American Pharmacists Association

2013 House of Delegates
Report of the Policy Committee

Revisions to the Medication Classification System
Ensuring Access to Pharmacists’ Services
Medication Take Back/Disposal Programs

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Revisions to the Medication Classification System

The Policy Committee recommends that the Association adopt the following statements:

1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug classification paradigms for prescription and nonprescription medications to allow greater access to certain medications under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.
   [Refer to Summary of Discussion items a and b.]

2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug classification system.
   [Refer to Summary of Discussion item c.]

3. APhA supports a patient care delivery model built on coordination and communication between pharmacists and other health care team members in the evaluation and management of care delivery.
   [Refer to Summary of Discussion item d.]

4. APhA supports the conclusion in Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the Surgeon General, 2011 that pharmacists have training in and are qualified to provide clinical interventions on the safe use of medications.
   [Refer to Summary of Discussion items e and f.]

5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications under FDA’s defined conditions of safe use.
   [Refer to Summary of Discussion item g.]

6. APhA supports the utilization of best practices and treatment algorithms to guide the evaluation and management of care delivery related to medications under FDA’s defined conditions of safe use.
   [Refer to Summary of Discussion items h and i.]

7. APhA encourages the inclusion of medications and services provided under FDA’s defined conditions of safe use within health benefit coverage.
   [Refer to Summary of Discussion item j.]

8. APhA supports compensation of pharmacists and other health care professionals for the provision of services related to FDA’s defined conditions of safe use programs.
   [Refer to Summary of Discussion item k.]
a. The committee understood “conditions of safe use” to refer to a concept FDA is considering to improve patient access to certain medications otherwise available by prescription under “conditions of safe use” as pursued by a manufacturer’s application to FDA. FDA has given the following examples to explain this concept:

- Conditions of safe use could improve access to medications for certain chronic conditions and life-saving emergency medications like antidotes and rescue medications.
- Conditions of safe use could include requiring pharmacist intervention to ensure appropriate medication use.
- Conditions of safe use could involve the use of approved innovative technologies to assist the patient in self-care selections of certain medications for use in the pharmacy or other setting (77 FR 12060).

The committee supported the concept of dispensing medications under conditions of safe use and the role that pharmacists can play to improve public health. Specifically, the committee supported the concept of revisions to the drug paradigm while maintaining the existing two-class prescription and nonprescription drug classification system, with the new concept adding flexibility for certain medications dispensed under conditions of safe use. In addition, the committee viewed the new drug paradigm fitting into the overall drug safety continuum much like risk evaluation and mitigation strategies (REMS) do by allowing access to certain prescription drugs. (See Figure 1.)

**Figure 1. APhA Drug Safety Continuum**

b. The committee viewed FDA’s potential new drug paradigm as a way to ensure that those patients with certain chronic conditions and conditions diagnosed by a medical provider maintain access to life-saving emergency drugs like antidotes and rescue medications. The committee supports FDA’s efforts to improve public health and patient access to certain medications under conditions of safe use because such revisions provide an opportunity for rechanneling undertreated or untreated patients into the health care system.
c. The committee recognizes that some state laws limit the ability of a pharmacist to provide services related to a revised drug classification system and encourages the states to make the necessary changes to allow patients access to these services.

d. Appreciating FDA’s statement that pharmacists have a key role to play in a potential new drug paradigm, the committee agreed that pharmacists must be able to access and share, as appropriate, required patient medical information in a timely and efficient manner and document such information through a process that is integrated into the pharmacy management system. Such a care delivery model facilitates improved communication(s) with the patient and his or her physician or other medical provider, leading to better continuity and quality of care.

e. The committee discussed pharmacists’ current education, training, and experience as related to the current range of pharmacist-provided services. The committee reviewed and recognized that the assessment of the patient and selection of a medication with conditions of safe use is within the current scope of practice of pharmacists. The recent report to the U.S. Surgeon General (Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the Surgeon General, 2011) clearly articulates the abilities and training of pharmacists that support pharmacists’ role within this new drug paradigm. Agreeing that pharmacists are well educated about product availability and appropriate indications for use, the committee felt that certification or other specialized training would not be necessary to implement FDA’s potential new drug paradigm.

f. The committee recognized the need to educate both health care professionals and the public about any new drug paradigm. Therefore, educational materials should be disseminated that focus on the availability of a product, the targeted patient population, processes and logistical requirements of the conditions of safe use program, and resource materials for the pharmacist.

g. The committee recognized that utilization of conditions of safe use for a specific product would be driven by a manufacturer’s decision to submit an application to FDA followed by FDA review and approval. The committee agreed that the opportunity for pharmacist and public input is critical in the development and review of conditions of safe use programs developed by manufacturers and approved by FDA.

h. The committee agreed that a pharmacist-patient intervention as part of a condition of safe use requirement used to determine appropriate dispensing should be built on consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers. In addition, the committee felt that the potential new paradigm should be consistent in the use of standardized, consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers.

i. The committee expressed the need for a standardized process to implement conditions of safe use programs aimed at achieving positive outcomes and efficiencies yet allowing for innovation. The committee expressed the need to limit variability in program logistics and processes to avoid the challenges of implementing REMS programs.
j. The committee recognized the need for removal of financial barriers to patient access to medications dispensed under conditions of safe use and emphasized the need for health benefit programs to include such medications and associated services.

k. The committee recognized that to sustain FDA’s current potential revision to the drug paradigm, an economically viable business model would be required that recognizes pharmacists’ value for services involving the evaluation, selection, and monitoring of medications dispensed under conditions of safe use.

**Attachment**

A. Background Paper prepared for the 2012–2013 APhA Policy Committee
REVISIONS TO THE MEDICATION CLASSIFICATION SYSTEM
(EXPANDING ACCESS TO PHARMACEUTICALS)

Background Paper Prepared for the 2012–2013 APhA Policy Committee

Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2012–2013 Policy Committee to recommend policy to the APhA House of Delegates related to expanding access to medications beyond the current drug classification and distribution system. Specifically, the Board asked the committee to explore concepts including the dispensing of certain medications without a prescription under “conditions of safe use,” which APhA previously referred to as OTC+. Conditions of safe use, as outlined by the Food and Drug Administration (FDA) in February 2012, could require a pharmacist intervention, dispensing in only certain health care settings (such as a pharmacy), or use of innovative technologies (such as kiosks and vending machines). In addition, the Board asked the Policy Committee to review the use of vending machines for the distribution of medications and to consider parameters for their use and the integration and role of pharmacists with the technology.

In March 2012, FDA held a public hearing to consider potential revisions to the drug classification paradigm that would allow FDA to approve dispensing of certain nonprescription medications under conditions of safe use. FDA aims to increase patient access and improve public health while maintaining the current two drug classifications of prescription and nonprescription (or over-the-counter [OTC]). Discussion of a potential new drug paradigm is a broad concept that has evolved from years of previous considerations of a third-class or behind-the-counter class of medications. APhA publically supported the concept in testimony at the hearing, in written comments, and at various other stakeholder meetings.

FDA generally has regulatory authority to continue discussions on this issue. As of October 2012, FDA is moving forward with this effort through an initiative called the Nonprescription Safe Use Regulatory Expansion (NSURE).

Summary of Key Concepts

- Interest has been growing to increase access to certain medications to improve patient care and public health and decrease health care costs.
- Through the NSURE initiative, FDA is considering a potential new drug paradigm that would allow the dispensing of certain nonprescription medications under “conditions of safe use,” which might include interventions by a pharmacist or other provider or use of innovative technologies.
- Conditions of safe use could leverage patient access to pharmacists to safely increase the availability of certain medications based on an application submitted by a manufacturer and approved by FDA. In addition, this new approach could improve communication and collaboration with the medical community.
- A revised drug paradigm provides an opportunity for pharmacists to reestablish a connection between the health care system and patients who may have untreated or undertreated conditions or who may need expanded access to life-saving rescue medications.
- Pharmacists have the knowledge and skills to effectively deliver conditions of safe use medications to enable patients to safely manage certain medications that are currently only available by prescription.
- APhA and other pharmacy organizations have highlighted the need to work with manufacturers and FDA to establish standardized processes of care, care algorithms and protocols, and education/awareness processes to implement pharmacist interventions included as part of a manufacturer’s approved application.
- Although the pharmacy community and certain other health care professionals are generally supportive of this new concept, concerns have been raised by the medical community and some consumer groups that a new paradigm could disrupt the patient-physician relationship.
- FDA is conducting ongoing outreach to stakeholders to clarify the intent of the NSURE initiative and is moving forward with discussions.

**Relevant APhA Policies**

APhA has adopted a number of policy statements that relate to the topic of “expanding access to certain medications.” Relevant policies are included at the conclusion of this background paper.

**Background**

**The Drug Classification System**

The United States has two categories of medications, created under the Durham-Humphrey Amendment of 1951 (P.L. 82-215) to the Federal Food, Drug, and Cosmetic Act, that are regulated and identified by FDA: nonprescription (OTC) medications and legend (prescription-only) medications. Nonprescription medications are generally those that meet the following criteria, as defined by FDA: (1) their benefits outweigh their risks, (2) the potential for misuse and abuse is low, (3) patients can use them for self-diagnosed conditions, (4) they can be adequately labeled, and (5) health care practitioners are not needed for the safe and effective use of the product.¹

The review process for prescription and nonprescription medications is conducted by the FDA Center for Drug Evaluation and Research. In addition, the Nonprescription Drug Advisory Committee aids in the evaluation of issues that arise regarding nonprescription products.

If a drug manufacturer believes that its prescription drug product is appropriate for nonprescription use, the manufacturer may elect to submit a new drug application to FDA to be considered for nonprescription status. If FDA determines that the drug is appropriate to be used
without a prescription, it approves the application and the manufacturer can market the drug as a nonprescription product. This process is commonly referred to as an “Rx to OTC switch” application and review process.

Related to FDA’s NSURE initiative, a drug manufacturer would generally follow a regulatory pathway to submit an application to seek approval for a nonprescription medication to be dispensed under conditions of safe use. Such an application must include information about the conditions of safe use to be reviewed and evaluated by FDA as part of the application review process.

**Overview of FDA’s NSURE Initiative: Considering a New Paradigm for Nonprescription Drug Classification Using Conditions of Safe Use**

As discussed at FDA’s March 22–23, 2012, public hearing, FDA is considering a potential new paradigm of nonprescription drug approvals. This new paradigm would expand the definition of what is considered nonprescription by linking the particular medication with “conditions of safe use,” which could include a pharmacist or other provider intervention or the use of innovative technologies.

FDA’s goals are to improve public health and increase patient access to certain medications that may currently be available by prescription-only. FDA also has focused on medications used to treat certain chronic conditions and medications for emergency antidote and rescue treatments.

