



## Report of the Task Force on Long-Term Care Pharmacy Rules

### Members Present:

Malcolm Broussard (LA), *chair*; Traci Collier (SC); Janet Hart (PA); Josh Kohler (NC); Rich Palombo (NJ); Tejal Patel (DE); Doug Robichaux (LA); Kari Shanard-Koenders (SD); Mitch Sobel (NJ); Robert Stout (NH).

### Others Present:

Mark Johnston, *Executive Committee liaison*; Ross Brickley, *American Society of Consultant Pharmacists (ASCP)*; William "Fitz" Fitzpatrick, *guest*; Melissa Halvorson, *PharmD Candidate*; Carmen Catizone; Melissa Madigan; Eileen Lewalski; Scotti Russell, Maureen Schanck; Amy Suhajda, *NABP staff*.

### Introduction:

The Task Force met on August 16-17, 2017, at NABP Headquarters in Mount Prospect, IL. This task force was established in response to Resolution 113-4-17, Task Force on Long-Term Care Pharmacy Rules, which was approved by the NABP membership at the Association's 113<sup>th</sup> Annual Meeting in May 2017.

### Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing state laws and regulations addressing the practice of long-term care pharmacy.
2. Review current requirements for long-term care pharmacy practice contained within the Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).
3. Recommend, if necessary, amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing applicable state regulation of long-term care pharmacy practice.
4. Recommend, if necessary, revisions to the CSA and CFR.

**Recommendation 1: NABP Should Amend the Model Act.**

The task force recommends that NABP amend the *Model Act*. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

**National Association of Boards of Pharmacy  
Model State Pharmacy Act**

**Article I**

**Title, Purpose, and Definitions**

...

**Section 105. Definitions.**

...

- (x) “Chart Order”<sup>±</sup> means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her ~~designated agent~~ licensed health care designee for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:
- (1) the full name of the patient;
  - (2) date of issuance;
  - (3) name, strength, and dosage form of the Drug prescribed;
  - (4) directions for use; and
  - (5) if written or electronic, the prescribing Practitioner’s signature<sup>2</sup> or the signature of the Practitioner’s ~~agent~~ licensed health care designee (including the name of the prescribing Practitioner).; ~~or if electronically submitted, the prescribing Practitioner’s electronic or digital signature.~~

Bidirectional transmission of chart orders between the Institutional Pharmacy and the Institutional Facility may occur unless prohibited by state law.

Renewal of ongoing Chart Orders shall be signed by the prescriber at the appropriate time interval based on facility type and federal regulation, state law or rule. Unless otherwise indicated, Chart Orders shall be ongoing until such time as the Practitioner discontinues the order and such discontinuation is communicated to the Pharmacy.

...

- (a3) “Institutional Facility” means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
- (1) hospital;
  - (2) Long-Term Care Facility;
  - (3) convalescent home;

---

<sup>±</sup> ~~Chart Orders that are written by the Prescriber’s agent shall be countersigned by the prescribing Prescriber within the required time period as required by state law or rule.~~

<sup>2</sup> A Practitioner’s signature for Chart Orders is only required to be maintained at the Institutional Facility unless otherwise required for controlled substances by state and federal law.

- (4) nursing home;
- (5) extended care facility;
- (6) mental health facility;
- (7) rehabilitation center;
- (8) psychiatric center;
- (9) developmental disability center;
- (10) drug abuse treatment center;
- (11) family planning clinic;
- (12) penal institution;
- (13) hospice;
- (14) public health facility;
- (15) athletic facility;-
- (16) assisted living facility; and
- (17) intermediate care facility for individuals with intellectual disabilities.

...

(b3) “Institutional Pharmacy”<sup>3</sup> means any place that is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care Services to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as “Drugs”) are Dispensed, Compounded, and Distributed.<sup>4</sup>

(c3) “Therapeutic Interchange” means substitution by the pharmacist of one medication for another medication with a similar therapeutic effect at the time of dispensing.

...

## National Association of Boards of Pharmacy Model Rules

...

### Model Rules for Institutional Pharmacy

#### Section 1. Applicability.

The following Rules are applicable to all Institutional Facilities and Institutional Pharmacies as defined in Section 105 of the Model State Pharmacy Act.2 below.

---

<sup>3</sup> Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.

