



TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Amendment of Section 29.7 of the Rules of the Board of Regents and Section 63.6 of the Regulations of the Commissioner of Education Relating to Electronic Prescriptions and to Electronic Recordkeeping by Pharmacists

DATE: June 11, 2012

AUTHORIZATION(S):

SUMMARY

Issue for Action

Should the Board of Regents amend section 29.7 of the Rules of the Board of Regents and section 63.6 of the Regulations of the Commissioner of Education relating to the requirements for electronic prescriptions and for the maintenance of records in electronic format by pharmacists?

Reason(s) for Consideration

Required by State Statute.

Proposed Handling

This matter will come before the Professional Practice Committee for recommendation and before the Full Board for action at the June 2012 meeting of the Board of Regents.

Procedural History

This item was discussed by the Professional Practice Committee at the April meeting of the Board of Regents. A Notice of Proposed Rule Making was published in the State Register on April 18, 2012. An Assessment of Public Comment is attached.

The comments received did not necessitate any change in the proposed amendment. Supporting materials for the proposed amendments are available upon request from the Secretary to the Board of Regents.

Background Information

The issue of electronic prescriptions was first addressed by the Department in 1999 when the Board of Regents approved regulations allowing pharmacists to receive such prescriptions. Electronic prescriptions reduce the likelihood of errors due to illegible handwriting or unclear oral communications. Together, misunderstood handwriting and oral communications have been identified as the root cause in approximately 55% of medication errors.

Full implementation of electronic prescribing has occurred more slowly than expected. In part, this was a result of continuing prohibition against e-prescribing of controlled substances, as physicians and other prescribers resisted purchasing systems that might ultimately not meet security demands being developed by the federal Drug Enforcement Administration (DEA) for controlled substances. The DEA has now published its final requirements, though few systems have been deemed qualified.

Chapter 590 of the Laws of 2011 amended section 6802 of the Education Law by adding definitions of the terms “electronic prescription,” “electronic,” and “electronic signature.” Chapter 590 also amended section 6810(6)(a) of the Education Law to require the use of an electronic signature to validate an electronic prescription and, when issuing an electronic prescription, to authorize the use of an electronic direction to direct the dispensing of a brand name drug rather than a generic equivalent drug.

The proposed amendments are needed to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education relative to electronic prescriptions and electronically maintained records of pharmacists to the statutory changes. The proposed amendment to section 29.7(a) of the Rules of the Board of Regents provides that, when used in the disciplinary rules relating to the profession of pharmacy, the term “signature” includes an electronic signature. The proposed amendment to section 63.6(a)(7) of the Regulations of the Commissioner of Education conforms that section to new terms and definitions included in Education Law §§6802 and 6810. In addition, section 63.6(a)(7) implements Chapter 590 by authorizing the use of an electronic direction in place of the prescriber’s handwritten notation, when issuing an electronic prescription for a brand name drug. Finally, the proposed amendment implements the requirement of the new law that requires prescriptions that are transmitted by facsimile to be manually signed.

Recommendation

VOTED: That section 29.7(a) of the Rules of the Board of Regents and section 63.6(a)(7) of the Regulations of the Commissioner of Education be amended, as submitted, effective July 11, 2012.

Timetable for Implementation

If adopted at the June meeting, the amendment will become effective July 11, 2012.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION
AND RULES OF THE BOARD OF REGENTS

Pursuant to sections 207, 6504, 6506, 6507, 6509, 6802 and 6810 of the Education Law and Chapter 590 of the Laws of 2011.

1. Subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, effective July 11, 2012, as follows:

(a) The requirements of this section set forth for written prescriptions shall also be applicable to [electronically transmitted] electronic prescriptions, as defined in section 63.6(a)(7)(i)(a) of this Title, unless otherwise indicated. For purposes of this section, "signature" shall include an electronic signature, as defined in section 63.6(a)(7)(i)(c) of this Title, when applicable, and "sign" shall include the affixing of an electronic signature. Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

(1) ...

(2) ...

(3) ...

(4) Refilling a prescription without entering on the reverse of the prescription or within the electronic record the date of the refill and the signature or readily identifiable initials of the pharmacist and of the intern, if applicable, dispensing the refill, except as provided in paragraph (8) of this subdivision. As a refill instruction, the pharmacist may accept a number of times, a time period, such as one year, or the Latin phrase pro re nata (abbreviated prn--meaning "as needed"). In the case of the latter, the pharmacist shall refill the prescription once only. The pharmacist receiving on oral order to refill a prescription shall reduce the order to writing or to an electronic record and shall sign or

initial it legibly as the recipient of the oral order. When a prescription is refilled, the date placed on the label shall be the date of the refill.

(5) Using or substituting without authorization one or more drugs in the place of the drug or drugs specified in a prescription. Unauthorized use or substitution occurs if the same is done without the knowledge and consent of the prescriber. If other than the ingredients specified are utilized by the pharmacist in compounding or dispensing the prescription, improper substitution shall be presumed unless there shall be entered upon the reverse of the original prescription or within the electronic record information setting forth the facts of the substitution, the date, time and manner in which authorization for substitution was given and the signature of the pharmacist who received such authorization.

(6) ...

(7) ...

