Report of the Task Force on Medication Collection Programs

Members Present:
John R. Dorvee (ME), chair; Edith Goodmaster (CT); James Kaminski (DE); John Kirtley (AR); Heather Pasquale (OH); Sandra “Sandy” Robinson (DE); Kenneth H. Schell (CA); Frank Whitchurch (KS); Betty Yamashita (UT)

Others Present:
Elizabeth Scott “Scotti” Russell, executive committee liaison; Robert Cowan, Eileen Lewalski, Sarah Fowle, NABP staff

Alternate Member:
Linda DeLaMare Sandberg, (UT)

Ex Officio Members:
Michael Grafton, Drug Enforcement Administration; Connie T. Jung, Food and Drug Administration

Guests:
Janet Goodwin, Environmental Protection Agency; Harry Hagel, American Pharmacists Association; Shirley Reitz, Group Health Cooperative

Introduction:
The Task Force on Medication Collection Programs met December 6-7, 2008 at the JW Marriott Starr Pass Hotel, Tucson, AZ.

This task force was established in response to Resolution 104-5-08, Task Force on Medication Collection Programs, which was approved by the NABP membership at the Association’s 104th Annual Meeting in May 2008.

Review of the Task Force Charge
Task force members reviewed their charge and accepted it as follows:

1. Evaluate the status of medication collection programs throughout the country.
2. Review state and federal laws and regulations, including those administered by the United States Drug Enforcement Administration, applicable to medication collection programs.
3. Suggest possible medication collection program protocols compliant with current, applicable state and federal laws and regulations.

4. Recommend revisions, if necessary, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) addressing this issue.

**Recommendation 1: Monitor Drug Enforcement Administration’s Release of the Advance Notice of Rulemaking Addressing the Return of Controlled Substances.**

The task force recommends that NABP monitor Drug Enforcement Administration (DEA) and its release of the Advance Notice of Rulemaking related to controlled substance medications and to comment at the appropriate time to advocate for DEA to allow licensed pharmacies to be repositories for unused controlled substances.

**Background:**

The task force members were provided information from the DEA representative who reiterated that currently, due to the legislative barriers, there is no method for pharmacists/pharmacies to accept consumer/patient returns of controlled substances. DEA recommends that until rule changes are implemented the best approach is for pharmacists to recommend that patients follow the Office of National Drug Control Policy’s guidelines for the proper disposal of prescription drugs or for community take-back programs that have been authorized by the DEA special agent in charge.

Members were informed that DEA is planning to release an Advance Notice of Rulemaking in early 2009 pertaining to this issue and that it is an area of interest to the new president-elect’s transition team. Members agreed that NABP should provide comments advocating rule changes that would allow patients to return controlled substances to their pharmacies.

**Recommendation 2: Provide Guidelines to the Boards of Pharmacy to Assist them in the Development of Medication Collection Programs.**

The task force recommends that NABP provide general guidelines for the boards of pharmacy to utilize when developing or revising medication collection programs to ensure compliance with applicable state and federal laws and regulations.

**Background:**

The task force reviewed the following medication collection programs that were presented by members, guests, and ex officio members and discussed the advantages and challenges of each program.

**Community-Based Drop-Off Programs (Northeast Recycling Council)**

Preannounced event where patients may drop-off unused, unwanted medications at a pre-designated location that has pharmacy and law enforcement supervision.

**Advantages**

- Medication is collected
- Organized – process is manageable and controlled


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- Efficient – no quantity restrictions
- Can collect controlled substances if authorized by DEA

Challenges
- Collections are infrequent and sporadic – limited reach
- Costly – requires expensive public notice
- Reliance on third parties for proper disposal

Mail-Back Programs (Safe Medicine Disposal Program for Maine)
Patients obtain postage-paid envelopes from participating community pharmacies, which are returned by mail to a centralized Maine Drug Enforcement Agency location, cataloged by program pharmacist, and then destroyed.

Advantages
- Convenient and accessible for patients
- Low-technology
- Lower cost than other statewide programs
- Data on returns can be analyzed
- Law enforcement agency can conveniently schedule disposal

Challenges
- Lack of specific accountability for returns due to lack of receipt verification
- Quantity/volume restrictions – size of envelopes
- DEA has not specifically approved these programs to date

Pharmacy Drop-Box Programs (Washington Group Health Cooperative)
Patients place unused/unwanted medications in disposal bins at participating group pharmacies, which are then screened for controlled substances, and transported by licensed entities to an incineration facility for high temperature destruction.

