What Would You Do?
Strategies to Deal With Everyday Pharmacy Law Issues in Community Practice

Joseph Bova
Patricia Donato
Fernando Gonzalez
Daniel Molino
John Westerman
• There are no conflicts on interest with the presenter today
What best describes your practice setting?

A. Community
B. Hospital
C. Nursing Home
D. Long term care
E. Academia
• Are you a supervising pharmacist?

A. Yes
B. No
C. You couldn’t pay me enough to do that!
SUPERVISING PHARMACIST

Education Law 6808
Rules of the Board of Regents Part 29.7
A pharmacist who is unable or unwilling to assume the responsibilities of the title of Supervising Pharmacist should not accept this appointment.
Responsibilities

- Proper record keeping
- Inventory management
- Insuring coverage of the pharmacy by licensed pharmacists
- Insuring unauthorized refills or drugs are dispensed
- Insuring proper security for the registered area
- Preventing unauthorized entry
Duties of Supervising Pharmacist

- Supervise the storage, sale, dispensing or compounding of drugs, poisons and restricted devices (i.e., hypodermis needles and syringes).

- Instruct **ALL** employees, either orally or in writing, at regular intervals relative to the appropriate activities in connection with the practice of pharmacy.

- When a Supervising Pharmacist is to be absent from a pharmacy at any time, he/she should be certain that another qualified pharmacist is present during his/her absence as provided under Education Law.
Be certain that the pharmacy is properly registered and operating in accordance with the present laws, rules and regulations. Use "reasonable" means to determine that the drugs being held for sale meet established standards (federal and state). Issue verbal and written notice to each of his/her subordinates concerning the laws, rules and regulations (federal, state, and local) relative to proper pharmacy practice. Insure that no prescription required drugs or devices are sold at wholesale unless the pharmacy possesses a New York State Board of Pharmacy wholesaler registration.
Discussion

- How many hours does a supervising pharmacist need to work?
- How long can a supervising pharmacist be on vacation or sick leave?
- Who is responsible for notifying the board of a change in supervision?
- How many days do I have to notify the board of a change in supervision?
Notice of Resignation of Supervising Pharmacist – PH226 ( 9 KB)

Notice of Change of Supervising Pharmacist – PH205 ( 8 KB)
Action: Application for consent order granted; Penalty agreed upon: 12 month stayed suspension, 12 months probation, $10,000 fine.

Summary: Registrant admitted to charges of failing to provide adequate supervision of a registered establishment, failing to prevent unlicensed persons from receiving oral prescriptions from prescribers, and failing to have the pharmacy under the immediate supervision and management of a licensed pharmacist at all hours when open.
Submitted questions:

An independent pharmacy offered her a position as SP. She is wondering if she takes the job, is she legally responsible for the prescriptions, inventories other pharmacist done in the past before she got hired????
Pharmacy Intern

Unlicensed person

Education Law §6806
Regulations of the Commissioner Part 63.2 and 63.4
Rules of the Board of Regents Part 29.7(a)(21)
Pharmacy Intern (Limited Permit)

- Students in an ACPE program or a foreign graduate that has passed NAPLEX and is approved are eligible for a limited (intern) permit.
- Authorizes practice as a pharmacist under the immediate personal supervision of a licensed pharmacist in New York State.
Role of Pharmacy Intern

A pharmacy intern may perform, under the supervision of a pharmacist, all of the functions delegated to pharmacists by law, rule or regulation except the administration of immunizations.
An unlicensed person may assist a pharmacist in the dispensing of drugs as provided for in Part 29.7 (a)(21)

No pharmacist shall obtain the assistance of more than two unlicensed persons in the performance of the activities

The pharmacist must provide appropriate supervision of unlicensed persons and ensure compliance with laws, rules and regulations
Role of Unlicensed Person

- Data entry
- Pulling drugs from stock and returning them to stock
- Counting drugs and placing them in containers
- Affixing labels to containers
- Preparing records
- Delivering a prescription to a patient (assuming counseling requirements have been met)
Unlicensed persons shall not:

- Receive oral prescriptions
- Interpret or evaluate a prescription
- Determine generic substitutions
- Sign or initial dispensing records
- Counsel patients
- Measure, weigh, compound or mix ingredients
- Perform any function that requires professional judgment
Manufacturing v Compounding
MANUFACTURING

Manufacturing requires

- Compliance with Current Good Manufacturing Practices (CGMP) regulations. CGMPS set requirements for methods, facilities, manufacturing controls, processing and drug packing.
- Compliance with federal labeling to provide for adequate directions for use.
- FDA approval prior to marketing (New Drug Application, Abbreviated New Drug Application, Therapeutic Biological Product Approval)
In NYS, all pharmacists, presuming they are competent to do so, may engage in compounding. However, compounding and dispensing by pharmacists and pharmacies is limited to patient-specific prescriptions or orders.
New York does not permit compounding “for physician’s office use” because it involves the dispensing of non-patient specific orders. Instead, New York considers this type of activity to be “manufacturing”.
Compounding Quality Act

Part of the Drug Quality and Security Act (DQSA) that was signed into law November 27, 2013

Compounding Quality Act – Title 1

- Amended 503A
- Added 503B
The practice of pharmacy is defined in Education Law §6801 as “the preparing, compounding, preserving, or the dispensing of drugs, medicine and therapeutic devices on the basis of prescriptions or other legal authority.” (Emphasis added).*
Prescriber Compounding

- Education law Section 6807 also allows limited compounding and dispensing by those licensed professionals (such as physicians and dentists) authorized to issue prescriptions in this state.
- Prescribers may only prepare products for delivery to their own patients.

Education Law 6807: [http://www.op.nysed.gov/prof/pharm/article137.htm#sect6807](http://www.op.nysed.gov/prof/pharm/article137.htm#sect6807)
A pharmacist may compound pursuant to patient specific prescription.
A pharmacist may NOT compound for office use

A registered pharmacy may not sell or transfer compounded prescriptions to another pharmacy despite common ownership of more than one pharmacy
PHARMACY COMPOUNDING

503A– TRADITIONAL PHARMACY PRACTICE
Provides pharmacies exemptions from 3 sections of the Federal Food, Drug, and Cosmetic Act (FDCA)

- Compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B));
- Labeling with adequate directions for use (section 502(f)(1)); and
- FDA approval prior to marketing (section 505)
Pursuant to a patient-specific prescription

Drug is compounded pursuant to the prescription in limited quantities by a pharmacist or physician

Drug is compounded in compliance with United States Pharmacopoeia (USP) chapters related to pharmacy compounding of bulk drug substances (USP 795 and USP 797)
Drug is compounded using bulk drug substances that are:
- manufactured by an FDA registered establishment
- accompanied by valid certificates of analysis

Drug is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP 795 & 797
Drug is not on the list of drugs withdrawn or removed from the market because they were unsafe or not effective

Drug is not a product that is essentially copies of commercially available drug products

Drug is not a product identified by FDA as too difficult to compound
Congressional Intent

“It is the intent of conferees to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations.”
503A Enforcement

NYS Board of Pharmacy will continue oversight and regulation of the practice of pharmacy, including prescription compounding
FDA intends to work cooperatively with states to address compounding activities that are in violation of FD&C Act, including 503A

Enforcement action by FDA

- Produced in insanitary conditions, mislabeled, does not meet purity and quality standards
- Misbranded, adulterated or unapproved
OUTSOURCING FACILITY

503B– OUTSOURCING FACILITY (OF)

- Provides that compounders of sterile drugs may register as “outsourcing facilities” and as such, qualify for certain exemptions from applicable FDCA manufacturer requirements, such as product approval and labeling requirements but NOT the requirement for compliance with current good manufacturing practices (CGMP).
503B OUTSOURCING FACILITY

