New York City Society of Pharmacists

Common Issues in Pharmacy Practice Law Update (NY)
Wednesday, April 2, 2014

Joseph J Bova, MS, RPhI
From time to time, the New York State Board of Pharmacy reviews laws, rules and regulations and shares interpretation of them by issuing “guidelines”.

While the same laws, rules and regulations should still be complied with, these guidelines may help to explain them.
To access these laws, rules and regulations, go to:

http://www.op.nysed.gov/prof/pharm/
Pharmacy

Pharmacy refers to the preparation and dispensing of drugs as well as the counseling of patients in the proper use of these drugs.

When your pharmacist counsels you about your prescription, the pharmacist may discuss the following information with you:

- The medicine's name
- What it is supposed to do
- When the medicine should be taken and for how long
- How the medicine should be taken
- Common side effects
- Foods, drinks, other medicines, or activities you should avoid while taking the medicine
- What you should do if you miss a dose
- How you should store the medicine
- If there are any refills of the prescription

Read more about this profession.
Pharmacy

Laws, Rules & Regulations

Consumer Information
Contact Information
License Statistics
Board Members Only

Pharmacists

License Requirements
License Application Forms
Practice Issues
FAQs
Continuing Education
Administration of Immunizations

Pharmacy Establishments

Laws, Rules & Regulations

Education Law

- Title VIII - links to all Articles
- Article 137 - Pharmacy

Rules of the Board of Regents

- Part 29 - Unprofessional Conduct

Commissioner's Regulations

- Part 52.29 - Pharmacy
- Part 63 - Pharmacy

Other Laws, Rules, Regulations (external link)

- New York State Department of Health
  - Public Health Law, Article 37, Physician's Assistants
  - Special provisions
§ 29.7 Special provisions for the profession of pharmacy.

a. The requirements of this section set forth for written prescriptions shall also be applicable to electronic prescriptions, as defined in Section 63.6(a)(7)(i)(a) of this Title, unless otherwise indicated. For purposes of this section "signature" shall include an electronic signature, as defined in section 63.6(a)(7)(i)(c) of this Title, when applicable, and "sign" shall include the affixing of an electronic signature. Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by Sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

1. Dispensing a written prescription which does not bear the name, address and age of the patient for whom it is intended; the date on which it was written; the name, strength, if applicable, and the quantity of the drug prescribed; directions for use, if applicable; and, the name, address, telephone number, profession and signature of the prescriber; provided that the pharmacist may record on the prescription the address and age of the patient, the strength and quantity of the drug prescribed, the directions for use and the prescriber's address, telephone number and profession if these are missing or unclear. If the address and age of the patient and the address, telephone number and profession of the prescriber are missing from the prescription, the pharmacist shall not be required to enter any of these items on the prescription if the information is otherwise readily available in the records of the pharmacy. Prescription labels must be legible. An order for a drug to be dispensed for an inpatient in a health care facility by the pharmacy of that facility may be transmitted to the pharmacy in accordance with written procedures approved by the medical or other authorized board of the facility. The items of information required by this paragraph which are found in the records regularly maintained by the facility and which are not essential to the execution of the order need not appear on the order which is transmitted to the pharmacy. A drug which is dispensed for an inpatient in a health care facility by the pharmacy of that facility may be labeled in accordance with the policy adopted by the medical or other authorized board of the facility. That policy shall insure that all the information required by law to be placed on prescription labels is readily available to all concerned parties and that accuracy and safety prevail in the dispensing process. The address of a patient in a hospital or other health care facility may, for the purpose of a prescription, be that of the facility. An order for a drug for a particular patient issued by a practitioner authorized to prescribe, and transmitted to a pharmacy for dispensing, shall constitute a prescription. Prescriptions written for controlled substances shall meet the requirements of Article 33 of the Public Health Law.

2. Failure by a pharmacist to reduce to writing, either through written communication or electronic record, a prescription transmitted orally, which writing or electronic record shall include all the information required by paragraph (1) of this subdivision and the signature, or the electronic equivalent of a signature, or readily identifiable initials of the receiver of the oral prescription, provided that oral prescriptions for controlled substances shall meet the requirements of Article 33 of the Public Health Law.

3. Failure by a pharmacist dispensing a prescription to enter on the prescription the date of dispensing and to sign or initial legibly the prescription in such a manner as not to interfere with any other information on the prescription; provided that when
Repackaging including....

