Electronic Prescriptions and Records for Hypodermic Needles and Hypodermic Syringes

Effective date: 10/9/13

Pursuant to the authority vested in the Commissioner of Health by Article 33 of the Public Health Law, Sections 80.131 and 80.133 of Part 80, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 80.131 is amended to read as follows:

80.131 Prescription, sale and possession of hypodermic syringes and hypodermic needles.

(a) For purposes of this section, "prescription" shall have the same meaning as provided in section 3302 of the public health law, as supplemented by the meaning provided in section 3381 of the public health law. It shall be unlawful for any person to sell or furnish, to any other person or persons, or to possess, a hypodermic syringe, [or] hypodermic needle, or a hypodermic syringe or hypodermic needle pre-filled with a non-controlled substance, except:

(1) pursuant to [an official New York State prescription or an out-of-state prescription] a prescription; or

(2) [to persons who have] such sale, furnishing or possession has been authorized by the commissioner [to obtain and possess such instruments]; or

(3) [in an emergency, pursuant to an oral prescription from a practitioner, if the pharmacist complies with the requirements of subdivision (b) of this section; or (4)] pursuant to Section 80.137 of this Part.

(b) [(1) In an emergency] Subject to the provisions of this section, a practitioner may orally prescribe or authorize a refill, and an employee of the prescribing practitioner, or a health care professional in a Residential Health Care Facility (RHCF) who is licensed by the state education department pursuant to the education law, may orally communicate a prescription or refill for, one or more hypodermic syringes or hypodermic needles. Subject to the provisions this section, a pharmacist may dispense, to an ultimate user, such hypodermic syringes or [and] hypodermic needles[,]; provided, however, the pharmacist shall:

[(i)] (1) contemporaneously reduce such oral prescription to a written or electronic memorandum indicating the name, address and telephone number of the prescriber, the name, [and] address, and age of the ultimate user, date on which the hypodermic syringe or hypodermic needle[s and/or syringe] was ordered, quantity prescribed, directions for use, [and] the name and strength of the drug, if applicable, number of refills authorized, the signature or readily identifiable initials of the pharmacist accepting the oral memorandum and documenting the fact that it is a telephone order; [and]

[(ii)] (2) [the pharmacist filling such oral prescription shall] indicate on the memoranda the date filled[,] and the number of the prescription under which it is recorded in the pharmacy prescription file, and sign or electronically sign the memorandum[.]; and

[(2)] (3) [The pharmacist shall] make a good faith effort to verify the identity of [both]

the practitioner and the practitioner's employee or RHCF professional, if applicable, and the ultimate user, if not known to the pharmacist.

[(3) No oral prescription shall be filled for a quantity of hypodermic syringes and/or needles which would exceed 100 hypodermic syringes and/or needles.

(4) Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a prescription. If the pharmacist fails to receive such prescription, he shall record on the oral prescription memorandum: "Prescription not received", and sign and date the recording.

(5) Follow-up prescriptions from prescribers shall be attached to the corresponding oral prescription memorandum and shall be filed in accordance with this section.

(6) The pharmacist receiving such follow-up prescriptions shall endorse on the face of such prescription his signature, the date of filling, the number of the prescription under which it is recorded in the pharmacy prescription file and that such prescription is a follow-up to the prior oral prescription. In addition, the pharmacist shall place on the back of the follow-up prescription the date of receipt, the pharmacy prescription number and the date the oral prescription was filled, as follows:

"Follow-up prescription to oral prescription, pharmacy prescription number.....,
filled on....., prescription received....."

(c) Emergency means that the immediate furnishing of a hypodermic syringe and/or needle is necessary for proper treatment, that no alternative is available and it is not possible for the practitioner to provide a written prescription at the time.

(d) It shall be unlawful for any person to obtain or possess a hypodermic syringe or hypodermic needle unless such possession has been authorized by the commissioner or is

pursuant to a prescription or such syringe or needle was provided to such person pursuant to Section 80.137 of this Part.]

[(e)] (c) A prescription for [a] one or more hypodermic syringes [and/] or hypodermic needles shall include:

(1) the name, address and age of the [person for whom intended] ultimate user;

(2) the name, address, telephone number and signature or electronic signature of the practitioner[.];

(3) the date on which it was issued; and

(4) the name, and strength of the drug, if applicable, the directions for use, the quantity of the hypodermic syringes or hypodermic needles prescribed, and the number of authorized refills.

