

## **IMPLEMENTATION OF COLLABORATIVE DRUG THERAPY MANAGEMENT (CDTM) IN NEW YORK STATE PURSUANT TO CHAPTER 21 OF THE LAWS OF 2011**

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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.

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### **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.