As outlined in the March 2012 public hearing announcement, FDA is considering the following possibilities:

- Including under certain conditions of safe use—
  - Requiring a pharmacist intervention to ensure appropriate nonprescription use.
  - Use of innovative technologies approved or cleared by FDA for use in the pharmacy or other setting.
- For some medications that require an initial prescription, making the product available as a nonprescription product with a condition of safe use for the purpose of product refill.
- For some medications that would otherwise require a prescription, approving them as nonprescription with some type of pharmacist intervention as their condition of safe use.
- Making the same drug product simultaneously available as both a prescription and nonprescription product with conditions of safe use.

FDA generally has regulatory authority to continue discussions on this issue. As of October 2012, FDA is moving forward with this effort through the NSURE initiative.

FDA also is working with the Brookings Institution Engelberg Center for Health Care Reform to hold a series of expert workshops to clarify the goals of the NSURE Initiative and explore a variety of NSURE topics identified through the public hearing, including interventions by health care professionals, use of innovative technology, and economic considerations. On November 8, 2012, Brookings held the first workshop, “Nonprescription Medications with Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions.” APhA presented information on utilization of pharmacists as part of dispensing nonprescription medications under conditions of safe use.
**Conditions of Safe Use Conceptually Similar to REMS**

APhA views the potential new drug paradigm being considered by FDA (i.e., conditions of safe use applied to medications that could be available without a prescription) as fitting into the overall drug safety continuum much like risk evaluation and mitigation strategies (REMS) do by improving access to certain high-risk prescription medications. Medications that require a REMS program may not have been approved or remained on the market without a REMS program because of the risks associated with their use. Similarly, certain low-risk REMS program drugs may be safe enough for patients to take without a prescription provided that conditions of safe use are added as a supplement to aid the patient. By focusing on less risk and the OTC side of the drug safety continuum (the gray column in Figure 1), we can visualize how a new drug paradigm and the NSURE initiative would allow more flexible access to drugs that would remain prescription-only without the conditions of safe use being considered by FDA.⁵,⁶

**Figure 1**

![Diagram of Potential New Drug Paradigm Being Considered by FDA](image)

**Perspectives of Other Organizations and Stakeholders**

Generally, pharmacy associations have supported the potential new drug paradigm while providing various insights into how the program could be formatted, potential benefits, and ways to ensure safety for patients. Alternatively, some medical groups, other provider groups, and patient/consumer groups have raised concerns about transitioning certain prescription-only medications to nonprescription status under conditions of safe use and the potential disruption to the prescriber-patient relationship. FDA recognizes such concerns and continues to engage in stakeholder dialogue to address them and clarify the intent of the NSURE initiative—to focus on the safe use of nonprescription medications. Overall, many stakeholders agree that any pathway
forward must include a process whereby manufacturers and FDA can receive public input on the development and design of proposed conditions of safe use.

Discussion

Access to Care
Through the NSURE initiative, FDA has highlighted its concern about the under treatment of certain chronic conditions and limited access to life-saving emergency antidotes. In addition, access barriers create a strain on the U.S. health care system as more individuals seek care in emergency rooms for severe conditions that could have been treated earlier and properly controlled. By considering ways to expand patient accessibility to medications used to treat certain conditions, and the services of health care professionals such as pharmacists, FDA is seeking to help improve patient access, reduce barriers, and improve public health.

The more than 60,000 pharmacies and 300,000 pharmacists in the United States provide a powerful workforce of health care professionals ready and prepared to assist the health care team in improving public health, empowering patient self-care, improving access to certain medications and to care providers, and helping to return patients to the health care system.

Training, Knowledge, and Skills of Pharmacists
Pharmacists are well qualified to provide patient interventions pursuant to dispensing a nonprescription product under conditions of safe use, just as they do with current prescription and nonprescription products. Today, all schools and colleges of pharmacy offer a 6-year Doctor of Pharmacy (PharmD) degree, with an increased curricular emphasis on clinical patient care services. In addition, education standards (through the Accreditation Council for Pharmacy Education) incorporate a team-based approach to patient care and pharmacists’ roles in public health, wellness, and prevention.

Furthermore, it is currently within the scope of practice in every state for pharmacists in all practice settings to obtain medication histories, review the patient’s medications to identify medication-related problems, engage collaboratively with physicians to resolve identified problems, educate the patient about proper use of medications, encourage adherence with prescribed medications and other therapies, document and communicate information and recommendations to other providers on the patient’s health care team, and provide wellness services, including immunizations. Pharmacists’ training and knowledge of medications exceeds that of other health professionals, making them ideally suited to manage costly chronic conditions through appropriate medication use, coordination and communication with the medical community, and opportunities that may be presented through FDA’s ongoing discussions and the NSURE initiative.

Benefits of the Potential New Drug Paradigm, Improving Access, and Redirecting Patients Into the Health Care System
APhA testified at FDA’s March 2012 public hearing on the potential new drug paradigm being considered by FDA. APhA stated its support for the concept, noting that the potential new drug paradigm could serve as an opportunity to improve patient access to certain medications. APhA also highlighted the opportunity to communicate and collaborate with FDA, manufacturers, the
medical community, and other stakeholders and emphasized that uncertainties can be addressed and resolved as the concept evolves.\textsuperscript{4,5}

In addition, the Association views revisions to the drug paradigm as an opportunity for patients to have another access point to life-saving emergency and rescue medications and, when appropriate, to medications for certain chronic conditions. Easing access requirements for certain life-saving medications, such as the epinephrine injection pen, glucagon, and albuterol rescue inhalers, has the potential to decrease the time to the first dose of these life-saving medications and possibly decrease the burden on emergency departments.

The potential new drug paradigm also serves as an opportunity to reconnect patients with the health care system. APhA testified that pharmacists care for numerous patients who may have fallen out of therapy, may have limited access to medical services, may be noncompliant with current medication regimens, or may have undertreated chronic conditions. To rechannel such patients into appropriate care, pharmacists can provide a valuable intermediate step and evaluate and direct patients to the appropriate nonprescription medication or refer patients to a physician or other appropriate medical care.

In addition, the new drug paradigm presents an important opportunity for pharmacists to further communicate and collaborate with physicians and other providers and build on the team-based approach to care. This concept is not intended to divert patients to the pharmacy instead of to their physician. Rather, the intent is to deliver care to patients who in many cases may not be seeing any health professional at all, who may have fallen out of the system, and who would benefit from a conversation with a health professional. The collaboration that results will be complementary to physician care.

Studies such as the Asheville Project and others programs have demonstrated that referrals to physicians increase when pharmacists are actively engaged in clinical interventions with patients.\textsuperscript{7,8} Pharmacists have been referring patients to physicians for years but would benefit from a better system to document and inform physicians when this occurs. By serving as an entryway for patients to regain access to the health care system, the new drug paradigm can facilitate better and earlier management of chronic conditions and thereby prevent emergency room visits as patients’ health declines.

**Key Points to Address for Success of Nonprescription Drug Availability Under Conditions of Safe Use**

Highlighted below are a variety of key points that APhA advocated through testimony, comment letters, and discussions with FDA, manufacturers, pharmacy organizations, physician and other prescriber organizations, and other stakeholders throughout 2012 as dialogue continued on FDA’s NSURE initiative.\textsuperscript{5,6}

Evidence and Clinical Experience

As currently described, APhA appreciates and understands that approval of any product in the new paradigm must be based on science, clinical evidence, and patient safety in actual use. Data must be based on clinical evidence of medication safety and efficacy when determining which products to include in a potential new drug paradigm. Numerous studies of pharmacist-provided
patient care services show increased patient access to and adherence with prescription drug therapies, reduced medication errors, improved outcomes, and reduced costs as a result of the pharmacist’s intervention. The health care system would realize similar benefits to improved public health if the new paradigm is implemented.

Public Input
There must be an opportunity for public input on a manufacturer’s proposal for a product moving through an FDA nonprescription application process when the manufacturer cites conditions of safe use. Processes must be in place whereby manufacturers and FDA gather input from pharmacists, physicians, other prescribers, and other stakeholders during the development, design, and review of a potential program.

Consistent Definitions and Processes
The process for drug availability under conditions of safe use must be defined in a uniform and standardized way. Any new paradigm must ensure that patient care and drug dispensing processes are not disjointed, variable, or confusing across different practice settings.

Use of Practice Algorithms
A pharmacist-patient intervention as part of a condition of safe use program to determine appropriate dispensing should be built on consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers. Such interventions could include screening, assessment and consultation, or referral of the individual to the physician or other appropriate health care provider. Furthermore, these processes may likely be developed in collaboration among the involved professions.

It is important to recognize the need for, and opportunity to engage in, efforts to work with manufacturers and FDA to establish standardized processes of care, care algorithms and protocols, and education/awareness processes to implement pharmacist interventions included as part of a manufacturer’s approved application utilizing conditions of safe use.

Communication Technology Support and Electronic Health Information
For the potential new drug paradigm to be successful, pharmacists and other health care professionals must have access to patients’ medical records, lab results, and medication histories, combined with a mechanism for effective communication between pharmacists, physicians, and patients. Pharmacist-patient care activities could be communicated through phone calls and faxes, but more efficient and effective communication could be achieved through the expanding use of health information technology (HIT) infrastructure and electronic health records (EHRs). A platform is needed that allows pharmacists to access, input, and document data regarding a patient’s medication use and history to ensure that communication between all parties is consistent and useful. Work is underway in this area through the Pharmacy e-HIT Collaborative, and the development of such technology must continue.

Furthermore, increased patient access to point-of-care screening tools, algorithms, video screens, survey screening tools, interactive kiosk stations, hotlines, Internet sites, text messaging, and other technologies for accessing appropriate medications could be beneficial as ways to create safe conditions for a particular product as pursued by a manufacturer. Such tools could support
interactions between the patient and the pharmacist and health care team, and they also could further integrate patient data into the pharmacy management system through HIPAA-compliant processes. Such integration could help ensure that these products are part of the patient’s medication history at the pharmacy and could be further integrated and documented into a patient’s EHR. Such processes would also help facilitate post market safety surveillance. In addition, patient self-care technology could provide information on contacting a pharmacist or other health care provider if the individual has questions or needs additional information.

Examples of technology and screening devices commonly used in pharmacies include point-of-care cholesterol screening, blood pressure monitors, blood glucose monitors, and bone density screenings. These and other screenings and devices are generally quick and simple to use and would allow the pharmacist to refer the patient to appropriate medical care or to properly choose a nonprescription medication for the patient and then continue to monitor for safety and effectiveness at subsequent visits to the pharmacy.

As HIT has evolved and continues to evolve, new and improved tools will be available to help pharmacists work with patients and their prescribers to better manage medications. Standardization in processes, functionality, and platforms is necessary to limit burden and ensure effective and efficient implementation.