[(f)] (d) Any [person] pharmacist selling or furnishing a hypodermic syringe or hypodermic needle pursuant to a prescription shall record upon [the face of] the prescription, [over] his or her signature or, as applicable, electronic signature, and the date of the sale or furnishing of the hypodermic syringe or hypodermic needle. Prescriptions and oral prescription memorandums shall be retained on file for a period of five years and be readily accessible for inspection by any public officer or employee engaged in the enforcement of this section. A prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription; provided, however, no such authorization shall be effective for a period longer than two years from the date the prescription is signed.

[(g) All renewals shall be recorded on the reverse side of the prescription and the date and quantity dispensed and the signature of the dispensing pharmacist shall be recorded.]

(e) A pharmacist receiving an oral authorization for the refill of a prescription for one or more hypodermic syringes or hypodermic needles shall enter on the original prescription or electronic record maintained on an electronic data processing system, the date, time, and name of the authorizing practitioner and the name of the practitioner's employee or RHCF professional, if applicable, and shall sign or electronically sign such record.

(f) Pharmacists at registered pharmacies may, at the express request and approval of a patient or a person authorized to act on behalf of the patient, and subject to the requirements of 8 NYCRR Section 63.6(8), transfer information relating to a prescription for one or more hypodermic syringes or hypodermic needles, including a prescription for one or more hypodermic syringes or hypodermic needles pre-filled with a non-controlled substance, or accept a transfer of such information from another registered pharmacy or a pharmacy authorized to do business in another jurisdiction for the exclusive purpose of providing one authorized refill per transfer.

(g) Any prescription for one or more hypodermic syringes or hypodermic needles prefilled with a controlled substance shall be issued and dispensed according to the requirements as set forth in 80.67, 80.68, 80.69, 80.70, 80.73 and 80.74 of this Part.

Section 80.133, subdivision (i) is hereby amended to read as follows:

80.133 Hypodermic syringes and needles; certificate of need.

* * * *

(i) [Destruction] Disposal of hypodermic syringes and needles.

(1) All hypodermic syringes and needles which are no longer usable or required shall be [destroyed as follows:] disposed of in a manner consistent with universal precautions so as to be rendered inoperable.

[(i) Disposable hypodermic units shall have the needle detached from the syringe prior to disposal.

(ii) Hypodermic syringes shall be crushed, broken or otherwise rendered inoperable.

(iii) Hypodermic needles shall be bent prior to disposal.]

(2) Procedures for disposal may include but are not limited to placement of such syringes, needles and disposable units in a leak-proof, puncture resistant container prior to disposal.

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Regulatory Impact Statement

Statutory Authority:

Section 3308(2) of the Public Health Law authorizes and empowers the Commissioner to make any regulations necessary to supplement the provisions of Article 33 of the Public Health Law in order to effectuate its purposes and intent.

The Department proposes amendments to the regulations that would effectuate the changes in § 3381 and § 3302 of the Public Health Law (PHL) resulting from Chapter 178 of the Laws of 2010.

Legislative Objectives:

Article 33 of the Public Health Law, officially known as the New York State Controlled Substances Act, was enacted in 1972 to govern and control the possession, prescribing, manufacturing, dispensing, administering and distribution of controlled substances within New York. The legislative purpose of Article 33 is to combat the illegal use of and trade in controlled substances and to allow the legitimate use of controlled substances in health care, including palliative care, veterinary care, research and other uses authorized by the law.

Needs and Benefits:

Hypodermic syringes and hypodermic needles are addressed in Article 33 of the Public Health law and in Part 80 of the Department's regulations. However they are not scheduled as a controlled substance and are, accordingly, not a controlled substance.

Nonetheless, current regulations impose many of the same restrictions on their prescription as would otherwise apply to controlled substances. The consequences of such treatment, and the benefits of the proposed amendments, include conforming the treatment of hypodermic syringes and hypodermic needles to that of non-controlled substances under State Board of Pharmacy rules and regulations and implementing the amendments to Article 33 of the Public Health law made by Chapter 178 of the Laws of 2010. A more specific description of the difficulties created by the current structure, and the benefits provided by the amendments, follows.

The current regulations allow a pharmacist to dispense a hypodermic needle and syringe only pursuant to a handwritten or oral prescription of a practitioner. That limitation precludes the use of an electronic prescription for hypodermic syringes and hypodermic needles and prevents a pharmacy from being able to transfer a prescription for hypodermic syringes and hypodermic needles to another pharmacy for dispensing of a refill. The amendments would allow pharmacists to transfer refills of a prescription for hypodermic syringes and hypodermic needles to another pharmacy, and would allow a practitioner to transmit an electronic prescription for hypodermic syringes and hypodermic needles to the pharmacy, thereby removing the current inconsistent treatment between hypodermic syringes and hypodermic needles and non-controlled substances. Allowing a prescription for hypodermic syringes and hypodermic needles to be electronically transmitted from the practitioner to the pharmacy and transferring an authorized refill from one pharmacy to another will ensure greater access of medications administered via injection.