Co Mingling of Drugs and the use of customized patient packaging (includes robotics)

Refer to: 29.7(a)(15)(i) and (ii)
Repacking of drugs in a pharmacy, except by a pharmacist or under his/her immediate and personal supervision. Labels on repacked drugs shall bear sufficient information for proper identification and safety.
A repacking record shall be maintained, including the name, strength, lot number, quantity and name of the manufacturer and/or distributor of the drug repacked, the date of the repacking, the number of packages prepared, the number of dosage units in each package, the signature of the person performing the repacking operation, the signature of the pharmacist who supervised the repacking, and such other identifying marks added by the pharmacy for internal recordkeeping purposes.
Drugs repacked for in-house use only shall have an expiration date 12 months, or 50 percent of the time remaining to the manufacturer's expiration date, whichever is less, from the date of repacking.
ii. Repacking drugs in customized patient medication packages (patient med-pak or patient medication package) unless the following conditions are complied with:

a. medications are packaged in moisture-proof containers that are either non-reclosable or are designed to show evidence of having been opened;
b. Medications are dispensed in containers that bear a label affixed to the immediate container in which the medications are dispensed in accordance with section 6810(1) of the Education Law. Such label shall include:

1. All information required by Education Law section 6810(1);

2. The name, strength, physical description or identification, and quantity of each medication;

3. The address and telephone number of the dispenser;
4. an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included therein;
5. a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and
6. any other information, including storage instructions or any statements, or warnings required for the medications contained in the package;
c. medications shall not be repackaged for or reissued to any patient other than to the patient for whom they are originally dispensed;
d. medications shall not be dispensed in customized patient medication packages, without the consent of the patient, the patient's caregiver, or the prescriber, and the patient or caregiver shall be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered;
e. controlled substances shall not be dispensed in customized patient medication packages;

f. medications that are unstable or therapeutically incompatible shall not be dispensed in customized patient medication packages; and
g.a record of each customized patient medication package shall be maintained by the pharmacist. Each record shall contain:

1. the name and address of the patient;
2. the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the department;
3. the name of the manufacturer or labeler and the lot number for each medication contained therein;
4. information identifying or describing the design, characteristics, or specifications of the customized patient medication package sufficient to allow subsequent preparation of an identical customized patient medication package for the patient;

5. the date of preparation of the customized patient medication package and the expiration date that was assigned;

6. any special labeling instructions; and

7. the name or initials of the pharmacist who prepared the customized patient medication package.
COMPOUNDING AND DISPENSING

VS.

MANUFACTURING
The State Board of Pharmacy receives a numbers of questions regarding the distinction between what constitutes compounding and dispensing, as opposed to manufacturing. Manufacturing is often also referred to as “bulk preparation”, “bulk compounding”, or “batch processing.”
Education Law section 6801 defines the practice of pharmacy 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). Section 6807 of the Education Law also allows limited compounding and dispensing by those licensed professionals (such as physicians and dentists) authorized to issue prescriptions in this state. In the latter case, prescribers may only prepare products for delivery to their own patients. No other individuals are authorized to compound or dispense prescriptions in New York State, and in fact, New York State provisions are consistent with federal laws and regulations.
The NY regulatory structure makes a distinction between compounding and dispensing and the repackaging or manufacturing of medications. This distinction is analogous to federal over-sight of the manufacturing processes that routinely use unlicensed personnel under strict supervision to prepare drugs in bulk quantities. The particular rule to be referenced in this regard is 8NYCRR29.7(a)(15). This rule allows, for example, the repackaging of a bottle of 1000 tablets into containers of 40 tablets each. An unlicensed person, under the supervision of a registered pharmacist can perform this repackaging. The rule requires specific record keeping when this form of repackaging is done, including:
(Note: a batch produced by a protocol requires a specific formula (recipe) and a detailed record.)

- Name and strength of the drug being packaged
- Name of the manufacturer and distributor, if different, and the manufacturer’s lot number
- Quantity of each container, and number of units prepared
- The date of the repackaging
- The expiration date of the manufacturer of the product and of repackaged containers
- The signature of the person performing the repackaging
- The signature of the pharmacist who supervised the repackaging
- Such other identifying marks needed for internal record-keeping purposes, and, if applicable, pursuant to a written protocol.
This rule has traditionally been interpreted to extend to beyond solid dosage forms to include the repackaging of injectable products. For example, a pharmacy may choose to prepare several hundred penicillin mini-bags, each containing one million units of drug, having started with higher concentrations. Another example would include the addition of two or more drugs to an IV solution pursuant to a specific written “batch” protocol with quality assurance checks. In these cases, the record-keeping requirements referenced above also apply.
Is there a minimum number of units that must be prepared or repackaged (batched)?

The rule does not indicate either an upper or lower limit for the repackaging of medications. Therefore, pharmacists must decide, based upon the anticipated needs of the pharmacy how best to utilize limited resources. It is imperative that, regardless of whether 1 or 1,000 units are being prepared for subsequent dispensing, a pharmacist consistently adheres to the standards for record keeping.
It is imperative to note that the manufacturing or bulk compounding of products is a procedure expressly allowed for each pharmacy.

A registered pharmacy may not sell or transfer such products to another pharmacy despite common ownership of more than one pharmacy.
We also note that a distinction can be made between manufacturing and simple reconstitution. For the purposes of this discussion, simple reconstitution is the addition of a diluent to a dry powder, such as the addition of a quantity of water to an antibiotic powder to prepare a suspension.
Such reconstitution is not compounding—However, pharmacists are still responsible for the preparation of such suspensions, and unlicensed personnel may not independently measure and weigh ingredients. Therefore, an unlicensed person may obtain a diluent for a pharmacist, but only prepare the suspension after a pharmacist has verified that the correct quantity of the proper diluent has been obtained.
Failure to comply with the referenced rules may result in a charge of professional misconduct or unprofessional conduct.
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.
Electronic Prescribing and Dispensing of Controlled Substances is now permissible in New York State Effective March 27, 2013 – Updated April 2013

Amendments to Title 10 NYCRR Part 80 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.
The amendments require the following

Computer applications utilized must meet federal security requirements. The federal requirements are included in the Drug Enforcement Administration Interim Final Rule regarding Electronic Prescriptions for Controlled Substances.

