

New Jersey Register
VOLUME 35, NUMBER 18
MONDAY, SEPTEMBER 15, 2003
RULE ADOPTION
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
EXAMINATION OF PATIENT'S CONDITION REQUIRED PRIOR TO DISPENSING DRUGS OR
ISSUING A PRESCRIPTION; EXCEPTIONS; FACSIMILE TRANSMITTED PRESCRIPTIONS;
ELECTRONICALLY TRANSMITTED PRESCRIPTIONS

Adopted New Rules: N.J.A.C. 13:35-7.1A, 7.4 and 7.4A

Proposed: September 3, 2002 at 34 N.J.R. 3059(a).

Adopted: February 18, 2003 by the State Board of Medical Examiners, William V. Harrer, M.D., President.

Filed: August 22, 2003 as R.2003 d.372, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30- 6.3).

Authority: N.J.S.A. 45:9-2 and 45:1-15.1.

Effective Date: September 15, 2003.

Expiration Date: September 20, 2004.

Summary of Public Comments and Agency Responses:

The Board received comments from the following:

1. Robert S. Rigolosi, M.D., President, Medical Society of New Jersey; and
2. Nancy T. Block, M.D., President, New Jersey Psychiatric Association.

COMMENT: Dr. Rigolosi, on behalf of the Medical Society of New Jersey (MSNJ), stated that the MSNJ supports the proposed new rule on facsimile transmission of prescriptions. The proposed new rule will provide physicians with additional flexibility in sending prescriptions. The commenter believes that the requirements outlined in the new rule are minimal and reasonable.

RESPONSE: The Board thanks the Medical Society of New Jersey for its support of proposed new rule N.J.A.C. 13:35-7.4, concerning facsimile transmission of prescriptions.

COMMENT: Dr. Rigolosi stated that the MSNJ strongly supports the proposed new rule concerning electronic transmission of prescriptions. The commenter notes that the MSNJ has long supported this and other measures aimed at helping to reduce medical errors by providing clearly written instructions for the dispensing of medications. The commenter also notes that the MSNJ believes that the new rule will provide physicians with greater flexibility in their practice and urges the Board to take whatever action is necessary to promote a change in Federal law so as to allow for the use of electronic prescriptions in all cases.

RESPONSE: The Board thanks the Medical Society of New Jersey for its support of proposed new rule N.J.A.C. 13:35-7.4A, concerning electronically transmitted prescriptions. As to the commenter's suggestion that the Board take appropriate action to promote changes in Federal law concerning the electronic transmission of prescriptions, the

Board notes that, as a State agency, it has no authority to initiate changes in Federal law.

COMMENT: Dr. Block, in behalf of the New Jersey Psychiatric Association, recommends that proposed new rule N.J.A.C. 13:35-7.1A be clarified to provide that prescribing medicine without first seeing a patient should be rare and should be avoided if at all possible, with the exception of a physician covering for a colleague who has a record base and has been treating the patient. In such a case, the covering physician should prescribe conservatively, and make a record of the transaction available to the patient's physician.

RESPONSE: The Board agrees with the commenter's assertion that dispensing drugs or issuing prescriptions to an individual without first conducting an examination of the patient should be avoided if possible, and has provided so in proposed new rule N.J.A.C. 13:35-7.1, which requires an examination of the patient unless certain circumstances are present. The Board believes that the list of circumstances set forth in N.J.A.C. 13:35-7.1(b), under which a practitioner may dispense drugs or issue prescriptions to an individual without first examining the person, are sufficiently limited to those situations in which absence of an examination will not place the patient in jeopardy and, therefore, the Board declines to amend the rule as suggested by the commenter.

COMMENT: Dr. Block believes that proposed new rule N.J.A.C. 13:35-7.1A should be amended to clarify that psychiatrists are not expected to perform a physical examination of a patient, but rather are expected to perform an adequate psychiatric evaluation before prescribing medication. The commenter notes that an appropriate general medical history, including a psychiatric history, should be taken, and any necessary referrals made for medical evaluation and treatment.

RESPONSE: Depending on the presenting condition of the patient and the specialty of the treating physician, the extent of the history taken and the physical examination performed on a patient may vary. For example, in the context of a psychiatric evaluation where the patient has had a history and physical examination by another practitioner, the history and physical examination may consist of, at a minimum, an initial face-to-face visit and a focused psychiatric history. The Board, therefore, declines to amend N.J.A.C. 13:35-7.1A as suggested by the commenter.

COMMENT: Dr. Block believes that some of the regulations, as currently worded, are too ambiguous. Specifically, the commenter noted that the requirement that faxed prescriptions contain the identification number of the facsimile machine used to transmit the prescription, could be read to refer to the identification number of the sending fax machine, or some other identifying number. The commenter recommends that the rule be re-written more simply and clearly to eliminate potential confusion on the part of physicians as to what the rule requires of them and their staff.

