Electronic Prescribing, Dispensing and Recordkeeping of Controlled Substances

Effective date: 3/27/13

SUMMARY OF EXPRESS TERMS

Part 80 (10 NYCRR)

The proposed regulations provide for electronic prescribing and dispensing of controlled substances and keeping of related records in light of recent amendments to Article 2-A and Article 33 of the Public Health Law.

Amendments will authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V and to allow a pharmacist to annotate, dispense, and electronically archive such prescriptions. The amendments also authorize a pharmacist to endorse a pharmacy's electronic prescription record with his or her electronic signature, and to include other required information on refills of prescriptions for controlled substances in an electronic record. (Note: existing regulations require a pharmacist to endorse such information on an original, hard copy prescription.) The amendments will also require all practitioners and pharmacists engaging in electronic prescribing and dispensing of controlled substances to utilize computer applications that meet federal security requirements to register such computer applications with the New York State Department of Health (the Department), Bureau of Narcotic Enforcement (the Bureau). The amendments will add language pertaining to circumstances including when:

1. electronic prescribing of controlled substances is temporarily not available;

2. a prescriber has been issued a waiver from the requirement for electronic prescribing of controlled substances;
3. a transmission of electronic prescriptions for controlled substances fails;
4. an electronic prescription for controlled substance is altered during transmission;
5. a prescription will be presented to a pharmacy located outside New York State; and
6. a pharmacy's computer system is experiencing downtime.

The amendments redefine "prescription" as referred to in this Part to include an electronic prescription. The amendments also include new definitions for "digital signature," "electronic signature," and "written prescription." The amendments include a statement that compliance does not alter requirements to comply with federal law or regulation.

The amendments allow for oral prescriptions for controlled substances to be reduced to electronic memoranda and for electronic prescriptions to serve as follow-up prescriptions to oral prescriptions. Amendments will also require a practitioner to annotate an electronic follow-up prescription to an oral prescription, thereby alerting the pharmacist that it is a follow-up prescription. The amended regulations will require electronic follow-up prescriptions be associated with or linked to the corresponding oral prescription, regardless of whether the oral prescription was reduced at the time of order to written or electronic memoranda.

The amendments will require proper safeguarding of practitioners' credentials issued for the purposes of signing electronic prescriptions. They require practitioners to

notify the Bureau upon discovery that such credentials have been lost or compromised, or that prescriptions have been purportedly forged electronically and signed using such lost or compromised credentials.

Section 6810(10) of the Education Law provides that "two years subsequent to the date on which regulations establishing standards for electronic prescriptions are promulgated…no practitioner shall issue any prescription in this state, unless such prescription is made by electronic prescription" with several exceptions, one of which is for practitioners who have been granted waivers based on certain statutory exceptions. Therefore, these amendments (Section 80.64) permit the Commissioner to issue such waivers to applying practitioners based on a showing of economic hardship, technological limitations and exceptional circumstances.

The amendments allow for electronic recordkeeping of controlled substance prescription data, provided that such data must remain readily retrievable for inspection by authorized representatives of the Bureau within a defined timeframe, and shall be accessible at the premises where the licensed activity is conducted.

The amendments prohibit the transmission of an electronic prescription for a controlled substance using a computer application that does not comply with federal requirements or is otherwise non-compliant.

Pursuant to the authority vested in the Commissioner of Health by Article 2-A and Article 33 of the Public Health Law, Sections 80.1, 80.63, 80.64, 80.67, 80.68, 80.69, 80.70, 80.73, 80.74, 80.75, 80.77, 80.78, 80.84, 80.100, 80.106, and 80.125 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 80.1 is hereby amended to read as follows:

§80.1 Definitions.

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(h) Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

(i) Electronic signature means the creation of an electronic identifier (i.e. an electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record) in accordance with regulations of the commissioner and the commissioner of education.

(j) Written prescription, for the purposes of this Part, and issued in New York State, shall mean an official New York State prescription form.

(k) Compliance with the requirements of this Part does not alter the responsibilities of the practitioner, pharmacist or pharmacy to comply with any applicable federal law or regulation.

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Section 80.63 is hereby amended to read as follows:

§80.63 Prescribing.

(a) A prescription as defined by the Public Health Law means:

(1) an official New York State prescription;

(2) an electronic prescription;

[(2)](3) an oral prescription; or

[(3)](4) an out-of-state prescription, which means a prescription issued in lieu of an official prescription by a practitioner in another state who is licensed by that state to prescribe controlled substances.

(b) The use of preprinted prescriptions which indicate the controlled substance or the strength, dosage and/or quantity of the controlled substance is prohibited. Such prohibition shall not apply to printed prescriptions generated by means of a computer or an electronic medical record system, provided such printed prescriptions are generated at

the time a practitioner prescribes a controlled substance for a patient.

(c)(1) No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except as otherwise permitted by this subdivision.

(2) Once the initial examination has been completed, the frequency and necessity for future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner: (i) had direct access to the patient's medical records and such records warrant continued controlled substance prescribing, or (ii) had direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for his or her own record and shall transmit to the initial prescriber the prescription information. The initial prescriber shall include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a

consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if: (i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient; (ii) an emergency exists; and (iii) the prescription does not exceed a five day supply as determined by the directions for use. An emergency means that the immediate administration of the drug is necessary for the proper treatment of the patient and that no alternative treatment is available. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of sections 80.68 and 80.70 of this Part.

Section 80.64 is hereby amended to read as follows:

§80.64 Who may issue.

(a) A prescription for a controlled substance may be issued only by a practitioner who is:

[(a)] (1) authorized to prescribe controlled substances pursuant to his licensed professional practice; and

[(b)] (2) either registered under the Federal Controlled Substances Act and in possession of a registration number from the Drug Enforcement Administration, United States

Department of Justice, or its successor agency, or exempted from such registration as an exempt official.

(b) A practitioner issuing an electronic prescription for a controlled substance, in addition to meeting the provisions as noted in paragraph (a) of this section, shall also:

(1) use an electronic prescribing application that is consistent with federal requirements; and

(2) register the certified electronic prescribing application with the New York State Department of Health, Bureau of Narcotic Enforcement.

(c) Prescriptions excepted from any electronic prescribing requirement set forth in Article 2-a of the public health law include prescriptions:

(1) issued by veterinarians;

(2) issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure. For the purposes of this Part, temporary technological or electrical failure shall be defined as: any failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption to a computer system, application, or device in such a manner that is reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this section and federal requirements. In the instance of a

temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control;

(3) issued by practitioners to whom the commissioner has granted a waiver, or a renewal thereof, from the requirement to use electronic prescribing. A waiver may be issued by the commissioner based upon a showing of a practitioner that his or her ability to issue an electronic prescription in accordance with this section is unduly burdened by:

(a) economic hardship;

(b) technological limitations that are not reasonably within the control of the practitioner; or

(c) other exceptional circumstance demonstrated by the practitioner.

The practitioner's showing shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination. The practitioner shall also provide any information which would tend to negate the need for a waiver. A waiver shall be granted by the commissioner for a specified period of time, but in no event for more than one year. A practitioner may apply for a renewal of a previously granted waiver. Any application for the renewal of a previously granted waiver shall include an updated statement of facts detailing the continuing circumstances in support of the renewal, along with any facts reasonably known to the practitioner which tend to weigh against the granting of a renewal. Any renewal granted shall be subject to the same requirements as the original waiver.

(4) issued by a practitioner under circumstances where such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition, provided that if such prescription is for a controlled substance, the quantity of controlled substances does not exceed a five day supply if the controlled substance were used in accordance with the directions for use; or

(5) issued by a practitioner to be dispensed by a pharmacy located outside the state.

(d) A practitioner who issues a prescription pursuant to paragraph (2) of subdivision (c) of this section shall file information about the issuance of such prescription with the department as soon as practicable, but in no instance more than 72 hours following the end of the technological or electrical failure that prevented the issuance of an electronic prescription.

(e) A practitioner who issues a prescription pursuant to paragraphs (4) or (5) of subdivision (c) of this section shall file information about the issuance of such prescription with the department within 48 hours of the date of issue.

(f) A practitioner who has been granted a waiver pursuant to paragraph (3) of subdivision (c) of this section shall notify the department in writing within five business days upon gaining the capability to issue an electronic prescription. Without regard to the original expiration date, the waiver granted to the practitioner shall terminate within a

reasonable period of time as determined by the department, allowing for the practitioner to make accommodations to begin issuing electronic prescriptions.

(g) Any prescription issued pursuant to paragraph (c) of this section shall be issued as an Official New York State prescription or an oral prescription in accordance with 80.63, 80.67, 80.68, 80.69 and 80.70.

Section 80.67 is hereby amended to read as follows:

§80.67 Schedule II and certain other substances.

(a) Prescriptions shall not be refilled for schedule II substances and:

Alprazolam

Bromazepam

Camazepam

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Clotiazepam

Cloxazolam

Delorazepam

Diazepam

Estazolam

Ethyl Loflazepate

Fludiazepam

Flunitrazepam

Flurazepam

Halazepam

Haloxazolam

Ketazolam

Loprazolam

Lorazepam

Lormetazepam

Medazepam

Midazolam

Nimetazepam

Nitrazepam

Nordiazepam

Oxazepam

Oxazolam

Pinazepam

Prazepam

Quazepam

Temazepam

Tetrazepam

Triazolam

[shall be issued on the official New York State prescription form and shall not be refilled.]

(b) Such prescription shall be written with ink, indelible pencil, typewriter, or by other electronic means approved by the department, and shall be signed by the practitioner. Electronic prescriptions may be created, signed, and transmitted electronically provided the practitioner complies with all other requirements for issuing a prescription for a controlled substance in this Part and with federal requirements for electronic prescribing of controlled substances. The [official] prescription shall contain the following:

(1) name, sex, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(2) the printed name, address, Drug Enforcement Administration registration number, telephone number, and handwritten signature of the prescribing practitioner. The printed name of the prescriber who has signed the prescription shall be imprinted or stamped legibly and conspicuously on the prescription, shall appear in an appropriate location on the prescription form and shall not be entered in or upon the space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be a substitute for or fulfill any legal requirement otherwise mandating that the prescription be signed by the

prescriber;

(3) specific directions for use, including, but not limited to the dosage and frequency of dosage and the maximum daily dosage;

(4) the date upon which such prescription was prepared and actually signed by the prescribing practitioner. A prescription shall be dated as of, and signed on, the date it is issued; and

(5) the quantity of dosage units prescribed. On an official New York State prescription, the quantity of dosage units prescribed shall be indicated in both numerical and written word form.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(7) A prescription generated on an electronic system and printed out or transmitted via facsimile is not an electronic prescription and shall be manually signed.