- Is engaged in the compounding of STERILE drugs
- Has elected to register as an outsourcing facility
- Complies with all of the conditions in section 503B
- Is NOT required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist
- May or may not obtain prescriptions for identified individual patients
Provide compounded drug to hospitals and health care providers with drugs that have been prepared under CGMP requirements and federal oversight.
503B CONDITIONS FOR OUTSOURCING FACILITY – FEDERAL

- Must comply with Current Good Manufacturing Practices (CGMP)
- Must be compounded under the supervision of a licensed pharmacist
- Will be inspected by the FDA
- Must report adverse events
- Report products compounded to the FDA
503B CONDITIONS FOR OUTSOURCING FACILITY – NY STATE

- OF’s located in or shipping 503B products into the state must be registered with the Board of Pharmacy
- Have an annual inspection
- Have a NYS registered pharmacist as supervisor
- Report all products produced every 6 months
- Report all adverse events
- Maintain registration with the FDA
Regents action

- Action: Application to surrender registration granted.
- Summary: Registrant did not contest charges of compounding medications without patient specific prescriptions and distributing the medications in bulk for office use without a wholesaler’s or manufacturer’s registration;
after receiving notification that a drug compounded at the pharmacy failed sterility testing, failing to inform the prescriber and/or patient receiving the drug that it failed sterility testing; compounding medications without patient specific prescriptions and distributing said medication in bulk without a wholesaler’s or manufacturer’s license, in willful or grossly negligent failure to comply with New York Education Law
compounding medications without patient specific prescriptions and distributing said medications in bulk for office use; on more than one occasion, dispensing written prescriptions which did not contain the address and/or age of the patient for whom the prescription was intended; selling a batch of an adulterated drug, Avastin, and being aware that a sample of said batch of Avastin had microbiological contamination, and not following the pharmacy’s established written procedure in handling microbiological contamination in violation of good manufacturing practices
FDA REFERENCES

- Compounding Quality Act– Title I of the Drug Quality and Security Act of 2013
- Insanitary Conditions at Compounding Facilities Draft Guidance
- Compounding: Inspections, Recalls, and other Actions at FDA
• Electronic prescriptions in New York State
"Electronic prescription" means 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.
The application must electronically accept and store all of the information that DEA requires to be annotated to document the dispensing of a prescription. The application must allow the pharmacy to limit access for the annotation, alteration (to the extent such alteration is permitted by DEA regulations), or deletion of controlled substance prescription information to specific individuals or roles. *The application must have an internal audit trail that documents whenever a prescription is received, altered, annotated, or deleted.* The application must conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified. Many of these requirements are standard functionalities for pharmacy applications.
Patient: Michael Bloomberg
Address: Gracie Mansion
NY NY 10012

Drug: Zocor 20mg
S: One qd after dinner

Date Sent: 03-20-13 (10:13:13)
Date Received: 03-20-13 (10:17:50)
DOB: 03-15-12
Phone: 914-304-6409

Dispense: 30 tablets
Refill: 3 times

Prescriber:
Michael Ballant, MD
145 Main Street Ossining NY 10520

Phone: 914-941-1263
Fax: 914-941-8626
NPI#: 1902958720

This prescription will be filled generically unless prescriber writes “DAW” in the box below

Authorized by: Susan Wright, Office Manager
Brand or generic?

Education Law 6810 allows the prescriber to electronically sign and insert an electronic direction to dispense the drug as written.
For example.....NCPDP Codes

• Ø   No Product Selection Indicated
• 1   Substitution Not Allowed by Prescriber
• 2   Substitution Allowed-Patient Requested Product Dispensed
• 3   Substitution Allowed Pharmacist Selected Product Dispensed
• 4   Substitution Allowed Generic Drug Not in Stock
Patient: Michael Bloomberg
Address: Gracie Mansion
NY NY 10012

Drug: Zocor 20mg
S: One qd after dinner

Date Sent: 03-20-13 (10:13:13)
Date Received: 03-20-13 (10:17:50)
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Phone: 914-304-6409

Dispense: 30 tablets
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Prescriber:
Michael Ballint, MD
145 Main Street Ossining NY 10520

Phone: 914-941-1263
Fax: 914-941-8626
NPI #: AP7474567
NPI#: 1902968720

May ID#: 8DBFBC7206054745A1P6A7PC0043315C9
SPID#: 6721355908601

This prescription will be filled generically unless prescriber writes "DM" in the box below.

Dispense As Written

Authorized by: Susan Wright, Office Manager
Signing Vs Transmitting

- The signing and transmission of an electronic prescription are two distinct actions.
- Only the practitioner may review and electronically sign the prescription.
- Once signed, an agent or employee of the practitioner may transmit the prescription on behalf of the practitioner. The act of transmission must be independent of the review and signature process.
Is an electronic facsimile of a prescription considered an electronic prescription?

No. A definition of an electronic prescription can be found in Section 3302 Article 33 Public Health Law and specifically states that a prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription. Click on the following link for Section 3302: Section 3302 Article 33 Public Health Law.
What exceptions are there from the requirement to electronically prescribe?

- The following is a list of exceptions from the requirement to electronically prescribe and may be accessed from the following link: Article 2A - Section 281.

- Prescriptions issued by veterinarians

- 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 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.
Will the use of Official New York State Prescription forms be prohibited as of March 27, 2015?

- Official New York State Prescription forms may be used in the event of a power outage or technical failure, or by practitioners who meet one of the exceptions listed in Article 2A - Section 281 or Title 10 Part 80 Section 80.64.

- Please review this section of the law and regulations, which may be accessed from the following links: Article 2A - Section 281 and Title 10 Part 80 Section 80.64.

- Part 80.64
Will practitioners be required to electronically prescribe non-prescription items, including durable medical equipment, which require a prescription for payment by the third party payor?

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.
Does an electronic prescription for a controlled substance require a follow-up hard copy prescription?

• No.
Can I accept an out-of-state electronic prescription for a controlled substance?

- A pharmacist may dispense a controlled substance medication pursuant to an out-of-state electronic prescription as defined in Section 80.78 Title 10 Part 80 Rules and Regulations on controlled substances. Electronic prescriptions may be created, signed and transmitted from another state, provided the practitioner complies with all requirements, state and federal, for issuing controlled substance prescriptions electronically. It is prudent on the part of the pharmacist to verify the authenticity of any controlled substance prescription presented to them.
How often do I have to register my certified pharmacy software application with BNE?

- The certified pharmacy software application must be registered with BNE at least every two years or whenever functionality related to controlled substance prescription requirements is altered, whichever occurs first.
What's the law regarding transferring new prescriptions that have never been filled at our pharmacy? Can new rx's be transferred?

What are the documentation requirements?

For non-controlled substances, yes. The requirements are the same as for transferred refills.
UPDATES ERXS IN NY

Until March 27, 2017
Dear Practitioners and Pharmacists:

This letter is to inform you of a blanket waiver with respect to the electronic prescribing requirements, pursuant to Public Health Law (PHL) § 281 and Education Law § 6810, that go into effect on March 27, 2016, for exceptional circumstances in which electronic prescribing cannot be performed due to limitations in software functionality. The exceptional circumstances for which this waiver applies are set forth in this letter.

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) - Accredited Standards Development Organization that represents virtually every sector of the pharmacy services industry specific to the transfer of data relation. The standards developed by NCPDP allow only a limited number of characters in the prescription directions to the patient, including, but not limited to, taper doses, insulin sliding scales, and alternating drug doses.
Similarly, for compound drugs, no unique identifier is available for the entire formulation. Typing the entire compound on one text line may lead to prescribing or dispensing errors, potentially compromising patient safety.