**Ability to Bill for Services**

A viable business model must be in place to ensure the long-term success of the potential new drug paradigm. In the current drug distribution system, pharmacists lack the resources or time to provide these services on a consistent basis without a business model that supports such activities. Therefore, if a manufacturer pursues approval of a nonprescription medication to be available under conditions of safe use that would require an intervention with a pharmacist, pharmacists must be able to bill via a standardized mechanism and must be compensated for the clinical services required to dispense such products. As payers realize the value of pharmacist-provided patient care and begin compensating according to the value of these services, pharmacists should have more opportunities to implement and focus on patient care activities through dispensing nonprescription medications under conditions of safe use.

In addition, FDA’s initiatives should not preclude payment for pharmacists’ services by the patient, third-party payers, state programs, Medicare, the sponsor, or others. Consideration should be given to legislatively provide the Centers for Medicare and Medicaid Services (CMS) with the option of creating a regulatory system whereby pharmacists could be compensated for providing these services to Medicare patients so that a viable, self-sustaining business model can be created if CMS or other payers see value in such an option.

**Insurance Coverage**

APhA recognizes that payers will need to determine payment policies for nonprescription medications that may require conditions of safe use. For some patients whose insurance plans may drop reimbursement for a prescription product if it transitions to nonprescription status, the potential increase in out-of-pocket expenses could limit patient uptake. However, if this proposal prevents major costs later in the system, insurance companies may consider covering such medications, similar to insurers paying pharmacists to provide immunizations and medication
therapy management (MTM) services. In addition, patients may be willing to pay out-of-pocket, particularly in emergency or life-threatening situations.

**Liability Considerations**
One concern is that if pharmacists dispense nonprescription medications under conditions of safe use, they could be viewed as prescribing and therefore be subject to increased liability. However, these services are already in the existing scope of practice of pharmacists. Minor revisions to liability carrier plans might result, but ultimately the activity envisioned within the potential new drug paradigm would fall under a state’s current scope of practice for pharmacists and thus presumably would be covered by pharmacists’ liability insurance plans.

**Provider Education on the New Paradigm**
Education about any revisions to the current drug paradigm must focus on the availability of a product, the targeted patient population, processes and logistical requirements of the program, clinical procedures, and resource materials for the pharmacist. Pharmacists are well qualified to provide clinical interventions on the safe use of a product, just as they already do with prescription and nonprescription products. APhA also suggests that through pharmacy’s extensive professional education programs and publications, organizations can help distribute appropriate information to pharmacists about requirements to dispense nonprescription products under conditions of safe use.

**Building on Success in Pharmacy and Access to Pharmacists’ Services**
Studies consistently support pharmacists’ involvement in the ongoing care of patients with chronic health problems. Highlighted below are several examples of pharmacists’ success in current, scalable patient care activities that have improved patient health and collaboration with the medical profession.

**Immunizations**
Over the past decade or so, all states have enacted laws to empower pharmacists to immunize. The Department of Health and Human Services and its agencies, such as the Centers for Disease Control and Prevention and CMS, and other immunization stakeholders are working with pharmacists across the country to increase immunization rates. More than 185,000 pharmacists have completed certificate training programs, and in the 2010–2011 influenza season, it is estimated that pharmacists administered approximately 20 million influenza vaccinations, thus meeting a major public health need for improved immunization rates and access. These activities occurred under protocols established with medical and/or public health practitioners. Similarly, with the potential new drug paradigm, pharmacists would be able to provide patients with quality information and services, allowing for the improvement of public health.

**Public Health Service**
The Public Health Service (PHS) serves as a successful model for optimizing pharmacist services. PHS pharmacists have nearly 50 years of successful collaboration with medicine to improve patient care. A 2011 PHS report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General*, supports pharmacists delivering patient care services through collaborative practice agreements as an accepted model of improved health care delivery that can meet growing health care demands in
the United States. Growing health care demands discussed in the report include the challenge of aligning health care coverage with access to care, the increasing burden on chronic care needs, and primary care provider shortages. The report includes 27 pages of studies that document the value of pharmacist services.9

Other key findings included an average savings of more than $10 for every $1 spent on clinical pharmacy services from 1988 to 2005. Moreover, in a survey of PHS physicians who work with pharmacists under collaborative practice agreements, 96% of respondents “reported seeing positive patient and health system outcomes from these patient care services.” U.S. Surgeon General Regina Benjamin, MD, MBA, publicly supported the report in a letter, saying it “provides the evidence health leaders and policy makers need to support evidence-based models of cost effective patient care that utilizes the expertise and contributions of our nation’s pharmacists as an essential part of the healthcare team.”10

APhA Foundation Projects
Community pharmacists are working with self-insured employers to improve patient outcomes as highlighted in the APhA Foundation’s work with the city of Asheville, NC, and through the Diabetes Ten City Challenge activities. These pharmacist-patient encounters have shown improved public health, positive clinical and economic outcomes, use of guideline-based care, improved patient education, collaboration among health care providers, and use of patient self-management strategies. In addition, studies such as the Asheville Project and others have demonstrated that health care quality outcomes improve and the number of referrals to physicians increase, as appropriate, when pharmacists are actively engaged in clinical intervention with patients.7

The Asheville Project began in 1997 as an effort by the City of Asheville, a self-insured employer, to provide education and personal oversight for employees with diabetes.7 Through the Asheville Project, employees with diabetes were provided with intensive education through the Mission-St. Joseph’s Diabetes and Health Education Center. Patients were then teamed with community pharmacists who ensured they were using their medications correctly and coached them on behavior changes to gain control of their disease. Pharmacists working with patients were able to improve vaccination rates, the number of patients receiving eye exams, and patients’ blood sugar levels. The project led pharmacists to develop thriving patient care services in their community pharmacies. Employees, retirees, and dependents with diabetes experienced improved A1c levels, lower total health care costs, fewer sick days, and increased satisfaction with their pharmacists’ services. The program is ongoing and has expanded to include other chronic conditions such as asthma, hypertension, and high cholesterol.

The Diabetes Ten City Challenge (DTCC) was a multistate community pharmacy health management program for patients with diabetes.11 Modeled after the Asheville program, DTCC successfully implemented an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines, and self-management strategies. Positive clinical and economic outcomes were identified for the patients who participated in the program for at least 1 year.
Specific to the treatment of hyperlipidemia, the APhA Foundation’s Project ImPACT Hyperlipidemia demonstrated that pharmacist-patient interventions helped to improve patient medication persistence and compliance rates from the national average of 40% to 90%. In addition, more than 60% of patients receiving care from a pharmacist in their community achieved their target therapeutic goals.¹²

These studies further document that pharmacists assist patients in managing their medications, increase patient compliance, improve patient safety, and improve overall health outcomes. This type of information further supports FDA’s consideration of dispensing with conditions of safe use that could include an interaction with a pharmacist.

Collaborative Practice and MTM
Currently, 46 states have laws authorizing pharmacist-provided patient care services through collaborative practice agreements. In these situations, physicians and pharmacists working as a team use their particular skills to the best effect for the benefit of the patient. Based on the physician’s diagnosis and protocols outlined in the collaborative drug therapy management (CDTM) agreement, CDTM activities could include pharmacist activities such as initiating, modifying, and monitoring a patient’s drug therapy; ordering and performing laboratory and related tests; and assessing patient response to therapy and other interventions. Because these activities require the same skills and knowledge, FDA’s NSURE initiative involving conditions of safe use and CDTM are similar in concept and could be similar in success as well.

Patient Access to Medications Through Vending Machine Dispensing
The FDA NSURE initiative includes discussion that a condition of safe use for dispensing a nonprescription medication could be the use of innovative technologies to increase patient access to certain medications. Such technologies could include vending machines, kiosks, and other evolving options. There also has been discussion that technology could be used to enhance the patient-pharmacist experience. A variety of vending machine, kiosk, and other technology products are currently being used in the marketplace, but not all have applicability to the provision of pharmacists’ services.

APhA recognizes the potential for technology and devices to enhance patient access to medications. Existing APhA policy calls for individuals to always have access to a pharmacist for questions and counseling. The Association has supported the use of innovative technology when appropriate as one of the options for FDA to consider as part of conditions of safe use and has advocated that such technologies should provide individuals with information to contact a pharmacist or other health care provider if they have questions or need additional information.
Conclusion

Pharmacists are well positioned in communities across the country and well trained to provide clinical services to patients with emergent and chronic care needs. As FDA and others consider new and innovative ways to increase access to certain medications, it is important that patients have access to pharmacists to assist and counsel patients to ensure that medications are used safely and effectively.

APhA supports the concept of dispensing medications with conditions of safe use and appreciates FDA mentioning the use of a pharmacist intervention in addition to innovative technologies as conditions of safe use. A potential new drug paradigm would improve patient access and public health by better leveraging the skills and accessibility of pharmacists, much like the profession has done with the success of pharmacist-administered immunizations. The Association also views the concept being considered by FDA as a great opportunity for pharmacists to further communicate and collaborate with physicians and other providers. Although logistical questions, challenges, and other uncertainties must be resolved, none are significant enough to prevent this important concept from becoming a reality.
References


Relevant APhA Policies

1. APhA urges the integration of pharmacy-based patient data into patient health records to facilitate the delivery of integrated care.
2. APhA recognizes pharmacists’ need for patient health care data and information and supports their access and contribution to patient health records.
3. APhA supports public policies that protect the patient’s privacy, yet preserve access to personal health data for research where the patient has consented to such research or where the patient’s identity is protected.
4. APhA encourages interdisciplinary discussion regarding accountability and oversight for appropriate use of health information.


Automation and Technology in Pharmacy Practice (2004)
1. APhA supports the use of automation and technology in pharmacy practice, with pharmacists maintaining oversight of these systems.
2. APhA recommends that pharmacists and other pharmacy personnel implement policies and procedures addressing the use of technology and automation to ensure safety, accuracy, security, data integrity and patient confidentiality.
3. APhA supports initial and on-going system-specific education and training of all affected personnel when automation and technology are utilized in the workplace.
4. APhA shall work with all relevant parties to facilitate the appropriate use of automation and technology in pharmacy practice.


Compensation for Cognitive Services (1987)
1. APhA recognizes that pharmacists provide to patients cognitive services (i.e., services requiring professional judgment) which may or may not be related to the dispensing or sale of a product.
2. APhA supports compensation of pharmacists for providing cognitive services (i.e., services requiring professional judgment) which may or may not be related to the dispensing or sale of a product.


Disparities in Health care (2009)
APhA supports elimination of disparities in health care delivery.

(JAPhA NS49(4):493 July/August 2009)

Drug Classification System (2006)
1. APhA supports restructuring the current drug classification system and drug approval process. Evidence should drive the restructuring beyond the current prescription and nonprescription classes to assure appropriate access to medications and pharmacist services, and improve medication use and outcomes.
2. APhA encourages pharmacists to exercise their professional judgment to manage access to nonprescription medications and dietary supplements to facilitate patient/caregiver interaction with their pharmacist

(JAPhA NS46(5):561 September/October 2006)(Reviewed 2011)

Emerging Technologies (1991)
1. APhA supports programs to monitor the development of emerging technologies and their impact on the delivery of pharmaceutical care.
2. APhA supports education of pharmacists regarding emerging technology including their development and impact on the delivery of pharmaceutical care.
3. APhA supports the inclusion of pharmacists in the development and application of the emerging technologies in the delivery of pharmaceutical care.

