



**NABP/ASCP JOINT REPORT:  
MODEL RULES FOR LONG-TERM CARE PHARMACY  
PRACTICE**



**Executive Summary:**

The National Association of Board of Pharmacy's (NABP) *Model State Pharmacy Act and Model Rules (Model Act)* serves as a resource to the state boards of pharmacy to promote uniform regulatory standards. As the number of our nation's seniors has grown, so to have the demands and challenges placed upon the pharmacists serving those seniors who live in long-term care facilities. Since the practice of pharmacy has evolved over the years with increased workload demands, changing roles of pharmacy technicians, and new technologies, so too have the regulatory guidelines and oversight responsibilities of the state boards. Not only will the practice of pharmacy need to adapt to the needs of seniors in long-term care facilities, but state boards of pharmacy and the pharmacists under their purview must understand the impact of these changes. Pharmacists practicing in long-term care must collaborate with state boards of pharmacy to update practice acts to ensure the protection of the health, safety and welfare of the public.

In late 2005, at the direction of the NABP Executive Committee, NABP convened its Task Force on Model Regulations for Long-Term Care (LTC Task Force), assisted by the American Society of Consultant Pharmacists (ASCP). The goal of the meeting was to review issues defined by and impacting the practice of pharmacy in long-term care settings and identify provisions of the *Model Act* that may necessitate revision with respect to long-term care pharmacy practice. As a result of the efforts of the Task Force, several practice areas within the long-term care setting were identified as areas in need of updating or inclusion within the *Model Act*. Most of these practice areas reflected the increasing level of service in long-term care settings and represented current standard of care that is regularly provided to patients in such settings. The suggested revisions to the *Model Act*, most of which were in the *Model Act's Model Rules for Institutional Pharmacy*, attempted to bridge the gap that currently exists between state pharmacy law and the level of service being provided in long-term care settings.

Also in late 2005, and again in mid-2006, NABP convened its Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions. This Task Force (Telepharmacy Task Force) recommended amending the *Model Act* to provide a more extensive regulatory framework for telepharmacy practice, including the use of remote dispensing systems in institutional and long-term care settings.

In sum, the revisions to the NABP *Model Act* suggested by these Task Forces represent an effort to recognize current standards of care in long-term care settings with appropriate regulation.

Subsequent to the meetings of each of these Task Forces, the recommended revisions were approved by NABP's Executive Committee. The revised *Model Act* can be found at <http://www.nabp.net/ftpfiles/NABP01/ModelActFINAL.doc>.

The goal of this Report is to provide background on the unique and highly skilled level of patient care in long-term care settings and to provide justification for updating state laws addressing pharmacy practice in these settings. As the practice of long-term care pharmacy has evolved, so too must the governing laws and regulations.

The practice issues identified by this Report are as follows:

1. The definitions of “long-term care facility” and “institutional pharmacy;”
2. The definition of prescription “drug order” to include “chart orders;”
3. The definition of “emergency medication kits” in long-term care settings and the need for starter-dose pharmacies in these settings;
4. Who may be defined as the agent of the physician in long-term care settings;
5. Repackaging medications dispensed by another pharmacy;
6. Medication therapeutic-interchange processes; and.
7. Remote pharmacy dispensing services.

## **1. The Definitions of “Long-Term Care Facility” (LTCF) and “Institutional Pharmacy”**

### **Background**

With the increasing demand for better quality care and a higher level of service, facilities, such as those offering assisted living accommodations or intermediate care for the mentally retarded, have come to more closely resemble traditional skilled nursing facilities. Special medication packaging and delivery services, for example, are now widely available in these facilities. These pharmacy services are needed to help ensure accurate and efficient administration of medications to residents and prevent diversion of controlled substances stored and administered in these facilities. Accordingly, these facilities should be defined in a way that recognizes this increasing level of pharmacy services. Alabama, for example, recently issued a final rule that includes assisted living in the definition of “institutional pharmacy.” Other state pharmacy practice acts should be updated to recognize the specialized care and services provided by these pharmacies.

Although the NABP *Model Act* included a definition of “long-term care facility” prior to the LTC Task Force meeting, the definition did not take into account certain long-term care facilities that receive institutional pharmacy services, but which may not be recognized as such. The LTC Task Force members agreed that the *Model Act’s Model Rules for Institutional Pharmacy* should be amended to recognize long-term care pharmacy practice as a subset of institutional pharmacy practice. With this in mind, LTC Task Force members recommended amendments to the definitions of “institutional facility” and “institutional pharmacy,” and an amendment to allow pharmacies serving long-term care facilities to provide emergency drug kits to be used in the absence of a pharmacist. Of note, these amendments exempt LTCF pharmacies from the patient counseling requirements of the *Model Act’s Model Rules for Pharmaceutical Care* and allow them to utilize a drug formulary system.

