

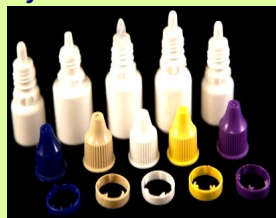
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FDA NEWS

FDA Warns of Eye Drop Safety Issue

The Food and Drug Administration (FDA) has issued a public warning about the possibility of eye injuries due to a common form of packaging used for ophthalmic medications. The warning involves eye drop bottles which have a safety seal or tamper-evident ring below the bottle cap (see photo below). When patients tilt the bottle to instill the drops, the safety seal or ring may fall off the bottle and injure the eye. The FDA is in the process of identifying all relevant products and will require a change in the packaging design. In the meantime, consumers and health care providers are encouraged to report adverse effects to the MedWatch program at: <http://www.fda.gov/Safety/MedWatch>



.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

Mandatory Electronic Prescribing Takes Effect in New York State on March 27, 2016

This month, New York becomes the second state to make electronic prescribing mandatory (Minnesota was the first, in 2011). As of March 27, all prescribing of both controlled and non-controlled substances must be done electronically, unless the prescriber or situation meets the requirements for one of the exceptions allowed by the state. Originally, there were 5 permanent exceptions to electronic prescribing described in the law (see *Table 1 below*). Additionally, on March 16 the Department of Health issued a temporary blanket waiver covering certain scenarios in which electronic prescribing cannot be performed due to limitations in software functionality (see *Table 2 below*). This new blanket waiver is effective until March 26, 2017.

Questions and Answers for Pharmacists Regarding E-prescribing

The following are some of the most frequently asked questions regarding mandatory electronic prescribing. The answers have been provided by the relevant agencies involved, including the Board of Pharmacy, Bureau of Narcotic Enforcement, and Department of Health. For more FAQs, see this month's *Law Review* column on page 2.

Q: Can a pharmacist fill a prescription issued on the Official New York State Prescription form after March 27, 2016?

A: Yes. Pharmacists are NOT required to verify that a practitioner properly falls under one of the exceptions from the requirement to prescribe electronically.

Q: Can written and/or oral prescriptions filled before March 27, 2016 be refilled after electronic prescribing becomes mandatory?

A: Yes.

Q: Are pharmacies required to print and maintain hard copies of e-prescriptions?

A: No. A hard copy is not required as long as the e-prescription is securely stored and maintained.

Table 1: Allowable Exceptions to Electronic Prescribing

- Prescriptions issued by veterinarians.
- Circumstances where electronic prescribing is not available due to temporary technological or electrical failure.
- Prescriptions issued by practitioners to whom the commissioner of health has granted a waiver from the requirement to use electronic prescribing.
- Circumstances where the prescriber 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 does not exceed a 5 day supply.
- Prescriptions issued by a practitioner to be dispensed by a pharmacy located outside New York State.

Table 2: Blanket Waiver from Electronic Prescribing

- Prescriptions containing 2 or more products to be compounded by a pharmacist.
- Prescriptions that contain long or complicated directions.
- Prescriptions containing certain elements required by the FDA or any other governmental agency that are not able to be accomplished with electronic prescribing.
- Non-patient specific prescriptions, including opioid antagonists, or prescriptions issued in response to a public health emergency.
- Prescriptions issued under a research protocol, or under approved protocols for expedited partner therapy, or for collaborative drug management.
- Prescriptions for patients in nursing homes and residential health care facilities as defined in section 2801 of the public health law.

MEDICAID UPDATE

Information Regarding the New
York State Medicaid Program

Medicaid Update on Electronic Prescribing Mandate

The New York State Department of Health has released guidelines for pharmacists regarding the upcoming implementation of mandatory electronic prescribing as it relates to filling prescriptions under the Medicaid program. In the February edition of the department's *Medicaid Update*, the following key points were presented:

- A prescription generated on an electronic system that is printed out on the Official New York State Prescription form or faxed is **NOT** an electronic prescription.
- Amendments to Title 10 NYCRR Part 80 New York Codes, Rules and Regulations on Controlled Substances have been adopted and became effective as final regulations on March 27, 2013. The amendments authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V and allow a pharmacist to accept, annotate, dispense and electronically archive such prescriptions.
- After March 27, 2016, a pharmacist is **NOT** required to verify that a practitioner properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from valid written, oral, or fax prescriptions that are consistent with current laws, regulations, and Medicaid policies.