Further, the New York State Department of Health (Department) is mindful that practitioners are required to issue non-patient specific prescriptions in certain instances, and that such prescriptions cannot be properly entered into the electronic prescription program.

Also, the Department acknowledges that in a nursing home/residential health care facility setting, electronic prescribing may not be available due to technological or economic issues or other exceptional circumstances, including a heavy reliance upon oral communications with the prescriber and pharmacy.
For these reasons, pursuant to the authority in Public Health Law § 281(3), I waive the following exceptional circumstances from the requirements of electronic prescribing:

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.
Practitioners issuing prescriptions in the above-listed exceptional circumstances may either use the Official New York State Prescription Form or issue an oral prescription; provided, however, that oral prescriptions remain subject to § 3334 and § 3337 of the PHL, which provide for oral prescriptions of controlled substances in emergencies and for other limited purposes, and subject to § 6810 of the Education Law. Pharmacists may dispense prescriptions issued on the Official New York State Prescription Form or oral prescriptions in the above-listed exceptional circumstances.
This waiver is hereby issued for the above-listed exceptional circumstances and shall be effective until March 26, 2017. Before March 26, 2017, I will determine whether the software available for electronic prescribing has sufficient functionality to accommodate these exceptional circumstances and whether New York’s nursing homes/residential health care facilities are better prepared to comply with e-prescribing requirements.
Memo dated 3/2/17 extends until 2018.…. 

For these reasons, pursuant to my authority in PHL § 281(3), I hereby continue to waive the following exceptional circumstances from the requirements of electronic prescribing:

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 for expedited partner therapy, collaborative drug management or comprehensive medication 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 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;

9. a pharmacist dispensing prescriptions issued under a research protocol, or under approved protocols for expedited partner therapy, or for collaborative drug management or comprehensive medication management; and

10. a pharmacist dispensing non-patient specific prescriptions, including opioid antagonists, or prescriptions issued in response to a declared public health emergency.
• Other waivers still in place
• § 3337. Oral prescriptions schedule III, IV and V substances.
The q&a released by BNE are clear- if any of the conditions exist that require a prescriber who is ERx certified to call in an Rx, for controlled drugs, this is limited to a 5 days supply. There is nothing that allows 30 days up to 100 for CIV.

To muddy the waters a little more, if the prescriber has a waiver than this prescriber MAY phone in 30 days/100 for C IV

.....2. No oral prescription shall be filled for a quantity of controlled substances which would exceed a five day supply if the controlled substance were used in accordance with the directions for use, except that with respect to a schedule IV substance such prescription shall not exceed a thirty-day supply or one hundred dosage units, whichever is less; provided, however, that this provision shall not apply to any schedule IV controlled substance limited to a five day supply by section thirty-three hundred thirty-four of this title (ed: benzos)
For all the Q & A:

THE NEW YORK STATE BOARD OF PHARMACY

GUIDELINE—ELECTRONIC RECORD-KEEPING REQUIREMENTS
Effective August, 2009 several amendments of rules and regulations were enacted to allow for the electronic maintenance of records by pharmacists. These provisions, and other clarifying information, may be viewed in their entirety at the following links:

http://www.oms.nysed.gov/press/PharmacyElectronicRecordkeeping.html

http://www.op.nysed.gov/prof/pharm/part63.htm#endorse

http://www.op.nysed.gov/title8/part29.htm#pha
Essentially, these provisions allow for the electronic receipt/copying/storage of many records without the need for hard-copy backup as previously required. In particular, those records required pursuant to article 137 of the education law and Regulations of the Commissioner of Education and Rules of the Board of Regents may be stored electronically.
Among the examples of records which may be maintained electronically are:

- Original prescriptions, received electronically or scanned, **both front and back as needed**
- Patient medication profiles
- Records of receipt and distribution of prescription drugs
- The daily log of all prescriptions filled and refilled, which also contain the identity of the pharmacist responsible for each prescription and other required information. Electronic “signatures” (which must be both unique and unalterable) may authenticate each pharmacist’s verification of the prescription for which the pharmacist is responsible.
It is imperative to know that all records previously required are still required. Recent amendments addressed the manner of storage, only. Further, Department representatives shall still have access to all requested documents, produced either in electronic or hard-copy fashion. All documents shall be readily retrievable, that is, available within 72 hours of a request if not immediately available.
Records required to be kept pursuant to other laws, rules and regulations may yet require hard-copy back up. Examples of this latter group of records are those pertaining to controlled substances and those relating to certain State and Federal payment plans such as Medicaid and Medicare.

Pharmacists are urged to consult with the plans and programs they participate in.
Failover Fax

Is an electronic prescription that fails over to facsimile (fax), "Failover fax", a valid prescription?

*Answer:* NO. A document that originated as an electronic prescription, but due to a temporary network outage or because your pharmacy is not enabled to receive prescriptions electronically, was converted to a computer-generated fax is NOT a valid prescription. A pharmacist receiving this order must call the prescriber, obtain confirmation of this prescription information, and document said confirmation as a telephoned prescription.
New Prescription Form

Prescriber: William Zarewitz
Transferred by designated agent: Zarewitz, William
145 Main Ave.
White Plains, NY 10601
Tel: 914-689-8880
Fax: 914-689-8880
NPI: 1134100933
NPI: 873158900

Pharmacy: [Redacted]
Briarcliff, NY 10510

Prescriber Order No.: FCWA-1002595-55966-2383
Rx Reference No.: [Redacted]

PRESCRIPTION AS FOLLOWS

Drug Prescribed: Norco (Opoid Capsule)
Quantity: 30 (3x10)
Dosage: 2 tablets daily
Directions: Take 1 caplet once a day only 30 days
Refill: [Redacted]
Expiry: [Redacted]

Diagnosis/Use: Primary 1013-9-941

Signature: William Zarewitz, M.D.

[Redacted]

This prescription will be filled specifically unless prescriber write in the box below

[Redacted]

Message: [Redacted]
[Redacted]

Confidential Notice: This contains confidential information protected by law and is only transmitted in a secure manner. If you are not this intended recipient, please contact the healthcare provider immediately at 914-689-8880 and stop this forwarding process or copying of this data strictly prohibited.

508-475-0450
Surescripts example when ERxs fail
An electronic prescription is not required for Over the counter (OTC) or durable medical equipment (DME) because these items are not prescription drugs.

A fiscal order (medical order) may be required for 3rd party reimbursement. However, fiscal orders are not prescriptions and are not subject to electronic prescribing requirements.
All records required under laws, rules and regulations administered by the Education Department may be maintained in an electronic format.

NOTE: Certain programs such as Medicaid and Medicare may have additional, hard-copy requirements.
Record Keeping

The information retained electronically should be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.
Record Keeping

- An original hard copy, facsimile or electronic prescription may be maintained electronically, provided it can be made available in hard copy upon request.

- An oral prescription may be electronically documented provided all required prescription information is entered into the electronic record and the electronic signature* or initials of the receiver of the prescription maintained.

*Electronic “signatures” must be both unique and unalterable.
Record Keeping

Daily log/record may be maintained electronically as allowed in Part 29.7(a)(8)

Daily log/record for all prescriptions must contain:

- Ordering practitioner
- Patient
- Assigned prescription number
- Pharmacist signature* or initials

*Electronic “signatures” must be both unique and unalterable.
What about robotics?

Do I have to contact the Board of Pharmacy if I install a robot?

Is it repackaging?
PATIENT COUNSELING
Which of the following best describes the NYS Counseling regulations?

A. Required on all Rxs
B. Required on all new Rxs and must be done by RPh or Intern
C. The offer to counsel is required on all Rxs and be offered by RPh
D. Delivered Rxs are exempt from counseling
• Remember to counsel all new Rxs or changes in therapy

• This must be done by pharmacist or pharmacy intern

• Anyone in pharmacy can make offer to counsel for refills

• See back of booklet for sample letter for Rx deliveries
I work at a closed door Specialty Pharmacy. What's the law regarding offering to counsel since we are not seeing patient face to face. Can an automated voice recording on the phone stating to speak to a pharmacist about their medication suffice offer to counsel? What other methods can we use to offer as counseling?