<sup>4</sup> States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed Pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed Pharmacy area to accommodate the need to store emergency supplies.

## **Section 2. Definitions.**

- (a) ~~“Chart Order” means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her licensed health care designee for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:~~
- ~~(1) the full name of the patient;~~
  - ~~(2) date of issuance;~~
  - ~~(3) name, strength, and dosage form of the Drug prescribed;~~
  - ~~(4) directions for use; and~~
  - ~~(5) if written, the prescribing Practitioner’s signature or the signature of the Practitioner’s agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner’s electronic or digital signature.~~
- (b) ~~“Institutional Facility”<sup>5</sup> means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):~~
- ~~(1) hospital;~~
  - ~~(2) Long Term Care Facility;~~
  - ~~(3) convalescent home;~~
  - ~~(4) nursing home;~~
  - ~~(5) extended care facility;~~
  - ~~(6) mental health facility;~~
  - ~~(7) rehabilitation center;~~
  - ~~(8) psychiatric center;~~
  - ~~(9) developmental disability center;~~
  - ~~(10) drug abuse treatment center;~~
  - ~~(11) family planning clinic;~~
  - ~~(12) penal institution;~~
  - ~~(13) hospice;~~
  - ~~(14) public health facility;~~
  - ~~(15) athletic facility.~~
- (c) ~~“Institutional Pharmacy”<sup>6</sup> means any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care Services to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as *Drugs*) are Dispensed, Compounded, and Distributed.<sup>7</sup>~~

## **Section 32. Personnel.**

---

<sup>5</sup>Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.

<sup>6</sup>States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

- (a) Each Institutional Pharmacy shall be directed by a Pharmacist, hereinafter referred to as the *Pharmacist-in-Charge*, who is licensed to engage in the Practice of Pharmacy in this State. The Pharmacist-in-Charge shall:
- (1) provide for the sufficient number and type of personnel to assist with the operation of the Institutional Pharmacy.
  - (2) oversee the supervision of Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and delivery personnel while performing duties in the Institutional Pharmacy and Institutional Facility.
  - (3) have policies and procedures for a Practitioner to delegate the transmittal of a Chart Order to a licensed nurse employed by, or contracted by, the Institutional Facility and acting within the scope of his/her practice.

**Section 4-3. Absence of Pharmacist at Pharmacies Located within an Institutional Facility.**

- (a) During such times as when an Institutional Pharmacy, which is located within an Institutional Facility, may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be “on call” during all absences.
- (b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet, Automated Pharmacy System or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:
- (1) Drugs are properly Labeled;
  - (2) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
  - (3) whenever access to the cabinet occurs, written Practitioner’s orders and proofs-of-use are provided;
  - (4) all Drugs therein are inventoried no less than once per week; unless stored in an Automated Pharmacy System;
  - (5) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
  - (6) written policies and procedures are established to implement the requirements of this Section 34.
- (c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given ~~eight-hour~~ shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing the patient name, room number, name of Drug, strength, amount, date, time, and

signature of nurse. The form shall be left with the container from which the Drug was removed.

#### **Section 4. Emergency Kit Use by Institutional Facilities**

- (a) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:
- (1) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.
  - (2) All emergency kit Drugs shall be provided and sealed by a Pharmacist; or his/her designee.
  - (3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.
  - (4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.
  - (5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist Pharmacy.
  - (6) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.
  - (7) Whenever an emergency kit is opened, the supplying Pharmacist Pharmacy shall be notified and the Pharmacist Pharmacy shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.<sup>8</sup>
  - (8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist Pharmacy shall replace the expired Drug.
  - (9) The Pharmacy that supplies controlled substances for emergency kits must comply with applicable state and federal requirements.

#### **Section 5. Drug Distribution and Pharmacist Care Services Control.**

- (a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient acquisition, handling, storage, Distribution and Dispensing of Drugs, including investigational Drugs, and for the provision of Pharmacist Care Services. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.
- (b) Pharmacist may engage in Therapeutic Interchange or formulary substitution as authorized by the facility's interdisciplinary committee<sup>9</sup> of health care providers, at a minimum to include a Practitioner and a Pharmacist. Proper record of this authority should be maintained at the Pharmacy.