The guidelines above are consistent with information we have received from other relevant agencies, including the Board of Pharmacy and the Bureau of Narcotic Enforcement. In general, the advice given is that pharmacists *may continue to fill* legitimate written and oral prescriptions issued after March 27, 2016.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Additional FAQs for Pharmacists Regarding Mandatory Electronic Prescribing in New York State

Mandatory electronic prescribing, for both controlled and non-controlled substances, becomes a reality in New York State on March 27, 2016. As of that date, all prescriptions must be delivered electronically from the prescriber directly to a pharmacy, unless the prescriber or situation falls under one of the exceptions listed on the front page of this issue. In our January issue we published a series of frequently asked questions about e-prescribing. Here are some additional FAQs, with answers provided by the New York State Department of Health.

Q: Are oral (phone in, verbal) prescriptions still permissible after March 27, 2106?

A: Yes, only if one of the following circumstances apply:

- Temporary power outage
- Temporary technical failure
- Practitioner has a waiver
- Practitioner is a Veterinarian
- Practitioner is out of state
- 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 substance **does not exceed a 5 day supply**

(Editor's note: Pharmacists accepting oral prescriptions after March 27, 2106 are NOT required to verify that the prescriber properly falls under one of the exceptions from the requirement to prescribe electronically.)

Q: Will practitioners be required to electronically prescribe non-prescription items, including durable medical equipment, which require a prescription for payment by a third party payor?

A: No, an electronic prescription will not be required. Section 281 (1) of the Public Health Law specifically references the use of electronic prescriptions for prescription drugs. A fiscal order may be required by third party payors for the purpose of payment. However, fiscal orders are not prescriptions and are not subject to the rules concerning electronic prescribing.

Q: New York State regulations state that the quantity of the dosage units and the number of refills must be indicated in both numerical and written word form on an Official New York State prescription (ONYSRx). Does this regulation pertain to electronic prescriptions as well?

A: No. While a quantity is required on all prescriptions, both the "numerical and written word form" are required to be on the ONYSRx form only. The intention of including both formats on the ONYSRx is to prevent alteration of the quantity or refills on a written prescription.

Q: Is the supervising physician's name required on an electronic prescription issued by a physician assistant?

A: Yes, the supervising physician's name is required on all prescriptions (controlled and non-controlled substances) issued by a physician assistant, including electronic prescriptions, handwritten official prescriptions, and official prescriptions generated on an EMR system.

Q: Can an unlicensed resident, intern, or foreign physician electronically prescribe controlled and non-controlled substances?

A: Yes. For further information see section 80.75 of the New York State Controlled Substance Rules and Regulations, available at www.pnnewsletter.com.

THERE'S AN APP FOR THAT: DIGITAL PHARMACY REFERENCES

How Many Pharmacists working today can remember a time when every pharmacy had a bookshelf filled with large, heavy reference books, and New York State law actually required the purchase of the 3 volume USPDI? Nowadays you can fit all the latest texts in the pocket of your lab coat, neatly tucked into your smartphone. In addition to a number of excellent subscription products, such as Lexicomp, there are also some free apps well worth downloading. We review some of the most popular below.

EPOCRATES



Website: www.epocrates.com

The most popular of all pharmacy apps, Epocrates has been offering its free drug reference since 1999, and is widely used by health care professionals.

Features:

- Detailed drug monographs (searchable by drug name or class)
- Interaction check
- Pill ID
- Calculators
- Tables

MEDSCAPE



Website: www.medscape.com

This news-intensive arm of WebMD is a great source for the latest research from leading medical journals.

Features:

- Most extensive medical news coverage of any currently available app (CE credit available)
- Detailed drug monographs (searchable by drug name or class)
- Interaction check
- Pill ID
- Calculators

MPR



Website: www.empr.com

Monthly Prescribing Reference is a well-respected subscription print publication for medical professionals.