The rule may be accessed via the U.S Department of Justice DEA Office of Diversion Control website. Contact your software vendor to determine if your application meets the above mentioned requirements.

Computer applications meeting federal security requirements must be registered with the Department of Health, Bureau of Narcotic Enforcement.
Pharmacy computer applications must use American Society for Automation in Pharmacy (ASAP) **Version 4.2** or greater in order to receive electronic prescriptions for controlled substances and to report those transactions to the Department of Health, Bureau of Narcotic Enforcement.

Pursuant to Public Health Law section 3302(37), an electronic prescription for controlled substances may only be issued in accordance with Department of Health regulations, as well as NYS Education Department regulations and federal requirements. NYS Education Department regulations may be accessed electronically.
By March 27, 2015, all prescriptions (including prescriptions for non-controlled substances) issued in New York State must be electronically transmitted, with certain limited exceptions.
If you have met all federal security requirements and would like to register the application with the Bureau of Narcotic Enforcement, send an email to:

narcotic@health.state.ny.us.

Include "Electronic Prescribing" in the subject.

• (Note: NCPDP Version 4.2 required)
Dear Pharmacy:

Effective March 27, 2013, amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances authorizes a pharmacy in New York State to annotate, dispense, and electronically archive electronic prescriptions for controlled substances in Schedules II through V received from a practitioner’s certified electronic prescribing computer application. For electronic prescribing of controlled substances (EPCS), the regulations require the pharmacy to register their certified computer application with the New York State Department of Health, Bureau of Narcotic Enforcement (BNE). To register your computer application with BNE, please complete the enclosed EPCS Registration form and email it to narcotic@health.state.ny.us with “Pharmacy EPCS Registration” in the subject line.

Pharmacies must also comply with the federal security requirements for EPCS as detailed in the Drug Enforcement Administration’s Electronic Prescriptions for Controlled Substances Interim Final Rule. In addition, to meet the New York State Public Health Law data submission requirements for EPCS, the pharmacy must submit controlled substance dispensing data to the Department of Health, Bureau of Narcotic Enforcement, using the American Society for Automation in Pharmacy (ASAP) format Version 4.2 or greater.

Please note as of March 27, 2015, electronic prescribing of controlled and non-controlled substances will be mandatory for practitioners, excluding veterinarians.

Questions regarding the EPCS registration form or process may be directed to BNE by emailing narcotic@health.state.ny.us or by calling 1-866-811-7957, Option 1.

Sincerely,

[Signature]

Terence J. O’Leary
Director
Bureau of Narcotic Enforcement
Pharmacy EPCS Registration
NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

Amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances, adopted on March 27, 2013, authorize pharmacies in New York State to accept, annotate, dispense and electronically archive electronic prescriptions for controlled substances (EPCS) in Schedules II through V received from practitioners. Pursuant to 10 NYCRR §§80.73(p) and 80.74(m), a pharmacy shall use a pharmacy computer application that meets the federal security requirements to process electronic prescriptions for controlled substances and shall register such pharmacy computer application with the New York State Department of Health (Department), Bureau of Narcotic Enforcement. The federal security requirements regarding Electronic Prescriptions for Controlled Substances are included in the Drug Enforcement Administration Interim Final Rule, 21 CFR 1300 et seq., and can be accessed via the following link: http://www.deadiversion.usdoj.gov/ecomm/e_rx/. To receive electronic prescriptions in compliance with New York State rules and regulations, this Pharmacy EPCS Registration form and the attestation herein must be completed and returned to the email address provided below. A copy of your DEA certification or third party audit approving your pharmacy software application must be available for inspection by Department personnel.

Section 3333 of the Public Health Law requires all pharmacies registered with New York State to electronically submit information regarding controlled substance dispensed data to the Bureau. To meet the New York State Public Health Law data submission requirements for electronic prescribing of controlled substances, the pharmacy must submit controlled substance dispensing data to the Bureau using the American Society for Automation in Pharmacy (ASAP) format Version 4.2 or greater since additional data elements compatible with electronic prescribing are included.

Pharmacy Name ___________________________

Pharmacy NCPDP/NABP* ___________________________ ASAP Version for Data Submissions ___________________________

*For chain pharmacies please attach a list of NCPDP/NABP numbers for those stores registered with the NYS Board of Pharmacy.

Contact Name ___________________________

Contact Email Address ___________________________ Contact Phone ___________________________

Name of Certified Pharmacy Software Application ___________________________ Software Version Certified ___________________________

Name of Software Application Provider (Company Name) ___________________________

Third Party Audit/Certifying Organization ___________________________ Date of Third Party Audit/Certification ___________________________

Attestation: I affirm that I am duly authorized to subscribe and submit this registration and attest on behalf of the above-named pharmacy and that the pharmacy listed above has received a DEA certification or third party audit that the pharmacy software application listed above meets federal security requirements for processing electronic prescriptions for controlled substances.