(8) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law;

and if the patient is limited English proficient, a specification of the preferred language indicated by the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(c) Except as provided for in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d)(1) A practitioner may issue a prescription for up to a three-month supply of a controlled substance, including chorionic gonadotropin, or up to a six-month supply of an anabolic steroid if used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

(i) panic disorders, designated as code A;

(ii) attention deficit disorder, designated as code B;

(iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;

(iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;

(v) narcolepsy, designated as code E; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

(2) Such prescription shall specify the condition being treated on the face of the prescription. The practitioner issuing such prescription shall either:

(i) specify the name of such condition on the face of the prescription; or

(ii) specify a code on the prescription to denote the condition for which the prescription has been issued, in accordance with codes designated in paragraph (1) of this subdivision.

(3) Either the name of the condition or one of the designated codes shall fulfill the requirement in:

(i) section 3332(3) of the Public Health Law for the specific condition to be given on the face of the prescription; and

(ii) section 3333(1) of the Public Health Law for the statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a 30 days' supply of a controlled substance.

(e) Such official New York State prescription or out-of-state written prescription for a patient enrolled in a hospice program or for a patient residing in a residential health care facility (RHCF) may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile, provided;

(1) the hospice program or RHCF is licensed or approved by the department;

(2) the dispensing pharmacy has a written agreement or contract with the hospice program or RHCF to dispense controlled substances to a patient of such program or facility;

(3) the practitioner shall note on the prescription that the patient is a “hospice patient” or “RHCF patient”; and

(4) within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(f) An official New York State prescription or an out-of-state written prescription for schedule II narcotic substance or for those controlled substances listed in subdivision (a) of this section 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 a person authorized by the practitioner, to the dispensing pharmacy by facsimile. Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(g) When an official New York State prescription or an out-of-state written prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(h) A practitioner may orally authorize a pharmacist to change information on an official New York State prescription or an out-of-state written prescription [form]. This

procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, the reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(i) When a pharmacist fills a prescription under subdivision (g) or subdivision (h) of this section, in a manner that would require the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(j) When a practitioner is notified that an electronic prescription was not successfully delivered, the practitioner shall indicate on any written or oral prescription issued as a replacement of the original electronic prescription that the prescription was originally transmitted electronically, to which pharmacy the prescription was originally transmitted, and that the original transmission failed.

(k) If the content of any of the information required by this Part for a prescription is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

Section 80.68 is hereby amended to read as follows:

§80.68 - Emergency oral prescriptions for schedule II substances and certain other controlled substances.

(a) In an emergency, a practitioner may orally prescribe and a pharmacist may dispense, to an ultimate user, controlled substances in schedule II and those controlled substances listed in section 80.67 of this Part; provided, however, the pharmacist shall:

(1) contemporaneously reduce such prescription to writing or, to the extent authorized by federal requirements, to an electronic record;

(2) dispense the substance in conformity with the labeling requirements applicable to the type of prescription which would be required but for the emergency; and

(3) make a good-faith effort to verify the identity of both the practitioner and the ultimate user.

(b) No oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply if the substance were used in accordance with the directions for use.

(c) Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist [the official New York State prescription] a written or an electronic prescription. Such prescription shall, in addition to

the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing." If the pharmacist fails to receive such prescription, he shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(d)(1) The pharmacist filling the prescription shall endorse upon the prescription the date of delivery, and his/her signature.

(2) The endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years. The prescription information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than the 15th day of the next month following the month in which the substance was delivered. The information filed with the department shall include but not be limited to:

(i) pharmacy prescription number;
(ii) pharmacy's national identification number;
(iii) patient name;
(iv) patient address, including street, city, state, ZIP code;
(v) patient date of birth;
(vi) patient’s sex;
(vii) date prescription filled;
(viii) metric quantity;

(ix) national drug code number of the drug;

(x) number of days supply;

(xi) prescriber's Drug Enforcement Administration (DEA) number;

(xii) date prescription [written] issued;

(xiii) serial number of official prescription form or an identifier designated by the department; and

(xiv) payment method.

(e) Emergency means that the immediate administration of the drug is necessary for proper treatment, that no alternative treatment is available and it is not possible for the practitioner to provide a [n official] written or electronic prescription for the drug at the time.

Section 80.69 is hereby amended to read as follows:

§Section 80.69 Schedule III, IV and V substances.

(a) In addition to the requirements set forth in sections 80.67 and 80.70 of this Part, substances in schedule III, IV or V shall be prescribed by a practitioner [only] on an official New York State prescription or, subject to the following, an electronic prescription, in good faith, and in the course of his/her professional practice. Electronic prescriptions may be created, signed and transmitted electronically provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part, and with federal requirements for electronic prescribing of

controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed.

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(2) the printed name, address, Drug Enforcement Administration registration number, telephone number and handwritten signature or, in the case of an electronic prescription, the electronic signature of the prescribing practitioner. The printed name of the prescriber who has signed the prescription shall be imprinted or stamped legibly and conspicuously on the prescription, shall appear in an appropriate location on the prescription form and shall not be entered in or upon the space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be a substitute for or fulfill any legal requirement otherwise mandating that the prescription be signed by the prescriber;

(3) specific directions for use, including but not limited to the dosage and frequency of dosage and the maximum daily dosage;

(4) the date upon which such prescription was actually signed by the prescribing practitioner. A prescription shall be dated as of, and signed on, the date when issued; and

(5) the quantity of dosage units prescribed and the number of times that the prescription may be refilled. On an official New York State prescription, the quantity of dosage units

and the number of times that the prescription may be refilled shall be indicated in both numerical and written word form.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(7) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and if the patient is limited English proficient, a specification of the preferred language indicated by the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(c) Except as provided in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, as specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d)(1) A practitioner may issue a prescription for up to a three month supply of a controlled substance if used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

(i) panic disorders, designated as code A;

(ii) attention deficit disorder, designated as code B;

(iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;

(iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;

(v) narcolepsy, designated as code E; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

(2) Such prescription shall specify the condition being treated on the face of the prescription. The practitioner issuing such prescription shall either:

(i) specify the name of such condition on the face of the prescription; or

(ii) specify a code on the prescription to denote the condition for which the prescription

has been issued, in accordance with codes issued by the department.

(3) Either the name of the condition or one of the designated codes shall fulfill the requirement in:

(i) section 3332(3) of the Public Health Law for the specific condition to be given on the face of the prescription; and

(ii) section 3333(1) of the Public Health Law for the statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a 30 days' supply of a controlled substance.

(e) Such official New York State prescription or out-of-state written prescription for a patient enrolled in a hospice program or for a patient residing in a residential health care facility (RHCF) may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile, provided;

(1) The hospice program or RHCF is licensed or approved by the Department;

(2) The dispensing pharmacy has a written agreement or contract with the hospice program or RHCF to dispense controlled substances to a patient of such program or facility;

(3) The practitioner shall note on the prescription that the patient is a “hospice patient” or “RHCF patient”; and

(4) Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(f) An official New York State prescription or an out-of-state written prescription for a Schedule III, IV, or V controlled substance 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 a person authorized by the practitioner, to the dispensing pharmacy by facsimile. Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(g) [Such] An official New York State prescription, an out-of-state written prescription, or an electronic prescription for a Schedule III, IV, or V controlled substance, other than such substances as listed in section 80.67 of this Part, may be refilled, but not more than

the number of times specifically authorized by the prescriber upon the prescription; provided, however, no such authorization shall be effective for longer than six months from the date the prescription is signed and that not more than five refills are made. When the initial prescription is [written] issued for a quantity of substance in excess of a 30-day supply under the authority of subdivision (c) of this section, the prescription may only be refilled once.

(h) Unless an earlier refilling is authorized by the prescriber, no prescription shall be refilled earlier than seven days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use.

(i) On refills the dispensing pharmacist shall indicate on the prescription the amount dispensed, the date dispensed, and the signature of the dispensing pharmacist. When refills are recorded in an electronic recordkeeping system:

(1) the pharmacist shall ensure that the computer application used for such recordkeeping shall:

(i) provide online retrieval of original prescription information; and

(ii) provide online retrieval of the current refill history for Schedule III, IV and V controlled substance prescriptions.

(2) each time an official New York State prescription or an out-of-state written prescription for a Schedule III, IV or V controlled substance is refilled, the dispensing

pharmacist shall document that the refill information entered into the computer has been reviewed and is correct by manually signing:

(i) a hard-copy printout of each day's controlled substance prescription refill data, or;

(ii) a bound log book containing a statement that the refill information entered into the computer that day has been reviewed and is correct as shown.

(3) When a prescription is received electronically, the prescription and all required annotations shall be retained electronically.

(4) The pharmacy shall employ a procedure to be used for documentation of refills of Schedule III, IV and V controlled substance prescriptions in the event of system downtime. The procedure shall ensure that refills are authorized by the original prescription and that the maximum number of refills authorized has not been exceeded.

(j) Prescriptions which indicate pharmacy prescription numbers only of prior controlled substances prescriptions are not valid and shall not be refilled.

(k) Upon expiration of the authorization of the prescription to be refilled or the six month limitation of the prescription, the practitioner shall execute a new prescription if he desires the medication to be continued.

(l) When a prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter the missing information on the prescription. The pharmacist shall write the date he or she

received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substances is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains the information through a good-faith effort.