---

<sup>7</sup> When the Pharmacy restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

<sup>8</sup> This is often referred to as the pharmacy and therapeutics committee or the quality assessment and assurance committee.

- (c) To ensure continuous patient care, the facility's director of nursing or their documented licensed health care designee shall be considered the legal agent of the Practitioner who is providing care for a patient in the facility and is thereby authorized to transmit the Chart Order to a Pharmacy.
- (d) The Pharmacist shall assess each patient's medication regimen based on a review of the health record, either remotely or on site, in a timely manner that promotes improving patient clinical outcomes, medication safety and education, and appropriate care management.
- (e) If the Institutional Pharmacy is not located within an Institutional Facility, a licensed nurse can restock an Automated Pharmacy System under the supervision of a Pharmacist by such means as bar code scanning technology.
- (f) Institutional Pharmacies either located within or not within Institutional Facilities may Dispense medication to patients upon discharge in order to ensure a transition of care between settings until a new Prescription Drug Order is issued.
- (b) ~~Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist in Charge shall, according to procedures specified in writing, have them turned in to the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.~~
- (c) ~~Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.<sup>40</sup>~~

## **Section 6. Shared Pharmacy Services Utilization for Immediate Need.<sup>11</sup>**

- (a) In accordance with the Model Rules for the Practice of Pharmacy and Shared Pharmacy Services, an Institutional Pharmacy may outsource services to another Pharmacy for the limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:
  - (1) has obtained approval from the Institutional Facility to outsource Shared Pharmacy Services for its inpatients and residents; and
  - (2) ~~provides~~ shares a valid Chart Order ~~to~~ with the Pharmacy it has contracted with for the Shared Pharmacy Services without the need to transfer.

---

<sup>9</sup>Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.

<sup>10</sup> Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.

## **Section 7. Packaging of Previously Dispensed Medication**

- (a) At a patient's or patient's caregiver's request, a Pharmacy may change the packaging of a Drug previously dispensed to the patient.
- (b) Any Pharmacy providing packaging services shall have in place policies and procedures to:
  - (1) assess whether the medication may be Adulterated or Misbranded; and
  - (2) package and label the medication in compliance with State and Federal requirements and USP standards.
- (c) The Pharmacy that packages a previously dispensed medication shall retain all original prescription information in accordance with State record keeping requirements.

## **Section 8. Institutional Pharmacy Delivery Room.**

Prescription Drugs, Devices, and other Products restricted to sale or Dispensing by, or under the supervision of, a Pharmacist must be stored in the Pharmacy and must not be sold, Delivered, or otherwise removed from a Pharmacy unless a Pharmacist is present, except:

- (a) Institutional Pharmacies that are not located within an Institutional Facility may accept Return or otherwise Deliver fulfilled, verified, and packaged prescription medication in the absence of a Pharmacist or when the Pharmacy is closed for business if:
  - (1) the prescription medications are placed in a secured delivery area equipped with adequate security, to prevent unauthorized entry, theft, and diversion. The secured delivery area must be:
    - (i) attached or located adjacent to the Pharmacy that fulfilled, verified, and dispensed the prescription medication;
    - (ii) have appropriate safeguards to ensure Drug Product integrity in accordance with USP-NF requirements.
  - (2) the Pharmacist-in-Charge, or designated Pharmacy staff and the approved delivery personnel have sole access to the secure delivery area.
  - (3) the Pharmacy and the Pharmacist-in-Charge shall maintain written policies and procedures for secured delivery area storage and removal of prescriptions.
  - (4) a Pharmacist or a Pharmacy, by means of its delivery personnel, may accept the return of the following Drugs or Devices to the secured delivery area:
    - (i) emergency kits;
    - (ii) prescription medications that were unsuccessfully Delivered by the Pharmacy personnel, or delivery personnel; and
    - (iii) prescription medications eligible for return pursuant to applicable state and federal law.