That is not sufficient. Please refer to section 63.6 of the Regulations of the Commissioner of Education that outlines the requirements for counseling when prescriptions are delivered
Who counseled this patient?
RETURNING PRESCRIPTION DRUGS TO STOCK
Placing in stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; provided, however, that in a health care facility, including but not limited to a general hospital, which has its own pharmacy and in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and labeled with the name of the drug, dosage strength, manufacturer's control number and expiration date, the unused unit dose of medication may be returned to the pharmacy of the facility for redispensing;
and provided further that unused medication may be returned to pharmacies by residential health care facilities in accordance with the provisions of 10 NYCRR 415.18(f) or by other facilities, including but not limited to county correctional facilities, provided that such other facilities utilize standards, policies and procedures determined by the State Board of Pharmacy to be equivalent to those enumerated in 10 NYCRR 415.18(f).
Pharmacists cannot ignore the financial drain that will occur if inventories are not carefully maintained. For this reason, many have questioned whether it is possible and proper to return drugs to stock when prescriptions have been prepared, though not delivered to a patient.
The New York State Board of Pharmacy advised that "dispensing" is a continuum that includes received and interpreting a prescription, packaging and labeling the medication, and delivering the filled prescription to the patient following proper counseling.
For a variety of reasons, many prescriptions are prepared for delivery to patients though never picked up or otherwise received by those patients.
Since these products have not left the control of the pharmacy, their return to stock and subsequent redispensing to other patients does not, in and of itself, constitute misbranding or adulteration. However, certain safeguards must be adhered to.
The following factors must be considered to assure the quality of medications is maintained:
Prescriptions that have not been picked up by or delivered to patients ("will call prescription") should be checked periodically.

Those prescriptions not dispensed (delivered) to patients should be assessed by a pharmacist to determine whether they might safely be returned to stock. For example, reconstituted antibiotic suspensions have a limited shelf life and are likely not eligible for redispensing.
Products deemed eligible for redispensing must never be mixed within stock bottles of different lot numbers and/or with different expiration dates. Likewise, manufacturers' stock bottles must never be over-filled. Mixing drugs from different lots and over-filling containers may lead to charges of misbranding/adulteration under federal and state laws. Therefore, the only safe manner in which drugs are returned to stock bottles is in those pharmacies in which all medications are tracked by lot numbers and expiration dates.
In those instances in which medications cannot be properly and safely returned to the original stock bottle, the medication may be held in the pharmacy in the container in which it has been repackaged. *(no need to “strip” Rx label)*

It is recommended that pharmacies develop an internal manner for so identifying these products.
Medications held for redispensing should be used as soon as possible; in no circumstance may these drugs, lacking original lot numbers and expiration dates, be dispensed to patients beyond 6 months from the date the drugs were first prepared for dispensing.
If the manufacturer or the FDA orders a recall of a drug product, pharmacists must assume products held in containers without lot numbers are included in the recall and proceed accordingly.
Submitted question:

I would like to know if the return to stock expiration date regulation has been updated from a 6 month date to a 12 month one. I am referring to any prescription medication that has been removed from the original stock bottle and placed in an amber vial which the patient does not pick up and the medication needs to be returned to the shelf. A 6 month expiration date from the date of dispensing was put on the bottle that was returned to stock, now I am told this has changed to 1 year. Is this the new regulation?
There has been no such change
Be prepared for a NYS Inspection
The University of the State of New York
Office of Professional Discipline

Pharmacy Inspection Report

Inspection conducted by:

Investigator:

Date: Time In/Out: / 

1. Routes
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
6. Medication Record
7. Complaint Received
8. Follow-up to Previous Inspection
9. Special Project or Renovation

Reg. name:

Trade name:

No. and Street:

City: County: Zip:

Reg. #:

Telephone:

Hours open per week:

# RA's Daily:

Pharmacists' Names

S.P.

Pharm.

Pharmacy

Pharm.

Pharmacist

Detailed description:

Details of Inspection:

Recommendation (completed in office):

I have received a copy of this inspection report.

Investigator:

Signature:

Supervisor:

Print name:

Title:

Date:

This is page of page(s)

OGJ 32K 826015.11.09.0 CML
<table>
<thead>
<tr>
<th>PHARMACY INSPECTION REPORT</th>
<th>☑️ Pharmacy</th>
<th>☑️ M/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspection #</td>
<td></td>
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<td>Investigator</td>
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<tr>
<td>Date</td>
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<tr>
<td>Time In/Out</td>
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</tr>
<tr>
<td>1. Routine</td>
<td>6. Medication Recall</td>
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</tr>
<tr>
<td>2. New Registration</td>
<td>7. Complaint Related</td>
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</tr>
<tr>
<td>3. Transfer Ownership</td>
<td>8. Follow-up to Previous Inspection</td>
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<tr>
<td>4. Discontinuance</td>
<td>9. Special Project or Renovation</td>
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</tr>
<tr>
<td>5. Change of Name/Address</td>
<td></td>
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<tr>
<td>Reg. name</td>
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<tr>
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<td>Zip</td>
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<td>Telephone</td>
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</tr>
<tr>
<td>Hours open per week</td>
<td># RXs daily</td>
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</tr>
<tr>
<td>Pharmacists' Names</td>
<td>Hrs. Per Week</td>
<td>License Number</td>
</tr>
<tr>
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</tr>
<tr>
<td>S.P.</td>
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<tr>
<td>Pharm.</td>
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<tr>
<td>Pharm.</td>
<td></td>
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</tr>
<tr>
<td>Intern</td>
<td></td>
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</tbody>
</table>
Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below. Be sure to include item number in explanation.

<table>
<thead>
<tr>
<th>Item</th>
<th>S</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Registration name on exterior</td>
<td>S</td>
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<tr>
<td>2. Licenses/current reg. displayed</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>3. Registered pharmacist on duty</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>4. Equip., facilities, and ref. items</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>5. Price list available/current</td>
<td>S</td>
<td>N</td>
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<tr>
<td>6. Drug stock current</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>7. Stock properly branded</td>
<td>S</td>
<td>N</td>
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<tr>
<td>8. Daily RX record</td>
<td>S</td>
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<tr>
<td>9. Required RX filings</td>
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<td>N</td>
</tr>
<tr>
<td>10. DEA records complete/available</td>
<td>S</td>
<td>N</td>
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<tr>
<td>11. Safety/approp. closures/containers</td>
<td>S</td>
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</tr>
<tr>
<td>12. RX labels required information</td>
<td>S</td>
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<tr>
<td>13. Valid RX formats</td>
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<td>N</td>
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<tr>
<td>14. Substitution law compliance</td>
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<td>N</td>
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<tr>
<td>15. Required information on RXs</td>
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<td>N</td>
</tr>
<tr>
<td>16. Refill authorization/fill</td>
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<tr>
<td>17. Refills in daily record</td>
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<td>N</td>
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<tr>
<td>18. Controlled substance compliance</td>
<td>S</td>
<td>N</td>
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<tr>
<td>19. General sanitation</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>20. Intern/unlicensed supervision</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>21. Counseling offered/given/refusals documented</td>
<td>S</td>
<td>N</td>
</tr>
<tr>
<td>22. Types of pharmacy (circle those applicable): retail, hospital,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>skilled nursing, assisted living, compounding, sterile preparation,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>internet, home delivery, mail delivery, nuclear, veterinary</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Details of Inspection


Recommendation (completed in office)

Investigator

Supervisor

I have received a copy of this inspection report.