(m) A practitioner may orally authorize a pharmacist to change information on a controlled substance prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(n) When a pharmacist fills a prescription in a manner that would require, under subdivision (l) or subdivision (m) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(o) When a practitioner is notified that an electronic prescription was not successfully delivered, the practitioner shall ensure that any written or oral prescription issued as a replacement of the original electronic prescription indicates that the prescription was

originally transmitted electronically, shall indicate which pharmacy the prescription was originally transmitted to, and that the transmission failed.

(p) If the content of any of the information required by this Part for a controlled substance prescription is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

Section 80.70 is hereby amended to read as follows:

§80.70 Oral prescriptions for schedule III, IV and V substances.

(a) Except as provided in sections 80.67 and 80.68 of this Part, a practitioner may orally prescribe and a pharmacist may dispense, to an ultimate user, controlled substances in schedule III, IV or V; provided, however, the pharmacist shall:

(1) contemporaneously reduce such prescriptions to written memoranda, or to the extent authorized by federal requirements, to an electronic record, indicating the name and address of the prescriber and the practitioner's Drug Enforcement Administration registration number, name and address of ultimate user, date on which the controlled substance was ordered, name and quantity of controlled substances prescribed, directions for use and the fact that it is a telephone order. The memoranda for such oral prescriptions shall be filed in the schedule III, IV and V prescription file, or in the case of

an electronic record, shall be filed electronically. The pharmacist filling such oral orders shall indicate on the memoranda the date filled, the signature of the pharmacist filling the prescription and the pharmacy prescription number under which it is recorded in the pharmacy prescription file;

(2) dispense the substance in conformity with the labeling requirements applicable to a written prescription; and

(3) make a good faith effort to verify the identity of both the practitioner and the ultimate user.

(b) No oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply, or with respect to schedule IV substances a 30-day supply or 100 dosage units whichever is less, if the substances were used in accordance with the directions for use; provided, however, that this provision shall not apply to any schedule IV controlled substance limited to a five day supply by section 80.68 of this Part.

(c) Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a[n official New York State prescription] written, or an electronic prescription. The electronic prescription, in addition to the information otherwise required, shall also have upon it the words: "Follow-up prescription to oral order." If the pharmacist fails to receive such

prescription, he shall record on the memorandum for said oral prescription this notation: "[Official] Follow-up prescription not received", the name of the pharmacist and the date of the recording.

(d) [Official f] Follow-up prescriptions from prescribers for schedule III, IV and V controlled substances shall be attached to or otherwise stored with the corresponding oral orders, and shall be filed in the schedule III, IV and V controlled substances file.

(e) The pharmacist receiving such [official] follow-up prescriptions shall endorse on such prescription his or her signature, the date of filling, the number of the prescription under which it is recorded in the pharmacy prescription file and the fact that such prescription is a follow-up to the prior oral order. In addition, he or she shall place on the follow-up prescription the date of receipt, the pharmacy prescription number and the date the oral order was filled, as follows: "Follow-up prescription to oral order, pharmacy prescription number ....., oral order filled on ....., follow-up prescription received ....." In the case of electronic prescriptions and where the pharmacy maintains such records electronically, such information may be created and maintained by the pharmacy in electronic form.

(f) The prescription information shall be filed with the department in accordance with section 80.73(f) of this Part.

Section 80.73 is hereby amended to read as follows:

§80.73 Pharmacists; dispensing schedule II substances and certain other controlled substances.

(a) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6806 of the Education Law and regulations thereunder in a registered pharmacy, may, in good faith and in the course of his/her professional practice, sell and dispense to an ultimate user schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part, provided they are dispensed pursuant to an official New York State prescription, an out-of-state prescription or an electronic prescription delivered within 30 days of the date such prescription was signed by the authorized practitioner or an oral prescription where permitted.

(b) No such substance shall be dispensed or sold unless it is enclosed within a suitable and durable container to which is affixed, in such a manner which would inhibit its removal, an orange label upon which is indelibly typed, printed or otherwise legibly written:

(1) the name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person having custody of such animal;

(2) the name, address and telephone number of the pharmacy from which such substance

is dispensed;

(3) specific directions for use as stated on the prescription;

(4) the name of the prescribing practitioner;

(5) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(6) the number of the prescription under which it is recorded in the pharmacy prescription file;

(7) the date of filling; and

(8) the name of the controlled substance or such code number assigned by the department for the particular substance pursuant to section 80.24 of this Part.

(c) A licensed, registered pharmacist in a registered pharmacy may, in good faith and in the course of his/her professional practice, sell and dispense, to an ultimate user, controlled substances [for which an official New York State prescription is required] upon the delivery to such pharmacist, within 30 days of the date such prescription was [signed] <u>issued</u> by an authorized practitioner, an official New York State prescription <u>or an out-of- state written prescription</u> transmitted by facsimile in accordance with section

80.67(e) or (f) of this Part.

(d) The pharmacist filling the prescription shall endorse upon the [official New York State] prescription his/her signature, the date of filling, and the number of the prescription under which it is recorded in the pharmacy prescription file.

(e) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

(f) The endorsed [official New York State] prescription shall be retained by the proprietor of the pharmacy for a period of five years. The prescription information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than the 15th day of the next month following the month in which the substance was delivered. The information filed with the department shall include but not be limited to:

(1) pharmacy prescription number;

(2) pharmacy's national identification number;

(3) patient name;

(4) patient address, including street, city, state, ZIP code;

(5) patient date of birth;

(6) patient's sex;

(7) date prescription filled;

(8) metric quantity;

(9) national drug code number of the drug;

(10) number of days supply;

(11) prescriber's Drug Enforcement Administration number;

(12) date prescription [written] issued;

(13) serial number of official prescription form, or an identifier designated by the department;

(14) payment method;

(15) number of refills authorized; and

(16) refill number.

(g) Emergency oral prescriptions for schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part may be dispensed by a pharmacist to an ultimate user in an emergency situation, provided the pharmacist shall:

(1) contemporaneously reduce such prescriptions to written memoranda or, to the extent authorized by federal requirements, to an electronic record and shall indicate on such memoranda the name and address of the prescriber and his/her Drug Enforcement Administration registration number, name and address of the ultimate user, date on which it is ordered, name and quantity of drugs prescribed, directions for use and the fact that it is a telephone order. The memoranda or electronic record for such emergency oral prescription shall be filed in the same manner as is otherwise required for such

prescription. The pharmacist filling such oral orders shall indicate on the face of such telephone order his/her signature, the date filled and the number of the prescription under which it is recorded in the pharmacy prescription file;

(2) dispense the substance in conformity with labeling requirements applicable to the type of prescription which would be required but for the emergency; and

(3) make a good-faith effort to verify the identity of both the practitioner and the ultimate user.

[(h)] (4)No emergency oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply if the substance were used in accordance with the directions for use.

[(i)] (5) Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a[n official New York State prescription] written or an electronic prescription. Such prescription shall, in addition to the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing". If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

[(j)] (h)Within 72 hours after transmitting a prescription to a pharmacist by facsimile in

accordance with section 80.67(e) or (f) of this Part, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or an original out-of-state written prescription. Such original prescription shall be attached to any prescription transmitted by facsimile. If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

[(k)](i) Such [official New York State] prescriptions shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions. The [original written] follow-up prescriptions shall be attached to, or otherwise associated with, the corresponding memoranda of oral [or telephone] orders or to prescriptions transmitted by facsimile. The information required in section 80.68(d)(2) of this Part shall be filed electronically with the New York State Department of Health, not later than the 15th day of the next month following the month in which the substance was delivered. The pharmacy must submit this information electronically to the department utilizing a transmission format acceptable to the department.

[(l)] (j) A pharmacist may partially fill a[n official New York State] prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part provided that:

(1) the pharmacist does not have a sufficient quantity to fill a[n emergency oral or official] prescription and he/she makes a notation of the quantity supplied on the

prescription [(or written record of the emergency oral prescription)]. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription;

(2) the patient is a resident in a residential health care facility ("RHCF") which is licensed or approved by the department; or

(3) the patient has been diagnosed as being terminally ill.

(4) when such [an official New York State] prescription is partially filled in accordance with paragraph (2) or (3) of this subdivision, the pharmacist shall:

(i) record on the prescription whether the patient is "terminally ill" or is a "RHCF patient"; and

(ii) record on the prescription the date of the partial filling, quantity dispensed, quantity remaining and the signature of the dispensing pharmacist.

(5) the [official New York State] prescription shall be valid for a period not to exceed 30 days from the date the prescription was issued by the practitioner unless terminated sooner upon notification from the practitioner of the discontinuance of medication. All

partial fillings filled under subdivision (1) of this section must occur within 30 days from the date the prescription was issued, except that partial fillings of prescriptions issued for more than a 30 day supply for patients residing in a residential healthcare facility or for patients enrolled in a hospice program that is licensed or approved by the department must occur within 60 days from the date the prescription was issued.

(6) the date of filling on the prescription shall be the date when the prescription has been filled to completion or the date when the pharmacy is notified by the practitioner that the prescription has been discontinued.

[(m)] (k) When an official New York State prescription or an out-of-state written prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

[(n)] (l) A practitioner may orally authorize a pharmacist to change information on an official New York State prescription or an out-of-state written prescription. This

procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(m) When a pharmacist fills a prescription in a manner that would require, under subdivision (k) or subdivision (l) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(n) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall conduct a reasonable search of the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

(o) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically

to a separate pharmacy, the pharmacist shall confer with the separate pharmacy to determine if the separate pharmacy received that prescription and if the separate pharmacy dispensed upon that electronic prescription. If the separate pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy shall mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy receiving the written or oral version shall not dispense the prescription and shall mark it as void.

(p) A pharmacist shall use a pharmacy computer application that meets federal security requirements to process electronic controlled substance prescriptions and shall register such pharmacy computer application with the New York State Department of Health, Bureau of Narcotic Enforcement.

Section 80.74 is hereby amended to read as follows:

§80.74 Pharmacists; dispensing schedule III, IV and V controlled substances.

(a) Except as provided in sections 80.67 and 80.73 of this Part, a licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6808 of the Education Law, and regulations thereunder, in a registered pharmacy may, in good faith and in the course of his professional practice, dispense to an ultimate user, controlled substances in schedule III, IV or V provided they are dispensed pursuant to a[n official New York State] prescription presented within 30 days of the date such prescription was signed by an authorized practitioner.

