

March 28, 2016

MCMS/7<sup>th</sup> District Branch Physicians/Staff –

As you know, the NYS E-prescribing mandate went into effect yesterday. Among the many e-prescribing questions MCMS has received, clarifying the process to follow when using an exemption is one of the most common. The letter below from DOH addresses this and other issues.

Exemption notices may be sent to the address below with the information listed in #2. Don't hesitate to reach out with questions.

Nancy

1. The email address will be: [erx@health.ny.gov](mailto:erx@health.ny.gov). This site is now live.
2. The practitioner's e-mail notification to the Department should include the following:
  - That it is a notification to the Department pursuant to Public Health Law Section 281(4) or (5);
  - Practitioner's name;
  - Practitioner's license number;
  - Practitioner's telephone number;
  - Practitioner's preferred work e-mail address;
  - Practitioner's work address;
  - Patient initials only (the Department does not want patient confidential information to be sent); and
  - The reason(s) for the exception(s), including the citation(s) to PHL Section(s) 281(3)(b), (d), and (e).

Nancy J. Adams  
Executive Director  
Monroe County Medical Society/American Academy of Pediatrics NY 1/Genesee Valley Medical  
Foundation  
132 Allens Creek Road  
Rochester, New York 14618  
585-473-4072 office  
585-729-5166 cell  
585-473-7641 fax



## MEMORANDUM

### **MEDICAL SOCIETY OF THE STATE OF NEW YORK**

99 WASHINGTON AVENUE, SUITE 408, ALBANY, NY 12210  
518-465-8085 • Fax: 518-465-0976 • E-mail: albany@mssny.org

Revised/Update  
March 28, 2016

#### **E-PRESCRIBING OF ALL SUBSTANCES TAKES EFFECT ON SUNDAY MARCH 27, 2016**

New York State's e-prescribing requirements for non-controlled and controlled substances will go into effect on Sunday, March 27, 2016.

According to the NYS Department of Health's Bureau of Narcotic Enforcement, more than 70,000 prescribers are already e-prescribing and other prescribers are continuing to register their certified software for controlled substances with the New State Department of Health. Practitioners should continue their efforts to become compliant with the law, including working with their software vendors to implement the additional security requirements needed for e-prescribing of controlled substances (EPCS), and registering their certified software applications with the Bureau of Narcotic Enforcement.

For physicians who prescribe controlled substances, there are additional steps to complete in order to electronically prescribe controlled substances. These include the following:

- First, the software you currently use must meet all the federal security requirements for EPCS, which can be found on the Drug Enforcement Agency's (DEA) web page. [http://www.deadiversion.usdoj.gov/ecom/e\\_rx/](http://www.deadiversion.usdoj.gov/ecom/e_rx/)  
**Note that federal security requirements include a third party audit or DEA certification of the software.**
- Second, you must complete the identity proofing process as defined in the federal requirements.
- Third, you must obtain a two-factor authentication as defined in the federal requirements.
- Fourth, you must register your DEA certified EPCS software with the Bureau of Narcotic Enforcement (BNE). Registration instructions are included in the FAQs.

A copy of the BNE's Frequently Asked Questions (FAQs) can be found at: [https://www.health.ny.gov/professionals/narcotic/electronic\\_prescribing/docs/epcs\\_faqs.pdf](https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/docs/epcs_faqs.pdf)

E-prescribing of non-controlled substances is also required under the law; however, registering of this system with the state is not necessary.

#### **Exceptions to the e-prescribing requirement:**

The law currently allows for a list of exceptions from the requirement to electronically prescribe and they are:

- Prescriptions issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure
- Prescriptions issued by a practitioner under circumstances where the 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. In addition to these circumstances, the quantity of controlled substances cannot exceed a five day supply if supply if the controlled substance were used in accordance with the directions for use.
- Prescriptions issued by a practitioner to be dispensed by a pharmacy located outside the state.
- Practitioners who have received a waiver or a renewal thereof for a specified period determined by the commissioner, from the requirement to use electronic prescribing.

However, each time a prescriber uses the power or electrical failure exception they must file information about the issuance of the paper prescription electronically to the Department of Health within 72 hours and 48 hours when a prescriber uses the exception where the practitioner reasonably determines that 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 or when the prescription will be dispensed by a pharmacy located out of state. MSSNY was informed yesterday by the DOH Bureau of Narcotic Enforcement that the information about "the issuance of the paper prescription" pursuant to one of these exceptions must include

- 1) That this is the notification required by PHL Section 281 (4) or 5
- 2) Physician's name
- 3) License number
- 4) Telephone number
- 5) Work email address
- 6) Work address
- 7) Patient's initials
- 8) The reason for invoking the exception including the citation to PHL Section 281 (3) technological or power failure, (d) patient harm or (e) out of state dispensing

Notably absent from this list is the number on the paper prescriptions written.

