Report of the Task Force on Centralized Prescription Filling

Members Present:
Charles R. Young (MA), chair; Patricia F. Donato (NY); Oren Peacock (TX); Thomas W. Wood (AR).

Others Present:
S. Patricia "Tris" McSherry, executive committee liaison; Carmen Catizone, NABP executive director/secretary; Janice Teplitz, Melissa Madigan, NABP staff.

Not Present:
Allan Dulwick (OR)

Invited Guests:

Introduction:
The Task Force on Centralized Prescription Filling met June 15-16, 2000, at the Hawthorn Hotel and Suites O'Hare/Rosemont in Rosemont, Illinois. The Task Force was established by the NABP Executive Committee in response to a growing interest among the state boards of pharmacy in the concept of central fill pharmacies and dispensing systems and a potential need for developing guidelines or model regulations that states may consider when reviewing the issue. An initial conference call meeting took place on April 10, 2000. During that meeting, the Task Force agreed that model regulations on the issue should be developed, but felt that more time and background information was needed to fully address the issues and competently develop model regulations. In response, the Executive Committee agreed that the Task Force should convene a second time in July.

Review of the Task Force Charge:
Task Force members reviewed their charge and, proposing no changes, accepted it as follows:
To identify the regulatory issues associated with centralized prescription filling systems and develop model regulations addressing those issues.
Recommendation 1:
The Task Force on Centralized Prescription Filling recommends to the Executive Committee that the following language be adopted for incorporation into the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).

Article I
Title, Purpose, and Definitions

Section 105. Definitions.

…
(g) “Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

Model Rules for Pharmaceutical Care

Section 3. Pharmacy Practice.

…
E. Labeling

…
(4)

…
(l) All drugs dispensed to a patient that have been filled via a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities.

…
P. Centralized Prescription Processing

(1) A Pharmacy may perform or outsource centralized prescription processing services provided the parties:
(a) have the same owner; or
(b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and
(c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(2) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:
(a) A description of how the parties will comply with federal and state laws and regulations;
(b) The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
(c) The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
(d) The maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order;
(e) The provision of adequate security to protect the confidentiality and integrity of patient information;
(f) The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

Comments

Section 3P. Comment
The purpose of this section is to allow for the use of centralized prescription processing services while at the same time requiring that each pharmacy involved in the process maintain responsibility for the accurate filling of the prescription drug order and comply with applicable state and federal pharmacy practice laws and regulations. This section is also intended to prevent any pharmacy from acting as a manufacturer or repackager of prescription drugs or devices.

Background:
Task Force members first listened to presentations by the National Association of Chain Drug Stores, the American Pharmaceutical Association, the Pharmaceutical Care Management Association, and creehan, mchenry inc., a consulting firm specializing in technology and systems for the pharmacy industry, regarding those organizations’ positions on centralized prescription processing. The invited groups urged that the proposed model language allow for flexibility. It was also noted that the central fill process may involve multiple scenarios that could conceivably encompass multiple pharmacy sites; an originating pharmacy, a central fill processing center, a central fill pharmacy, and a dispensing pharmacy. In some cases the originating pharmacy may be the same as the dispensing pharmacy.

Also critical to the development of regulatory language is the need for security and accountability, which the task force members agreed, has to follow the prescription. Final accountability, they felt should rest with the dispensing pharmacist, since the patient only interacts with the pharmacist who hands them the drug product and counsels them on its use. For this reason, task force members strongly believed that the proposed regulations had to have a strong consumer focus that allowed the prescription to be tracked throughout the dispensing process. The model for a central fill pharmacy, they noted, differs in some respect from the mail service model, which has sometimes been viewed as a pattern for the central fill process.

Members, recognizing that centralized prescription processing is a growing activity in pharmacy practice and that boards of pharmacy would benefit from model regulations or guidelines, discussed the concerns identified by the boards of pharmacy regarding the centralized fill process, particularly the legal responsibilities of each party and labeling issues.
The Task Force discussed the circumstances that have lead to the implementation of centralized prescription processing systems, including an increased prescription volume, an increased incidence of errors, and a shortage of pharmacists. They also looked at the various activities that could be performed by pharmacies involved in centralized prescription processing; for instance, drug utilization review, claims adjudication, refill authorizations, and necessary interventions, as well as the actual filling of the prescription. Noting that all activities involved in the centralized processing of prescriptions involve the practice of pharmacy, members were emphatic in their position that all parties performing these activities be licensed pharmacies, and that each be responsible for the accurate filling of the prescription drug order and comply with all applicable state and federal pharmacy practice laws and regulations. Task Force members also pointed out that in regards to licensure, there may be instances in which the “licensed pharmacy” may not be an actual “pharmacy,” but may be a different licensed entity such as a “licensed PBM,” as recommended by the 1999-2000 Task Force on Licensing of Pharmacy Benefit Managers. Such entities may perform such activities as claims adjudications, DURs, and/or interventions, apart from the filling and dispensing of prescriptions.

On the issue of labeling, members expressed concern about which pharmacy’s address and phone number should appear on the label. They felt it was important that patients be provided information about a single pharmacy to contact with questions or concerns (most likely the pharmacy from which the product is dispensed) and not be confused by the appearance of the names, addresses, and phone numbers of all pharmacies involved in the dispensing process. On the other hand, they wanted any pharmacist in the process to be able determine which pharmacy performed which dispensing activities by simply looking at the vial label. The task force determined that it would be most efficient and least confusing to the patient if some sort of identifiable code indicating where the prescription was filled were placed on the label to serve as a dispensing and pharmaceutical care audit trail of the prescription. Task Force members noted that some states require an “opt-in” and “opt-out” process in regards to central fill. In such states, the patient must be aware of the various steps involved in central fill.

Recommendation 2:
The Task Force on Centralized Prescription Filling recommends to the Executive Committee that NABP convene a task force to look into the practice of pharmacies dispensing prescriptions via the Internet and consider model regulations to address the regulatory issues associated with this practice.
Background:

Noting that centralized prescription processing activities have been undertaken by many of those pharmacies that dispense prescriptions via the Internet, and recognizing the numerous public health concerns associated with the oversight and review of Internet dispensing, the Task Force recommended that NABP look that this issue with an eye toward developing regulations addressing this type of practice. The Task Force felt that a good starting point for any new regulations might be NABP’s Verified Internet Pharmacy Practice Sites (VIPPS) criteria.

Task Force members recognize that centralized prescription filling is a viable means of addressing the pharmacist workforce shortage and urge the Executive Committee to place the adoption of these model regulations on a fast track for acceptance.