Signature

Print name

Title _____________________________ Date __________
PROPER PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES NY STATE
Bureau of Narcotic Enforcement
• What about the DEA??
New York State Department of Health

Bureau of Narcotic Enforcement

http://www.health.ny.gov/professionals/narcotic
Narcotic Enforcement

Changes to Controlled Substance Schedules in New York State

Effective August 14, 2011, the following changes were made to the controlled substance schedules in Section 3366 of the New York State Public Health Law. The changes are summarized below.

Schedule I Additions
- 4-methylmethcathinone (Mephedrone)
- Methylendioxypyrovalerone (MDMA)

Effective October 13, 2010, the following changes were made to the controlled substance schedules in Section 3366 of the New York State Public Health Law. The changes are summarized below. Where applicable, some common brand name pharmaceutical preparations containing the controlled substances are listed in bold:

Schedule II Additions
- Opiates
  - Lidocaine (i.e., Xylocaine)
  - Language defining anabolic steroid was amended; unless specifically excepted or unless listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids and dehydroepiandrosterone), that promotes muscle growth, or any material, compound, mixture or preparation which contains any amount of the following substances:
    - 41 New Anabolic Steroids
    - 13 Anabolic Steroid names were clarified

Schedule III Additions
- Embutramide (i.e., Embutidine)

Schedule IV Additions
- The new law made no additions to Schedule IV.

Schedule V Additions
- Pregabalin (i.e., Lyrica)
Laws and Regulations

Follow the instructions below to view the laws and regulations governing controlled substances and the official prescription forms in New York State.

Laws

- Visit New York State Legislature
  - Select the link for "Laws of New York".
  - Select the link for "Title 21 - Public Health".
  - Select the link for "Title 21 - Official New York State Prescription Forms".
  - Select the link for Article 22 - Controlled Substances.

- Download a printable version of Public Health Law Article 22 - Controlled Substances (PDF, 39KB, 16pg) - Current as of October 25, 2011.

Regulations

- Visit Part 60 - Controlled Substance Regulations
  - Select the link for "Search Title 16".
  - In the "Search for" field, type "Part 60" and click the "Search" button.
  - Select the link for "Part 60 - Rules and Regulations On Controlled Substances".
  - Download a printable version of Part 60 - Rules and Regulations On Controlled Substances (PDF, 425KB, 145pg) - Current as of May 13, 2009.

- Visit Part 910 - Official New York State Prescription Forms Regulations
  - Select the link for "Search Title 16".
  - In the "Search for" field, type "Part 910" and click the "Search" button.
  - Select the link for "Part 910 - Official New York State Prescription Forms".

http://public.health.ny.gov
Changes to Controlled Substance Schedules in New York State

Effective August 14, 2011, the following changes were made to the controlled substance schedules in Section 3366 of the New York State Public Health Law. The changes are summarized below.

**Schedule I Additions**
- 4-cholesten-3-one (Mephedrone)
- Methyleneoxymethyl-1P-(1P-hydroxyethyl)-pent-9-en-2-one

Effective October 13, 2010, the following changes were made to the controlled substance schedules in Section 3366 of the New York State Public Health Law. The changes are summarized below. Where applicable, some common brand name pharmaceutical preparations containing the controlled substances are listed in bold.

**Schedule II Additions**
- Opiates
- Labeled anabolic steroid (i.e., nandrolone)
- Language defining anabolic steroid was amended. Unless specifically excepted or unless listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmaceutically related to testosterone (other than estrogens, progesterone, corticosteroids and dehydroepiandrosterone) that promotes muscle growth, or any material, compound, mixture or preparation which contains any amount of the following substances:
  - 15 New Anabolic Steroids
- 16 Anabolic Steroid names were clarified

**Schedule III Additions**
- Embutramide (i.e., Embutane)

**Schedule IV Additions**
- The new law made no additions to Schedule IV.

**Schedule V Additions**
- Pregabalin (i.e., Lyrica)

Electronic Prescriptions for Controlled Substances

The March 31, 2010 Federal Register contained a Drug Enforcement Administration (DEA) Interim Final Rule with Request for Comment regarding Electronic Prescriptions for Controlled Substances. The DEA has revised its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense and archive these electronic prescriptions. The DEA rules became effective June 1, 2010.

In anticipation of adoption of the DEA rule, the Department of Health has been working to update its regulations to allow for electronic...
<table>
<thead>
<tr>
<th>Narcotic Enforcement</th>
<th>Practitioners</th>
<th>Pharmacies</th>
<th>Licensed Facilities/Individuals</th>
<th>Consumers</th>
<th>Law Enforcement</th>
<th>Forms</th>
<th>Laws &amp; Regulations</th>
<th>Contact</th>
<th>Narcotic Enforcement Home</th>
</tr>
</thead>
</table>
Narcotic Enforcement

Changes to Controlled Substance Schedules in New York State

Effective August 14, 2011, the following changes were made to the controlled substance schedules in Section 3306 of the New York State Public Health Law. The changes are summarized below.

Schedule I Additions

- 4-methylmethcathinone (Mephedrone)¹
- Methyleneoxyxymethamphetamine (MDPV)²

Effective October 13, 2010, the following changes were made to the controlled substance schedules in Section 3306 of the New York State Public Health Law. The changes are summarized below. Where applicable, some common brand name pharmaceutical preparations containing the controlled substances are listed in bold.

Schedule II Additions

- Oxycodone
- Lisdexanet Amanda (i.e., Vyvanse)
- Language defining an anabolic steroid was amended: Unless specifically excepted or unless listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids and dehydroepiandrosterone) that promotes muscle growth, or any material, compound, mixture, or preparation which contains any amount of the following substances:
  - All New Anabolic Steroids²
  - 18 Anabolic Steroid names were classified²

Schedule III Additions

- Embutanida (i.e., Embutane)

Schedule IV Additions

- The new law made no additions to Schedule IV.

Schedule V Additions

- Pramabain (i.e., Lyrica)

Electronic Prescriptions for Controlled Substances

The March 21, 2010 Federal Register contained a Drug Enforcement Administration (DEA) Interim Final Rule with Request for Comment regarding Electronic Prescriptions for Controlled Substances. The DEA has revised its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense and archive these electronic prescriptions. The DEA rule became effective June 1, 2010.

In anticipation of adoption of the DEA rule, the Department of Health has been working to update its regulations to allow for electronic...
Regulations...80.63...Prescribing

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

(1) an official New York State prescription;

(2) an oral prescription; or

(3) 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.
• What about electronic?  What about transfers?
(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; and (ii) an emergency exists; and....
• (iii) the prescription does not exceed a 5 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 section 80.68 and section 80.70 of this Part. (80.68 defines emergency and 80.70 are the rules for oral Rxs for controls)
Who May Prescribe Controlled Substances (NY)?

A physician (including DOs), dentist, podiatrist, veterinarian, scientific investigator (limited), or other person licensed, or otherwise permitted to dispense, (including duly authorized Midwives, Nurse Practitioners, Physician Assistants and pharmacists in a CDTM setting***)

*NOT TO INCLUDE OPTOMETRISTS*
Official prescriptions written by a Physician's Assistant must contain the imprinted (stamped or typed) name of both the Physician's Assistant and the Supervising Physician and DEA # of PA (same for non controls).

Same applies to RPh in CDTM

It is not required to be countersigned by the supervising physician.