Health Information Technology (2009)
1. APhA supports the delivery of informatics education within pharmacy schools and continuing education programs to improve patient care, to understand interoperability among systems, to understand where to find information, to increase productivity, and to improve the ability to measure and report the value of pharmacists in the health care system.
2. APhA urges that pharmacists have read/write access to electronic health record data for the purposes of improving patient care and medication use outcomes.
3. APhA encourages inclusion of pharmacists in the defining, development and implementation of health information technologies for the purpose of improving the quality of patient-centric health care.
4. APhA urges public and private entities to include pharmacist representatives in the creation of standards, certification of systems, and integration of medication use systems with health information technology.

(JAPhA NS49(4):492 July/August 2009) (Reviewed 2010)

Independent Practice of Pharmacists (2009)
1. APhA recommends that plans and payers contract with and appropriately compensate individual pharmacist providers for medication therapy management and other clinical services rendered without requiring the pharmacist to be associated with a pharmacy.
2. APhA supports adoption of state laws and rules pertaining to independent practice of pharmacists that are consistent with APhA policy.
3. APhA, recognizing the positive impact that pharmacists can have in meeting unmet needs and managing medical conditions, supports the adoption of laws and regulations, and creation of payment mechanisms for appropriately trained pharmacists to autonomously provide patient care services that include prescribing as part of the health care team.

(JAPhA NS 49(4):492 July/August 2009)

Personal Health Records (2010)
1. APhA supports patient utilization of personal health records, defined as records of health-related information managed, shared, and controlled by the individual, to facilitate self-management and communication across the continuum of care.
2. APhA urges both public and private entities to identify and include pharmacists and other stakeholders in the development of personal health record systems and the adoption of standards, including but not limited to terminology, security, documentation, and coding of data contained within personal health records.
3. APhA supports the development, implementation, and maintenance of personal health record systems that are accessible and searchable by pharmacists and other health care providers, interoperable and portable across health information systems, customizable to the needs of the patient, and able to differentiate information provided by a health care provider and the patient.
4. APhA supports pharmacists taking the leadership role in educating the public about the importance of maintaining current and accurate medication-related information within personal health records.

(JAPhA NS40(4):471 July/August 2010)

Pharmaceutical Care and the Provision of Cognitive Services with Technologies (1991)
1. APhA supports the utilization of technologies to enhance the pharmacist's ability to provide pharmaceutical care.
2. APhA believes that the use of technologies should not replace the pharmacist/patient relationship.
3. APhA emphasizes that maximizing patient benefit from technologies depends upon the pharmacist/patient relationship.
4. APhA affirms that the utilization of technologies by pharmacists shall not compromise the patient's right to confidentiality.

Pharmacist Prescribing (1987)

1. APhA supports authority for pharmacists to select non-prescription and certain prescription medications as part of pharmacists’ responsibilities to design, implement, and monitor drug regimens for patients, in consultation with practitioners when appropriate.


Pharmacist Primary Care (2007)

1. APhA recommends the use of pharmacists as primary care providers, alone or in collaboration with other providers, in community pharmacy-based health clinics.


Pharmacy-based Screening and Monitoring Services (1989)

1. APhA supports projects that demonstrate and evaluate various pharmacy-based screening and monitoring services.


Prescribing by Pharmacists (1980)

1. APhA supports the concept of a team approach to health care in which health professionals perform those functions for which they are distinctively educated. APhA recognizes that the pharmacist is the expert on drugs and drug therapy on the health care team and supports a prescribing role for the pharmacist, based on the specific diagnosis of a qualified health practitioner.


Roles in Health Care for Pharmacists (2004, 1978)

1. APhA shall develop and maintain new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services.
2. APhA supports legislative and judicial action that confirms pharmacists’ professional rights to perform those functions consistent with APhA’s definition of pharmacy practice and that are necessary to fulfill pharmacists’ professional responsibilities to patients they serve.


1. APhA recognizes the need to protect the health of the American people through proper instruction in the safe and effective use of the more complex home-use diagnostic and monitoring products.
2. APhA recognizes that the pharmacist is a widely available and qualified health professional to advise patients in the use of the more complex home-use diagnostic and monitoring products.


The Pharmacist’s Role in Laboratory Monitoring and Health Screening (2003)

1. APhA supports pharmacist involvement in appropriate laboratory testing and health screening to include pharmacists directly conducting the activity, supervision of such activity, and ordering and interpreting such tests and communicating such test results.
2. APhA supports revision of relevant laws and regulations to facilitate pharmacist involvement in appropriate laboratory testing and health screening as essential components of patient care.
3. APhA encourages research to further demonstrate the value of pharmacist involvement in laboratory testing and health screening services.
4. APhA supports public and private sector compensation for pharmacist involvement in laboratory testing and health screening services.
5. APhA supports training and education of pharmacists and pharmacy students to direct, perform, and interpret appropriate laboratory testing and health screening services. Such education and training should include proficiency testing, quality control, and quality assurances.
6. APhA encourages collaboration and research with other health care providers to ensure appropriate interpretation and use of laboratory monitoring and health screening results.

2012–2013 APhA Policy Committee Report

Ensuring Access to Pharmacists’ Services

Recommendation—Ensuring Access to Pharmacists’ Services

_The Policy Committee recommends that the Association adopt the following statements:_

1. APhA encourages patients, health care professionals, and payers to recognize and support patient care roles for pharmacists that help address primary care shortages.
   [Refer to Summary of Discussion items a and b.]

2. APhA encourages payers to recognize and compensate pharmacists as health care providers.
   [Refer to Summary of Discussion items b and c.]

3. APhA encourages the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists’ services.
   [Refer to Summary of Discussion item c.]

4. APhA supports pharmacists’ ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
   [Refer to Summary of Discussion item d.]

5. APhA supports recognition by payers that compensable pharmacy services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
   [Refer to Summary of Discussion item e.]

6. APhA encourages the development and implementation of a standardized process for verification of pharmacists’ credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
   [Refer to Summary of Discussion items f and g.]

7. APhA advocates for pharmacists having access to clinical and claims data to support treatment, payment, and health care operations.
   [Refer to Summary of Discussion item h.]

8. APhA encourages the integration of pharmacists’ service level and outcome data with other health care provider data.
   [Refer to Summary of Discussion item i.]

**Summary of Committee Discussion**

a. The committee reviewed the growing shortage of primary care physicians in both rural and urban areas. Because more physicians are choosing subspecialty areas of focus instead of primary care, more patients are experiencing access problems, and that situation will continue into the future. Augmenting this concern is the upcoming influx of Medicaid beneficiaries through the Affordable Care Act (ACA; PL 111-148). The committee recognized that to meet the primary care requirements of the new health care
law, states must authorize allied medical team members to practice at the top of their licenses. Understanding the extensive literature demonstrating that when pharmacists are involved in patient care activities, quality improves and costs to the health care system decline, the committee felt strongly that pharmacists’ patient care roles should be both recognized and supported.

b. The committee acknowledged that recognition of pharmacists’ value is one of the highest priorities for the profession and APhA as evidenced publically by its elected leadership and by the topic’s integration throughout the Association’s strategic plan. In addition, the committee discussed the positive response to the “change.org” petition submitted to and recognized by the White House in 2012. The petition calls for the recognition of pharmacists as health care providers under the Social Security Act. Understanding the importance of “provider status” to fully participate in a number of private and public health care initiatives, such as accountable care organizations and medical homes, the committee felt strongly that payers should recognize pharmacists as health care providers.

c. As part of pharmacists’ efforts to improve public health, the committee agreed that to ensure the provision of pharmacist-provided services to patients, an economically viable model must be in place. The model would include standardized processes for provision, documentation, and claims submissions. To this point, the committee reviewed and recognized that one of the barriers to pharmacist compensation is nonstandardized credential verification processes by multiple payers and felt that a streamlined process would benefit payers and providers.

d. The committee discussed the need for contracting, direct billing, and payment opportunities for pharmacists to enable the identification of the individual pharmacist providing patient care services. The model discussed by the committee would be similar to the current medical model in which payment is made to the provider or to the provider’s employer. The committee discussed the possibility of using the NPI number as a billing mechanism to identify the pharmacist within a practice who provides patient care services.

e. The committee recognized the breadth of pharmacists’ services that a patient might require and agreed that payers’ policies must support recognition of not only comprehensive medication management services (generalized) but also targeted (focused) services provided by pharmacists.

f. The committee recognized potential confusion regarding the terms “credentialing” and “certification.”

Within the context of this policy report, the following definitions apply to “credentials” and “credentialing”: (Source: Council on Credentialing in Pharmacy—Guiding Principles for Post-licensure Credentialing of Pharmacists, February 2011)
**Credential**: Documented evidence of professional qualifications. Academic degrees, state licensure, residency certificates, and certification are all examples of credentials.

**Credentialing**: (a) The process of granting a credential (a designation that indicates qualifications in a subject or area); (b) The process by which an organization or institution obtains, verifies, and assesses an individual’s qualifications to provide patient care services.

The committee reviewed the importance of pharmacists leading the discussion on this topic, which is currently a market-driven matter. A standardized process has yet to be developed for recognizing existing credentials that pharmacists possess. To ensure a process available for use with multiple payers, the committee suggested a standardized system that is coordinated nationally.

g. The committee strongly stated that another certification for the provision of patient care services by pharmacists is not needed and that the process and requirements for identification of knowledge, skills, and qualifications should be standardized.

h. The committee discussed the importance of the availability of claims data in addition to clinical data for the efficient and effective provision of pharmacists’ services. This information is necessary for the assessment of adherence and other important clinical markers to provide a comprehensive picture of a patient’s status.

i. The committee discussed the importance of outcomes data to vendors, payers, and purchasers. To provide for consistency with other health care team members and to ensure the positive future direction of the profession, the committee determined the need for integration of pharmacists’ service level and outcomes data with other health care provider data. The committee recognized the value pharmacists’ services provide to the health care team and to patient outcomes and the need to advocate for this integration.

**Attachment**

A. Background Paper prepared for the 2012–2013 APhA Policy Committee
ENSURING ACCESS TO PHARMACISTS’ SERVICES

Background Paper Prepared for the 2012–2013 APhA Policy Committee

Issue

The APhA Board of Trustees directed the 2012–2013 Policy Committee to recommend policy to the APhA House of Delegates related to ensuring access to pharmacists’ clinical services and addressing the role of payers and providers in patient care. The Board asked the Policy Committee to explore barriers to recognition of pharmacists’ value and issue policy statements that articulate concerns and propose solutions and guidance to the profession, payers, and public.