Notification to the Department of Health should be sent to: [erx@health.ny.gov](mailto:erx@health.ny.gov)

Additionally, MSSNY strongly recommends that use of the exceptions be included in the patient's medical record.

And, on March 16, 2016, NYS Health Commissioner Howard Zucker, MD issued a statement providing for 12 additional exemptions to the e-prescribing mandate. Those exceptions are as follows:

1. any practitioner prescribing a controlled or non-controlled substance, containing two (2) or more products, which is compounded by a pharmacist;
2. any practitioner prescribing a controlled or non-controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;
3. any practitioner prescribing a controlled or non-controlled substance that contains long or complicated directions;
4. any practitioner prescribing a controlled or non-controlled substance that requires a prescription to contain certain elements required by the federal Food and Drug Administration (FDA) that are not able to be accomplished with electronic prescribing;
5. any practitioner prescribing a controlled or non-controlled substance under approved protocols under expedited partner therapy, collaborative drug management or in response to a public health emergency that would allow a non-patient specific prescription;
6. any practitioner prescribing an opioid antagonist that would allow a non-patient specific prescription;
7. any practitioner prescribing a controlled or non-controlled substance under a research protocol;
8. a practitioner prescribing a controlled or non-controlled substance either through an Official New York State Prescription form or an oral prescription communicated to a pharmacist serving as a vendor of pharmaceutical services, by an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined in section twenty-eight hundred one of the public health law.
9. a pharmacist dispensing controlled and non-controlled substance compounded prescriptions, prescriptions containing long or complicated directions, and prescriptions containing certain elements required by the FDA or any other governmental agency that are not able to be accomplished with electronic prescribing;
10. a pharmacist dispensing prescriptions issued under a research protocol, or under approved protocols for expedited partner therapy, or for collaborative drug management;
11. a pharmacist dispensing non-patient specific prescriptions, including opioid antagonists, or prescriptions issued in response to a public health emergency issued; and
12. a pharmacist serving as a vendor of pharmaceutical services dispensing a controlled or non-controlled substance through an Official New York State Prescription form or an oral prescription communicated by

an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined in section twenty-eight hundred one of the public health law.

The above-listed exceptional circumstances will be effective until March 26, 2017. **According to an email that MSSNY received on March 17, 2016 from the NYS Bureau of Narcotics Enforcement, any use of these the exceptions does not require physicians to notify the Department of Health that they are using the exception.**

A copy of the Commissioner's letter can be found here:

[http://www.mssny.org/Documents/2016/Public\\_Health/E-prescribing/DOH\\_Commissioner\\_on\\_Eprescribing.pdf](http://www.mssny.org/Documents/2016/Public_Health/E-prescribing/DOH_Commissioner_on_Eprescribing.pdf)

#### **Waivers from e-prescribing requirement**

NYS Department of Health has issued over 2,600 one year waivers to prescribers. The law provides that physicians may apply for a waiver of the e-prescribing requirement for a) economic hardship b) technological limitations that are not reasonably within the control of the physician, or c) other exceptional circumstances.

Once a physician has received a waiver, they may issue the prescription on a paper script. According to the NYS Department of Health Bureau of Narcotic Enforcement, there is nothing in the law that says a physician must notify the pharmacy that they have received a waiver; however, physicians can place their waiver number on the script should they want to do so. Pharmacies should dispense medication whether the script has been e-prescribed or presented on the official NYS Prescription paper form.

#### **Information on obtaining a one year wavier is available at:**

[http://www.mssny.org/MSSNY/Public\\_Health/E-Prescribing/Online\\_Electronic\\_Prescribing\\_Waiver\\_Applications.aspx](http://www.mssny.org/MSSNY/Public_Health/E-Prescribing/Online_Electronic_Prescribing_Waiver_Applications.aspx)

The ISTOP legislation enacted in 2012 required e-prescribing of ALL substances. Regulations pertaining to the E-prescribing requirements were adopted on March 27, 2013. The Medical Society of the State of New York was successful in obtaining a one year delay in the implementation of the e-prescribing mandate due to the fact that the vendors were not in compliance with the DEA rules for EPCS. A copy of the regulations can be found at:

[http://www.health.ny.gov/regulations/recently\\_adopted/docs/2013-02-13\\_electronic\\_prescribing\\_dispensing\\_and\\_recordkeeping\\_of\\_controlled\\_substances.pdf](http://www.health.ny.gov/regulations/recently_adopted/docs/2013-02-13_electronic_prescribing_dispensing_and_recordkeeping_of_controlled_substances.pdf)

Additional information regarding e-prescribing may be accessed at the following links:

[http://www.health.ny.gov/professionals/narcotic/electronic\\_prescribing/](http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/)

<http://www.op.nysed.gov/prof/pharm/pharmelectrans.htm>