Rx’s only within scope- must be patient of supervising MD
Certified Nurse Practitioner (NP)

- Uses own Rx Blank
- All Rx info including “F” reg number
- May prescribe controlled substances if registered with DEA for all classes
- Own signature appears on Rx
Prescribing within scope of practice

- MDs
- Vets
- DDS
- Podiatrists
- RPAs
- NP **
- RPh
Nurse Practitioners specialty prefixes

- And the letter “F”
- Acute care  43
- Adult care   30
- College Health  31
- Community Health  32
- Family Health  33
- Gerontology  34
- Holistic Nursing  45
- Neonatology  35
CNPs continued

- Ob/Gyn 36
- Oncology 37
- Palliative Care 44
- Pediatrics 38
- Perinatology 39
- Psychiatry 40
- School Health 41
- Women’s Health 42
Purpose of issue  80.65
80.65 Purpose of issue. A prescription, in order to be effective in legalizing the possession of controlled substances, shall be issued for **legitimate medical purposes only**. The responsibility for the proper prescribing and dispensing of controlled substances shall be on the physician, dentist, podiatrist, veterinarian or other authorized practitioner, **but a corresponding liability shall rest with the pharmacist who fills the prescription.**
An order purporting to be a prescription, issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with narcotics or other controlled substances sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning of subdivision 30 of section 3302 of the Public Health Law and the person knowingly filling such an order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances.
Section 80.63 requires a practitioner to physically examine a patient prior to initially prescribing a controlled substance. Issuing an Rx for a c.s. solely on the basis of a questionnaire or other medical history submitted to a practitioner over the internet does not meet the requirements of a physical examination or establish a legitimate practitioner-patient relationship and is not a valid Rx......
Once the initial examination has been made, the necessity for future examinations, and their frequency, is a matter of clinical judgment based on generally accepted medical standards.
Profession: Pharmacist; Lic. No. XXXXXX; Cal. No. 23515  
Regents Action Date: January 15, 2008  
Action: Application for consent order granted; Penalty agreed upon: 1 year actual suspension, 1 year stayed suspension, 2 years probation, $5,000 fine.  
Summary: Licensee did not contest charges of dispensing medications, including controlled substances, pursuant to internet prescriptions; failing to maintain a record of internet prescriptions dispensed;
• Written prescriptions for controlled substances
All prescriptions written in NY must be written on an official NYS Rx (no matter where they are to be filled)
Or be acceptable ERxs
How long is a c.s. Rx valid?

- 80.73 Pharmacists.

(a)...... presented within 30 days of the date such prescription was issued by the authorized practitioner
Note: DEA # in most cases will not be imprinted. In order for a controlled substance Rx that is written to be valid, the DEA # of the prescriber MUST be on the Rx....
Adhesive stickers and labels containing only patient information are valid for use on official prescriptions for *non-controlled substances* if they are affixed permanently to the prescription. Patient information includes the patient name, address, and date of birth.
**Maximum Daily Dose**

It is the view of BNE that controlled substance regulations require the prescriber to indicate the MDD on all controlled substance Rxs. The pharmacist is required to indicate the specific directions for use, as stated on the prescription, on the label. Therefore, if the prescriber indicates an MDD on the Rx, the pharmacist should indicate this on the label.
• I understand what is required but what if it is missing?
• NY BNE regulations (80.68 and 80.69) allow pharmacies to add/change patient information (except patient name) through good faith effort utilizing their professional judgment. The pharmacist may also add or change information after obtaining authorization from the practitioner...
### Regs 80.68 and 80.69

Adding or changing information on a written Rx for a controlled drug in New York

<table>
<thead>
<tr>
<th>Add w/ Pract. authorization</th>
<th>Add without auth. with good faith effort</th>
<th>Never add</th>
<th>Change w/ Pract. authorization</th>
<th>Change without authorization</th>
<th>Never change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pract DEA #</td>
<td>Patient address</td>
<td>Patient Name</td>
<td>Pract DEA #</td>
<td>Patient address</td>
<td>Patient Name</td>
</tr>
<tr>
<td>Instit. DEA #/ suffix</td>
<td>Patient sex</td>
<td>Pract. signature</td>
<td>Instit. DEA #/ suffix</td>
<td>Patient sex</td>
<td>Pract. signature</td>
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<tr>
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<td>Date written</td>
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<td>Quantity</td>
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<td>Strength</td>
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<tr>
<td></td>
<td></td>
<td>Dosage form</td>
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<td></td>
</tr>
</tbody>
</table>

Reprinted in back of booklet
What about institutional DEA numbers?
The only practitioners who, upon authorization from the facility, may use the facility's DEA number to issue controlled substance prescriptions for patients of such facility are **unlicensed residents, unlicensed interns and unlicensed foreign physicians**. Residents, interns and foreign physicians are not eligible for their own DEA registration number. Anyone may use institutional blanks
• How much can I dispense?
• 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.
• This rule is true for all classes of controlled substances
• But I thought I could give a three month’s supply?
• 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.
Condition Codes for up to a 3 month supply of a controlled drug or up to a six month supply of an anabolic steroid or chorionic gonadotropin (HCG)

<table>
<thead>
<tr>
<th>Code A: Panic Disorder</th>
<th>Code B: Attention Deficit Disorder</th>
<th>Code C: Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code D: Relief of pain in patients suffering from diseases known to be chronic and incurable.</td>
<td>Code E: Narcolepsy</td>
<td>Code F: Hormone deficiency states in males, gynecologic conditions that are responsive with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema.</td>
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# Written Rxs

<table>
<thead>
<tr>
<th>Class</th>
<th>Maximum Qty allowed</th>
<th>Up to 90 days?</th>
<th>Up to 90 days with refills?</th>
<th>Up to 180 days?</th>
<th>Refills?</th>
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<tr>
<td>C II</td>
<td>Up to 30 days supply</td>
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<td>No</td>
<td>Yes</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>C III</td>
<td>Up to 30 days supply</td>
<td>Yes</td>
<td>Yes-1 only</td>
<td>No</td>
<td>Up to 6 within 6 months of date of issue</td>
</tr>
<tr>
<td>C IV</td>
<td>Up to 30 days supply</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>Up to 30 days supply</td>
<td>Yes</td>
<td>Yes-1 only</td>
<td>No</td>
<td>Up to 6 within 6 months of date of issue</td>
</tr>
</tbody>
</table>
New legislation enacted to limit initial opioid prescribing to a 7 day supply for acute pain. Effective July 22, 2016.
TO FURTHER REDUCE OVERPREScribing of OPIOid MEDICATIONS,
EFFECTIVE JULY 22, 2016, INITIAL OPIOid PRESCRIBING FOR ACUTE PAIN IS
LIMITED TO A 7 DAY SUPPLY. A practitioner may not initially prescribe more than a
7-day supply of an opioid medication for acute pain. Acute pain is defined as pain,
whether resulting from disease, accidental or intentional trauma, or other cause, that
the practitioner reasonably expects to last only a short period of time
This rule SHALL NOT include prescribing for chronic pain, pain being treated as a part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with existing rules and regulations, any appropriate renewal, refill, or new prescription for an opioid.
Can a pharmacist dispense/fill a prescription for a 30-day supply of an opioid?

A. Yes. Although pharmacists may continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws and regulations.
• The leaflet reprinted in the back of this booklet is required to be given to each patient or caregiver every time ANY controlled drug is dispensed.

• This applies to NEW AND REFILLS

• E version is acceptable (page 6-7)
Partial filling at patient request

Refer to 80.74: 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.