Features:

- Abbreviated drug monographs (searchable by drug name or class)
- News updates
- Calculators
- Charts
- App contains advertisements at bottom of page

MICROMEDEX



Website: www.micromedex.com

Micromedex is the successor to the USPDI. App is *not* free if your company doesn't have an institutional subscription (a \$2.99 annual fee will apply).

Features:

- Detailed drug monographs (searchable by drug name or class)
- Good source for off-label uses (lists non-FDA approved indications)
- Good source for toxicology data
- Somewhat awkward interface

FDA DRUG SHORTAGES



Website: www.fda.gov

This official FDA app is the go-to source for information on drug shortages. Very helpful when you need to explain *why* a drug is not available, and when it may be available again.

Features:

- Searchable by drug name or class
- Lists current drug shortages, resolved drug shortages, and discontinuations
- Gives reason for shortage and availability and estimated shortage duration

ORANGE BOOK EXPRESS



Website: www.fda.gov

Official app for the FDA Orange Book (technically known as *Approved Drug Products with Therapeutic Equivalence Evaluations*).

Features:

- Search by active ingredient or proprietary name, manufacturer, application or patent number
- Search all marketing statuses (Rx, OTC, Discontinued) with one search
- Identify Reference Listed Drugs and determine if a product has a therapeutic equivalent

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ASK PRN...

Can a pharmacist fill a prescription for a controlled substance that does not contain the maximum daily dose (MDD)?

According to the Bureau of Narcotic Enforcement, omission of the MDD does *not* render the prescription invalid for dispensing. Pharmacists must exercise professional judgment when determining if clarification from the practitioner is necessary when an MDD is not included on a prescription. Pharmacists may call the prescriber and add the MDD to the prescription with the prescriber's authorization.

If a pharmacist receives an electronic prescription for a controlled substance which is missing required information which can not be added, such as the quantity to be dispensed, can the pharmacist call the prescriber for a 5 day emergency supply?

Yes. If the patient is in immediate need of the medication, the pharmacist may take an emergency 5 day supply oral prescription over the phone. Alternatively, the prescriber

may transmit a new electronic prescription containing the missing information, after first cancelling the original prescription. The list of items which may NOT be added or changed on a controlled substance prescription is as follows:

NEVER ADD	NEVER CHANGE
Patient Name	Patient Name
Practitioner Signature	Practitioner Signature
Date Written	Date Written
Drug Name	Drug Name
Quantity	

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW

that the symbol of pharmacy, the Bowl of Hygeia (seen here at right), is based on figures from ancient Greek mythology?¹ Hygeia, the goddess of health, was one of the daughters of Asclepius, god of medicine and healing. Hygeia is usually depicted with a serpent, the symbol of healing and renewal, and a bowl, perhaps containing a medicinal potion. Hygeia is also the source of the word "hygiene," and one of her sisters was Panacea, whose name became the word for a "cure-all." Asclepius is also associated with a well-known emblem, the serpent entwined around a staff, which is the international symbol of medicine.



PHARMACY FUN

Speaking of ancient mythological types, the Roman figure Janus was the god of both beginnings and endings, as well as lending his name to the first month of the year. In his honor we present a puzzle matching beginnings and endings, alphabetically speaking. There are a number of prescription drugs which have a generic name that begins with the letter "A", while their brand name begins with the letter "Z", or vice-versa. For example, there used to be a prescription version of *Aspirin* sold under the brand name *Zorprin* (named for the fact that it released the active ingredient in a zero-order kinetics fashion). We can think of 5 other examples of this Alpha-Omega situation, all of which are currently marketed prescription drugs. As an added incentive this month, we are offering a small prize: the first reader to submit all 5 correct answers will receive a custom-printed **PRN** binder, perfect for storing back issues of this periodical for easy reference. Simply send your answers to puzzle@prnnewsletter.com. Good luck!

Answers to last month's **PHARMACY FUN**:

Across: 2. GG 4. AC 5. TR 6. ADHD 8. OC **Down:** 1. GABA 3. GERD 5. THC 7. DO

References:

1. Ron Gasbarro, Pharm. D., *It was all Greek to them*. Special Supplement to Drug Topics: The Bowl of Hygeia. October, 2005.