(b) Such substances may be dispensed only if packaged and labeled in conformity with provisions set forth in section 80.73(b) of this Part.

(c) A licensed, registered pharmacist in a registered pharmacy may, in good faith and in the course of his/her professional practice, sell and dispense, to an ultimate user, controlled substances for which a[n official New York State] prescription is required upon the delivery to such pharmacist, within 30 days of the date such prescription, or official New York State prescription, or an out-of-state written prescription if sent by facsimile in accordance with subdivision (e) or subdivision (f) of section 80.69 of this Part was [signed] issued by an authorized practitioner[, an official New York State prescription transmitted by facsimile in accordance with section 80.69(e) or (f) of this Part].

(d) Within 72 hours after transmitting a prescription to a pharmacist by facsimile in accordance with section 80.69(e) or (f) of this Part, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. Such original prescription shall be attached to the [official] prescription transmitted by facsimile. If the pharmacist fails to receive such original [official] prescription, he/she shall notify the department in writing within seven days from the date of dispensing the substance.

(e) The pharmacist filling the [official] prescription shall endorse on such prescription

his/her signature, the date of filling, and the number of the prescription under which it is recorded in the pharmacy prescription file. Such endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years. Prescription information from the filling of such prescription shall be filed with the department in accordance with section 80.73(f) of this Part.

(f) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

(g) When a prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him to enter the missing information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(h) A practitioner may orally authorize a pharmacist to change information on a controlled substance prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the

ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the face of the prescription and initial the change.

(i) When a pharmacist fills a prescription in a manner that would require, under subdivision (g) or subdivision (h) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

[(i)] (j) Except as provided in sections 80.67 and 80.73 of this Part, a pharmacist may partially fill a prescription for a controlled substance provided that:

(1) each partial filling is recorded in the same manner as a refill;

(2) the total quantity dispensed does not exceed the total quantity prescribed for a 30-day period.

(k) When a pharmacist receives a prescription for a schedule III, IV or V controlled substance that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall check the records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

(l) When a pharmacist receives a prescription for a schedule III, IV or V controlled substance that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist shall check with an employee at that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy shall mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the written version shall not dispense the prescription and shall mark the prescription as void.

(m) A pharmacist shall use a pharmacy computer application that meets federal security requirements to process electronic controlled substance prescriptions, and shall register such pharmacy computer application with the New York State Department of Health, Bureau of Narcotic Enforcement.

Part 80.75 is hereby amended to read as follows:

§80.75 Institutional dispensers.

(a) Institutional dispensers licensed by the department may cause controlled substances to be administered or dispensed for use on the premises only pursuant to a written order by a practitioner for such medication. A[n official New York State] prescription is not required for inpatient use. In an emergency situation in which a physician determines that it is necessary to transfer a critically ill patient from one hospital to an alternative medical facility, an institutional dispenser may cause a single dose of a controlled substance to be dispensed to the medical attendant accompanying the patient if the duration of the

transfer may reasonably be expected to exceed three hours.

(b) An institutional dispenser may dispense controlled substances for use off its premises only pursuant to a prescription issued by a practitioner. All such prescriptions for outpatient use shall be filled only in a hospital pharmacy or other registered pharmacy. However, a practitioner in the emergency room of a hospital without a full-time pharmacy and when the services of a registered pharmacy are not available may dispense controlled substances to a patient in an emergency situation. For the purposes of this subdivision, an emergency means that the immediate dispensing of the controlled substance is necessary and no alternative treatment is available. The practitioner may dispense no more than a 24-hour supply in accordance with directions for use and must conform with the applicable labeling requirements of section 80.71 of this Part.

(c) Official New York State prescription forms are available for use by institutional dispensers. Institutional dispensers shall register with the department to be issued official prescriptions.

(1) The registration application for an institutional dispenser shall include but not be limited to the requesting institution's name, primary or other practice site address(s), the Federal registration number or exemption certificate, where applicable, a State agency license number, if applicable, and shall be signed by a person authorized by the institution to request such forms.

(2) An institutional dispenser's registration shall be without fee and subject to approval by the department. Such registration shall be valid for a period of two years.

(3) An institutional dispenser registered to be issued official prescription forms shall order such forms in the manner required by the department. The number of prescriptions requested by the institution shall be subject to approval by the department and shall be issued free of charge in the manner and quantity approved by the department.

(4) Official prescription[s] forms shall be sent to the institutional dispenser's primary address. Primary address is the address of a registered institution's Federal Drug Enforcement Administration (DEA) registration or, if such facility is not required to be registered with DEA, an address designated as the primary address in the facility's registration with the department.

(d) Staff practitioners are required to use such forms to prescribe controlled substances for outpatient use, indicating the practitioner's Drug Enforcement Administration registration number on the form. Staff practitioners may create, sign and transmit electronic prescriptions for controlled substances for outpatient use provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part and with federal requirements for electronic prescribing of controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed.

(e) Interns or residents are required to use the Drug Enforcement Administration registration number of the institution and the code number assigned by the institution for such purpose. Any [physician] practitioner who is an intern, resident or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the physician is employed, provided that:

(1) the dispensing or prescribing is in the usual course of his professional practice;

(2) the [physician] practitioner is authorized or permitted to do so by the laws of New York State;

(3) the hospital or institution has determined that the [physician] practitioner is permitted to dispense or prescribe drugs in New York State;

(4) the [physician] practitioner acts only within the scope of his employment in the hospital or institution; and

(5) the hospital or institution authorizes the intern, resident, or foreign physician to dispense or prescribe under its registration number and assigns a specific code number for each [physician] practitioner so authorized.

(f) It is the responsibility of the dispensing institution to obtain all official prescriptions for outpatient use and to assign such prescriptions to staff practitioners and interns and to insure the security of all such official prescriptions. Institutions obtaining official New York State prescriptions shall establish a system of control and security which will include the following:

(1) A record of all such prescriptions received.

(2) A record of all such prescriptions assigned to staff practitioners.

(3) A system requiring that such prescriptions be kept under lock and key when not in use.

(4) A system whereby official prescriptions are surrendered to the institution if the practitioner to whom they were assigned terminates his affiliation with the institution.

(5) A system whereby the Bureau of Narcotic Enforcement, New York State Department of Health, is notified immediately of the loss, destruction or theft of any such official prescriptions assigned to the institution.

(6) A system whereby the institution has a sufficient number of official prescriptions in reserve for use by the institution.

(g) Staff practitioners, interns, residents, or foreign physicians who are authorized to dispense or prescribe controlled substances in a hospital or other institution and use the institution's official New York State prescription forms, [or] other hospital or institutional forms, or the institution's electronic prescribing application must conform to the requirements of sections 80.67, 80.69 and 80.71 of this Part.

Section 80.77 is hereby amended to read as follows:

§80.77 Practitioners; control and reporting of official New York State prescription forms and electronic prescribing credentials.

* * * * *

(c) Practitioners shall retain sole possession and safeguard credentials used to sign electronic prescriptions for controlled substances and shall not share such credentials with any other person. The practitioner shall not allow any other person to use such credentials to sign prescriptions for controlled substances.

(d) Practitioners shall immediately notify the Bureau of Narcotic Enforcement that his or her credentials used to sign electronic prescriptions for controlled substances have been lost, stolen or compromised.

(e) Practitioners shall immediately notify the Bureau of Narcotic Enforcement upon discovery that one or more prescriptions issued under that practitioner's DEA registration

were prescriptions the practitioner had not signed or were not consistent with the prescription the practitioner signed.

Section 80.78 is hereby amended to read as follows:

§80.78 Pharmacists; dispensing out-of-state prescriptions; schedule II, III, IV and V controlled substances.

(a) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6808 of the Education Law, and regulations thereunder, in a registered pharmacy may, in good faith and in the course of his/her professional practice, dispense to an ultimate user, controlled substances in schedule II, III, IV and V upon delivery to such pharmacist of an out-of-state prescription within 30 days of the date such prescription was signed by an authorized practitioner.

(b) Such prescription shall have been written with ink, indelible pencil, typewriter, or by other electronic means approved by the department, and shall be signed by the practitioner. Electronic prescriptions may be created, signed and transmitted electronically, provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part and with federal requirements for electronic prescribing of controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed. The prescription shall contain the following:

(1) name, sex, address and age of the ultimate user for whom the substance is intended,

or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(2) the printed name, address, Drug Enforcement Administration registration number, telephone number and the handwritten signature or, in the case of an electronic prescription, the electronic signature of the prescribing practitioner;

(3) specific directions for use, including, but not limited to, the dosage and frequency of dosage;

(4) the date upon which such prescription was prepared and actually signed by the prescribing practitioner. The prescription shall have been dated as of, and signed on, the date it is issued[.]; and

(5) the quantity of dosage units prescribed.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(c) Out-of-state prescriptions shall be dispensed in conformity with provisions set forth in this Part for official prescriptions and electronic prescriptions. Prescription information from [the original filling of] all out-of-state prescriptions for a controlled substance shall

be filed with the department in accordance with section 80.73(f) of this Part.

(d) Pharmacies shall file out-of-state prescriptions for a controlled substance in the same manner as otherwise required by this Part [for official prescriptions].

Section 80.84 is hereby amended to read as follows:

§80.84 Physicians and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction.

Pursuant to the provisions of the Federal Drug Addiction Treatment Act of 2000 (106 P.L. 310, div. B, title XXXV, section 3502(a)), an authorized physician may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

(a) An approved controlled substance shall mean the following controlled substance which has been approved by the Food and Drug Administration (FDA) and the New York State Department of Health for the treatment of narcotic addiction:

(1) buprenorphine

(b) An authorized physician is a physician specifically registered with the Drug Enforcement Administration to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction, and approved for such purpose pursuant to the provisions of Article 32 of the Mental Hygiene Law.

(1) The total number of such patients of an authorized physician at any one time shall not exceed 30.