The written prescription requirement also precludes the dispensing of hypodermic syringes and hypodermic needles by pharmacists to patients in nursing homes pursuant to a patient specific prescription form, which would otherwise be permitted under the Education Law. The proposed amendments would allow a practitioner to prescribe all non-controlled substances, including hypodermic syringes and hypodermic needles, on one patient-specific prescription form.

Existing regulations only allow the prescribing practitioner to orally authorize a prescription for up to 100 hypodermic syringes or hypodermic needles, in an emergency situation, and require that a written follow-up prescription be sent to the pharmacy within 72 hours. The amendments would allow oral prescriptions for hypodermic syringes and hypodermic needles to be issued in the same manner as for non-controlled substances, the prescribing of which is not currently subject to either quantity or refill limitations or the requirement for a follow-up hard copy prescription. The proposed amendments would also authorize an employee of the prescribing practitioner or a health care professional in a Residential Health Care Facility (RHCF) to orally communicate a prescription for hypodermic syringes and hypodermic needles to the pharmacist.

Existing regulations require a pharmacist to reduce an oral prescription for hypodermic syringes and hypodermic needles to a written memorandum. The amendments would allow, but not require, an oral prescription to be reduced to an electronic, rather than a written, memorandum, simplifying the refill process as many pharmacists already create an electronic record when dispensing a prescription. Providing that option will eliminate the need for duplicate record-keeping by those pharmacists who utilize electronic systems.

The current regulations require pharmacists to endorse a prescription with a handwritten signature and other required information upon the original hardcopy prescription when dispensing refills for prescriptions issued for hypodermic syringes and hypodermic needles. Retrieving the hard copy of the prescription in order to document the authorized refills is a time-consuming process. At the time of dispensing, the pharmacist must search for the folder in which the original hard copy prescription is filed, find that particular prescription, endorse and document the dispensing, place the prescription back in the file folder and return the folder to the storage cabinet. The same process is repeated for all refill requests for hypodermic syringe and hypodermic needle prescriptions. As noted previously, many pharmacists already utilize electronic record-keeping systems, and an electronic record is often already created at the time of dispensing, including refills. The amendments would eliminate the need for duplicate recording and record-keeping, as it would allow the dispensing record to be made and kept in electronic form, as it currently is the case for non-controlled substance prescriptions.

In addition to decreasing practitioner's and pharmacist's workloads, these proposed regulations will increase efficiency, minimize the potential for medication errors and ensure that patients in New York state will have greater access to their practitioners and pharmacists when questions arise or counseling is needed on their prescription medications, which will ultimately lead to enhanced patient care and safety. Populations that would especially benefit from these changes include patients requiring medication administration via injection including, but not limited to, patients with diabetes, Hepatitis C, clotting and other blood disorders. This patient population is often

non-ambulatory or requires nursing care assistance or assistance by family members, and is less likely to obtain a written official prescription for their necessary injectable medications directly from their prescriber.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The State Education Commissioner's regulations currently allow prescriptions for non-controlled substances to be electronically transmitted from a practitioner to a pharmacy and the transfer of a prescription to another pharmacy for the dispensing of a refill. Although the proposed rule is not mandatory, pharmacies and practitioners may require changes to electronic system menus and procedures to include hypodermic syringes and hypodermic needles, which could result in additional programming costs.

Costs to State and Local Government:

The proposed rule does not require the state or local government to perform any additional tasks therefore; it is not anticipated to have a fiscal impact on the State or local government, except that electronic prescribing of hypodermic syringes and hypodermic needles will reduce the number of prescriptions written on official New York State prescription forms, which are paid for by the State. Similarly, as the regulations permit, but do not require, the use of electronic prescriptions or records, it will not require local government to incur any costs beyond those assumed voluntarily as part of a decision to move towards electronic prescribing and electronic records. Furthermore, the proposed

amendments do not result in any costs to state or local government beyond or different from those applicable to private practices or pharmacies.

Costs to the Department of Health:

The proposed rule will affect how prescriptions for hypodermic syringes and hypodermic needles may be issued and dispensed but does not impose additional record keeping or system processes to the State. Therefore, there will be no additional costs to the Department.

Local Government Mandates:

The proposed rule does not constitute a mandate, as it does not require the use of electronic prescriptions or records, nor does it impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other specific district.