Primary Care Shortages

Circumstances in the market and most recently the provisions of the Affordable Care Act have resulted in a shortage of primary care providers that is expected to greatly worsen by 2020. Pharmacists are well positioned to assist the other members of the health care team in addressing the primary care needs of the American public. Support for pharmacists fulfilling this role can be found throughout the published literature, including two recently released federal agency documents: the U.S. Public Health Service’s *Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General, 2011,* heralding pharmacists as vital members of the health care team (which the Surgeon General publically supported) and the CDC program guide for public health, *Partnering with Pharmacists in the Prevention and Control of Chronic Diseases.* As highly accessible providers able to provide a wide array of services, pharmacists are a valuable resource for closing the gap in the availability of primary care providers.

Pharmacists’ Role on the Health Care Team

As medication experts, pharmacists play a critical role in the provision of patient care services on the health care team. Pharmacists are capable of providing a range of services including, but not limited to, medication interaction monitoring, patient counseling, disease state management, comprehensive medication reviews, and medication management in transitions of care. As outlined in *Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the Surgeon General, 2011,* pharmacists’ patient care services have grown beyond functions tied to medication product and delivery. Pharmacists currently practice in a variety of settings under collaborative practice agreements and other models of integrated care. Programs such as the Asheville Project, the Diabetes Ten City Challenge, Project ImPACT Hyperlipidemia, and many others have shown that pharmacists’ clinical services improve patient outcomes and decrease overall health care costs.
Pharmacist Education

Doctor of Pharmacy Curriculum
Since 2004, an individual must attain a doctor of pharmacy degree, commonly referred to as a PharmD, in order to practice pharmacy. This program requires a minimum of 2 years of pre-professional coursework and 4 academic years of professional study. The PharmD curriculum focuses on developing practitioners who are capable of providing pharmaceutical care to patients, managing a pharmacy, promoting public health, and providing drug information and education. Upon completion of the program, graduates are expected to have received thorough instruction in six major areas: pharmaceutical chemistry, pharmacognosy, pharmacology, business management, pharmacy practice, and clinical skills. The PharmD curriculum prepares pharmacists to provide clinical services to patients in order to optimize medication use.7

Postgraduate Training and Certification
Upon graduation, many student pharmacists choose to complete 1 to 2 years of postgraduate training in a residency program. The first postgraduate year of training, referred to as PGY-1, is typically in a general pharmacy practice setting in either a hospital, community pharmacy, ambulatory care, or managed care setting. Of those who go on to complete a second postgraduate year of training, or PGY-2, many choose a specialty area of focus such as cardiology, oncology, or pediatrics. PGY-1 and PGY-2 residencies are accredited by the American Society of Health-System Pharmacists (independently or in collaboration with other pharmacy organizations).7,8 Pharmacists may complete a variety of practice-based continuing pharmacy education activities (formerly referred to as certificate training programs). These programs require a minimum of 15 contact hours and “enhance practice competencies through the systematic acquisition of specified knowledge, skill, attitudes, and behaviors.”8 Upon completion of these continuing education activities, the pharmacist receives a Certificate of Completion.

For those pharmacists practicing in a focused or advanced area of pharmacy practice, board certification is available from the Board of Pharmacy Specialties (BPS) to recognize their expertise. Pharmacists who attain board certification have demonstrated a high level of competence through successful completion of a written examination. Certification is maintained via a recertification process that occurs every 7 years. Board certification is currently available in six specialties: ambulatory care pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pharmacotherapy, and psychiatric pharmacy.8 The Commission for Certification in Geriatric Pharmacy also offers certification focused in that area of practice.

Pharmacists’ Clinical Services: Generalized and Focused

Generalized Patient Care Services: Comprehensive Medication Management
Comprehensive medication management includes an assessment of the patient’s entire medication regimen including over-the-counter products, vitamins, and herbals. The pharmacist looks for ways to optimize therapy by addressing drug interactions, adverse drug reactions, and medication use issues. These services are usually conducted privately between the pharmacist and the patient during a pre-scheduled appointment. The process includes an assessment of the
patient’s medication regimen, identification of any medication-related problems, collaborative
development of a care plan, and follow-up to track patient outcomes and reevaluate the care plan.

**Focused Patient Care Services**

In some settings, pharmacists provide targeted services for a specific disease state, such as
diabetes, or patient population, such as geriatric or pediatric patients. Other focused services
include health and wellness screenings, immunization administration, anticoagulation
management, and evaluating a patient’s genetic information in order to optimize drug therapy.
Pharmacists may choose to specialize and attain BPS certification or may obtain specific training
through focused education or experiential programs.

The acuity of the patient’s condition(s) impacts the scope of services provided and the skillsets
required from the pharmacist. However, whether the services are generalized or focused, they
can be provided only when a viable and sustainable business model exists.

**Pharmacist Challenges and Barriers**

**Payment for Pharmacists’ Services**

Pharmacists who have implemented services report many benefits, including increased patient
satisfaction, improved patient care, and increased professional satisfaction. Pharmacists are using
a variety of systems and models to implement medication therapy management (MTM) and other
patient care services. As the practice of pharmacy continues to evolve, some pharmacists are
exploring new professional opportunities by providing MTM services as a separate,
independently owned practice. Emerging opportunities exist for pharmacists with the desire to
begin providing MTM services on their own or to expand the services they already provide into
other settings. However, without a viable business model, these activities will continue to be
difficult to initiate and sustain. Currently, pharmacists are not recognized as health care providers
under Medicare Part B of the Social Security Act. This lack of recognition poses a barrier for
pharmacists to bill and be paid by Medicare in the same way that other health care providers are
under the medical benefit using the fee-for-service system. Recognition of pharmacists as
providers affects payment not only from Medicare but also from Medicaid and most private
payers, who model their payment systems on those established by Medicare. Without the proper
financial incentives, the pharmacy business model cannot allow for pharmacists’ clinical services
to be provided to patients.\(^9\)

With the passage of the Medicare Modernization Act and Medicare Part D, pharmacists were
recognized as providers of certain MTM services and became eligible to receive payment for
those services. This legislation does not allow pharmacists to bill Medicare directly, however,
which has created another set of barriers in the marketplace. Rather than being paid directly by
Medicare, pharmacists are paid by the Medicare Part D prescription drug plan that manages a
particular Medicare patient’s prescription benefit. Rather than paying pharmacists directly,
Medicare requires that the plans provide a mechanism for patients who meet specific criteria to
have access to MTM services as part of an administration fee that Medicare pays to the
prescription drug plan. It is up to that Part D plan to determine how these services are provided.
Some organizations have utilized networks of pharmacists in the community that are organized by MTM provider companies such as Mirixa® or Outcomes MTM™. These organizations use their MTM services platforms to facilitate payment and billing between the pharmacist and the pharmacy benefits manager or ultimate payer. Although this arrangement gives pharmacists the opportunity to provide services to patients and be recognized financially for those interventions, pharmacists often find that those opportunities are limited because of strict requirements for patient eligibility. Also, since the Medicare Part D plans are responsible only for the drug spend and not the medical benefit, their financial incentives are linked to limiting the drug spend and are not aligned with a focus on long-term total health care cost savings. Because pharmacists’ clinical services focus extensively on improving patient medication adherence, even though total health care costs go down, the drug spend often increases. Success has been seen in Medicare Advantage plans, which include both medical and prescription coverage. This model allows the payer to recognize the financial benefit of providing payment for pharmacists’ clinical services.

The intent of the MTM provision of Medicare Part D is to give patients access to the valuable clinical services that pharmacists can provide and, in turn, to optimize patient medication use and prevent long-term complications. This objective, however, cannot be realized until the Medicare payment system aligns the payment for pharmacists’ clinical services with the medical benefit, which is the area in which cost savings associated with those services will be realized.

Medical homes, accountable care organizations, and other emerging integrated care models show potential for the integration of pharmacists’ clinical services into daily patient care activities. Although these systems are modeled to maximize preventive health care long-term savings and improve quality, which are the focus of pharmacists’ clinical services, pharmacists are still facing barriers to integration into these systems because they are not recognized as patient care providers under the Social Security Act. Because the business model for medical homes and accountable care organizations depends on the current fee-for-service model, pharmacists still cannot be fully compensated for the care they can provide.

Process Standardization: Care Delivery
For pharmacists’ clinical services to be widely utilized across the health care spectrum, it is important for patients to be able to have a similar experience no matter where or from whom they receive services. To achieve this consistency, it is important for the profession to collaboratively adopt practice standards, as other professions have. Work has been initiated by the Joint Commission of Pharmacy Practitioners (JCPP) to develop a consensus within the profession on a standardized process of care for pharmacists to use in providing patient care. Once adopted, this care process must be taught within all of the colleges of pharmacy and widely shared with current practitioners. Of note, collaboration with other members of the health care team is a crucial part of the pharmacy care delivery process, and buy-in from other health care professionals is important during the care process development.

Process Standardization: Documentation and Claims Submission
Because payment for services under Medicare Part D is controlled by the Part D prescription drug plans, each organization can have a different format for the submission of claims, different requirements for documentation, and a different process for verifying a pharmacist’s credentials. For pharmacists’ clinical services to be widely available to all patients who need them,
standardizing this process is crucial. Currently, the administrative burden associated with managing all of the different requirements is a barrier to the successful integration of clinical services into many pharmacy practices. Advances in electronic health information technology (HIT) standards and implementation in pharmacy practice are helping to address this challenge, but progress is slow.

**Availability of Health Information**

For the benefits of pharmacists’ patient care services to be fully realized, it is important that practitioners have access to the data management infrastructure that currently exists in the health care industry. Effective processes can be achieved by integrating pharmacists and the data relevant to pharmacists’ patient care services into electronic health records (EHRs) and other HIT resources. Efforts are currently underway to further develop standardized electronic structured documents that can be used to securely exchange patient care information in a machine-readable format. These structured documents will contain codified information using Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT) to assist in documenting and exchanging relevant patient care information between pharmacists, other health care providers, and other relevant parties. Relevant data that need to be exchanged include care notes, intervention records, lab and assessment values, patient information, and claims data.

**Conclusion**

Pharmacists are capable of closing the gap in primary care, improving patient outcomes, and helping to control overall health care spending. It is imperative that the barriers currently preventing patients from access to these medication experts be addressed and resolved. In the current climate of health care reform, pharmacy must be represented at the table as new delivery systems and payment models are developed and implemented.

Areas to be addressed include:

- Pharmacist recognition as providers of patient care and valued members of the health care team
- Development of sustainable business models for pharmacists’ clinical services
- Standardization of the pharmacist’s process of care and patient expectations
- Reduction of administrative burdens to the provision, documentation, and billing of patient care services by pharmacists
References


5. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: Final economic and clinical results. JAPhA. 2009;49,e52–e60.


Relevant APhA Policy

2011, 1994 APhA’s Role in the Development and Support of New Payment Systems
1. APhA should continue its work with pharmacy benefits' managers and other private and public payers to develop innovative pharmacy benefit designs and compensation strategies for pharmacists' services.
2. APhA will endorse benefit design concepts that recognize and compensate pharmacists for their cognitive services to maximize therapeutic outcomes.