(2) An authorized physician prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing a[n official New York State] prescription in accordance with section 3332 of the Public Health Law and section 80.69 of this Part, shall also [write] include his/her unique DEA identification number on the prescription.

(c) A pharmacist may dispense an approved controlled substance for the treatment of narcotic addiction pursuant to a prescription issued by an authorized physician. Such dispensing shall be in accordance with Section 3333 of the Public Health Law and Section 80.74 of this Part.

Section 80.100 is amended to read as follows:

REPORTS AND RECORDS

§80.100 General requirements. (a) Records of all transactions concerning controlled substances required to be kept by manufacturers, distributors, importers, exporters, institutional dispensers, persons conducting research, instructional, analytical or maintenance treatment programs, pharmacies and practitioners shall be kept for a period of five years from the date of transaction.

(b) Records, orders and prescriptions required by this Part or article 33 of the Public Health Law, shall be readily available and promptly produced for inspection and copying upon request by authorized representatives of the Bureau of Narcotic Enforcement, New York State Department of Health.

(c) Records, orders and prescriptions required by this Part or provisions of article 33 of the Public Health Law shall be maintained at the premises where the licensed activity is conducted. Records, orders and prescriptions required by this Part or provisions of article 33 of the Public Health Law that are maintained electronically shall be made available to the department upon request, in a hardcopy format that is readily understandable, at the premises where the licensed activity is conducted.

(d) Records, orders and prescriptions required to be maintained by this Part or article 33 of the Public Health Law and which may be required as evidence of a violation in connection with an investigation by this department shall be released to authorized

representatives of the Bureau of Narcotic Enforcement, New York State Department of Health, upon request and upon the furnishing of a receipt therefor.

Section 80.106 is hereby amended to read as follows:

§80.106 Pharmacies.

(a) Pharmacies shall keep records of all controlled substances received and delivered or disposed of by them.

(1) The records of controlled substances received by pharmacies shall include date of receipt, name and address of vendor, and kind and quantity of such drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to satisfy this record requirement for schedule III, IV, and V controlled substances provided it includes all required information and is maintained in a separate file. Duplicate copies of Federal order forms for schedule II controlled substances shall be retained.

(2) The records of all controlled substances delivered or disposed of shall consist of the prescriptions filled for such drugs. The prescription shall indicate the name and address of the prescriber, Drug Enforcement Administration registration number, signature of the prescriber, name and address of the patient, date of issue, date of dispensing by pharmacist, serial number, type and quantity of drug and such other information as may be required by this Part or provisions of article 33 of the Public Health Law.

(b)(1) Schedule II controlled substances prescriptions shall be maintained together in a separate file.

(2) Schedule III, IV and V controlled substances prescriptions shall be maintained together in a separate file.

(c) If a prescription for a Schedule II, III, IV or V controlled substance is created, signed, transmitted and received electronically, all records related to that prescription shall be retained electronically. These records shall be readily retrievable from all other records, and shall be easily readable or easily rendered into a format that a person can read.

(d) If a pharmacy ceases to use an application service provider, the pharmacy shall ensure that the application service provider transfer any records subject to this Part to the pharmacy in a format that can be displayed, read, and printed, and in a manner readily accessible to, and readable by, representatives of the department.

[(c)] (e) Pharmacies shall keep a separate record of all controlled substances distributed to an automated dispensing system and returned to the pharmacy from such system.

[(d)] (f) Pharmacies shall keep a separate record for an automated dispensing system for all records required by this Part.

Section 80.125 is hereby amended to read as follows:

§80.125 Fraud and deceit. (a) No person shall:

(1) obtain or attempt to obtain a controlled substance prescription or a controlled substance, or procure or attempt to procure the administration of a controlled substance:

(i) by fraud, deceit, misrepresentation or subterfuge;

(ii) by the use of a forged or altered prescription or written order;

(iii) by the concealment of a material fact; or

(iv) by the use of a false name or the giving of a false address;

(2) willfully make a false statement in any prescription, order, report or record required by this Article;

(3) falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacy, pharmacist, intern, nurse, physician, dentist, veterinarian or other authorized person, for the purpose of obtaining a controlled substance;

(4) make or utter any false or forged prescription or false or forged written order; [or]

(5) affix any false or forged label to a package or receptacle containing controlled substances[.]; or

(6) willfully transmit an electronic prescription using an application or application provider that the practitioner knows does not comply with federal requirements or is otherwise non-compliant.

(b) Possession of a false or forged controlled substance prescription by any person other than a pharmacist in the pursuance of his profession shall be presumptive evidence of his intent to use the same for the purpose of illegally obtaining a controlled substance.

(c) Any person who, in the course of treatment, is supplied with controlled substances or a prescription therefor by one physician and who, without disclosing the fact, is supplied during such treatment with controlled substances or a prescription therefor by another physician shall be guilty of a violation of this Part.

SUMMARY OF 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 provision of Article 2-A and Article 33 of the Public Health Law in order to effectuate their purpose and intent. The Department proposes amendments to the regulations that would effectuate the changes to the Public Health Law (PHL) resulting from Chapter 178 of the Laws of 2010 and Chapter 447 of the Laws of 2012 amending Articles 2-A and 33 of the Public Health Law.

Legislative Objectives:

The legislative purpose of Article 2-A of the PHL, among other provisions, is to establish standards for electronic prescriptions for controlled substances and provide that all prescriptions made in this State must be made by electronic transmission with certain specified exceptions.

Needs and Benefits:

The Department is proposing amendments to Part 80 of the regulations to allow practitioners to electronically write and transmit prescriptions for controlled substances; permit pharmacies to receive, dispense, maintain and archive records of these electronic prescriptions; allow pharmacists to endorse a pharmacy's electronic record with an electronic signature and other required information for refills of controlled substances; and authorize a pharmacist to document an oral prescription for controlled substances to an electronic record. The result would be a reduction in paperwork and a potential

reduction in prescription forgery and the number of medication errors due to illegible handwritten prescriptions or misunderstood oral prescriptions.

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

Costs will be related to purchasing computer application systems. Regarding existing computer applications for electronic prescribing of non-controlled substances, it is expected that those existing applications already have some of the functions required.

C**osts 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 an adverse fiscal impact. It will reduce the number of prescriptions written on official New York State prescription forms, which are paid for by the State, so there may be a positive fiscal impact to the State.

Costs to the Department of Health:

The Department of Health does not anticipate increased administrative costs. Any increased administrative cost is expected to be offset by a decrease in the administrative support related to the paper-based Official Prescription Program.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities.

Paperwork:

Ultimately, these regulations will result in a reduction in paperwork; however, there is paperwork and processing associated with obtaining authorization. Hospitals and other institutional practitioners may conduct this process in-house as part of their own

DEA approved procedure. It is anticipated that these activities will occur initially upon implementation of electronic prescribing of controlled substances in a practice setting or a pharmacy, or when a new practitioner or pharmacist joins a practice.

Duplication:

Some requirements of this proposed regulation duplicate requirements set forth in the Drug Enforcement Administration's (DEA) regulations. Certain provisions of this proposed regulation duplicate regulations required by §6810 of the Education Law.

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 DEA sets minimum maintenance and retention standards for controlled substance records at two years; New York's is five years from the date of transaction. Federal requirements do not currently require practitioners or pharmacies to notify the DEA when their prescribing or dispensing computer applications become certified as meeting federal security standards; New York requires such notification. Federal regulations require that oral authorizations for controlled substances be immediately reduced to writing by the pharmacist; New York allows oral authorizations for controlled substances to be reduced to written memorandum or electronic record.

Compliance Schedule:

The proposed rule permits but does not require utilization of electronic prescribing. However, two years after the regulations implementing Chapter 447 of the

Laws of 2012 become final, use of electronic prescriptions and the requirements of these regulations will be mandatory for all prescribers.

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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 provision of Article 2-A and Article 33 of the Public Health Law in order to effectuate their purpose and intent. Such regulations are required with regard to electronic prescriptions pursuant to Chapter 447 of the Laws of 2012, which also authorizes the Department to promulgate such regulations on an emergency basis. The Department proposes amendments to the regulations that would effectuate the changes in §3332, §3333, §3334, §3337 and §3370 of the Public Health Law (PHL) resulting from Chapter 178 of the Laws of 2010 and the addition of Title III to Article 2-A of the Public Health Law resulting from Chapter 447 of the Laws of 2012.

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 allow the legitimate use of controlled substances in health care, including palliative care, veterinary care, research and other uses authorized by the law while combating the illegal use of and trade in controlled substances. The legislative purpose of Article 2-A of the Public Health Law, among other provisions, is to establish standards for electronic prescriptions

for controlled substances that are feasible and lawful under federal law. It also further provides for the mandatory use of electronic prescriptions by practitioners in this State, with certain specified exceptions. The proposed amendments are required by changes to Article 33 of the Public Health Law made by Chapter 178 of the Laws of 2010 and, more recently, to Article 2-A of the Public Health Law pursuant to Chapter 447 of the Laws of 2012.

Needs and Benefits:

These amendments are required to allow for the electronic prescribing of controlled substances in New York State. On March 31, 2010 the US Drug Enforcement Administration (DEA) published the Interim Final Rule (IFR) entitled "Electronic Prescriptions for Controlled Substances" (75 FR 16236, March 31, 2010). The effective date was June 1, 2010. The federal regulations provide practitioners the option of electronically writing and transmitting prescriptions for controlled substances. The regulations also permit pharmacies to receive, dispense and archive these electronic prescriptions. The regulations provide practitioners, hospitals and pharmacies with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substance dispensing.

The Department is proposing amendments to Part 80 regulations to allow practitioners to electronically write and transmit prescriptions for controlled substances in New York State provided that the practitioner has met all DEA requirements for transmitting the prescription securely. The amendments will also permit pharmacies to receive, dispense, archive and maintain records of these electronic prescriptions provided

that the pharmacy has met all DEA requirements. In addition, the amendments would allow pharmacists to endorse a pharmacy's electronic record with an electronic signature and other required information for refills of controlled substances. The Department is also proposing to amend Part 80 regulations to authorize a pharmacist to document an oral prescription for controlled substances in an electronic record. Existing regulations require a pharmacist to document such oral prescription in a written memorandum.