RESPONSE: The Board believes that the proposed new rules, as adopted, are clear and unambiguous and will provide practitioners with sufficient guidance as to their obligations and responsibilities concerning the transmission of facsimile and electronic prescriptions. As to the commenter's specific concern regarding the identification number of the facsimile machine, N.J.A.C. 13:35-7.4A(c) clearly states that the transmission of the facsimile prescription must contain the identification number of the facsimile machine which is used to transmit the prescription to the pharmacy, that is, the sending facsimile machine. The Board does not believe that N.J.A.C. 13:35-7.4A(c) needs further clarification.

Summary of Agency-Initiated Changes:

During its review of the comments submitted on proposed new rules N.J.A.C. 13:35-7.1A, 7.4 and 7.4A, the Board of Medical Examiners was made aware of comments received by the Board of Pharmacy on its proposed new rules, N.J.A.C. 13:39-5.8A and 5.8B, concerning the filing of facsimile and electronic prescriptions, which were published in the New Jersey Register on September 3, 2002, at 34 N.J.R. 3064(a), and are adopted in a notice of adoption published elsewhere in this issue of the New Jersey Register. Several of the comments submitted to the Board of Pharmacy requested clarification of portions of N.J.A.C. 13:39-5.8A and 5.8B. After reviewing the comments, the Board of Pharmacy has made several amendments to the proposed new rules on adoption. The Board of Medical Examiners has reviewed the amendments made by the Board of Pharmacy, and has determined that similar amendments should be made to its proposed new rule N.J.A.C. 13:35-7.4A, in order to ensure consistency in the application of the rules governing the transmission and filing of facsimile and electronic prescriptions.

The Board of Pharmacy has amended the definition of electronic prescription set forth in N.J.A.C. 13:39-5.8B to specifically include computer to computer and computer to facsimile transmissions, in light of the fact that currently most prescriptions that are generated by computer are sent by the generating computer to a facsimile machine. An e-fax script, that is, a prescription sent from a computer to a facsimile machine, is created electronically the same way that a computer to computer prescription is and, unlike a traditional facsimile prescription, cannot be hand signed. The e-fax script is only being received on a fax machine because the given pharmacy lacks the necessary software to accept the prescription by way of computer. The Board notes that the type of transmission contemplated by N.J.A.C. 13:35-7.4 and 13:39-5.8A is the traditional facsimile transmission, that is, a transmission from one facsimile machine to another. Such prescriptions require a handwritten original signature. An electronic prescription, on the other hand, is defined in new rules N.J.A.C. 13:35-7.4A and 13:39-5.8B as a prescription which is transmitted by computer device. The prescription transmission contemplated in N.J.A.C. 13:35-7.4A and 13:39-5.8B includes computer to computer and computer to facsimile transmissions because both types of transmissions are generated and sent by computer. Practitioners can send, and pharmacists can accept, electronic prescriptions sent by either type of transmission. Therefore, in order to eliminate any confusion and to make its rule consistent with the Board of Pharmacy rule, the Board is amending the definition of electronic prescription set forth in N.J.A.C. 13:35-7.4A(a), on adoption, to specifically include computer to computer and computer to facsimile transmissions.

The Board of Medical Examiners is also amending N.J.A.C. 13:35-7.4A(b), on adoption, to correct an omission made in the original proposal. N.J.A.C. 13:35-7.4A(b), as proposed, provides that a practitioner shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is included on an electronic prescription, except that a New Jersey Prescription Blank (NJPB) shall not be required. In addition to the exception for the use of an NJPB, subsection (d) should have also provided an exception for the handwritten original signature requirement in N.J.A.C. 13:35-7.2(d) because an electronic prescription cannot be hand signed. Therefore, on adoption, N.J.A.C. 13:35-7.4A(d) provides that a practitioner shall ensure that an electronic prescription contains all information required by N.J.A.C. 13:35-7.2(d), except that a handwritten original signature and an NJPB shall not be required. The Board notes that the Board of Pharmacy rule N.J.A.C. 13:39-5.8B has also been amended on adoption to provide that a handwritten original signature shall not be required for an electronically transmitted prescription.