2011 Pharmacists as Providers Under the Social Security Act
APhA supports changes to the Social Security Act to allow pharmacists to be recognized and paid as providers of patient care services, including but not limited to medication therapy management.
(JAPhA NS51(4) 482; July/August 2011)

2011 Pharmacist’s Role in Health Care Reform
1. APhA affirms that pharmacists are the medication experts whose accessibility uniquely positions them to increase access to and improve quality of health care while decreasing overall costs.
2. APhA asserts that pharmacists must be recognized as the essential and accountable patient care provider on the health care team responsible for optimizing outcomes through medication therapy management (MTM).
3. APhA asserts the following:
   a. Medication Therapy Management Services: Definition and Program Criteria is the standard definition of MTM that must be recognized by all stakeholders.
   b. Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM
   c. Service Model, as adopted by the profession of pharmacy, shall serve as the foundational MTM service model.
4. APhA asserts that pharmacists must be included as essential patient care provider and compensated as such in every health care model, including but not limited to, the medical home and accountable care organizations.
5. APhA actively promotes the outcomes-based studies, pilot programs, demonstration projects, and other activities that document and reconfirm pharmacists’ impact on patient health and well-being, process of care delivery, and overall health care costs.
(JAPhA NS51(4) 482; July/August 2011)

2011 The Role and Contributions of the Pharmacist in Public Health
In concert with the American Public Health Association’s (APHA) 2006 policy statement, “The Role of The Pharmacist in Public Health,” APhA encourages collaboration with APHA and other public health organizations to increase pharmacists’ participation in initiatives designed to meet global, national, regional, state, local, and community health goals.
(JAPhA NS51(4) 482; July/August 2011)

2010 Personal Health Records
1. APhA supports patient utilization of personal health records, defined as records of health-related information managed, shared, and controlled by the individual, to facilitate self-management and communication across the continuum of care.
2. APhA urges both public and private entities to identify and include pharmacists and other stakeholders in the development of personal health record systems and the adoption of standards,
including but not limited to terminology, security, documentation, and coding of data contained within personal health records.

3. APhA supports the development, implementation, and maintenance of personal health record systems that are accessible and searchable by pharmacists and other health care providers, interoperable and portable across health information systems, customizable to the needs of the patient, and able to differentiate information provided by a health care provider and the patient.

4. APhA supports pharmacists taking the leadership role in educating the public about the importance of maintaining current and accurate medication-related information within personal health records.

(2010 JAPhA NS40(4):471 July/August)

2009 Health Information Technology

1. APhA supports the delivery of informatics education within pharmacy schools and continuing education programs to improve patient care, to understand interoperability among systems, to understand where to find information, to increase productivity, and to improve the ability to measure and report the value of pharmacists in the health care system.

2. APhA urges that pharmacists have read/write access to electronic health record data for the purposes of improving patient care and medication use outcomes.

3. APhA encourages inclusion of pharmacists in the defining, development and implementation of health information technologies for the purpose of improving the quality of patient-centric health care.

4. APhA urges public and private entities to include pharmacist representatives in the creation of standards, certification of systems, and integration of medication use systems with health information technology.

(2009 JAPhA NS49(4):492 July/August) (Reviewed 2010)

2009 Independent Practice of Pharmacists

1. APhA recommends that plans and payers contract with and appropriately compensate individual pharmacist providers for medication therapy management and other clinical services rendered without requiring the pharmacist to be associated with a pharmacy.

2. APhA supports adoption of state laws and rules pertaining to independent practice of pharmacists that are consistent with APhA policy.

3. APhA, recognizing the positive impact that pharmacists can have in meeting unmet needs and managing medical conditions, supports the adoption of laws and regulations, and creation of payment mechanisms for appropriately trained pharmacists to autonomously provide patient care services that include prescribing as part of the health care team.

(2009 JAPhANS 49(4):492 July/August)

2008 Billing and Documentation of Medication Therapy Management (MTM) Services

1. APhA encourages the development and use of a system for billing of MTM services that:
   a. includes a standardized data set for transmission of billing claims;
   b. utilizes a standardized process that is consistent with claim billing by other healthcare providers;
   c. utilizes a billing platform that is accepted by the Centers for Medicare and Medicaid Services

2. (CMS) and is compliant with the Health Insurance Portability and Accountability Act (HIPAA)
3. APhA supports the pharmacist’s or pharmacy’s choice of a documentation system that allows for transmission of any MTM billing claim and interfaces with the billing platform used by the insurer or payer.


5. APhA supports efforts to further develop CPT codes for billing of pharmacists’ services, through the work of the Pharmacist Services Technical Advisory Coalition (PSTAC).


2008 Pharmacy Practice-based Research Networks
1. APhA supports establishment of pharmacy practice-based research networks (PBRNs) to strengthen the evidence base in support of MTM and pharmacy primary care services.

2. APhA encourages collaborations among stakeholders to determine the minimal infrastructure and resources needed to develop and implement local, regional and nationwide networks for performing pharmacy practice-based research.

3. APhA encourages pharmacy residency programs to actively participate in pharmacy practice-based research networks.

(JAPhA NS48(4):471 July/August 2008)

2007 Pharmacist Primary Care
1. APhA recommends the use of pharmacists as primary care providers, alone or in collaboration with other providers, in community pharmacy based health clinics.


2005, 1993 Documentation
1. APhA encourages development of systems that document review of patient therapy, the type and intensity of services provided, and the result or outcome of the services.

2. APhA believes that systems of payment and documentation must be compatible with contemporary computer systems used by providers and payers and should emphasize administrative efficiency.


2005, 1977 Government-Financed Reimbursement
1. APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.

2. APhA regards equitable compensation under any government-operated or -financed, third party prescription programs as requiring payments equivalent to a participating pharmacist's prevailing charges to the self-paying public for comparable services and products, plus additional, documented, direct and indirect costs which are generated by participation in the program.

3. APhA supports those government-operated or -financed, third-party prescription programs which base compensation for professional services on professional fees and reimbursement for products provided on actual cost, with the provision of a specific exception to this policy in those instances when equity in professional compensation cannot otherwise be attained.

2005, 1980 Inclusion of Pharmacist-Provided Patient Care Services in Health Programs
APhA supports the inclusion of pharmacist-provided patient care services in health care programs that are
developed and/or funded by governments and private agencies and organizations.

2005, 1993 Payment System Reform
1. APhA must advocate reform of pharmacy payment systems to enhance the delivery of
   comprehensive medication-use management services.
2. APhA must assume a leadership role, in cooperation with other pharmacy organizations, patients,
   other providers of health services, and third-party payers, in developing a payment system reform
   plan.
3. APhA should encourage universal acceptance of all components of pharmaceutical care and their
   integration into pharmacy practice to support payment for services.

2004, 1980 Development of the Cost Effectiveness of Clinical Pharmacy Services
APhA encourages development and maintenance of programs, tools, and data useful in assessing the cost
effective nature and benefits of patients oriented services within all areas of pharmacy practice.

2004, 1979 Drug Regimen Review (DRR) by Pharmacists
APhA endorses adequate compensation for pharmacists by the patient, the government, and/or all other
third-party programs for performing drug regimen review in all settings where drug therapy is used.

2004, 1978 Roles in Health Care for Pharmacists
1. APhA shall develop and maintain new methods and procedures whereby pharmacists can increase
   their ability and expand their opportunities to provide health care services.
2. APhA supports legislative and judicial action that confirms pharmacists’ professional rights to
   perform those functions consistent with APhA’s definition of pharmacy practice and that are
   necessary to fulfill pharmacists’ professional responsibilities to patients they serve.

2003, 1992 The Pharmacist's Role in Therapeutic Outcomes
1. APhA affirms that achieving optimal therapeutic outcomes for each patient is a shared
   responsibility of the health care team.
2. APhA recognizes that a primary responsibility of the pharmacist in achieving optimal therapeutic
   outcomes is to take an active role in the development and implementation of a therapeutic plan and
   in the appropriate monitoring of each patient.
(Reviewed 2010)(Reviewed 2011)

1997 Collaborative Practice Agreements
1. APhA supports the establishment of collaborative practice agreements between pharmacists and
   other health care professionals designed to optimize patient care outcomes.
2. APhA shall promote the establishment and dissemination of guidelines and information to
   pharmacists and other health care professionals to facilitate the development of collaborative
   practice agreements.
1995 Continuum of Patient Care
1. APhA advocates and will facilitate pharmacists' participation in the continuum of patient care. The continuum of patient care is characterized by the interdisciplinary care provided a patient through a series of organized, connected events or activities independent of time and practice site, in order to optimize desired therapeutic outcomes.
2. APhA will facilitate pharmacists' participation in the continuum of patient care by:
   - Achieving recognition for the pharmacist as a primary care provider;
   - Securing access for pharmacists to patient information systems, including creation of the necessary software for the purpose of record maintenance of cognitive services provided by pharmacists;
   - Developing means and methods to establish and enable pharmacists' direct participation in the continuum of patient care.

1995 Integrated Risk/Capitation Payment Systems
1. APhA should provide pharmacists with tools to evaluate compensation for their pharmaceutical care services through mechanisms based on concepts other than fee-for-service.
2. APhA must facilitate both economic and clinical research on cost-to-outcomes benefits of pharmaceutical care services under integrated risk/capitated health care systems.
3. APhA affirms the principle that any pharmacist or pharmacy that adheres to a program's quality standards and agrees to accept its compensation plan shall be able to participate in an integrated risk/capitated system or network.

1994 Product and Payment Systems
1. APhA shall work with public and private sectors in developing timely educational processes which assist pharmacists to implement patient care, understand new payment systems, and apply emerging therapeutic advances to achieve desired patient outcomes.
2. APhA supports payment systems that distinguish between compensation for the provision of pharmaceutical care and reimbursement for product distribution.
3. APhA shall participate in the identification, development, and implementation of models for procurement and handling of therapeutic and diagnostic pharmaceutical products and devices which assure the continuous provision of pharmaceutical care by pharmacists.

1993 Pharmacists' Services
1. APhA supports development of pharmacy payment systems that include reimbursement of the cost of any medication or device provided; the cost of preparing the medication or device; the costs of administrative services; return on capital investment; and payment for both the dispensing-related and non-dispensing pharmacy services.
2. APhA believes that appropriate incentives for the pharmacist providing care should be part of any payment system.
1987 Compensation for Cognitive Services
1. APhA recognizes that pharmacists provide to patients cognitive services (i.e., services requiring professional judgment) which may or may not be related to the dispensing or sale of a product.
2. APhA supports compensation of pharmacists for providing cognitive services (i.e., services requiring professional judgment) which may or may not be related to the dispensing or sale of a product.