If the pharmacy becomes aware or is notified of any issues which render the software application non-compliant with federal regulations or if the pharmacy is switching to a different software application, the application will not be used to process electronic prescriptions for controlled substances until the application meets federal requirements and is registered. When the software is once again compliant, the pharmacy will register the new certification with the Bureau of Narcotic Enforcement.

Signature ___________________________ Date ______/____/____

(Chain/Franchise/Store Owner/Representative’s signature)

Print Name ___________________________ Title ___________________________

Please email the completed form to narcotic@health.state.ny.us with “Pharmacy EPCS Registration” in the subject line.

NYSDOH/Bureau of Narcotic Enforcement
Pharmacy EPCS Registration
Riverview Center
150 Broadway
Albany, NY 12204
• ERXs for Compounds
• Can Surescripts handle Rx's that contain compounded ingredients in the drug field?
It is a standardization issue. The current version of the NCPDP SCRIPT Standard, Version 10.6, which was just recently adopted by CMS for Medicare e-prescribing, is not designed to accommodate transmitting information for compounded prescriptions. That functionality doesn’t come into play until SCRIPT 10.7 (and subsequent versions).
Thus, it is an issue for all participants—EHR systems aren’t ready to transmit compounded information correctly and coherently, the Surescripts network can’t handle compounds because CMS hasn’t authorized the industry to move to SCRIPT V10.7, and pharmacy practice management systems aren’t able to receive and process the information. I’m afraid this one won’t be a quick fix, because normally several years elapse between when CMS adopts versions of NCPDP SCRIPT.
- 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
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.
Agents of prescribers....

Education law 6802\(^1\) and Regulations of the Commissioner of Education make no provision for the delegation of transmission of electronic prescriptions to an agent. Further, federal and State regulations for prescribing of controlled substances explicitly prohibit such delegation.
Brand or generic?

Education Law 6810\(^1\) allows the prescriber to electronically sign and insert an electronic direction to dispense the drug as written.
Patient: Michael Bloomberg
Address: Gracie Mansion
NY NY 10012

Drug: Zocor 20mg
S: One qd after dinner
Dispense: 30 tablets
Refill: 3 times

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

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

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

This prescription will be filled generically
unless prescriber writes 'DAW' in the box below
Dispense As Written

Authorized by: Susan Wright, Office Manager
Patient: Michael Bloomberg
Address: Gracie Mansion
NY NY 10012

Drug: Zocor 20mg
S: One qd after dinner

Dispense: 30 tablets
Refill: 3 times

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

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

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

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

Dispense As Written

Authorized by: Susan Wright, Office Manager
<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>Anabolic Steroid</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>C II</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td>C III</td>
<td></td>
<td>Yes</td>
<td>Yes- 1 only</td>
<td>No</td>
<td>Up to 5 within 6 months of date of issue</td>
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<tr>
<td>C IV</td>
<td>Benzodiazepines</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>C IV</td>
<td></td>
<td>Yes</td>
<td>Yes- 1 only</td>
<td>No</td>
<td>Up to 5 within 6 months of date of issue</td>
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<tr>
<td>CV</td>
<td></td>
<td>Yes</td>
<td>Yes- 1 only</td>
<td>No</td>
<td>Up to 5 within 6 months of date of issue</td>
</tr>
</tbody>
</table>
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:</th>
<th>Panic Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code B:</td>
<td>Attention Deficit Disorder.</td>
</tr>
<tr>
<td>Code C:</td>
<td>Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity.</td>
</tr>
<tr>
<td>Code D:</td>
<td>Relief of pain in patients suffering from diseases known to be chronic and incurable.</td>
</tr>
<tr>
<td>Code E:</td>
<td>Narcolepsy</td>
</tr>
<tr>
<td>Code F:</td>
<td>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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</table>
### 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>
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<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>
</tr>
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<td>Directions</td>
<td>Patient age</td>
<td>Date written</td>
<td>Directions</td>
<td>Patient age</td>
<td>Date written</td>
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<td>Diag Code</td>
<td>Drug name</td>
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<td>Drug name</td>
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<tr>
<td>MDD</td>
<td>Quantity</td>
<td>Quantity</td>
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<td>MDD</td>
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<td>Strength</td>
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<td>Dosage form</td>
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<td>Class</td>
<td>Maximum Quantity</td>
<td>Refills</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Anabolic Steroids</td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other C II s</td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C III</td>
<td>Up to 5 days supply</td>
<td>None*</td>
<td>Required but no reporting needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>5 Days emergency only</td>
<td>None allowed</td>
<td>Required and must report if not rec’d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C IV</td>
<td>Up to 30 days – max 100 dosage units</td>
<td>None *</td>
<td>Required but no reporting needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C V</td>
<td>Up to 5 days supply</td>
<td>None *</td>
<td>Required but no reporting needed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Whenever a prescription is written for a brand name drug with the letters “daw” in the required box, or its electronic equivalent, a pharmacist MUST dispense the brand ordered. A pharmacist may not dispense a therapeutic equivalent, even at the express request of the patient.
Whenever a prescription is written for a drug using its generic name, followed by the name of a specific manufacturer/distributor, it shall be handled as a brand name drug.
Whenever a prescription is written using a brand name, but not incorporating a “daw” in the box, or its electronic equivalent, a pharmacist must dispense a drug which is a less-expensive, to the patient, therapeutically equivalent product, if one is available. Therapeutically equivalent is defined as being “A” or “AB” rated. Nothing in this section shall prohibit a pharmacist from dispensing a brand name product in cases where the cost to the patient is less than the generic equivalent.
Whenever a prescription is written using a brand name, but not incorporating a “daw” in the box, or its electronic equivalent as noted above, and a therapeutic equivalent is temporarily unavailable, a pharmacist has two options:

- The pharmacist may dispense the brand and charge the price that would have been charged for the generic, or
If the circumstance can be deemed an emergency, a pharmacist may dispense the brand at its usual and customary cost. The law defines an emergency as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated.
Whenever a prescription is written for a brand-name drug, without the letters “daw” in the required box, or its electronic equivalent and generic brand product(s) are available though not deemed therapeutically equivalent (not “A” or “AB” rated), a pharmacist may use his/her professional judgment in determining which product to select; that is, a pharmacist may dispense a brand, or choose a generic (chemically) equivalent that has not been proven therapeutically equivalent.
Whenever a prescription is written for a brand name drug, without a “daw” in the box”, or its electronic equivalent for which neither a therapeutically equivalent nor generically (chemically) equivalent is available, the brand will, of course be dispensed. However, if a therapeutically equivalent subsequently becomes available, and a prescription has remaining refills, a pharmacist may:

- Continue to dispense remaining refills with the brand, or
- Consult with the patient and dispense the therapeutic equivalent, or
- Consult with a prescriber and obtain a new prescription for either the brand or therapeutically equivalent product.
Whenever a prescription is dispensed for a newly approved generic, the pharmacist may fill the prescription with the generic drug if the prescriber did not indicate “DAW” on the original prescription. There is no prohibition against continuing to dispense the brand however. In the event that a generic is dispensed, a new prescription number may be assigned and reference should be made on the new Rx indicating the original Rx number.
When choosing among these alternatives, the best interests of patients must determine. Should a pharmacist choose an alternative that benefits the pharmacist over the patient, charges of unprofessional conduct may be considered. Further when a change in product occurs, a pharmacist MUST counsel the patient to assure avoidance of confusion and proper compliance.
It must also be noted that this guidance does not address specific laws administered by the Medicaid law which allow the State to determine drugs covered under that program, and otherwise exempt certain provisions of the drug substitution laws.
Needles and Syringes in NY

- There is no longer a limit of 100 for oral orders
- eRxs now acceptable
- Refills can be recorded electronically
- Rxs can be transferred
- Rx still valid for 2 years from date of issue
What am I?

H_{3}C-N

H

OCH_{3}
According to Chapter 357 of the Laws of 2013, products containing dextromethorphan as an active ingredient cannot be sold to persons under eighteen without a prescription, and any establishment selling such products must request proof of age. This law pre-empts local laws and goes into effect March 26, 2014.
Expedited Partner Therapy (EPT) for the Treatment of Chlamydia trachomatis (Ct)

In New York
Expedited Partner Therapy Definition

The clinical practice of treating the sex partners of patients diagnosed w/ a curable STD by providing prescriptions or medications to the patient to take to his/her partner without the health care provider first examining the partner.
Chlamydia trachomatis (Ct)

- Majority of infections asymptomatic
- Untx’d infection can result in long term sequelae
  - PID, chronic pelvic pain, ectopic pregnancy, infertility
- Most commonly reported infection in NYS
- Annual screening for sexually active women ≤25
- Can be treated w/ single dose therapy
- Must treat sex partners to prevent reinfection
Chlamydia trachomatis cont.

- High rates repeat Ct infection in 4-6 mos after treatment

- Repeat Ct infection ↑ risk for sequelae

- Many female re-infections attributable to resuming sex with an untreated sex partner

- Low treatment rates for male partners to Ct

→ Need additional tools for getting partners treated
What are the benefits of EPT?

- Compared to standard practice\(^1\), EPT:
  - Decreases re-infection in index patient
  - Increases proportion sex partners treated
  - Gets treatment to sex partners unlikely to seek care
Legal status of EPT in NYS

EPT legal in NYS for Chlamydia

• Law (January 2009)
• Regulations (October 2010)
• Provider guidelines (March 2011)
• Sunset (2014)
EPT Law & Regulations

Summary

- Permissible for Ct only

- May *not* give if Ct index patient co-infected w/ GC or Syphilis

- Partner treatment may be provided as medication, or prescription
EPT Law & Regulations

Summary

• Each patient must be given informational material to give to their sexual partner(s)
  — Specifies content of informational materials
  — Each patient must be counseled to tell partner(s) to read material before taking medication