In addition, Federal Drug Enforcement Administration regulations set forth at 21 C.F.R. § 1306.11(e) and (g) provide that a pharmacist may fill a facsimile prescription, without obtaining an original written prescription prior to dispensing, for a Schedule II narcotic substance for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or for a patient enrolled in a hospice care program. In light of these Federal requirements, the Board has determined that N.J.A.C. 13:35-7.4(e)1 and 3 should be amended on adoption to refer to Schedule II narcotic substances, as opposed to Schedule II substances. The Board notes, however, that N.J.A.C. 13:35-7.4(e)2, as proposed, is consistent with Federal standards and does not require amendment because 21 C.F.R. § 1306.11(f) provides that a facsimile prescription may be filled, without obtaining an original written prescription prior to dispensing, for a Schedule II substance for a resident of a long term care facility.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rules are governed by N.J.S.A. 45:9-1 et seq., and are not subject to any Federal standards or requirements. The Board notes, however, that the requirements for the facsimile and electronic transmission of prescriptions for controlled substances set forth at N.J.A.C. 13:35-7.4(e) and (f) and 7.4A(g) and (h) are consistent with the Federal DEA standards articulated at 21 C.F.R. §§ 1306.11 and 1306.21.

Full text of the adoption follows:

<< NJ ADC 13:35-7.1A >>

13:35-7.1A Examination of patient's condition required prior to dispensing drugs or issuing a prescription; exceptions

(a) Except as provided in (b) below, a practitioner shall not dispense drugs or issue prescriptions to an individual, pursuant to the requirements of this subchapter, without first having conducted an examination, which shall be

appropriately documented in the patient record. As part of the patient examination, the practitioner shall:

1. Perform an appropriate history and physical examination;
2. Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
3. Formulate a therapeutic plan and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
4. Ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

(b) Notwithstanding (a) above, an examination of the patient's condition shall not be required prior to the dispensing of drugs or the issuance of a prescription under the following circumstances:

1. In admission orders for a newly hospitalized patient;
2. For a patient of another physician for whom the practitioner is taking calls;
3. For continuation medications on a short term basis for a new patient prior to the patient's first appointment;
4. For an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription;
5. For a patient examined by a healthcare professional who is in collaborative practice with the practitioner; and
6. When treatment is provided by a practitioner for an emergency medical condition.

(c) For purposes of this section, the term "emergency medical condition" as used in (b) above means:

1. A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:

- i. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
- ii. Serious impairment to bodily functions; or
- iii. Serious dysfunction of any bodily organ or part.

<< NJ ADC 13:35-7.4 >>

13:35-7.4 Facsimile transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, a facsimile prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription issued by the practitioner which is transmitted by a device which sends an exact image to the receiver.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided on each facsimile prescription, except that an NJPB shall not be required for the prescription.

(c) The transmission of a facsimile prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription to the pharmacy;
2. The time and date of the transmission of the prescription;
3. The name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted; and
4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(d) A practitioner shall provide verbal verification of the facsimile prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the facsimile prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(e) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule II controlled substance, provided that the patient is given the original signed NJPB which is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (e)1, 2 and 3 below:

1. A prescription for a Schedule II <<+narcotic+>> substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.
2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.
3. A prescription for a Schedule II <<+narcotic+>> substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription.

(f) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule III, IV, or V controlled substance consistent with the requirements of this section. The facsimile shall serve as the original written prescription.

(g) If a facsimile prescription is provided for a Schedule II substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or for a resident of a long term care facility, or for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State, or for a Schedule III, IV or V controlled substance, the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with the original written prescription.

(h) A practitioner shall not enter into any agreement with a pharmacy that requires facsimile prescriptions be transmitted to that particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

<< NJ ADC 13:35-7.4A >>

13:35-7.4A Electronically transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, as defined in N.J.A.C. 13:75-7.1, may transmit, or have an authorized agent transmit, an electronic prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative,

consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription which is transmitted by a computer device in a secure manner<<+, including computer to computer and computer to facsimile transmissions+>>.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided in each electronic prescription, except that <<+a handwritten original signature and+>> an NJPB shall not be required for the prescription.

(c) A practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription unless the prescription is transmitted by an authorized agent as provided in (e) below.

(d) To maintain confidentiality of electronic prescriptions, the practitioner shall ensure that the electronic system used to transmit the electronic prescription has adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of such records, and shall include, at a minimum, electronic encryption.

(e) A practitioner may authorize an agent to electronically transmit a prescription provided that the full name and title of the transmitting agent is included on the transmission, and provided that the practitioner's authorized agent does not sign the electronic prescription.

(f) A practitioner shall provide verbal verification of an electronic prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the electronic prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(g) A practitioner or the practitioner's authorized agent may transmit an electronic prescription to a pharmacy for a Schedule II controlled substance, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(h) A practitioner or his or her authorized agent may transmit an electronic prescription to a pharmacy for a Schedule III, IV, or V controlled substance, provided that the original signed prescription for presentation at the pharmacy, an oral prescription, or a facsimile prescription is provided. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(i) A practitioner shall not enter into any agreement with a pharmacy which requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's choice.