### **Outcomes:**

- The definition of “institutional facility” in the *Model Act* was revised to include long-term care facility.
- The definition of “institutional pharmacy” was modified to mean “any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmaceutical Care 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.”

## **2. Definition of Prescription Drug Order to Include Chart Orders**

### **Background:**

In the current long-term care practice setting, caregivers commonly refer to the patient's medical chart to determine when a prescription drug refill is needed and to record, monitor, and make necessary changes to a patient's medication therapy. The caregiver or health professional administering the medication uses the "chart order" within the medical chart as the reference for completing the medication administration record. This one consistent record is essential to the delivery of quality health care and to ensure that medication administration errors are minimized. With this in mind, LTC Task Force members felt the *Model Act* should be updated to incorporate this unique, yet important aspect of patient care in long-term care settings. Prior to the LTC Task Force meeting, the *Model Act* included a definition of "Prescription Drug Order," which includes the date of issuance, name, strength, and dosage form of the drug prescribed, directions for use, and the prescriber's signature. The LTC Task Force, however, recognized that other components of a "Prescription Drug Order," such as the full name and street address of the patient, the DEA number of the prescribing practitioner, quantity of the drug prescribed, and number of refills, are not typically included on orders in institutional settings. The LTC Task Force, therefore, recommended the recognition of orders in institutional settings via the inclusion of the term and definition for "Chart Order" as a lawful and valid prescription drug order utilized in an institutional facility.

### **Outcome:**

A definition of Chart Order was created in the *Model Act* under the *Model Rules for Institutional Pharmacy*.

## **3. The Need for Starter Dose Pharmacies in the Long-Term Care Setting and Definition of Emergency Medication Kits for Use Therein**

### **Background:**

Arbitrary restrictions on the availability of initial doses of medications in long-term care facilities compromise the quality of care rendered to residents. There are situations where long-term care residents require immediate care that may easily be provided by an emergency drug kit or a starter dose pharmacy. These patients, especially those who are frail elderly, cannot wait until the next day to receive their medications. Emergency kits and starter dose pharmacies allow the patient to receive an immediate dose of a medication not currently on that patient's medical chart. Use of starter dose pharmacies is particularly important in rural areas where the closest pharmacy may be 50 miles away.

The LTC Task Force agreed that institutional pharmacies, and specifically those that provide services to long-term care facilities, should be allowed to utilize centralized prescription processing arrangements to provide continuous services to inpatients. "Centralized Prescription Processing" and "Centralized Prescription Filling" as recognized in the *Model Act*, allow a pharmacy to process a request from another pharmacy to fill or refill a prescription drug order or

to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations and therapeutic interventions. The LTC Task Force members recommended that centralized prescription services be incorporated into the *Model Rules for Institutional Pharmacy*, recognizing the use of a valid chart order and specifying that the institutional pharmacy outsourcing services have been approved by the institutional facility.

**Outcomes:**

- The need for emergency medications in long-term care settings was resolved by amending the *Model Rules for Institutional Pharmacy* to allow the use of emergency kits to meet the immediate therapeutic needs of patients pursuant to a Chart Order.
- The need for starter-dose pharmacies in the long-term care setting was addressed by creating a new section in the *Model Rules for Institutional Pharmacy* entitled “Centralized Prescription Processing for Immediate Need,” which allows an institutional pharmacy to outsource services to another pharmacy under specific guidelines defined in the *Model Act* for the purposes of assuring that drugs or devices are attainable to meet the immediate needs of patients of the institutional facility.

#### **4. Who Can Be Defined as the Agent of the Physician in Long-Term Care Settings**

**Background:**

At this time, the US Drug Enforcement Administration (DEA) does not recognize long-term care or nursing facility staff as agents of prescribers, prohibiting them from transmitting orders for controlled substances for prescribers to pharmacies. This position was conveyed in an April 2001 *Federal Register* notice, as part of DEA’s efforts to solicit comments on preventing accumulation of controlled substances at long-term care facilities. In that notice, the DEA stated that since no legal agency relationship exists between the long-term care facility nurse and the physician, long-term care facility nurses who relay changes in medication therapy to pharmacists are not in compliance with legal controlled substance prescription requirements.