(C III, CIV (except benzos) and CV)

All part fills must be done within 30 days

If CIIs or benzos are reduced the balance of the Rx is void.
Partial fill— not in stock

• (I) A pharmacist may partially fill an 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:
the pharmacist does not have a sufficient quantity to fill an 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 with 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.
• Telephoned Rxs for controlled drugs
INFORMATION REQUIREMENTS. Oral Rxs

- Prescriber’s name, address, **DEA number**
- Patient’s name, full address
- Date of oral order
- Name, quantity, and directions for use of drug and maximum daily dose (MDD) **
- Generic substitution (permitted or prohibited)
- Notation (telephone order)
- Pharmacist’s initials or signature
• How much is permitted for a phoned or faxed Rx for a controlled drug?
<table>
<thead>
<tr>
<th></th>
<th><strong>Maximum Quantity</strong></th>
<th><strong>Refills</strong></th>
<th><strong>Covering Rx</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anabolic Steroids</strong></td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
</tr>
<tr>
<td><strong>Other C II s</strong></td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
</tr>
<tr>
<td><strong>C III</strong></td>
<td>Up to 5 days supply</td>
<td>None*</td>
<td>Required but no reporting needed</td>
</tr>
<tr>
<td><strong>Benzodiazepines</strong></td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
</tr>
<tr>
<td><strong>C IV</strong></td>
<td>Up to 30 days-max 100 dosage units</td>
<td>None *</td>
<td>Required but no reporting needed</td>
</tr>
<tr>
<td><strong>C V</strong></td>
<td>Up to 5 days supply</td>
<td>None *</td>
<td>Required but no reporting needed</td>
</tr>
</tbody>
</table>
Emergency defined: all must exist and determination is made by the prescriber. *You should note this on Rx*

1) Immediate administration of the drug is necessary

2) No alternative treatment is available

3) No possible way to write the Rx now
• What about refills? And what does refill prn mean?
• What about a followup or covering Rx?
Prescribers must send follow-up prescriptions to pharmacies within 72 hours of placing the oral order. Upon receiving a follow-up prescription, pharmacists must endorse on the face of the prescription the prescription number, date of filling, their signatures, and the statement that the prescription is a follow-up. The following statement must be placed on the back of the prescription: “Follow-up prescription to oral order _____ [Rx number], oral order filled on _ [date], issued prescription received ____ [date].”
The oral order must be attached to the follow-up prescription and filed in the Schedule III, IV, and V files. When a follow-up prescription is not received, the pharmacist must record on the back of the oral order the statement “Written prescription not received,” with the date and the name of the pharmacist, and place it in the appropriate file.
CII's and Benzodiazepines

- When a follow-up Rx is not received, the pharmacist must notify the NYS Bureau of Controlled Substances in writing within seven days. The DEA must also be notified, but the method and time frame are not specified in federal law. Although not required by federal or state regulations, it is good practice for a pharmacist to note when a follow-up prescription is not received, and date, sign, and file the oral memorandum in the appropriate prescription file.
If the written followup prescription differs in relation to the substance, strength, or directions for use, the pharmacy MUST consider the written prescription “a new prescription” which DOES NOT COVER the oral prescription.”
E RX Covers– effective since March 2013

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.
“Canceling the Rx”….80.73

The pharmacist filling the prescription shall endorse upon the face of 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.
Refills..............

Each time a controlled substance is dispensed, the dispensing pharmacist must sign the actual prescription form, date it, and indicate the quantity dispensed. (A computer-generated sticker may be used for the date of dispensing and quantity dispensed, but **not** the signature of the dispensing pharmacist.)

Exception– new*****
... 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.
File it…3 separate

- Non Controls- including n/s
- III, IV, V  (including benzos)
- II
**Maximum Daily Dose**

The pharmacist is required to indicate the specific directions for use, as stated on the prescription, on the label. Therefore, if the prescriber indicates an MDD on the Rx, the pharmacist should indicate this on the label.
PHARMACIST LABELING of C/S under the ORANGE LABEL LAW

allow the choice of:

a. ORANGE label & 2 caution labels (1 federal & 1 state caution label)
b. ORANGE tape over white label & 2 caution labels
c. Your standard label with 2 ORANGE caution labels using black lettering on the caution labels

Federal Caution Label or (FEDERAL) TRANSFER CAUTION LABEL
(for CII, CIII, and CIV only) READS:

“CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was intended”

State Caution Label for ALL C/S dispensed in NEW YORK STATE
READS:

“CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED”
Controlled Substance Inventory

This federal requirement is strengthened by New York State in Part 80 (80.100; 80.111; 80.112)

- Biennial (every two years) on May 1\textsuperscript{st} of ODD years \textcolor{red}{(2017!)}
- Recorded as to OPEN or CLOSE of the day’s business
- Schedule II inventory (actual count) separate from CIII, CIV & CV
- Signed by the person taking it
- Records maintained on the premises
- Maintained for 5 years
Controlled substance prescriptions issued "For Office Use" are not valid for dispensing by a pharmacy, since such prescriptions must be issued solely for a specific patient.

(same for non controls)
Controlled Substances for Office Use

Public Health Law, Section 3320, requires practitioners to obtain any controlled substances for use in their practice **only from a manufacturer or distributor** licensed by the Bureau of Narcotic Enforcement.
• Prescriptions from out of state may be filled for controlled substances. The usual precautions to be taken.

• Use “zzzzzzzzz” in the file for the serial number.
What do you do?
Do I need to ask everyone for identification when picking up a controlled substance?
What do you do?

• Can pharmacist from NEW YORK legally deny transfer of a refill to another pharmacy?

• Technically, a pharmacist could do that; but we would hope the needs of the patient were the primary consideration
What do you do?

- Can an agent or employee of the prescriber electronically create and electronically transmit an electronic prescription to the pharmacy?

- EVERY electronic prescription has to be personally approved by the prescriber—once approved most systems allow the prescriber to transmit. Presumably, another person could affect the transmission FOLLOWING explicit, non–delegated approval of the prescription by the prescriber.
What do you do?

- Can a NYS pharmacy dispense compounded medication for in-office use to prescribers?

- No “in office” use is not acceptable. A prescription must be patient-specific.
What do you do?

• If a pharmacist compounds a medication with all OTC ingredients is a prescription required to sell to patient?

• Yes, a prescription is needed.
What do you do?

- Is it legal for a pharmacy to take back unused prescription medications and refund to the original purchaser?

- For controlled substances, the answer is no, they may never be returned to pharmacy.

- For non-controlled may accept the return for the purpose of destruction & may not be re-used.
What do you do?

- Can a dentist prescribe anti-depressants?

- Dentist may not treat depression, however a dentist may prescribe meds for depression FOR AN (off-label) USE. Such as treating TMJ pain. This would not be outside the scope.
Can a prescription for Suboxone be refilled?

The answer is yes 5 times within a 6 month’s from the date of MD’s issuance.
What do you do?

- How many CE credits do I need per each three-year registration period?

- A minimum of 45 CE credits is required for every 3 year registration. At least 23 must be live & 3 credits must be on reducing med errors.
What do you do?

- I have a narcotic shortage at my pharmacy who should I report it to?

- Each company may have different reporting procedures but as the S.P. or Pharmacist in Charge, you must report to:
  - DEA– using form 106
  - BNE–using form 2094
I'm in a hospital setting. Upon discharge sometimes patients get Rx for drugs which need prior authorization. Can pharmacist get those approvals if they have enough information regarding doctor, insurance and a valid diagnosis under legal parameters?
I know that there is a law that states that a pharmacist is to use their clinical judgment and has the right to deny a prescription if they truly feel that the prescribed medication will cause harm to the patient. I am unsure if this is a state law or federal law but I would love to cite the law. Is there anyway that you would be able to track down this law and tell me where I can find it?

There is no such law in New York State that explicitly states what is otherwise considered professional judgment.
What-do-you-do?

I was told that NY is a “no-call” state-if an Rx is presented for 30 with two refills, I can change it to 90 days.

No such thing exists- you must call the prescriber to do this
What –do- you- do?

I know that there is a law that states that a pharmacist is to use their clinical judgment and has the right to deny a prescription if they truly feel that the prescribed medication will cause harm to the patient.