Paperwork:

Authorizing electronic prescriptions and electronic record keeping for prescriptions of hypodermic syringes and hypodermic needles, including those prefilled with non-controlled substance medication, will result in a reduction of paperwork. Authorizing a practitioner to prescribe hypodermic syringes and hypodermic needles on a patient specific prescription form for residents in nursing homes rather than being issued on a separate official prescription will save valuable time and decrease paperwork for the practitioner.

Not requiring a written follow-up prescription to the oral communication of a prescription for hypodermic syringes and hypodermic needles decreases paperwork for both the practitioner and pharmacist.

Duplication:

The requirements of the proposed regulation conform to those of the State Education Law and the State Education Commissioner's regulations. The requirements of this proposed regulation do not duplicate any other state or federal requirement.

Alternatives:

Changing the regulations was required by virtue of amendments to statute. There were no significant alternatives to be considered during the regulatory process.

Federal Standards:

The regulatory amendments do not exceed any minimum standards of the federal government.

Compliance Schedule:

The proposed rule does not constitute a mandate, as it does not require the use of electronic prescriptions or records; therefore, a time schedule is not necessary to achieve compliance with the rule.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

This proposed rule will affect all New York State registered pharmacies and pharmacists dispensing hypodermic syringes and hypodermic needles. Records retrieved from the Education Department's Board of Pharmacy show that as of March 31, 2011 there were a total of 4,874 registered pharmacies and 22,344 registered pharmacists in the State of New York. Of these totals, 2,336 represent small business establishments and 94 are owned by government entities, accounting for 48% and 1.9% respectively of the total number of pharmacies.

Compliance Requirements:

The State Education Commissioner's regulations currently allow prescriptions for non-controlled substances to be electronically transmitted from a practitioner to a pharmacy. They also allow for the transfer of information related to a prescription to another pharmacy for the dispensing of a refill. Practitioners and pharmacists are required to maintain a record when a prescription for hypodermic syringes or hypodermic needles is issued or dispensed, respectively. The proposed amendments simply conform the requirements with regard to hypodermic syringes and hypodermic needles to these requirements, and eliminate unnecessary requirements imposed by the current regulations. They do not require the undertaking of processes not already in use with regard to non-controlled substances, and provide the option of using electronic prescriptions and records with regard to hypodermic syringes and hypodermic needles.

Small businesses and local governments would retain the option to prescribe, dispense, and keep records manually. Accordingly, a small business regulation guide will not be prepared.

Professional Services:

The regulations do not require the use of any additional professional services. However, if an entity chose to implement the option of utilizing an electronic prescription or electronic record with regard to hypodermic syringes and hypodermic needles, professional information technology assistance might be required to alter electronic system menus and procedures to accommodate that change.

Compliance Costs:

Since the amendments would allow practitioners and pharmacists to retain the option to prescribe, dispense and keep records manually, initial and annual costs for continuing compliance with the proposed rule is not a factor. However, if an entity chose to implement the option of utilizing an electronic prescription or electronic record with regard to hypodermic syringes and hypodermic needles, professional information technology assistance might be required for implementation and maintenance of the altered electronic system menus and procedures.

A cure period is not required to be incorporated in the regulations pursuant to Chapter 524 of the Laws of 2011 insofar as the proposed amendments do not involve the establishment or modification of a violation or of penalties associated with a violation.

Economic and Technological Feasibility:

Compliance with the proposed regulations is economically and technologically feasible since most pharmacies already use an electronic system as part of the process of dispensing prescriptions. According to data from the Department's Bureau of Narcotic Enforcement, as of April 25, 2011, approximately 4.4% of the 80,605 practitioners registered with the New York State Official Prescription Program are currently using an electronic medical record system. The option of an electronic prescription for a hypodermic syringe or hypodermic needle is simply being made available as an alternative to the use of an Official New York State prescription. Those practitioners that do not currently use an electronic medical record system will not be required to begin using one.

Minimizing Adverse Impact:

The regulations are not expected to result in any adverse impact upon pharmacies, pharmacists, practitioners, or patients.

Small Business and Local Government Participation:

During the drafting of these regulations, the Department consulted with the State Education Department's Board of Pharmacy. The Department also consulted with representatives from 1) the Pharmaceutical Society of the State of New York, the membership of which consists of pharmacists and others who have an interest in the practice of pharmacy, including owners of small businesses, vendors, employees of pharmacies and employees of private and government institutions and 2) the New York

Chapter of the American Society of Consultant Pharmacists, the membership of which consists of pharmacists who provide consulting services to private or government owned residential health care facilities. Issues and comments relevant to dispensing, record keeping, transfer of refills, electronic prescriptions and use of a patient specific prescription form in different pharmacy settings were discussed at open forums such as the New York State Pharmacy Conference meetings and the Pharmacy Advisory Committee (PAC) meetings. Pharmacy conferences are held quarterly for the purpose of sharing information among stakeholders in the practice of pharmacy, including representatives from the colleges of pharmacy in New York State, government agencies, regulatory agencies, and all pharmacy practice settings. The PAC acts as an advisory body to the Department of Health on pharmacy issues related to the Medicaid Program. Pharmacists have been utilizing electronic records for over 30 years and the State Education Department's Board of Pharmacy has allowed such records for non-controlled substances for over 15 years. The regulations were drafted taking into consideration the pharmacist's comments and suggestions with respect to the current laws and regulations and how the amendments would affect the overall dispensing process.