The pharmacy community has requested that the Department implement regulations that would reflect the industry's use of electronic prescriptions and recordkeeping. The New York State Education Department's Board of Pharmacy has allowed such records for over 15 years with regard to non-controlled substances. Practitioners that currently transmit electronic prescriptions for non-controlled substances and have implemented electronic health records are preparing to integrate electronic prescriptions for controlled substances.

Benefits of the proposed amendments include a reduction in paperwork for DEA registrants who prescribe and dispense controlled substances, a potential reduction in prescription forgery, and a potential reduction in the number of medication errors due to illegible handwritten prescriptions or misunderstood oral prescriptions. The proposed amendments will implement the recent changes to Article 33 of the Public Health Law made by Chapter 178 of the Laws of 2010 and to Article 2-A of the Public Health Law made by Chapter 447 of the Laws of 2012. A more specific description of the current structure of prescribing and dispensing controlled substances, and the benefits provided by the amendments, follows.

The current regulations define a prescription as an "official New York State prescription," an "oral prescription" or "an out-of-state prescription." The amendments add "electronic prescription" to the definition of prescription. Updating the definition of prescription for the purposes of this Part provides for the inclusion of electronic prescriptions, unless otherwise noted, throughout the provisions of Part 80.

The DEA regulations were a response to identified existing and potential problems that occur when electronic prescriptions for non-controlled substances are written and transmitted. It was essential that the rules created to allow for the electronic prescribing of controlled substances did not inadvertently facilitate diversion and abuse and undermine the ability to identify those who engage in diversion. DEA's goals were to ensure that non-registrants did not gain access to electronic prescription computer applications to generate or alter prescriptions for controlled substances and to ensure that a prescription record, once created, could not be repudiated. Current Part 80 regulations do not address computer application security. The amendments require that practitioners who will engage in electronic prescribing of controlled substances, and pharmacists who will receive, dispense and archive controlled substance prescriptions use an electronic computer application that meets the federal security requirements. The amendments also require that practitioners and pharmacists register such computer application certifications with the New York State Department of Health, Bureau of Narcotic Enforcement. The benefit of these computer requirements to the State would be the maintenance of a closed system of controls on controlled substance prescribing and dispensing within New York State, while allowing the Bureau to fully investigate the fraud, diversion and abuse of controlled substances.

To allow for the electronic prescribing of controlled substances and corresponding dispensing upon those electronic prescriptions, the proposed changes to New York State regulations include:

1. allowing for the electronic prescribing of Schedule II, III, IV and V controlled substances;
2. clarifying exceptions to electronic prescribing under certain circumstances;
3. explaining that a prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and must be manually signed;
4. clarifying that the quantity of dosage units prescribed and the number of refills authorized (where permissible) be indicated in both numerical and written word form on an official New York State prescription but is not required in both forms on an electronic prescription;
5. requiring that an electronic prescription shall contain all the requirements of an official New York State prescription, and that an electronic signature, as defined in this Part, shall satisfy the signature requirement, in this Part, on an electronic prescription;
6. allowing a pharmacist to annotate prescriptions electronically in the event of an incomplete prescription or if a practitioner orally authorizes a pharmacist to change information on a prescription;
7. defining what a practitioner and a pharmacist must do when he or she is notified that an electronic prescription was not successfully delivered; and

8. requiring that if the content of information required by this Part is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid.

Existing regulations require a pharmacist to reduce an oral prescription for controlled substances, that is, a prescription telephoned to a pharmacy by a prescribing practitioner, 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 process as most pharmacists already create an electronic record of a prescription. Existing regulations also require an official New York State prescription form as a follow-up to an oral prescription. The amendments would allow the use of an electronic prescription as a follow up to an oral order. A pharmacist would also be permitted to notify the Bureau electronically in the event a required follow-up prescription is not received, unlike current regulations that require written notification. Providing these options will eliminate mandated paperwork by practitioners and pharmacists who utilize these electronic options, increasing efficiency within their practices.

Current regulations address the importance of safeguarding blank official New York State prescription forms, and require an immediate report should those forms be lost or stolen. Amendments would extend such safeguarding and reporting requirements to a practitioner's credentials utilized to electronically prescribe controlled substances. These measures support the integrity and nonrepudiation of electronic prescriptions for controlled substances.

Amendments extend recordkeeping requirements to electronic records, requiring that they be readily retrievable and readable, accessible at the premises where activity is conducted, and available to the Department upon request. Amendments also provide requirements for the transfer of usable, printable electronic records in the event a pharmacy changes computer application providers. Amendments also prohibit the use of computer applications that are non-compliant with federal security requirements.

In addition, technical issues such as spelling, grammar and punctuation were corrected where necessary.

These proposed regulations promote the safe and effective use of prescription drugs while curbing the diversion of such drugs. They should decrease practitioners' and pharmacists' workloads by increasing efficiency within their practices. Utilizing modern prescription technology has the potential to minimize medication errors and ensures that patients in New York State will have greater access to their practitioners and pharmacists when questions or concerns arise or counseling is needed. This should lead to enhanced patient care and safety. Populations that would especially benefit from these changes include patients with pain who are suffering from conditions or diseases known to be chronic and incurable. Patients within this population may be non-ambulatory, may require nursing assistance or assistance by family members and may be less likely to obtain written prescriptions for their pain control from their prescriber in a timely manner. Also, filling such written prescriptions at a pharmacy may entail significant wait-times for the patient.

These amendments are being proposed to provide practitioners and pharmacies with the ability to use the industry's modern electronic technology to prescribe, dispense and archive prescriptions for controlled substances in Schedules II through V. The amendments will increase practitioners' and pharmacists' efficiency by reducing paperwork and streamlining workflow and will ultimately contribute to enhanced patient care. Electronic prescribing also has the potential to reduce prescription forgery and to reduce errors associated with poor handwriting. The medical and pharmacy communities in New York have supported amendments allowing the electronic prescribing of controlled substances. While supportive of a move to electronic prescribing of controlled substances, certain members of the medical community and particular professional societies have expressed concerns with the requirement to electronically prescribe controlled substances. The most commonly expressed concerns have been the financial impact to practitioners and the limited technological capabilities of some practitioners. These amendments contain exceptions to this requirement which address those concerns, detailing circumstances when a waiver is appropriate.

Costs:

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

Pharmacies, practitioners, and institutions will incur costs related to compliance with security requirements set forth in the federal rule allowing for electronic prescribing of controlled substances. Costs will be related to purchasing computer application systems to comply with federal computer security standards. For those practitioners and

pharmacies that already use existing computer applications for electronic prescribing of non-controlled substances, it is expected that those existing applications already have some of the functions required by the federal rule. Where additional functionality is needed, it may be added as an upgrade or patch, as occurs routinely with most software applications.

Prescribers will be required to obtain identity proofing which will result in additional costs related to completing an application for a credential or digital certificate and to pay for the credential. In March 2010 the DEA issued an Economic Impact Analysis of the Interim Final Electronic Prescription Rule which can be viewed on the Office of Diversion Control website www.deadiversion.dea.gov . However, as virtually all such requirements, and the costs associated with them will be imposed by federal law as a result of the DEA regulations. The proposed amendments to the Department's regulations should not, on their own, impose any additional costs not already resulting from federal law, aside from the nominal cost of retaining electronic and paper records for an additional three years (the current regulations require retention of paper records for five years, as opposed to the two years required by federal law; the regulations would simply extend that requirement to the newly-authorized electronic records).

Costs to State and Local Government:

The proposed rule does not require the state or local government to perform any additional tasks beyond those which may be required by federal law, except as described in the “Costs for Implementation” section, above. Therefore, it is not anticipated to have an adverse fiscal impact on the State or local government. Electronic prescribing of

controlled substances will reduce the number of prescriptions written on official New York State prescription forms, which are paid for by the State, therefore; there may be a positive fiscal impact in that regard. 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 Department of Health does not anticipate increased administrative costs associated with the implementation of electronic prescribing of controlled substances. The Department will modify the current registration process used for the Official Prescription Program to accommodate registration of computer application certifications with the New York State Department of Health, Bureau of Narcotic Enforcement. Any increased administrative costs are expected to be offset by a decrease in the administrative support related to the paper-based Official Prescription Program.

Local Government Mandates:

The proposed rule does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other specific district beyond those which may be required by federal law, except as described in the "Costs for Implementation" section, above.

Paperwork:

Ultimately, authorizing electronic prescriptions and electronic record keeping for controlled substances will result in a reduction in paperwork. For prescriptions created, signed, transmitted, and received electronically, all records must be retained electronically. However, there is paperwork and process associated with obtaining authorization to electronically prescribe controlled substances, as required by DEA. Each registered practitioner will be required to apply to a credential service provider approved by the DEA to undergo identity proofing and obtain a credential. Hospitals and other institutional practitioners may conduct this process in-house as part of their own DEA approved procedure. At both practitioners' offices and at pharmacies, implementing the DEA's procedure will require entering logical access control data into the electronic prescription application. This will grant permission to practitioners to electronically prescribe controlled substances and pharmacists to dispense upon those electronic prescriptions. It is anticipated that these activities will occur initially upon implementation of electronic prescribing of controlled substances in a practice setting or a pharmacy, or when a new practitioner or pharmacist joins a practice.

Practitioners and pharmacists will be required to review security logs to determine if security incidents that have been identified by the application provider compromised or could have compromised the integrity of the electronic prescribing process. Any such incidents must be reported to the application service provider and any other identified agency or enforcement authority as required by regulation. However, as virtually all such requirements and the costs associated with them will be imposed by federal law as a result of the DEA regulations, the proposed amendments to the Department's regulations

should not, on their own, impose any additional costs not already resulting from federal law, aside from the nominal cost of retaining electronic and paper records for an additional three years (the current regulations require retention of paper records for five years, as opposed to the two years required by federal law; the regulations would simply extend that requirement to the newly-authorized electronic records).