I am unsure if this is a state law or federal law but I would love to cite the law. Is there anyway that you would be able to track down this law and tell me where I can find it?

63.6(b)(8)(I)(a)(e)...
Nothing in this subparagraph shall prevent a pharmacist or pharmacy intern from refusing to dispense a prescription if, in his or her professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient.
I understand that the supervising MD’s name must be imprinted on an Rx if written by a PA, but is there any leeway to call and ask for the supervising MD’s name and add it onto the prescription?

There is no provision to add this information
Needles and Syringes in NY

- There is no longer a limit of 100 for oral orders
- eRx is now acceptable
- Refills can be recorded electronically
- RxS can be transferred
- Rx still valid for 2 years from date of issue
Immunization
What immunizations are certified pharmacists be able to administer?

Certified pharmacists will be able to administer influenza, pneumococcal, meningococcal, acute herpes zoster (shingles), tetanus, diphtheria or pertussis vaccinations to adults 18 years of age or older.
From whom may a certified pharmacist accept prescriptions/orders for immunizations?

A pharmacist may accept a patient-specific prescription for an immunization from a physician or from a nurse practitioner. Likewise, a pharmacist may administer immunizations based on a non-patient specific order from a physician or nurse practitioner located within the same county, or from a physician or nurse practitioner from an adjacent county.
What is allowed with a patient specific order versus a non-patient specific order?

A pharmacist may administer any of the following immunizations: influenza, pneumococcal, meningococcal, acute herpes zoster (shingles), tetanus, diphtheria or pertussis vaccinations to adults 18 years of age or older pursuant to a patient specific order.
A pharmacist may administer any of the following immunizations: influenza, pneumococcal, meningococcal, acute herpes zoster (shingles), tetanus, diphtheria or pertussis vaccinations to adults 18 years of age or older pursuant to a non-patient specific order provided the order is signed by a New York State licensed physician…..
or nurse practitioner practicing in the same or adjoining county the pharmacist will be administering vaccine, **and the immunization is in accordance with the most current Advisory Committee for Immunization Practices (ACIP).** A non patient specific immunization cannot be administered outside of ACIP guidelines, for example, the current ACIP guideline for herpes zoster only allows for administration to patients 60 years of age and older.
When administering an immunization in a pharmacy, the licensed pharmacist shall provide an area for the immunization that provides for a patient's privacy.

The privacy area should include a clearly visible posting of the most current "recommended adult immunization schedule" published by the advisory committee for immunization practices (ACIP).
Prior to administering the immunization, inform the patient of the total cost of the immunization or immunizations, subtracting any health insurance subsidization, if applicable. In the case the immunization is not covered, the pharmacist must inform the patient of the possibility that the immunization may be covered when administered by a primary care physician or practitioner.
Standing orders

- The ability of pharmacists to get physicians to sign these continues to be a barrier in some areas. Hopefully legislation will be passed that eliminates the county restriction. Until then, the NYC Commissioner of Health will offer signed standing orders to pharmacists.
Each year, NYC sends out this memo:

Dear Pharmacist,

The New York City (NYC) Department of Health and Mental Hygiene (DOHMH) is hosting an orientation for pharmacists interested in providing immunization services under a NYC DOHMH non-patient specific standing order. Pharmacists certified to administer influenza, pneumococcal and Meningococcal vaccines but do not have a standing order are encouraged to attend. Pharmacists must participate in this orientation to vaccinate under a DOHMH standing order, including those pharmacists who attended previous DOHMH orientations.

There will be two orientation sessions and you need to only attend one...
This is in response to your March 2, 2017 letter requesting clarification of the reporting requirements of immunizations by a pharmacist. Specifically, you have asked if pharmacists are legally required to report to both the primary care physician (PCP) and to the New York State Immunization Information System (NYSIIS)*.

New York State Education Law (EDL) Article 137, Title 8, Section 6801 and Public Health Law (PHL) Article 21, Title 6, Section 2168 must be considered to provide a complete response. While EDL Section 6801(2)(a) requires a pharmacist that administers an immunization to report to the PCP or NYSIIS. PHL Section 2168(3)(a) mandates that pharmacists that administer immunizations to persons under 19 years of age enter the immunizations into NYSIIS and Section 2168(3)(b)(ii) requires that pharmacists that administer immunizations to persons 19 years of age or older enter the immunizations into NYSIIS upon consent of the patient. When you consider the requirements of both EDL and PHL together, the pharmacist must do both.

If you have additional questions, please feel free to contact this office at 518.474.3817 ext. 130, or by email at pharmbd@nysed.gov.
Which of the following are NOT true for a Supervising Pharmacist (SP)?

1. May assign their SP responsibilities to other staff
2. Responsible for eliminating misbranded and adulterated drugs from inventory
3. Must make certain a qualified pharmacist is present when the pharmacy is open
4. Must insure the pharmacy is properly registered and operating in compliance with current laws, rules and regulations
Which of the following functions may a pharmacy intern NOT perform under the supervision of a pharmacist?

1. Administer an influenza vaccine
2. Transfer a prescription to another pharmacy
3. Take a verbal order from an authorized agent of the prescriber
4. Counsel a patient on the proper use of an inhaler
In NYS, an unlicensed person may NOT do which of the following?

1. Count tablets
2. Approve prescription information
3. Affix a prescription label to a container
4. Receive electronically transmitted prescriptions for pharmacist to accept
A pharmacist may NOT do which of the following?

1. Provide medications, syringes and other supplies needed by an RN to execute a non-patient specific protocol
2. Dispense a non-patient specific prescription to a physician
3. Administer Zostavax to a 50 year old patient based on a patient specific prescription
4. Prepare and dispense a patient specific prescription to be administered by the prescriber
Which of the following is NOT considered manufacturing?

1. Compounding medications for physician’s office use
2. Compounding an ointment for a patient based on a patient specific prescription
3. Compounding OTC drugs to be sold OTC to patients
4. Production of approved drugs for distribution
Is a pharmacy required to print and maintain a hard copy of an electronic prescription?

1. No
2. Yes
3. Unsure
Which of the following is considered a valid prescription in NYS?

1. A prescription converted to a computer-generated fax
2. An ONYSRX manually signed and faxed to a pharmacy
3. A prescription emailed directly from the prescriber to the pharmacy
4. All of the above
If a pharmacist takes a telephone order from a physician for an Epipen® or an Imitrex® kit, should the pharmacist ask for a follow-up prescription to be mailed to the pharmacy?

A. Yes  
B. No
When testosterone (as a powder, in oil, etc.) is mixed into an ointment or cream, what schedule is the final product?

A. Not controlled
B. II
C. III
D. IV
E. V
Can a physician write and a pharmacist fill a prescription for Depo®-Testosterone for office use in NY?

A. Yes
B. No
May a pharmacist obtain a code from a prescriber and add it to a controlled prescription written for more than a 30-day supply of a controlled substance (e.g., Phenobarbital tab. 30 mg., #60, Sig: one tab. Daily)?

A. Yes  
B. No  
C. What’s a code?
Only a pharmacist can sign a DEA 222 form

A. True
B. False
Do I have to pull the original prescription and sign it every time
I refill a controlled substance Rx?

A. Yes
B. No
C. Maybe
Which of the following does not have to be printed on the label of the container for a controlled substance in New York?

A. Name of the patient  
B. Date filled  
C. Address of patient (to include city & state)  
D. Address of pharmacy  
E. DEA number of pharmacy
In New York, “prn” for refills for a controlled substance allows only one refill

A. True
B. False
True or False

Pharmacies utilizing a computerized filling system do not have to go back to the original when refilling needles/syringes

A. True
B. False
True or False

Prescription refills for needles and syringes are transferable from one pharmacy to another

A. True
B. False
• Thank you for coming......

• Return clickers !!!