



## Task Force on Mail Delivery Prescriptions

### Members Present:

David R. Work, *Chair* (NC); Mark T. Conradi (AL); Kendall M. Lynch (TN); Audrey H. Neely (IL); Herbert E. VonGoerres (DE); Charles R. Young (MA).

### Others Present:

Drexel Douglas, *Executive Committee Liaison*; Carmen A. Catizone, *NABP Executive Director/Secretary*; Melissa Madigan, *NABP Staff*.

### Invited Guests

Tim Grady, *United States Pharmacopeia*; Del Konner, *Pharmaceutical Care Management Association*; Larry Pilot, *Pharmaceutical Care Management Association*; Joseph G. Valentino, *United States Pharmacopeia*.

### Absent:

Janet H. Shipton (MO)

### Introduction:

The Task Force on Mail Delivery of Prescriptions (TFMDP) met January 23, 1998, at NABP headquarters in Park Ridge, Illinois. The Task Force was established by the NABP Executive Committee in response to Resolution No. 93-16-97, *Maintenance Medications*, which was approved by the delegates to the Association's 93<sup>rd</sup> Annual Meeting in San Diego, California. Resolution 93-16-97 reads as follows:

**Whereas**, increasing health care costs and managed care are resulting in the delivery of an increasing number of prescriptions for maintenance medications by mail or any other commercial carrier; and

**Whereas**, this system of delivery may result in patients with serious chronic medical conditions not receiving their medications when needed; and

**Whereas**, it is important that their drug therapy not be interrupted;

**Therefore Be It Resolved** that NABP create a task force to address the problems and safety concerns surrounding the delivery of prescriptions by mail or any other commercial carrier.

### Review of the Task Force Charge

Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

1. Review the present system of delivering medications by mail and commercial carrier;
2. Assess whether such delivery is safe; and
3. Determine the need for model regulations to address any concerns or problems noted.

### **TFMDP Recommendation #1**

The Task Force on Mail Delivery of Prescriptions recognizes that the issue of drug product integrity during shipment by mail or common carrier is still developing and, therefore, cannot be voted upon at this time. The Task Force recommends that the NABP Executive Committee closely follow this issue and, should it be determined that drug product integrity cannot be assured by pharmacies shipping medications in such a manner, take further action at that time.

#### **Background:**

Task Force members identified the maintenance of drug product integrity as one of the key issues surrounding the delivery of medications by mail or common carrier, recognizing that temperature and humidity variations experienced during shipment may be so extreme as to compromise product integrity.

United States Pharmacopeia (USP) vice president and general counsel Joseph Valentino and vice president for USP's Department of Drug Standards Tim Grady informed Task Force members about a recent study performed by the USP, which sought to determine the temperature and humidity conditions to which drugs are subjected when shipped through the mail during the summer months. Between June and August of 1996, electronic temperature and humidity indicators were packaged and shipped through the mail to different parts of the country. The study measured the results in terms of USP's definition of controlled room temperature (generally 20-25°C or 68-77°F), and found that only 8.4 percent of the packages experienced temperature variations within the excursions allowable under that definition. Of the remaining packages, 65.5 percent experienced what were considered warm conditions (30-40°C or 86-104°F), and 26.1 percent experienced excessive heat (more than 40°C or 104°F). The study also showed the packages were exposed to significant spikes in relative humidity. The study authors concluded that there could be a need to require that temperature devices accompany selected medications.

Noting that no drugs were actually shipped and that USP planned to repeat its study during the summer 1998, the Task Force, while expressing concerns regarding product integrity during shipment, felt that the question of whether or not shipped medications are at risk of degradation could not yet be answered and that further studies were indicated. Accordingly the Task Force agreed that NABP should continue to monitor the activities being performed by USP in this area. Some Task Force members questioned whether or not such information could be obtained directly from the pharmaceutical manufacturers themselves based on their own product stability studies. Noting that such information was likely of a proprietary nature, members felt that access to such information would be unlikely, but agreed that NABP should at least pursue this option.

When and if it is discovered that certain medication are at risk of being rendered ineffective or unsafe if subjected to the temperature and/or humidity conditions found during shipment, the Executive Committee should take further appropriate action. Should it be necessary at some point to amend the *NABP Model State Pharmacy Act and Model Rules (Model Act)* to assure product integrity during shipment, the following language, modified from Section 6 of the Model Rules for Sterile Pharmaceuticals, may be appropriate:

**Delivery Service:** The Pharmacist-in-Charge shall assure the environmental control of all products shipped. Therefore, any pharmaceutical must be shipped or Delivered to a

patient in appropriate temperature-controlled (as defined by USP Standards) Delivery containers and stored appropriately in the patient's home.