## **Model Rules for the Practice of Pharmacy**

### **Section 13. Prepackaging.**

- (a) A Pharmacy may Prepackage Drugs under the following circumstances:



- (1) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;
- (2) containers utilized for Prepackaging shall meet, as a minimum requirement, Class B container standards as referenced by the USP;
- (3) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;
- (4) the Prepackaged Drugs are labeled with the following components:
  - (i) Drug Name;
  - (ii) Drug Strength;
  - (iii) Pharmacy Control and Manufacturer lot number;
  - (iv) Name of the Manufacturer or Distributor of the Drug or National Drug Code; and
  - (v) Beyond-Use Date-, which shall be the Manufacturer's expiration date or one that is required under USP standards, whichever is earlier;
- (5) ~~(vi)~~ Records of all Prepackaging operations are maintained and include the following:
  - (i) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;
  - (ii) the name of the Manufacturer or Distributor of the Drug;
  - (iii) Pharmacy Control and Manufacturer lot number;
  - (iv) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;
  - (v) the name, initials, or identification codes of the Certified Pharmacy Technician or Certified Pharmacy Technician Candidate that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
  - (vi) the date the Drug is Prepackaged.
- ~~(6)~~~~(vii)~~ All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs, or with requirements in the current edition of an official compendium.
- (b) Pharmacies that store Drugs within an automated counting device or Automated Pharmacy System may, in place of the required Label, maintain records for lot numbers and beyond-use dates that are required on the Label as long as it is fully traceable and is readily retrievable during an inspection.
- (c) The Repackaging of Drugs shall follow applicable state and federal law.

### **Background:**

The task force discussions began with a review of recommended revisions by Ross Brickley from the American Society of Consultant Pharmacists (ASCP). The task force members opined that pharmacies that provide pharmacy services to patients in long-term care facilities often have to operate under pharmacy laws and rules that are written for community pharmacy or pharmacies that are located within an institutional facility, such as a hospital pharmacy. The members learned that as health care evolves long-term care facilities and assisted living facilities are caring for more complicated patients than ever before. The members were asked to consider if current regulations adequately serve patients' medication needs as they transition through various levels of care.

The task force discussed the benefits to patient care and health care delivery that would occur if nurses in institutional facilities could be delegated authority by the prescriber to transmit orders from an institutional facility to pharmacies located outside the institutional facility in order to provide medications in a timely manner. However, task force members noted that such delegated authority is currently only permitted by United States Drug Enforcement Administration (DEA) policy for the transmission of controlled substance orders if a formal agent agreement has been executed. Another challenge to dispensing drugs in a timely manner for pharmacies that serve long-term care facilities and assisted living facilities is the lag time between the patient's admission and the time it takes the pharmacy to receive new chart orders. The task force supported the notion that state pharmacy laws and rules should be amended to allow one institutional pharmacy to dispense enough discharge medication until new chart orders are acquired by the subsequent pharmacy. The members also agreed to keep the shared pharmacy services section for continuity of care. Members proposed that their recommended amendments will facilitate care between settings and enhance patient-centered care.

The members reviewed the definition of "chart order" and recommended that the definition be amended to allow the prescriber's authorized agent's signature or his/her designated health care designee's signature to be valid and that regulatory boards should allow for the bidirectional transmission of chart orders to enhance communication between the pharmacy and health care providers at the institutional facility and to provide more accurate and complete information among all providers involved in the patient's care. Furthermore, in order to ensure that the patient is not left without needed medication, the task force members recommended that, for patients being cared for in an institutional facility, the chart order should be deemed active until discontinued by the prescriber.

It was brought to light that the existing provisions outlined in the *Model Act* for access to drugs during the absence of a pharmacist are not applicable to pharmacies that serve long-term care and other institutional facilities that are not located on the same premises as the institutional facility. Therefore, amendments were made to this section to clarify that after-hours access to drugs, either by means of a night cabinet or by entry into the pharmacy, is only applicable to pharmacies located on site relative to the institutional facility. However, since emergency kits are used in long-term care facilities and hospital settings alike, a separate section was delineated for emergency kits to make it applicable to both settings.

Furthermore, the drug distribution and control section was amended to reflect technological advances in pharmacy and considerations for streamlining the delivery of pharmacist care services. Members proposed that pharmacists who serve long-term care facilities should be granted the professional discretion, as hospital pharmacists are, to perform formulary substitutions pursuant to the authorization from the pharmacy and therapeutics committee or the quality assessment and assurance committee, depending on the setting. Members also agreed that medication therapy management could occur more expeditiously or more often if state pharmacy laws or rules allowed this to be performed remotely as delineated in the

Provision of Pharmacist Care Services Outside of a Licensed Pharmacy section in the *Model Act*. As technology evolves to provide the possibility of remote verification, the task force members were in consensus that states should allow nurses to restock automated pharmacy systems under the direct supervision of a pharmacist by means of appropriate technology to facilitate drug delivery to patient care settings.