The amendments will reduce the amount of paperwork required by allowing a pharmacist to reduce an oral prescription to an electronic (versus a written) memorandum. A pharmacist will also be allowed to notify the Bureau electronically in the instance when a required follow-up prescription to an oral order was not received from the practitioner. Allowing an electronic follow-up prescription from a practitioner for an oral communication of a prescription for controlled substance prescriptions decreases paperwork for both the practitioner and pharmacist.

Current regulations require pharmacists to endorse a written prescription with a handwritten signature and other required information upon the original hardcopy prescription when dispensing refills for prescriptions issued for controlled substances. This process is repeated for all refill requests of written controlled substance prescriptions, which can be up to five separate occasions. The amendments to the regulation would eliminate the need for duplicate recording and record-keeping, as it would allow the electronic dispensing record to serve as annotation, storage, and retrieval of refill information for original written prescriptions for controlled substances in schedules III, IV and V. This is consistent with current regulations for non-controlled substance prescriptions. A manual signature is still required upon the initial filling of a written controlled substance prescription.

Duplication:

Some requirements of this proposed regulation duplicate requirements set forth in the DEA regulations entitled "Electronic Prescriptions for Controlled Substances," 21 CFR Parts 1300, 1304, 1306 and 1311.

Certain provisions of this proposed regulation duplicate regulations required by §6810 of the education law. Those include provisions for exceptions to electronic prescribing under certain circumstances.

Alternatives:

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

Federal Standards:

The DEA sets minimum maintenance and retention standards for controlled substance records at two years. New York's regulations are more stringent in that they require records of all transactions concerning controlled substances be kept for a period of five years from the date of transaction. Federal requirements do not currently require practitioners or pharmacies to notify the DEA when their prescribing or dispensing computer applications become certified as meeting federal security standards. New York's regulations are more stringent as they require such notification.

Federal regulations require that oral authorizations for controlled substances be immediately reduced to writing by the pharmacist. New York amended regulations allow

oral authorizations for controlled substances to be reduced to written or electronic memorandum.

Compliance Schedule:

The proposed rule permits but does not require utilization of electronic prescribing. However, two years after the regulations implementing Chapter 447 of the Laws of 2012 become final, use of electronic prescriptions and the requirements of these regulations will be mandatory for all prescribers.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

This proposed rule will affect New York State practitioners and pharmacists who electronically prescribe and dispense prescriptions for controlled substances. Records retrieved from the Education Department's Office of the Professions show that as of July 2, 2012 there were a total of 135,735 practitioners (physicians, dentists, physician assistants, and nurse practitioners) registered in the State of New York. Records retrieved from the Education Department's Board of Pharmacy show that as of February 22, 2011 there were a total of 5,579 registered pharmacies and as of July 2, 2012 there were 23,460 registered pharmacists in the State of New York. Of these totals, approximately 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. Based on their analysis, the United States Drug Enforcement Administration (DEA) has determined that while the rule will impact a substantial number of small entities, it will not impose a significant economic impact on any small entity. The Department has considered that analysis, and concurs with it. Costs to small business entities in New York beyond those incurred by complying with the federal rule will be negligible.

Compliance Requirements:

The proposed rule permits but does not require utilization of electronic prescribing. However, two years after the regulations implementing Chapter 447 of the

Laws of 2012 become final, use of electronic prescriptions and the requirements of these regulations will be mandatory for all prescribers.

Professional Services:

Currently, a practitioner who electronically prescribes controlled substances must apply to a federally approved credential service provider or certification authority to obtain their authentication credentials or digital certificates. Before any computer application can be used to prescribe, dispense, or archive electronic prescriptions for controlled substances, it must be reviewed, tested, and determined by a third party to meet all of the requirements of the federal rule. The third party audit must be performed by a qualified person as defined in the federal rule. Alternatively, the computer application may be certified by a certifying organization whose review process has been approved by DEA as stated in the federal rule. Professional information technology subject matter expertise may be required to upgrade and maintain computer applications to accommodate electronic prescribing and recordkeeping.

Compliance Costs:

Based on their analysis, DEA has determined that while the federal rule will impact a substantial number of small entities, it will not impose a significant economic impact on any small entity. Costs to small business entities in New York beyond those incurred by complying with the federal rule will be negligible.

Amendments to the regulation will require any business entity that participates in electronic prescribing of controlled substances ensure that their system complies with the

DEA requirements by either purchasing a certified computer software application or working with software vendors that have obtained the appropriate computer software certification. Amendments also require any practitioner to undergo the identity-proofing process. The DEA's Economic Impact Analysis addresses the impact of the Interim Final Rule on small business entities. The analysis addresses both initial costs and ongoing costs to the smallest practitioner (i.e. a solo practitioner) and to independent pharmacies. Costs to practitioners include those incurred with prescribing software or application, identity proofing and credential, labor costs to complete the application, access control training and to set logical access controls, all requirements to electronically prescribe controlled substances. Ongoing costs will be renewal of the credential, review of security logs and maintenance of the computer application. For pharmacies, costs will include the incremental cost that their application provider charges for programming and audits, the cost of reviewing security logs and initial access control setting and training. Ongoing labor costs will be incurred for reviewing security logs, and maintenance of the computer application, although reprogramming is a routine practice in the software industry and applications are routinely updated to add features and fix problems. Pharmacies also pay a transaction fee to intermediaries per electronic prescription to ensure the pharmacy system will be able to capture the data electronically.

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:

Most pharmacies currently employ an electronic system to process and dispense prescriptions. Many practitioners employ electronic prescribing systems or electronic health record systems to comply with the American Recovery and Reinvestment Act. The Department believes that this trend will continue. Practitioners that do not currently electronically prescribe will be compelled to do so by statute, in accordance with these amendments. Practitioners and pharmacists can expect an initial economic impact due to practitioner identity-proofing, and upgrades to most prescribing and dispensing computer applications to bring them into compliance with computer security requirements in the federal rule. Subsequent to initial implementation, computer application recertification as required, and identity-proofing of new practitioners will be ongoing costs incurred. The DEA has approved a number of certifying organizations whose certification processes verify and certify that a computer application meets the requirements of 21 CFR Part 1311. Alternatively, computer application providers may obtain a third party audit to verify and certify computer applications. Amendments to the regulation will cause practitioners and pharmacies to incur costs, especially in undergoing identity-proofing, obtaining an authentication credential, and in computer application installation or upgrade. In its economic analysis, the DEA concluded that overall, while it recognizes that the costs of the rule are not trivial, they are not great enough to discourage adoption of electronic prescribing. Implementation of these amendments is economically and technologically feasible at this time.

Minimizing Adverse Impact:

These regulations will allow practitioners and pharmacists to change the way they prescribe and dispense prescriptions for controlled substances from written prescriptions to electronic media. They provide for electronic recordkeeping requirements by pharmacies. To minimize any undue burden on a particular practitioner, the regulations provide for a waiver process for practitioners to be exempted from the requirement to electronically prescribe based upon economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner.

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 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 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, and electronic prescriptions 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. The Department also consulted with the National Association of Chain Drug Stores, an organization dedicated to advancing the interests and objectives of the chain community pharmacy industry, and with various other pharmacy leaders and stakeholders. 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 pharmacy community's comments and suggestions with respect to the current laws and regulations and how the amendments would affect the overall dispensing process.

The Department consulted with the Medical Society of the State of New York, an organization dedicated to promoting and maintaining high standards in medical education and in the practice of medicine in an effort to ensure that quality medical care is available to the public. The Department also consulted with the Greater New York Hospital Association and the New York City Health and Hospitals Corporation. Input was also received from the Office of Professional Medical Conduct, and the New York Chapter of the American College of Physicians. Amending current regulations to allow for the electronic prescribing of controlled substances was met with general approval. However, opposition has been expressed to the requirement that all prescriptions be transmitted electronically. Most frequently expressed concerns were the expected cost to practitioners as well as technological barriers facing technologically naïve practitioners.

The Department is confident that the exceptions and waiver process provided for in the statute address these concerns.

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 and impose minimal additional recordkeeping and other compliance requirements beyond what is required in the federal rule.

Costs:

The DEA's Economic Impact Analysis addresses both initial costs and ongoing costs to practitioners and pharmacies. Costs to practitioners include those incurred with prescribing software or application, identity proofing and credential, labor costs to complete the application, access control training and to set logical access controls, all requirements to electronically prescribe controlled substances. Ongoing costs will be renewal of the credential, review of security logs and maintenance of the computer application. Compliance with amendments to New York State's regulations would not incur significant costs above those required by the DEA regulations.

For pharmacies, costs will include the incremental cost that their application provider charges for programming and audits, the cost of reviewing security logs and initial access control setting and training. Ongoing labor costs will be incurred for reviewing security logs, and maintenance of the computer application, although reprogramming is a routine practice in the software industry and applications are routinely updated to add features and fix problems. Costs to business entities in New York, including those located in rural areas, beyond those incurred by complying with the federal rule, will be negligible.

Minimizing Adverse Impact:

These regulations will allow practitioners and pharmacists practicing in rural areas to change the way they prescribe and dispense prescriptions for controlled substances from written prescriptions to electronic media. They provide for electronic recordkeeping requirements by pharmacies. To minimize any undue burden on a

particular practitioner once Article 2-A mandates electronic prescribing, the regulations provide for a waiver process for practitioners to be exempted from the requirement to electronically prescribe based upon economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. It is anticipated that these waiver categories will sufficiently address burdens of rural providers.

Rural Area Participation:

During the drafting of these regulations, the Department consulted with various statewide groups whose constituencies include rural areas, e.g.: the State Education Department's Board of Pharmacy, the Pharmaceutical Society of the State of New York and the New York Chapter of the American Society of Consultant Pharmacists. Pharmacy conferences were also 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 Department also consulted with the National Association of Chain Drug Stores, an organization dedicated to advancing the interests and objectives of the chain community pharmacy industry in rural and metropolitan areas, and with various other pharmacy leaders and stakeholders. The regulations were drafted taking into consideration the pharmacy community'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 Medical Society of the State of New York and the Greater New York Hospital Association.