### **TFMDP Recommendation #2**

The Task Force on Mail Delivery of Prescriptions recommends to the Executive Committee that the *Model Act* be revised to require pharmacies that ship medications by mail or common carrier to implement a mechanism by which they may verify that a patient or caregiver has actually received the delivered medication. The Task Force further recommends that such a mechanism include a waiver provision that allows the patient or caregiver to request delivery without verification, and advises the patient or caregiver of the possible consequences of receiving delivery without verification.

#### **Background:**

Task Force members discussed the issues surrounding the verification of receipt of medications shipped by mail or common carrier. While some expressed concern about patients or caregivers not receiving their medications should they not be at home to accept shipment, all members agreed that documenting that the patient or caregiver has received their medications is in the best interest of the public health. Such documentation assures that medications are not left in mailboxes or on doorsteps where theft and exposure to temperature and humidity extremes can occur. Members agreed, however, that such documentation may pose a hardship or may not be in the best interest of some patients.

With these concerns in mind, the Task Force agreed that a recommendation to the Executive Committee that the *Model Act* be amended to require pharmacies that ship medications by mail or common carrier to establish some sort of mechanism to verify that a patient or caregiver has received the delivered medication was in order. The Task Force further agreed that such a mechanism should include a waiver provision that allows the patient or caregiver to request delivery without verification as long as the waiver provision advises the patient or caregiver of the consequences of receiving delivery without verification (i.e., possible theft or exposure to the elements).

Task Force members also discussed the related concept of pharmacies documenting the receipt by patients of *all* prescription medications, specifically in the outpatient pharmacy setting. Members agreed that requiring, for example, positive identification and a signature at the time of dispensing would likely reduce the incidence of prescription fraud. It was noted that due to third-party payor requirements, a large number of patients or caregivers are already signing for their prescriptions. Therefore, any additional burden on pharmacies to obtain signatures would be minimal. Although it was conceded that this subject was outside the scope of the Task Force charge, members felt it important enough to recommend that the Executive Committee examine this option as a means of reducing fraud.

### **TFMDP Recommendation #3**

The Task Force on Mail Delivery of Prescriptions recommends to the Executive Committee that the *Model Act* be revised to require pharmacies that ship medications by mail or common carrier to establish a mechanism by which patients can secure their medications from alternative pharmacists/pharmacies in situations when the medication is not delivered or deliverable.

**Background:**

Task Force members expressed concern about natural disasters, problems with delivery service, and similar situations that may prevent patients who routinely receive their maintenance medications via the mail or common carrier from receiving a new supply of medication before they run out and must go without it for a period of time. Several members stated that such scenarios form the basis for a large number of complaints received by their boards from members of the public.

Del Konnor, executive vice president of the Pharmaceutical Care Management Association (PCMA), explained that PCMA's members already have internal quality control procedures that include some sort of mechanism by which patients who do not or cannot receive their medication by mail can obtain medications from a local or alternate pharmacy. Task Force members, while recognizing the value of such a mechanism, noted that not all pharmacies who ship medications by mail or common carrier are members of PCMA and that the number of complaints regarding this issue is great. Members also felt that the current mechanisms in place to provide patients with medications from their local pharmacies seemed to place too great a burden on the community pharmacist and, at times, involved numerous phone calls over several days.

With these concerns in mind, the Task Force agreed to recommend that the *Model Act* be amended to require that pharmacies shipping medications by mail or common carrier establish a mechanism by which patients can secure their medications from alternate pharmacists/pharmacies in situations when the medication is not delivered or deliverable. It was further suggested that such pharmacies be required to submit a written description of such a mechanism to the board office where it would be kept on file. A consensus could not be reached on this issue.

Although no recommendations were made, Task Force members recognized the value of a recent amendment to Tennessee's law, which appears to lessen the risk to pharmacist who fills a prescription for a patient who normally receives medications by mail or common carrier. This amendment states that:

No program administrator shall deny or withhold payment to any pharmacy for duplicate prescription refills, or prescriptions refills that are dispensed early in relation to the prior day's supply dispensed, where such refills are for the purpose of replacing lost or destroyed medication or providing the patient with the quantity necessary for extended travel away from the community in which the patient resides or for any other bona fide reason that causes the patient to be without medication, when the discontinuation of the medicine would, in the pharmacist's professional judgment, place the patient at risk of harm.

**TFMDP Recommendation #4**

The Task Force on Mail Delivery of Prescriptions recommends that the Executive Committee examine the practice of therapeutic interchange pursuant to formularies and, if necessary, take action regarding the issues surrounding this practice, particularly with regard to contacting the physician to request permission to interchange, and informing and counseling the patient about the interchange.

**Background:**

Although outside the scope of the Task Force charge, the issue of therapeutic interchange was identified as an issue of collateral to the subject of prescription delivery by mail. Of particular concern was the practice by some pharmacies that dispense prescriptions by mail to provide therapeutic interchange either without appropriate prescriber permission or without adequately informing the patient about what to expect as a result of the interchange. Task Force members felt that the problems associated with the process of therapeutic interchange were on the rise and that attention by the Executive Committee is necessary.