Advantages
- Convenient and accessible
- Secure/Accountable
- Health Insurance Portability and Accountability Act compliant
- High temperature destruction – most ecological
Challenges

- Requires time-consuming screening by pharmacy staff to ensure DEA compliance (no controlled substances)
- More costly than mail-back programs
- Adequate space required in pharmacy for bins
- Limitations on what can be disposed due to the size of the opening of bin

SMARxT Disposal (US Fish and Wildlife Service, American Pharmacist’s Association and Pharmaceutical Research and Manufacturers of America)

Educational Web site sponsored by the above public-private partnership that provides information pertaining to the potential environmental impact from improperly disposed of medications and provides proactive guidance and proper disposal alternatives.

Advantages

- Complies with DEA
- Convenient
- Low cost

Challenges

- Requires continuous educational campaign
- Disposed in landfills – possible contamination of waterways and poisoning of animals
- No consumer/patient feedback
- Possibly subject to diversion

Task force members agreed that although all of the previously mentioned medication collection programs are advantageous in that they achieve the collection of some unused/unwanted medications, challenges still exist, particularly with the collection of controlled substances. Again, members referred to Recommendation 1 and reiterated the importance of NABP commenting on the future DEA rulemaking notice.

In regard to suggesting possible medication collection program protocols that comply with current, applicable state and federal laws and regulations, the members agreed that boards of pharmacy should focus on the following factors:

1. Involved entities
2. Regulating authority to ensure compliance with applicable state and federal rules and regulations
3. Responsibility for program implementation
4. Program funding  
   a. Identify funding streams such as applicable grants  
   b. Perform an ongoing cost-based analysis  
5. Program components  
   a. Method of collection  
   b. Record keeping  
   c. Storage/security  
   d. Transportation  
   e. Disposition  
      i. High-temperature incineration preferable; or  
      ii. Disposal in landfills  

**Recommendation 3: Work with Appropriate Entities to Research Methods that Reduce the Amount of Unused Medications.**  

The task force recommends that NABP work with the appropriate stakeholders to research the feasibility of establishing methods that will reduce the amount of unused prescription medications that require disposal.  

**Background:**  

Task force members discussed how decreasing the amount of unused medications may be a crucial factor to this issue and how vitally important going “up-stream” is in the grand scheme of medication collection programs. Primarily reducing the amount of unwanted/unused medication could be key to solving the problem, although at this time the evidence is unclear whether excretion versus disposal is the cause of environmental contamination. Members discussed how patients are accustomed to “super-sizing” everything including their prescription medications, which potentially lead to increased unwanted/unused amounts that require disposal. Additionally, many third-party payers encourage and provide financial incentives for three-month supplies of medication even when a patient has not been stabilized on a particular drug or dose. Task force members agreed that a two-pronged approach that includes an educational component and a shift to create incentives for ordering smaller quantities when appropriate was necessary to achieve this goal. Realizing the effect on stakeholders, members concluded that further research is necessary to assess this recommendation’s feasibility.  

**Recommendation 4: Amend the Model Act**  

The task force recommends the following amendment to the Model Act, specifically to the Model Rules for the Practice of Pharmacy. The revisions recommended by the task force are denoted by underlines and strikethroughs.
Section 2. Personnel.

(i) Patient Counseling

(1) Upon receipt of a Prescription Drug Order and following a review of the patient’s record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:

i) the name and description of the Drug;

(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;

(iii) intended use of the Drug and expected action;

(iv) special directions and precautions for preparation, Administration, and use by the patient;

(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(vi) techniques for self-monitoring Drug therapy;

(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;

(viii) prescription refill information;

(ix) action to be taken in the event of a missed dose; and

(x) Pharmacist comments relevant to the individual’s Drug therapy, including any other information peculiar to the specific patient or Drug.

Background:

The task force agreed that patient education plays a major role in reducing the amount of unused/unwanted medications and that an excellent initial step would be for NABP to revise the Model Act to include the appropriate safe disposition of medications in the counseling provisions. Members concluded that pharmacists should counsel patients regarding the proper disposal of medications and can also recommend seeking additional information from sources such as SMARxT Disposal and the Office of National Drug Control Policy.
Recommendation 5: Work with Boards of Pharmacy and Appropriate State and Federal Agencies to Research Medication Reuse Programs.

The task force recommends that NABP work with the boards of pharmacy and appropriate state and federal agencies, such as Food and Drug Administration, to research programs for the reuse of previously dispensed prescription medications to determine whether safe and legally compliant methods can be utilized.

Background:

The task force reviewed several prescription medication reuse programs currently in existence. Members discussed the societal value of reuse programs and why medications should be reused instead of destroyed. Members concurred that medication in long-term care facilities are maintained in a closed environment and may be appropriate for reuse. However any programs in the community pharmacy setting will necessitate different requirements. All members agreed that any medication collection programs for reuse must be compliant with all state and federal regulations including standards of the United States Pharmacopeia to ensure public safety.