• Specify how to prescribe & fill EPT prescriptions

• HCP and pharmacists protected from liability if practice consistent with law/regs
EPT Law & Regulations

Informational materials shall:

(1) Encourage partner to consult HCP for full eval as preferred alternative to EPT & regardless of whether take med
(2) Disclose risk of potential adverse drug reactions/interactions
(3) Inform partner possible co-morbidity - could go untx'd
(4) Inform partners - seek care if sx of more serious infection
(5) Recommend partner who could be pregnant consult HCP asap
(6) Instruct patient and partner to abstain >= 7 days after each tx'd to avoid reinfection
(7) Inform partner at high risk for HIV to consult HCP for full eval and HIV/STD testing
(8) Inform patient and partner how to avoid repeat Ct
    www.nyc.gov/health/ept
EPT Law & Regulations

Prescribing and filling

"Whenever a health care practitioner provides EPT through the use of a prescription:

(1) The designation “EPT” must be written in the body of the prescription form above the name of the medication and dosage for all prescriptions issued.

(2) If name, address, and DOB of sexual partner are available, this should be written in the designated area of the prescription form; and

(3) If the sexual partner’s name, address, and DOB are not available, the written designation “EPT” shall be sufficient for a pharmacist to fill the prescription."
EPT Law & Regulations

Liability language

A health care provider who reasonably and in good faith renders expedited partner therapy in accordance with section 2312 of the Public Health Law and this section, and a pharmacist who reasonably and in good faith dispenses drugs pursuant to a prescription written in accordance with section 2312 of the Public Health Law and this section shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct”
EPT Health Care Provider Guidelines
Language re: prescribing

- Recommended treatment regimen - Azithromycin 1 gram orally in a single dose
- If sex partner is allergic to Azithromycin, the partner should seek medical care as soon as possible so a health care provider can provide a suitable alternative tx
Additional resources

NYC EPT website

NYS EPT website
http://www.health.state.ny.us/diseases/communicable/std/ept/index.htm

CDC EPT website
http://www.cdc.gov/std/ept/
Challenges

• HCP using single prescription to treat both index patient and partner(s)
  — Must write separate script for each partner

• Electronic health records and e-prescribing systems present special obstacles
  — Prescribing from electronic health records (EHR)

• Prescribing when partner name not available
  — Electronic prescribing
  — Call-in or mailing in prescriptions
Expedited Partner Therapy (EPT) is a strategy for treating the sex partners of persons diagnosed with Chlamydia trachomatis (Ct). EPT allows health care providers to provide patients with medication or a prescription to deliver to his/her sex partner(s) without a prior medical evaluation or clinical assessment of those partners.
Is EPT legal for any other sexually transmitted infections (STIs)?

A: No. EPT was legalized in New York State (NYS) on January 23, 2009 for Ct infections only.
What is the recommended treatment for Ct using EPT?

The recommended EPT treatment for Ct is 1gm of Azithromycin in a single oral dose.
What is Chlamydia?

Ct is the most commonly reported bacterial STI nationwide and in New York State (NYS). Repeat Ct infections increase the risk of adverse outcomes such as Pelvic Inflammatory Disease (PID), infertility, and ectopic pregnancy.

Having an untreated sex partner is an important risk factor for reinfection, so treating the sex partners of a person diagnosed with Ct is critical to interrupting the spread of Ct and reinfection.
Randomized controlled trials have found EPT to decrease rates of Ct reinfection among index patients and increase the proportion of sex partner’s reported to be treated for Ct.
Whenever a health care provider provides EPT using a prescription, the prescription shall include: (1) name and address of the health care provider/establishment in which it was written; (2) date the prescription was issued; (3) name and dosage of the medication; (4) directions for the use of the drug by the patient; (5) number of refills (which will be “zero”); (6) the designation "EPT" must be written in the body of the prescription form above the name of the medication and dosage for all prescriptions issued;
(7) if the name, address, and date of birth of the sex partner are available at the time the prescription is written, this should be written in the designated area of the prescription form; and (8) if the sex partner's name, address, and date of birth are not available at the time the prescription is written, the written designation of “EPT” shall be sufficient for the pharmacists fill the prescription; if needed, this information can be obtained when the patient’s sex partner or designee drops off or picks up the prescription at the pharmacy.
Is “EPT” sufficient for the pharmacist to fill the prescription?

According to NYS Public Health Law Section 2312, a pharmacist can legally fill a prescription with the designation of “EPT” even when a sex partner’s name, address, and date of birth are not listed on the prescription. However, if needed, the pharmacist can request this information when the prescription is dropped off or picked up at the pharmacy.
Is liability for providers and pharmacists addressed in this legislation?

A health care provider who reasonably and in good faith renders EPT in accordance with Public Health Law section 2312 and section 23.4, and a pharmacist who reasonably and in good faith dispenses drugs pursuant to a prescription written in accordance with Public Health Law section 2312 and section 23.4, shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct.
Who will assume the cost for the sex partner’s medication?

Medication costs may be self-pay (paid by the person who picks up the prescription) or paid by the sex partner’s health insurance. The health department or some medical offices may choose to dispense medications to both patients and partners at no cost instead of writing a prescription.
To whom should medication be billed?