The Department also consulted with the New York State Veterinary Medical Society, the New York State Society of Physician Assistants, the Medical Society of the State of New York, the Nurse Practitioner Association of New York State, and the New York State Nurses Association. The proposed amendments met with general approval and the feedback received from the licensed health care providers was positive.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed rule will apply to pharmacies and pharmacists located in all rural areas of the state. Outside of major cities and metropolitan population centers, the majority of counties in New York contain rural areas. These can range in extent from small towns and villages and their surrounding areas, to locations that are sparsely populated. According to the Education Department's Board of Pharmacy, there are a total of 735 registered pharmacies and 2,381 registered pharmacists located in rural counties, which account for 15.1% of the pharmacists and 13.5% of the pharmacies registered in the State of New York.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

Electronic record keeping systems have been available to pharmacists for over 30 years. And, for over 15 years the State Education Department's Board of Pharmacy has allowed electronic records for non-controlled substances. The proposed amendments reflect the industry's widespread and ongoing use of electronic records. Practitioners and pharmacists would retain the option to prescribe, dispense and keep records manually as the amendments permit, but do not require, the use of electronic prescriptions or data systems.

Costs:

Since the amendments would allow practitioners and pharmacists to retain the option to prescribe, dispense and keep records manually, initial and annual costs for continuing compliance with the proposed rule is not a factor in rural areas. However, if practitioners and pharmacists in a rural area chose to implement the option of utilizing an electronic prescription or electronic record with regard to hypodermic syringes and hypodermic needles, professional information technology assistance might be required for implementation and maintenance of the altered electronic system menus and procedures.

Minimizing Adverse Impact:

The proposed regulations allow, but do not mandate, the use of electronic data systems for the prescribing and dispensing of prescriptions for hypodermic syringes and hypodermic needles. Therefore, no adverse impact on rural areas is anticipated.

Rural Area Participation:

During the drafting of this regulation, the Agency met with and solicited comments from the New York Chapters of the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the Chain Pharmacy Association of New York, the New York State Council of Health-System Pharmacists, the Pharmacists Society for the State of New York, the New York State Education Department's Board of Pharmacy, the New York State Veterinary Medical Society, the New York State Society of Physician Assistants, the Medical Society of the State of New York, the Nurse

Practitioner Association of New York State and the New York State Nurses Association, all of which provide representation to licensed health care providers in rural areas. The suggestions were met with approval and the feedback received from the licensed health care providers was positive.

Job Impact Statement

A Job Impact Statement is not included because the Department has concluded that the proposed regulatory amendments will not have a substantial adverse effect on jobs and employment opportunities. The basis for that conclusion is that these amendments merely authorize, but do not require, the use of electronic prescriptions, recordkeeping, and simplified dispensing obligations with regard to hypodermic syringes and hypodermic needles, as provided by Article 33 of the Public Health Law. Accordingly, they provide the opportunity for increased efficiency, and will not, in themselves, have a substantial adverse effect upon jobs and employment opportunities. The amendments do not fundamentally change any obligations under the existing regulations.

Assessment of Public Comment

Public comments were submitted to the NYS Department of Health (DOH) in response to the regulation. The public comment period for this regulation ended on July 22, 2013. The Department received a total of five comments from representatives of the pharmacy community, including a school of pharmacy, independent pharmacy, and chain pharmacy. The comments resonated with positive enthusiasm.

Four of the five comments were similar and positive, stating that the adoption of these regulations is an obvious benefit to prescribers, pharmacists and, most importantly, to the patients they serve. Summarized below is the Department of Health's response to one comment:

COMMENT: A commenter representing the pharmacy community expressed concern over potential cost burdens to pharmacies as they attempt to conform and implement electronic record keeping processes, but also stated that the benefit to such processes far outweighs any incremental cost suffered.

RESPONSE: Electronic recordkeeping is optional. Pharmacies retain the option to keep records manually. Initial and annual costs for continuing compliance with the regulations is not a factor.