1977 National Health Insurance: Pharmaceutical Service Benefit
1. A National Health Insurance pharmaceutical service benefit must include acceptable methods for ensuring equitable reimbursement to pharmacists for products and services which are to be provided under the program.
2. Reimbursement to pharmacists for dispensed medication and devices under a NHI plan should be based on professional fees for professional services, plus reimbursement for the actual cost of any drug product or device provided.
3. A NHI, pharmaceutical service benefit must optimize administrative efficiency and minimize administrative costs.

2012–2013 APhA Policy Committee Report

Medication Take-Back/Disposal Programs

Recommendation—Medication Take-Back/Disposal Programs

The Committee recommends that the Association adopt the following statements:

1. APhA encourages pharmacist involvement in the planning and implementation of medication take-back/disposal programs.
   [Refer to Summary of Discussion items a and b.]

2. APhA supports increasing public awareness regarding medication take-back/disposal programs.
   [Refer to Summary of Discussion item b.]

3. APhA urges public and private stakeholders, including local, state, and federal agencies, to coordinate and create uniform, standardized regulations and funding sources for the proper and safe disposal of unused medications.
   [Refer to Summary of Discussion items c and d.]

4. APhA recommends ongoing access to medication take-back and disposal programs, including but not limited to mail-back envelopes and secure drop boxes.
   [Refer to Summary of Discussion item e.]

Summary of Committee Discussion

a. The committee recognized the importance of pharmacist involvement in the development and implementation of medication take-back/disposal programs, as well as utilizing the opportunity to educate the public on safe and appropriate medication use.

b. The committee identified a concern by the public regarding confidentiality. These privacy concerns include providers, like pharmacists, having direct involvement in the actual medication drop-off process. The committee agreed that it may be more advantageous for pharmacists to be involved with public education concerning proper drug disposal rather than directly participating at specific medication take-back/disposal events.

c. The committee agreed that funding is critical for medication take-back programs to be accessible and encouraged APhA to work with the Pharmaceutical Research and Manufacturers of America (PhRMA), local, state, and federal agencies and other stakeholders to explore the various funding options. Concerning existing laws, the committee agreed that administrative barriers at the local, state, and federal levels must be addressed to provide for continued medication take-back and disposal programs. To illustrate the administrative challenges in existing law, the committee discussed a current requirement that coordinators of take-back programs be responsible for having collected items sorted and removing hazardous and biohazardous items that may have been
commingled in collection receptacles. Understanding the variety of laws and regulations that must be considered when coordinating medication take-back events, the committee agreed that efforts must be made to harmonize these requirements to reduce barriers. The committee also referenced existing APhA policy concerning medication disposal.

d. With reports of a small number of pharmacies misappropriating drugs from take-back events, the committee discussed the possibility of credentialing pharmacies to take medications back but decided that this step would be an overregulation and should not be pursued.

e. The committee agreed that access to medication take-back programs should continue on an ongoing basis—not just once or twice a year. The committee also discussed the growing number of hazardous waste rules in states that can affect take-back activities and recognized the difficulty in not allowing controlled and noncontrolled medications to be accepted in the same container. The committee supported continued work with applicable local, state, and federal agencies to ensure that the public’s access to medication take-back/disposal opportunities is not overshadowed by regulatory burden.

Attachment

A. Background Paper prepared for the 2012–2013 APhA Policy Committee
MEDICATION TAKE-BACK/DISPOSAL PROGRAMS

Background Paper Prepared for the 2012–2013 APhA Policy Committee

Issue
The American Pharmacists Association (APhA) Board of Trustees has directed the 2012–2013 Policy Committee to recommend policy to the APhA House of Delegates related to medication take-back or medication disposal programs. Specific areas of focus identified by the Board for consideration by the Committee included, but are not limited to, development of uniform federal and state laws to guide safe disposal of medications and hazardous household medications; effective and available medication take-back systems and programs in the community and local pharmacies; public awareness education regarding proper medication disposal; liability considerations with medication take-back and disposal; pharmacists’ and student pharmacists’ role in public education and take-back programs; and financial support for such programs. In addition, the Policy Committee might explore policy related to the reuse and return of medication.

Summary of Key Concepts
- Medication take-back and disposal programs empower the public to take an active role in protecting the environment and their community.
- Medication take-back programs help reduce the risk of accidental overdoses or poisonings in the household as well as drug diversion, although access to appropriate disposal systems is limited.
- Pharmacists and pharmacies are ideal points of access to collect unused or expired medications, and patients prefer to return medicines to pharmacies or other health care settings.
- A lack of alignment exists between federal and state laws concerning pharmacy-based medication take-back or disposal programs, as well as financial and conceptual support for these programs.
- Although public awareness of the issue of medication disposal is increasing, limitations of disposal program availability and a lack of awareness of differences between controlled versus noncontrolled medication take-back guidelines are significant points of confusion for the public.
- It is important to demonstrate that medications collected for disposal are clearly separated from pharmacy medication inventory stocked for dispensing to ensure that medications stored for disposal are not intermingled with pharmacy dispensing inventory.
• Statutory-authorized medication donation programs should have these medications stored as a separate inventory within the pharmacy.

• Controls and limitations on pharmacist and pharmacy liability associated with any pharmacy-based medication take-back or disposal program are imperative to the successful implementation of such programs.

• The target audience for dialogue relating to medication disposal/take-back policies includes, but is not limited to, boards of pharmacy; state pharmacy associations; the Drug Enforcement Administration (DEA); the White House Office of National Drug Control and Policy (ONDCP); the Food and Drug Administration (FDA); national, state, and local pharmacy organizations; other health care professionals; state legislatures; pharmaceutical manufacturers; environmental agencies; consumer groups; and public safety or public health organizations.

Discussion

Introduction

Medication take-back and disposal programs attempt to address the public health concerns of communities by (1) reducing diversion and misuse of excess and discarded medications by teens and others, (2) preventing ingestion by pets and children, and (3) protecting the environment.

The Centers for Disease Control and Prevention (CDC) determined that unintentional poisoning in the United States was the leading cause of accidental death among people aged 25 to 64 and the second leading cause of death (following motor vehicle accidents) for people of all ages. With more than 91% of unintentional poisonings associated with prescription medications, particularly painkillers or controlled substances, pharmacists and their health care colleagues have a particularly imperative role to play in the prevention of accidental poisoning in the United States while ensuring that those who need medicines have access to them.\(^1\) CDC cites multiple ways to prevent accidental poisonings and has created a patient education program called the Up and Away and Out of Sight initiative (www.upandaway.org) to educate patients about appropriate storage and disposal guidelines for unused medicines, primarily targeting children’s safety.\(^2\) CDC also created the PROTECT initiative (www.cdc.gov/MedicationSafety/protect/protect_Initiative.html#Background), which brings together pharmaceutical manufacturers, health care providers, and other key stakeholders to address the packaging and storage of medicines to prevent accidental poisonings.\(^3\) CDC also cites an increasing economic burden associated with poisonings. In 2005, poisonings caused lost productivity and medical expenses exceeding $33.4 billion.\(^1\)

An important consideration in preventing poisonings is the safe removal of unused or expired medications from the drug supply chain, thereby preventing the abuse of such medicines. Research has further supported the fact that approximately 70% of those who acquire controlled substances by a means other than a prescription do so from a friend or directly from their own home. Because most accidental poisonings involve controlled substances, the passage of the Secure and Responsible Drug Disposal Act of 2010 (P.L. 111-273) prompted important discussion relating to the disposal of medicines. The Act amended the Controlled Substances Act (21 U.S.C. 822) to empower the U.S. Attorney General to promulgate regulations authorizing the collection and disposal of controlled substances directly by terminal users—patients, caregivers,
and others. DEA then convened a public meeting on January 19–20, 2011, to engage stakeholders in sharing with DEA any key considerations for potential new regulations related to the disposal or take-back of controlled substances. Thereafter, a variety of local- and national-level activities took place related to the prevention of accidental poisonings and providing a safe mechanism for the collection of unused or expired medications in the home as an imperative public health concern. APhA testified at the DEA public meeting in support of the role of pharmacists and pharmacies in take-back programs, in increasing patient and community awareness of disposal options, and in working with DEA as the agency drafts regulations to improve options for medication disposal.

**DEA Public Meeting on Laws Governing the Disposal of Controlled Substances**

The January 2011 DEA public meeting to gather information on take-back programs and the disposal of controlled substances included discussions of the potential impact of these programs and the time and financial investments associated with the disposal containers. Recommendations from key stakeholders at the meeting, including APhA and other national pharmacy associations, pharmaceutical manufacturers, and Sharps Compliance, Inc. (responsible for the TakeAway program) were provided in the public meeting. The groups collectively recommended that DEA draft regulations for the return of controlled substances in alignment with those for the return of noncontrolled substances. Because the public is generally unaware of the difference between the two classes of medicines, the limited financial resources to operate public education campaigns should not focus on teaching the public the difference between the two; instead, it should focus on creating awareness of the importance of safely disposing of medicines. Several pharmacy and community organizations that have successfully created community or state-based disposal programs reported that significant cost and time are associated with screening medicines to determine whether they are controlled versus noncontrolled substances. This effort would result in an added cost to the systems that support disposal programs.

The source of most medications that ultimate users (patients who are dispensed the medication) also was discussed extensively at the 2011 public meeting. Potential sources discussed at the meeting included medicines from a deceased family member, mail service or other pharmacies that dispense 90-day supplies, and users’ own unused prescriptions. Most DEA and other medication take-back days do not individually account for sources or even the class of medicines (controlled/noncontrolled), which makes estimates of such numbers difficult.

At the January 2011 DEA meeting, the National Community Pharmacists Association presented pictures from the “Waste Not, Want Not” program showing what pharmacists have seen as a result of policy requiring 90-day supply or autorefilling of prescriptions, even though the patient asked for the medication to stop. Generally, feedback from national medicine take-back days indicates that the majority of returned medicines are not controlled substances, but rather over-the-counter medicines or noncontrolled medications. Requiring new systems to separate the intake of controlled versus noncontrolled substances would create a heightened risk for pharmacies, which are increasingly identified and robbed by individuals seeking controlled substances. From 2006 to 2010 alone, DEA reports that pharmacy robbery rates increased by 80%, with most incidents involving controlled substances. Systems in place to remove these substances from the communities also should ensure that locations where ultimate users drop off medicines are not put at added risk.
APhA testified at the DEA 2011 meeting, highlighting APhA’s role in implementing the **SMARxT Disposal program** in partnership with the U.S. Fish and Wildlife Service and PhRMA. APhA also advocated for the following steps:

- Supporting the need for various options to implement voluntary take-back or other programs, and the importance of ensuring that pharmacists and pharmacies have an opportunity to work with their communities on such programs;
- Working with ONDCP to ensure increased coordination among federal agencies on activities, requirements, and recommendations related to disposal of medications;
- Ensuring that various options for implementing voluntary disposal programs, including the commingling of controlled substances and other medications, are available to states, local communities, and individual locations;
- Allowing designated disposer or agent registration for pharmacists and pharmacies, or other appropriately certified community locations, to receive controlled substances from patients for disposal;
- Limiting paperwork, such as cataloguing, for take-back programs and locations; and
- Exploring external funding options to cover costs for take-back programs.