Billing the sex partner’s prescription under the patient’s name would be considered fraudulent.
If a sex partner is allergic to Azithromycin what are the alternatives?

Other states have been using EPT for approximately 8 years and no adverse events and/or life threatening allergic reactions have been reported to date. If the sex partner is known to be allergic to azithromycin, erythromycin, clarithromycin, or any macrolide or ketolide, azithromycin should not be given and the partner should be instructed to see a physician for appropriate treatment. Providers using EPT are required by law to give patients educational materials to give to his/her sex partner(s). These materials will address allergic reactions, potential side effects, and contraindications to taking azithromycin. Patients and their partners should call 311 for more information.
The partner should be referred to a physician or emergency room for appropriate treatment.

Q: How should pharmacists conduct patient record keeping for “EPT” prescriptions?

A: EPT prescriptions should be documented/filed like any other non-controlled substances prescriptions.
What are the educational material requirements for patients provided with EPT?

Each patient provided with antibiotics or a prescription for EPT in accordance with section 2312 of the Public Health Law must be given informational materials for the patient to give to his/her sex partner(s). Each patient shall be counseled by his/her health care provider to inform his/her sex partner(s) that it is important to read the information contained in the materials prior to the partner’s taking the medication.
Be prepared for a NYS Inspection
# PHARMACY INSPECTION REPORT

**Pharmacy**

---

**Inspection #**

**Conducted by**

**Investigator**

**Date**

**Time In/Out**

---

**1. Routine**

**2. New Registration**

**3. Transfer Ownership**

**4. Discontinuance**

**5. Change of Name/Address**

---

**Reg. Name**

**Trade Name**

**No. and Street**

**City**

**County**

**Zip**

**Reg. #**

**Telephone**

**Hours open per week**

**# RXs daily**

---

### Pharmacists’ Names

<table>
<thead>
<tr>
<th>Hrs. Per Week</th>
<th>License Number</th>
<th>License Date</th>
<th>License Displayed</th>
<th>Registration Displayed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

### Intern.

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.

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

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**Details of Inspection**

---

**Recommemation (completed in office)**

I have received a copy of this inspection report.

**Investigator**

**Supervisor**

**Print name**

**Title**

**Date**

---

This is page ___ of ___ page(s)
Office of Professional Discipline  
Pharmacy Registration Checklist

Applicant
Name: ________________________________

Address: ________________________________

Investigator: ________________________________ Date: ________________________________

<table>
<thead>
<tr>
<th>PREMISES</th>
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</thead>
<tbody>
<tr>
<td>Registered area not less than 300 square feet</td>
</tr>
<tr>
<td>Compounding area not less than 100 square feet</td>
</tr>
<tr>
<td>Name of owner on exterior of premises</td>
</tr>
<tr>
<td>If pharmacy is operated as a dept; permanent partition at least 9/6&quot;, correct sign/hours, separate security system</td>
</tr>
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</table>

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<thead>
<tr>
<th>FACILITIES, EQUIPMENT, AND UTENSILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighing device sensitive to 6mg</td>
</tr>
<tr>
<td>Metric weights, if needed</td>
</tr>
<tr>
<td>Devices capable of measuring volumes from 0.1ml to 500ml</td>
</tr>
<tr>
<td>Mortar and pestle</td>
</tr>
<tr>
<td>Hot and cold running water in compounding area</td>
</tr>
<tr>
<td>Adequate lighting, heating and ventilation</td>
</tr>
<tr>
<td>Drug storage refrigerator (36-46 F) and thermometer, Freezer (13-14 F), Controlled Room Temperature (68-77 F)</td>
</tr>
<tr>
<td>Sanitation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REFERENCES</th>
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</thead>
<tbody>
<tr>
<td>Copies of laws, rules, regulations governing the practice of pharmacy in NYS</td>
</tr>
<tr>
<td>Reference resources necessary to carry on the practice of pharmacy</td>
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</table>

<table>
<thead>
<tr>
<th>MISCELLANEOUS</th>
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</thead>
<tbody>
<tr>
<td>Initial controlled drug inventory of new or transferred registration</td>
</tr>
<tr>
<td>Rx label bears name of registrant</td>
</tr>
<tr>
<td>License and registration certificate of supervising pharmacist</td>
</tr>
<tr>
<td>Owner and supervising pharmacist present during inspection</td>
</tr>
</tbody>
</table>

**FOR TRANSFER OF OWNERSHIP AND CHANGE OF ADDRESS ONLY**

| Pick up current registration certificate | S | N |
On May 17, 2011 Governor Andrew Cuomo signed into law a bill authorizing certain pharmacists to engage in Collaborative Drug Therapy Management (CDTM) within New York’s teaching hospitals and affiliated clinics. The new law, and required regulations, took effect on Thursday, September 14, 2011. The following questions and answers are intended to assist qualified pharmacists and institutions to implement CDTM as quickly as possible.
IMPLEMENTATION OF COLLABORATIVE DRUG THERAPY MANAGEMENT (CDTM) IN NEW YORK STATE PURSUANT TO CHAPTER 21 OF THE LAWS OF 2011

On May 17, 2011 Governor Andrew Cuomo signed into law a bill authorizing certain pharmacists to engage in Collaborative Drug Therapy Management (CDTM) within New York’s teaching hospitals and affiliated clinics. The new law, and required regulations, took effect on Thursday, September 14, 2011. The following questions and answers are intended to assist qualified pharmacists and institutions to implement CDTM as quickly as possible.