(8) Failure to maintain in a form which provides for ready retrieval of prescriptions a daily record of all prescriptions filled and refilled which identifies clearly the practitioner who ordered the prescription, the patient for whom the prescription is intended, the signature or readily identifiable initials of the pharmacist who filled or refilled the prescription, and the number assigned to the prescription where applicable. The record of the dispensing of a drug for an inpatient in a health care facility, including but not limited to general hospital, by the pharmacy of that facility may be maintained in a form which is consistent with the record of the total health service provided to the patient provided the information required by this paragraph is readily retrievable and available. Original prescriptions filed in accordance with the provisions of paragraph (7) of this subdivision may constitute the record of the initial filling of those prescriptions. The daily

record may be maintained by a manual system or, alternatively, by an electronic data processing system which meets the following requirements:

(i) ...

(ii) ...

(iii) ...

(iv) A pharmacist, and a pharmacy intern, if applicable, using a computerized system shall sign or initial the original prescription at the time of the first dispensing as provided in paragraph (3) of this subdivision and the signature or initials of the pharmacist shall be entered into the computer record of the dispensing.

(v) For all refills of a prescription, the records introduced into the system shall be sufficient if:

(a) the signature or initials of the pharmacist who dispensed the refill are entered by such pharmacist at the time of dispensing; and

(b) a printout or electronic record is produced of all prescriptions filled and refilled each day and the pharmacist(s) whose signature or initials appear(s) on the printout sign(s), either manually or electronically, the printout or electronic record to indicate that it is an accurate record.

(9) ...

(10) ...

(11) ...

(12) ...

(13) ...

(14) ...

(15) ...

(16) ...

(17) ...

(18) ...

(19) ...

(20) ...

2. Paragraph (7) of subdivision (a) of section 63.6 of the Regulations of the Commissioner of Education is amended, effective July 11, 2012, as follows:

63.6(a)(7) [Electronically transmitted] Electronic prescriptions.

(i) For the purposes of this section:

(a)[, electronically transmitted] electronic prescription means a prescription created, recorded, [transmitted] or stored by electronic means; issued with an electronic signature; and transmitted by electronic means;[, including but not limited to facsimile but excluding any such prescription for a controlled substance under Article 33 of the Public Health Law.]

(b) electronic means of or relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities; and

(c) electronic signature means an electronic sound, symbol, or process, attached to or logically associated with an electronic prescription, executed or adopted by a person with the intent to sign the prescription, and effectively secured from alteration by an unauthorized third party;

(ii) A pharmacist may, based upon his or her professional judgment, accept an [electronically transmitted] electronic prescription from a prescriber, to the pharmacy of the patient's choice, subject to the following requirements:

(a) the prescription shall contain [the signature, or] the electronic [equivalent of a] signature[,.] of the prescriber;

(b) in the case of an [electronically transmitted] electronic prescription,[other than facsimile transmission,] such prescription shall be electronically encrypted, meaning protected to prevent access, alteration or use by any unauthorized person;

(c) [a permanent hard copy of an electronically transmitted] an electronic prescription or a hard copy of an [electronically transmitted] electronic prescription stored securely and permanently [by electronic means] shall be [produced and] maintained at the pharmacy for a period of five years from the date of the most recent filling, provided that, if the prescription is maintained electronically, it shall be made available to the Department in hard copy upon request. [A permanent facsimile copy shall be considered a hard copy];

(d) except when the prescriber inserts an electronic direction to dispense the drug as written, the prescriber's electronic signature shall designate approval of substitution by a pharmacist of a drug product pursuant to section 206(1)(o) of the Public Health Law. Notwithstanding any other provision of this section or any other law, when a generic drug is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required. If the generic drug product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the brand name product at his regular price. In such instances the pharmacist shall record the date, hour and nature of the medical emergency on the back of the prescription or within the electronic record of the prescription and keep a hard-copy or electronic record of all such prescriptions;

(e) such prescriptions shall be processed in accordance with the requirements of section 29.7 of this title, provided, however, that prescriptions for controlled substances shall be filled in accordance with the requirements of Article 33 of the Public Health Law; and

[(e)] (f) in accepting an [electronically transmitted] electronic prescription, the [pharmacists] pharmacist shall be subject to the applicable requirements of Part 29 of this Title relating to unprofessional conduct, including but not limited to section 29.1(b)(2) and (3) of this Title.

(iii) An original hard copy prescription that is created electronically or otherwise may be transmitted from the prescriber to the pharmacist by facsimile and must be manually signed, provided, however, that prescriptions for controlled substances shall be filled in accordance with the requirements of Article 33 of the Public Health Law. A permanent hard copy of a prescription transmitted by facsimile shall be stored securely and permanently in hard copy or by electronic means and shall be maintained at the pharmacy for a period of five years from the date of the most recent filling, provided that, if the prescription is maintained electronically, it shall be made available to the Department in hard copy upon request.

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Proposed Rule Making in the State Register on April 11, 2012, the State Education Department received the following comments.

1. COMMENT:

One writer, representing the New York City Pharmacists Society, wrote in general support of the proposed amendments. However, the writer suggested that prescriptions, both those for controlled substances and those that are for non-controlled substances, that are converted to a facsimile transmission should be considered a true electronic prescription. The writer also believes the proposed amendment will affect a pharmacist's current means of communicating with a prescriber to obtain authorization for additional refills on existing prescriptions.

DEPARTMENT RESPONSE:

Education Law §6802, as recently amended by Chapter 590 of the Laws of 2011, specifically provides that facsimile transmissions must be manually signed and therefore, are not electronic prescriptions. Federal requirements promulgated by the Drug Enforcement Administration and those being developed by the Bureau of Narcotic Enforcement of the New York State Department of Health also preclude facsimile transmissions from being considered electronic prescriptions in that facsimile transmissions lack required security features. With regard to the writer's second comment, the proposed amendment relates to new prescriptions, and not to refill authorizations on existing prescriptions.