In the long-term care setting, physicians are not on-site at the nursing facility and typically visit the facility only once per month to see patients. As a result, they rely on nursing facility staff to transcribe and communicate orders to the long-term care pharmacy. These orders are a part of the residents’ medical chart and are recognized as valid prescriptions in many states. In fact, NABP recently adopted a resolution formally recognizing chart orders as valid prescription orders in the long-term care setting.

Because many of the residents in long-term care face chronic or acute pain situations, allowing the nurse to act as an agent of the physician will result in better patient care, especially in the area of pain management. In many of these cases, the orders are simply refills for controlled substance medications that have run out. Currently, refill requests must be faxed to the physician’s office and then faxed to the long-term care pharmacy each time the patient’s medication runs out and a refill is needed, regardless of the day or time, and regardless of whether or not the off-site physician is near a fax machine. This process would be much more efficient if the nurse were able to take a verbal order from the physician and then communicate that order along to the long-term care pharmacy. This, however, is not allowed by DEA. To

remedy this, DEA has suggested that nurses, rather than contact the physician for an order, contact the provider pharmacy, and have the pharmacist contact the physician. This, according to the DEA, will avoid multiple contacts or phone calls to the physician. This may not, however, be the case. If the prescribing physician has a question about the patient that only the nurse can answer, multiple contacts and phone calls are still necessary. Again, more effective patient care would be provided if nurses could be considered agents of the prescribing physician in these instances.

Prior to the LTC Task Force meeting, the *Model Act* did not specify the legality of the relationship between a practitioner and a practitioner's agent. The *Model Act*, therefore, was amended to clarify that an agency relationship between a facility nurse and prescriber can exist in conformance with facility policies and procedures.

**Outcome:**

- In the NABP *Model Act*, it was clarified that an agency relationship between a prescriber and a staff nurse can exist, in compliance with state law, at an institutional facility, but that such agent must be authorized by that facility to do so in the facility's written policies and procedures in accordance with applicable state and federal laws. In addition to this, the LTC Task Force urged NABP to adopt a resolution to encourage the DEA to reexamine its interpretation of the agency relationship between the long-term care facility and alternate care site nurses to consider recognizing the agency relationship in the presence of written facility policies and procedures. This would allow the long-term care nurse to legally communicate controlled substance orders and changes to such orders to pharmacists responsible for the care of the patient. This resolution was subsequently approved by NABP's member boards.

## **5. Repackaging Medications Dispensed by Another Pharmacy**

**Background:**

In formulating this recommendation, the LTC Task Force members emphasized the difference between "repackaging" and "prepackaging." According to the *Model Act*, the act of "repackaging" is considered "manufacturing," which is defined as the "production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis." Manufacturing includes the packaging or repackaging of a drug or device or the labeling or relabeling of the container of a drug or device for resale by pharmacies, practitioners, or other persons."

LTC Task Force members wanted to distinguish pharmacies that perform repackaging and re-labeling operations beyond the usual conduct of dispensing from those performing "prepackaging" operations, emphasizing that the former are subject to state and federal laws and regulations with respect to manufacturing. The state boards of pharmacy and the FDA recognize that many pharmacies engage in "prepackaging." According to FDA's Compliance Policy Guide 7132.06, FDA recognizes prepackaging by hospital pharmacies dispensing to patients of the hospital. In the long-term care pharmacy setting, this practice is similar with respect to long-term

care pharmacies prepackaging medications for residents of the long-term care facility served by that pharmacy. As stated in FDA Compliance Policy Guide 7132.06:

**“Prepackaging**

We do not believe that “prepackaging” by the hospital pharmacy for dispensing within the hospital, or for outpatient dispensing, or for transferal to another unit of the hospital, would require registration under Section 510 of the Federal Food, Drug, and Cosmetic Act. However, repackaging of a drug which is sold to another hospital, whether or not such other hospital is under the control of the same corporation, would require registration under Section 510.”

It is standard practice in today’s long-term care environment for pharmacists to prepackage medications from the manufacturer’s original packaging into unit dose blister cards for residents of long-term care facilities. The practice of providing specialized or compliance packaging has been a hallmark of long-term care pharmacy practice to help reduce medication administration errors and assist facility and pharmacy staff in identifying drug diversion. This practice was recently recognized by the Centers for Medicare & Medicaid Services (CMS) as one of ten service and performance criteria that is commonly provided by long-term care pharmacy.