1. What facilities are eligible to participate in CDTM?

   Teaching hospitals, including any diagnostic center, treatment center, or hospital-based outpatient departments (including outpatient clinics), are included. However, residential health care facilities and nursing homes are excluded. A “teaching hospital” is any hospital licensed pursuant to article twenty-eight of the public health law that is eligible to receive direct or indirect graduate medical education payments pursuant to article twenty-eight of the public health law.

2. What are the experience and/or qualifications required for a pharmacist to enter into a written agreement or protocol with a physician authorizing collaborative drug therapy management?

   The pharmacist must be employed by or otherwise affiliated the facility, and meet the following education and experience requirements:
   - master of science in clinical pharmacy or a doctor of pharmacy degree;
   - maintain a current unrestricted license; and
   - have a minimum of two years of experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation;
   OR
   - bachelor of science in pharmacy;
   - maintain a current unrestricted license; and
   - within the last seven years, have a minimum of three years of experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation.

3. Will qualified pharmacists be required to obtain an additional certification or documentation from the State Education Department (SED)?

   No. Qualified pharmacists, consistent with the law and provisions of the hospital within which they practice, may engage in CDTM without specific approval from SED. We note that for all licensed professionals unprofessional conduct includes “practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform....”
4. What patient notice and consent are required by the law?

Each patient who is eligible to receive collaborative drug therapy management must be notified:

a. that there is a written agreement or protocol on collaborative drug therapy management;
b. that participation in collaborative drug therapy management is voluntary and that the patient may choose not to participate;
c. that collaborative drug therapy management will not be utilized unless the patient or patient’s authorized representative consents, in writing, to such management;
d. that the consent to such management will be noted on the patient’s medical record;
e. that the patient or the patient’s authorized representative may choose to discontinue collaborative drug therapy management at any time;
f. that, if such management is discontinued, the discontinuance will be promptly noted on the patient’s medical record; and
g. that the existence of a written agreement or protocol on collaborative drug therapy management and the patient’s consent to such management will be disclosed to the patient’s primary care physician and any other treating physician or healthcare provider.

Written consent to collaborative drug therapy management must be obtained from the patient or the patient’s authorized representative in order for such management to be used with the patient. The law does not preclude incorporation of the elements of the CDTM consent into the general patient consent.

5. What activities does the law allow pharmacists engaged in CDTM to undertake?

In accordance with the required written agreement or protocol, a pharmacist may adjust or manage a drug regimen of a patient who is being treated by the participating physician for a specific disease or disease state. Such adjustment or management shall be done only pursuant to a patient specific written order or protocol made by the patient’s physician, and may include adjusting:

a. drug strength;
b. frequency of administration; or
c. route of administration.

The participating pharmacist may not substitute or select a drug which differs from that initially prescribed by the patient’s physician, unless such substitution is expressly authorized in the written order or protocol.

6. Is a prescription from a pharmacist engaged in CDTM acceptable?

A pharmacist engaged in CDTM may write prescriptions using a facility issued Official New York State Prescription, provided that the collaborating physician is identified on the prescription.
7. Must adjustments to a prescribed drug regimen be counter-signed by a collaborating physician?

The adjustments must be in accordance with the written agreement or protocol between the participating physician and pharmacist and with the patient specific written order. If those documents do not require a counter-signature by a collaborating physician, the new law does not otherwise require one. The name of the collaborating physician should be provided to the pharmacist dispensing the medication.

8. Is physician notification is required?

The pharmacist shall be required to immediately enter into the patient record any change or changes made to the patient’s drug therapy and shall use any reasonable means or method established by the facility or the department to notify any of the patient’s other treating physicians with whom he or she does not have a written agreement or protocol regarding such changes.

9. Must CDTM protocols be submitted to the Department?

No. Protocols should be made available for review upon request of the Department, but need not be routinely submitted to the Department.

10. If we have legally permissible facility-approved procedures in place already, do we need to suspend them until the law is fully implemented or otherwise cease clinical activities?

No. The law specifically allows current legally permissible processes to continue.

11. Does the new law allow participating pharmacists to order and evaluate the results of laboratory tests?

Participating pharmacists may evaluate clinical laboratory tests related to the drug therapy management for the specific disease or disease state specified within the protocol. They may order such clinical laboratory tests, only if specifically authorized by the protocol and only to the extent necessary to discharge their responsibilities under the new law.

12. Will participating pharmacists and institutions be required to report results of implementation of CDTM to the State Education Department?

Yes. As part of the legislation, the Department is required to submit a report to the legislature documenting the impact of CDTM on patient care. This report is due no later than May of 2014. Those institutions impacted by CDTM will be contacted by the Department to determine the best way to collect and report data.