The task force members were in unison about prepackaging being an essential component of institutional pharmacy services. The task force members discussed that prepackaging should not be confused with repackaging, which requires Food and Drug Administration (FDA) registration and compliance with corresponding FDA regulations. The members agreed that the proposed amendments to the Prepackaging section, which currently exists in the Model Rules for the Practice of Pharmacy, will help align the section with United States Pharmacopeia prepackaging standards. Attention was also given to the fact that third-party payers, such as the Veterans Health Administration, will not reimburse for medication that was already dispensed by another pharmacy or requires the patient to receive the medication only by mail. Therefore, the task force also recommended that new rules should be added to allow for the packaging of medication previously dispensed by another pharmacy.

Members reviewed proposed rules from ASCP to address delivery rooms in pharmacies that serve long-term care facilities in multiple locations and considerable distances apart. In such cases drug deliveries and returns occur throughout the day and in the evening when the pharmacy may be closed. Therefore, the task force members agreed to include provisions to allow for the fulfillment of drug deliveries and returns when a pharmacist is not present or when the pharmacy is closed, by allowing access to a secure area by delivery personnel in conformity with policies and procedures approved by the pharmacist-in-charge.

**Recommendation #2: NABP Should Collaborate with DEA to Recommend Revisions to the United States Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).**

The task force recommends that NABP collaborate with DEA to recommend revisions to the CSA and CFR in order to facilitate the adoption of the task force recommendations related to controlled substances.

**Background:**

The task force recommends that NABP work with DEA to align federal laws and rules with those in the *Model Act*. The task force noticed that DEA does not define “long-term care facility” in federal regulations. Members agreed that a definition of long-term care facility will help acknowledge the unique nature of this health care setting and will clarify the responsibilities pharmacies undertake to serve them. The task force supports amendments to federal and state laws and rules to improve patient care by allowing prescribers to delegate the transmission of chart orders to pharmacies by nurses in long-term care facilities, including those for controlled substances. The task force supports any changes necessary for institutional facility employees to be authorized agents of prescribers in order to transmit controlled substance prescriptions or chart orders to the pharmacy. Furthermore, as electronic health records become a standard

for patient care, the task force opined that DEA should amend federal regulations to allow for the bidirectional transmission of chart orders to allow pharmacists and other practitioners to exchange up-to-date and complete patient information. The dialogue with DEA should also include a discussion regarding the requirement for central fill pharmacies to return filled prescriptions to the originating pharmacy to help reduce medication waste and improve efficiency, while reducing opportunities for diversion. Furthermore, the task force supports messaging that medications, including controlled substances, should not be stockpiled awaiting pharmacist destruction if in long-term care facilities DEA and local authorities allow destruction by institutional facility staff.

The task force also discussed the need to exempt pharmacies that dispense controlled substances to institutionalized patients in long-term care facilities from positive identification requirements as required by many states prior to the dispensing of a controlled substance prescription, since this is burdensome and the identification of the patient is already routinely handled by the institutional facility. The Model Prescription Monitoring Program Act found in the *Model Act* already includes footnote to exempt pharmacies from reporting requirements for patients in institutional facilities.

**Recommendation #3: NABP Executive Committee Should Allow the Task Force to Continue Its Work in Drafting Recommended Revisions to the United States Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).**

The task force requests that the NABP Executive Committee consider allowing the task force to continue its work in drafting recommended revisions to the CSA and CFR by electronic means and conference calls.

**Background:**

The task force concluded that, in order to fulfill the charge of the task force, members should continue to convene electronically and/or by conference call to draft recommended language for the CSA and CFR to facilitate implementation of the task force recommendations, particularly those related to controlled substances. Members recognize that laws and rules related to controlled substances in long-term care facilities are outdated and need to be revised to better serve this patient population. The task force wishes to expand on the work of previous task forces related to long-term care facility regulation. Task force members are intent on drafting CSA and CFR revisions that can be presented to the DEA to initiate change in federal laws and rules to align with current health care needs and to lead to better patient care.