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, based on analysis performed by the United States Drug Enforcement Administration with regard to their electronic prescribing requirements, with which the amendments are overwhelmingly consistent, and given that the regulations are simply implementing an underlying requirement imposed by the legislature through the Public Health Law. The proposed amendments do not change the frequency with which prescriptions are issued and dispensed, although they do change the manner in which they are issued and dispensed. The amendments provide the opportunity for increased efficiency, allowing practitioners and pharmacists more clinical face to face time with their patients, and will not, in and of themselves, have a substantial adverse effect upon jobs and employment opportunities.

Assessment of Public Comment

Public comments were submitted to the NYS Department of Health (DOH) in response to this regulation. The public comment period for this regulation ended on March 4, 2013. The Department received the following comments. These comments and the Department of Health's responses are summarized below:

1. COMMENT: A commenter representing the pharmacy community questioned whether there is a definition of time related to temporary technological or electronic failure.

RESPONSE: The regulation does not set forth a specific time frame for "temporary." Recognizing that technological failures can vary from a momentary occurrence, corrected within minutes or hours, to a widespread power failure that could last days or even weeks, the definition centers on intervening factors that interfere with a practitioner's ability to use his or her electronic prescribing application that are not reasonably under the control of the practitioner. This flexibility allows the regulation to be appropriately enforced in a wide array of situations, including those that are not necessarily foreseeable.

2. COMMENT: A commenter representing the pharmacy community questioned if there was a time limit on the renewal of waivers.

RESPONSE: Section 80.64 of the proposed regulations would require that a renewal of a waiver be "subject to the same requirements as the original waiver", which means that it will be limited to no more than one year.

3. COMMENT: A commenter representing the pharmacy community questioned whether a prescription generated by a practitioner's computer and transmitted to a pharmacy fax would be considered an electronic prescription.

RESPONSE: New York State Public Health Law §3302(37) defines an electronic prescription as "a prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the commissioner and the commissioner of education and consistent with federal requirements. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and must be manually signed." Further, §3302(38) of the Public Health Law states that "'electronic' means of or relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities. 'Electronic' shall not include facsimile." A prescription generated by a practitioner's computer and transmitted to a pharmacy fax would, therefore, not be considered an electronic prescription.

4. COMMENT: A commenter representing the pharmacy community requested clarification relating to recordkeeping for refills of Schedule III, IV and V drugs

when the prescription was written on an Official New York State Prescription form or an out-of-state written prescription.

RESPONSE: In the proposed regulation, 10 NYCRR §80.69(i) provides an option for electronic recordkeeping of refills for prescriptions when they are received electronically, on an Official New York State Prescription form, or on an out-of-state written prescription. Pharmacists utilizing electronic recordkeeping of such refills will be required to "document that the refill information entered into the computer has been reviewed and is correct by manually signing: (i) a hard-copy printout of each day's controlled substance prescription refill data, or: (ii) a bound log book containing a statement that the refill information entered into the computer that day has been reviewed and is correct as shown." Pharmacists who do not utilize an electronic recordkeeping system for such prescriptions and related refills must indicate on the written prescription form "the amount dispensed, the date dispensed, and the signature of the dispensing pharmacist." However, "[w]hen a prescription is received electronically, the prescription and all required annotations shall be retained electronically."

5. COMMENT: Clarification was requested related to 10 NYCRR §§80.68(c) and 80.70(c), follow-up prescriptions and whether references to oral or verbal prescriptions would include prescriptions transmitted via facsimile.

RESPONSE: The reference to oral and verbal prescriptions in the context of 10 NYCRR §§80.68(c) and 80.70(c) does not include prescriptions transmitted via facsimile. Under

this proposed regulation, follow-up prescriptions to oral and verbal prescriptions for Schedule II narcotics shall be either a written or an electronic prescription with the annotation "Authorization for emergency dispensing." 10 NYCRR §80.73(g)(5). Follow-up prescriptions to oral and verbal prescriptions for Schedule III, IV, and V shall be by either a written or an electronic prescription with the annotation "Follow-up prescription to oral order." Prescriptions transmitted from a practitioner to a pharmacy via facsimile must be on an Official New York State Prescription form and be manually signed. In this case, the original hard copy Official New York State Prescription form that was transmitted via facsimile and manually signed is required as the follow-up prescription.

6. COMMENT: A commenter representing a diagnostic and treatment center with multiple sites requested clarification related to how a pharmacy would verify that a prescriber has met the DEA requirements to electronically prescribe a controlled substance.

RESPONSE: In accordance with federal requirements in 21 CFR §1311.102(d), "[b]efore initially using an electronic prescription application to sign and transmit controlled substance prescriptions, the practitioner must determine that the third-party auditor or certification organization has found that the electronic prescription application records, stores, and transmits the [required information] accurately and consistently." Pharmacy applications are also subject to approval by a third party auditor or certification organization to ensure that the application will consistently import, store and display the

information required for prescriptions, provide the indication of signing, display the number of refills and import, store and verify the practitioner's digital signature. A breakdown in either system should not allow a prescription to be transmitted. Nothing in the proposed New York State regulations or the federal regulations relieves a practitioner or a pharmacy of their responsibilities to ensure the validity of a controlled substance prescription.

7. COMMENT: A commenter representing a diagnostic and treatment center with multiple sites requested clarification regarding how a pharmacy would know that a prescriber is exempt from the electronic prescribing mandate as a result of a waiver or other exemption listed in the proposed regulation.

RESPONSE: These regulations do not require a pharmacist to verify whether a practitioner was granted a waiver or if the practitioner properly used an enumerated exemption to the statutory requirement to transmit prescriptions electronically. However, nothing in the proposed regulations relieves a practitioner or a pharmacy of their current responsibilities to ensure that any controlled substance prescription is otherwise legal, regardless of the format. Similarly, any person licensed or certified under Article 33 has a continuing duty to promptly notify the Department of an incident of theft, loss, or possible diversion of controlled substances.

8. COMMENT: A commenter representing a diagnostic and treatment center with multiple sites requested clarification related to the provision allowing an oral

prescription to be reduced to a written memorandum. The commenter questions whether the regulations will eventually shift to require a pharmacy to reduce an oral prescription solely to an electronic memorandum.

RESPONSE: The provision allowing a pharmacist to reduce an oral prescription to an electronic memorandum is an option in addition to a written memorandum. 10 NYCRR §§80.68(a)(1) & 80.70(a)(1). This response will not comment on potential future regulations.

9. COMMENT: A commenter representing a diagnostic and treatment center with multiple sites requested clarification regarding an incorrectly written electronic prescription and the ability of the pharmacist to correct the prescription.

RESPONSE: The references to altered prescription information in sections 80.67(k) and 80.69(p) of the regulation do not apply to changes that occur after receipt at the pharmacy. Rather, those sections are only in reference to changes that occur during transmission of the prescription. Changes made by the pharmacy once a prescription is received are governed by the same laws and regulation that apply to paper prescriptions. 21 CFR §§1306 & 1311.

10. COMMENT: A commenter representing a diagnostic and treatment center with multiple sites requested clarification regarding how a pharmacy can determine if a transmission of a controlled substance prescription was altered.

RESPONSE: Practitioners and pharmacies are required to utilize a third party auditor or certification organization to ensure that their electronic prescribing applications will consistently record, store and transmit the required information accurately and consistently and, for pharmacies, will import, store and display the information required for prescriptions, provide the indication of signing, display the number of refills, and will import, store and verify the practitioner's digital signature. A breakdown in either system should not allow a prescription to be transmitted, and an approved pharmacy application should identify if a controlled substance prescription was converted into a fax transmission. An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission. Alteration during transmission can also be identified by comparing the digitally signed prescription retained by the electronic prescription application and the digitally signed prescription retained by the pharmacy. 21 CFR §§1306 & 1311.

11. COMMENT: Two commenters expressed concerns related to the costs pharmacies and practitioners will need to incur to upgrade their software systems to meet these new requirements in light of significant reductions in health care reimbursements.

RESPONSE: Electronic prescribing of controlled substances and compliance with the related proposed regulations are optional for the next two years. The corresponding

Regulatory Impact Statement filed with these regulations indicate pharmacies, practitioners, and institutions will incur costs related to compliance with security requirements set forth in the federal rule allowing for electronic prescribing of controlled substances. Compliance with the federal rule will result in costs related to purchasing computer application systems that comply with federal computer security standards. Please note that the regulations do provide for waivers in cases of economic hardship.

12. COMMENT: A coalition representing a number of consumer advocacy groups and individuals supported a position that the proposed regulation include a requirement related to the section of the electronic prescription wherein prescribers may indicate whether an individual is limited English proficient and, if so, a specification of the preferred language. The coalition suggested a drop down menu in the prescription application that includes pre-populated language options rather than the anticipated free-entry text option.

RESPONSE: These regulations do not require the specific functionality requested by the commenter. However, all prescriptions must comply with the requirements related to Limited English Proficient patients promulgated by the State Education Department pursuant to Section 6829 of the Education Law.

13. COMMENT: The Hospice and Palliative Care Association of New York State submitted a comment concerning the development of new infrastructure for electronic prescribing.

RESPONSE: Pursuant to the federal rule, electronic prescriptions will be transmitted from prescriber to pharmacy, and may be transmitted through an intermediary. 21 CFR §§1306. These transmissions will be encrypted by the prescriber's electronic prescribing application and subsequently decrypted and authenticated by the pharmacy's application. 21 CFR §1311. Such encrypted electronic prescriptions for controlled substances can be transmitted through currently available options, including web-based portals. No other new infrastructure need be developed.

14. COMMENT: The Hospice and Palliative Care Association of New York State expressed concern about a pharmacist's duty to report controlled substance dispensing information in "real time."

RESPONSE: The regulations do not define "real time" or change the current time frame in which a pharmacy must report information about dispensed controlled substances. The Hospice and Palliative Care Association of New York State's concerns will be considered in future regulations which the Department plans to address the definition of "real time." The time frame in which the pharmacy must report information about controlled substances is currently "not later than the 15th day of the next month following the month in which the substance was delivered" to the patient. (10 NYCRR §80.73(f).)

15. COMMENT: A supportive comment from an individual was received relating to the allowance for electronic prescribing of controlled substances by practitioners.