at one time because N.J.S.A. 45:9-22.19b.(3) specifically requires physicians to determine that the issuance of the separate [page=118] prescriptions "does not create an undue risk of diversion or abuse." The Division, therefore, declines to amend the rule as the commenter suggests. In addition, the Division notes that any economic impact that may be borne by physicians as a result of issuing prescriptions for a 90-day supply of medications at one time is attributable to the enactment of the statutory requirement in N.J.S.A. 45:9-22.19 and not the proposed amendment, which is intended only to clarify the procedures associated with accepting and filling such prescriptions.

3. COMMENT: Ms. Boyer, on behalf of the Board of Pharmacy, requested clarification regarding the application of the proposed amendments to prescribers other than licensed physicians, noting that N.J.S.A. 45:9-22.19, applies only to physicians. The commenter requested that to avoid confusion the Division notify all affected prescribers authorized to issue prescriptions for Schedule II controlled dangerous substances about the limitations of N.J.S.A. 45:9-22.19.

RESPONSE: N.J.S.A. 45:9-22.19 expressly authorizes physicians licensed by the State Board of Medical Examiners to issue multiple prescriptions to a patient at one time so the patient may receive a total of up to a 90-day supply of a Schedule II medication. The enabling statute does not apply to other licensed prescribers in the State who are authorized to prescribe controlled dangerous substances. Therefore, the proposed amendments to N.J.A.C. 13:45H-7.5, establishing requirements for the filling of these prescriptions, expressly refer to the issuance of such prescriptions by physicians. Prescribers other than licensed physicians are not permitted to issue multiple prescriptions at one time for a Schedule II medication and, therefore, such prescribers are not referenced in N.J.A.C. 13:45H-7.5(a)1 of the amended rule. However, in order to avoid confusion, the Division will advise other licensed prescribers, by means of an alert on the Division's website at www.njconsumeraffairs.gov, that the authority to issue multiple prescriptions for a Schedule II medication for a total of a 90-day supply applies only to licensed physicians.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment is governed by N.J.S.A. 24:21-9 (P.L. 2007, c. 244) and 45:9-22.19 (P.L. 2009, c. 165). The Division notes, however, that the adopted amendment is consistent with Federal Drug Enforcement Administration requirements set forth at 21 CFR 1306.12, which authorize the issuance of multiple prescriptions for a total of up to a 90-day supply of Schedule II controlled substances.

Full text of the adoption follows:

SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES

13:45H-7.5 Manner of issuance of prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued, except as provided in (a)1 below. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (for example, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written in ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by a secretary or agent of the practitioner for the signature of the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law or rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules.

1. When up to three separate prescriptions for a total of up to a 90-day supply of a Schedule II controlled substance are issued to a patient by a physician pursuant to N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165), a pharmacist shall fill such prescriptions.

i. All three prescriptions may be accepted at one time and held pending filling as indicated below:

(1) The first prescription shall be filled no later than 30 days after the date of issuance; and

(2) The second and third prescriptions shall be filled no later than 30 days after the date indicated on the prescription as the earliest date on which the prescription may be filled.

ii. Prescriptions presented individually shall be filled as indicated below:

(1) The first prescription shall be filled no later than 30 days after the date of issuance;

(2) The second and third prescriptions shall be presented to the pharmacy and filled no later than 30 days after the date indicated on the prescription as the earliest date on which the prescription may be filled.

iii. A patient shall not be provided with more than a 30-day supply of a Schedule II medication at one time.

(b)-(c) (No change.)