Accordingly, the boards of pharmacy in many states, including Arizona, Minnesota, Montana, and Nevada, have developed prepackaging regulations that specify labeling and recordkeeping requirements. The LTC Task Force members, recognizing that prepackaging activities are a common occurrence, suggested that the *Model Act* incorporate specific regulatory guidance for this activity.

**Outcome:**

- By creating a definition under the *Model Rules for Pharmaceutical Care* for “prepackaging,” NABP distinguished “prepackaging” from “repackaging,” and clarified that repackaging medications previously dispensed by another pharmacy is considered manufacturing.

**6. Medication Therapy Management Services**

**Background:**

NABP’s *Model Act* allows pharmacists to provide medication therapy management services as an element of pharmacist care.<sup>1</sup> Under the Model Act, medication therapy management services are intended to optimize therapeutic outcomes for patients and may include:

- (1) Performing or obtaining necessary assessments of the patient’s health status;
- (2) Formulating a medication treatment plan;

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<sup>1</sup> NABP’s Model Act definition of “medication therapy management” is derived from the definition approved July 27, 2004 by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy\*\*, the National Association of Chain Drug Stores, the National Community Pharmacists Association and the National Council of State Pharmacy Association Executives.

\*\* Organization policy does not allow NABP to take a position on payment issues.

- (3) Selecting, initiating, modifying, or administering medication therapy;
- (4) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- (5) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (6) Documenting the care delivered and communicating essential information to the patient's other primary care providers;
- (7) Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
- (8) Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
- (9) Coordinating and integrating Medication Therapy Management services within the broader health care-management services being provided to the patient; and
- (10) Such other patient care services as may be allowed by law.

The NABP Model Act recognizes that certain Medication Therapy Management Services may need to be performed within the confines of a collaborative practice agreement or formulary system managed by a Pharmacy and Therapeutics Committee within an institutional setting. These services can prove invaluable to patient care. In long-term care settings, collaborative agreements or formulary systems that allow pharmacists to select, initiate, and/or modify medication therapy can be particularly beneficial.

It is important to differentiate medication therapy management services from medication regimen review services in the long-term care setting, which are mandated as a component of a broad range of nursing facility regulations in the Centers for Medicare and Medicaid Services (CMS) State Operations Manual (SOM).

**Outcome:**

- NABP encourages state boards of pharmacy to review and seek revision of statutes or rules to strengthen legislation for pharmacist involvement in medication therapy management services, including those that allow pharmacists to select, initiate and/or modify medication therapy services pursuant to a collaborative practice agreement with a prescriber.

## **7. Remote Pharmacy Dispensing Services**

**Background:**

NABP's Telepharmacy Task Force developed a framework for the provision of remote pharmacy services while considering current regulatory and patient safety standards, allowable scope of practice, the use of pharmacy support personnel, and maintenance of quality assurance procedures. The Telepharmacy Task Force developed these recommendations recognizing the national pharmacist shortage and the potential to effectively provide pharmacist care services using electronic technologies to patients at a distance.

**Outcome:**

- NABP added to the *Model Act* definitions of "remote pharmacy," "remote dispensing site," and "coordinating pharmacy" to provide the basic framework for the provision of remote



pharmacy services. A “remote pharmacy” is a “pharmacy staffed by a pharmacist, pharmacy intern, or certified pharmacy technician that is electronically linked to the coordinating pharmacy via a computer system and/or a video/auditory communication system approved by the board.” A “remote dispensing site” is a site located within an institutional facility or a clinic that utilizes an automated pharmacy system and that is electronically linked to the coordinating pharmacy via a computer system and/or a video/auditory communication system approved by the Board. A “coordinating pharmacy” is a pharmacy responsible for the practice of telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites.”

- The *Model Act* was amended to add regulations addressing the registration/licensure of the primary and remote sites (coordinating pharmacy, remote pharmacy, and remote dispensing site), remote site personnel, remote patient counseling, the use of automated dispensing technologies, security, policies and procedure maintenance, quality assurance, recordkeeping, and the restriction of remote sites to areas or communities that are underserved.

### **Conclusion:**

The NABP and ASCP recommend that the seven practice issues addressed in this Report be reviewed and adopted as appropriate by state boards of pharmacy. Pharmacists must understand the impact of these changes and collaborate with state boards of pharmacy to update state pharmacy practice acts to ensure the protection of the health, safety and welfare of the public. This will allow pharmacists to practice to the full extent of their skills and knowledge and serve the unique needs of the growing population of frail elderly patients residing in long-term care facilities.