**Public Education and Awareness of Proper Safe Medication Disposal**

**FDA Disposal Recommendations**

FDA currently provides consumer information for the public to guide the proper disposal of unused or expired medicines. The guidance was originally developed in 2007 and was updated in 2009 in cooperation with ONDCP. FDA guidance for the public urges that users do not flush medicines unless specifically directed to do so by information on FDA’s website. FDA directs users to flush controlled medicines to avoid diversion of the medicines and identifies medicines that are considered controlled. For medicines not on FDA’s list of medicines that should be flushed, the agency recommends that unused or expired medicines be mixed with undesirable substances such as coffee grounds or kitty litter, sealed in a plastic bag, and discarded as part of household trash. FDA also recommends that patients stay informed on upcoming national medicine take-back days to dispose of medicines.

ONDCP included medication disposal as a priority in its 2011 National Drug Control Strategy outlining efforts to address prescription drug abuse and coordinate efforts across federal agencies. The four key focus areas include prescriber and patient education, prescription monitoring programs, medication disposal, and enforcement strategies. Additional information about the strategy is available at www.whitehouse.gov/sites/default/files/ondcp/ndcs2011.pdf.

**SMARxT Disposal Program**

APhA, in partnership with the U.S. Fish and Wildlife Service, launched the **SMARxT Disposal** website and was joined by PhRMA in 2008. The initiative launched smarxtdisposal.net and included educational information to promote FDA’s guidelines for medication disposal and raise
awareness of the environmental impact of improperly disposed medicines. The campaign simplifies the disposal process by offering three tips:

1. Do not flush medicines unless expressly indicated to do so in FDA’s recommendations because of a medicine’s high abuse potential.
2. Mix a medicine you wish to dispose of with an unappealing substance and discard it in a sealed plastic bag in household trash.
3. Always consult your pharmacist with any questions about medicines.

SMARTxT Disposal also urges users to appropriately clear their personal identifiable information from prescription bottles when disposing of them.9

**State Prescription Drug Return, Reuse, and Recycling Laws**

The National Conference of State Legislatures (NCSL) tracks state legislation to create prescription drug recycling, repository, or redistribution programs for unused medications. Although details of the laws vary, most allow the return of prescription drugs in single use or sealed packaging from state programs, nursing homes, and other medical facilities. The medicines are then redistributed for use by needy residents who cannot afford to purchase their prescribed drugs. Some states include provisions for the financial terms of the donations or regulating resale. Virtually all laws include some restrictions designed to ensure the purity, safety, and freshness of the products.10 Typically, most programs include the following stipulations:

- All donated drugs must not be expired and must have a verified future expiration date.
- Controlled substances, defined by DEA, usually are excluded and prohibited.
- A state-licensed pharmacist or pharmacy must be part of the verification and distribution process.
- Each patient who is to receive a drug must have a valid prescription form in his/her own name.

According to NCSL, at least 38 states and Guam have enacted such laws and programs to date. Not all laws or programs are operational.10

As an example of state activities, the Drugs for Cancer program, which is enacted in six states (Colorado, Florida, Kentucky, Minnesota, Nebraska, and Wisconsin), focuses on accepting and distributing cancer-related prescription drugs. A program is referenced in Michigan but may not be operational.

In addition to donating unused medications, some states allow medications to be returned to a pharmacy’s stock if they have been maintained in a controlled system. Examples include return of medication from a nursing home or from a hospital patient floor to the pharmacy.
Practical Guidelines for Consumers Hoping to Donate Drugs

NCSL has compiled a guide to consumers wishing to donate drugs. Many state restrictions exist on who can donate the types of medications and the procedures that must be followed. Many states require that donations meet the following standards:

- Only certain professionally designated persons can make a donation. For example, the Kansas law states that only “health facilities and pharmacies” can donate medications. Connecticut, Pennsylvania, and Rhode Island have similar limitations. Other states do allow patients to donate directly, for example, Arizona, Florida, and Iowa.
- Tablets in opened or partly used bottles are never accepted. Generally the packaging must be intact, meeting an exact standard such as the Kentucky law, “Upon inspection, the drug must be in its original, unopened, sealed, and tamper-evident unit dose packaging.”
- Old drugs are never accepted. Expiration dates must be visible and usually at least 6 months later than the date of donation. (Many prescription products carry an expiration date approximately 1 year after the original date of the purchase.)
- Commonly, donated drugs must be delivered to a specific type of medical or pharmacy facility. Some may require the donor to sign a form or waiver.
- Financial compensation is usually prohibited. Donations may be tax-deductable if the medications were paid for by the individual patient and taxpayer. Beyond donation programs, patients and other individuals may not sell any prescription drugs. Such transactions are strictly regulated by State Boards of Pharmacy and other state and federal laws.

Existing Collection Programs

The 160% rise in poisonings from 1999 to 2009 has prompted national and local efforts to identify opportunities to remove unused or expired medications from homes. All such programs exclude needles, other sharps, and most liquids over 3 ounces. Examples of existing programs are described below.

The American Medicine Chest Challenge

The American Medicine Chest Challenge (AMCC) (www.americanmedicinechest.com) was launched nationally in 2010 following a successful pilot in New Jersey. The program creates a national medicine take-back or disposal day each year on the second Saturday in November at no cost to communities. Program partners include PhRMA, the Partnership at DrugFree.Org, the Generic Pharmaceutical Association, the American College of Emergency Physicians, and local law enforcement agencies.

The AMCC event requires collaboration between a local law enforcement organization and a community group. The community group utilizes AMCC toolkits to promote the event but must partner with a law enforcement agency with regional collection sites to collect all medicines from the event. An important benefit to AMCC collection is that patients are able to turn in both controlled and noncontrolled substances, unlike at other events where only noncontrolled substances are accepted and patients are turned away at times.
AMCC also allows for a permanent collection box to be placed at a location, at the law enforcement agency’s discretion. That law enforcement agency is ultimately responsible for protecting the integrity and security of the box and its ultimate incineration; therefore, controlled and noncontrolled medicines can be returned both to the permanent collection sites year round and at the annual disposal event in November.\textsuperscript{11} However, since the law enforcement agency is ultimately responsible for the integrity of the controlled substances, most choose to maintain the collection box within the premises of the actual law enforcement agency, which may operate under more restricted hours than a hospital or community pharmacy. Multiple studies support the understanding that individuals are less likely to visit law enforcement agencies to return medicines than they would be to use locations such as pharmacies, hospitals, and other health care settings.\textsuperscript{4} Pharmacists also may use the point of the medication disposal to counsel patients on medication adherence and identify the cause of the medication return. This interaction allows the pharmacist to identify whether the patient started a new medication or experienced an adherence issue.\textsuperscript{4}

**DEA National Prescription Drug Take-Back Day**

DEA has implemented a semiannual national prescription drug take-back initiative in the fall and spring of each year. The event held on April 28, 2012, collected 552,161 pounds of controlled and uncontrolled medicines from communities across the United States. Collectively, over the past 2 years, the four national take-back days collected more than 1.5 million pounds of medicines. DEA expects to hold additional take-back days in the future until final regulations are in place to improve options for disposing of controlled substances.\textsuperscript{12}

Community organizations interested in participating in collection events must partner with local law enforcement. Controlled and noncontrolled medications may be collected at DEA National Prescription Drug Take-Back Day events. Disposed medications are routed to regional collection sites by an authorized law enforcement agent and incinerated. Although these 1-day collections are a substantial step towards reducing drug diversion and removing potentially harmful medicines from the home, they do not provide a permanent solution for the collection of unused or expired medicines.

**Sharps Compliance, Inc.**

Existing programs offer patients the option to partner with Sharps Compliance, Inc., and its national TakeAway medication disposal program.\textsuperscript{13} This program exists in several different forms, but none of the TakeAway disposal suppliers can accept controlled substances and the medication must be maintained in its original container, distinguishing this program from DEA’s National Take-Back Day, which allows for loose medicines to be collected outside of their original containers.

In partnership with the National Community Pharmacists Association (NCPA), Community Pharmacy Foundation (CPF), pharmaceutical manufacturers, and other national partners, Sharps Compliance, Inc.’s TakeAway Environmental Return System is part of www.disposeymeds.org. This public education website, launched by NCPA, teaches the public about the environmental impact of the unsafe disposal of medicines and provides a locator link for patients to identify pharmacies that utilize the TakeAway Environmental Return System.\textsuperscript{14} NCPA member pharmacies receive a discount for the actual 10-, 20-, or 40-gallon disposal systems and are listed on both disposeymeds.org and TakeAway’s national website for
disposal site locations. The program collected more than 70,000 pounds of medicine through April 2012. The disposal boxes are all tamper resistant and include postage for return freight box via United Parcel Service. Some state pharmacy associations have provided this program for free to pharmacies in their states through land/water/environmental grants or through Board of Pharmacy grants that offset the cost for the disposal boxes from TakeAway. The sustainability of such programs relies on the availability of funds or the willingness of participating pharmacies to assume the cost of supplies. All such programs do not allow for the return of controlled substances at the pharmacy without direct law enforcement involvement. In addition, this type of program cannot currently be enacted in every state because of various state laws that restrict the settings and conditions of medication take-back.

TakeAway is also available from Walgreens, Safeway, Rite Aid, CVS, and other national pharmacy chains that have made disposal envelopes available for purchase in the pharmacy. Walgreens launched the partnership in September 2010 and has since collected more than 25,000 pounds of medicines for disposal through the program. Patients may purchase a prepostage stamped and paid envelope to ship their old or expired medicines for disposal; the envelopes can be dropped in a United States Postal Service mail box. The disposal systems again do not allow for any controlled substances to be included in the TakeAway envelope. TakeAway also makes available toolkits for participating pharmacies to promote the program to patients and caregivers. Again, without the involvement of law enforcement, controlled substances cannot be returned through these programs. Since this class of medications is most frequently associated with abuse, overdoses, and accidental ingestion, a nationwide need exists to address the collection of controlled substances.

**Conclusion**

The safe and appropriate disposal of medicines is a significant environmental and safety concern for communities. Restricting access to unused or expired medicines in the home and encouraging patients to regularly dispose of these products can create a significant impact on preserving public health. However, programs that are in place should allow for the return of all medicines, including controlled substances returned to a designated collection site. Furthermore, although they have a great impact in removing tons of potentially harmful medicines from the home, 1-day collections do not provide a permanent mechanism for patients to dispose of products year-round. Although several public education campaigns exist related to the return of medicine, the public is still unaware of the difference between the return of controlled versus noncontrolled medicines. Any changes in the Controlled Substances Act that DEA is proposing should not create processes that generate an added time and financial barrier, or require the screening/separating of the types of medicines being returned. It is important that a variety of sites be presented to the public related to the disposal of medicines, including pharmacies and other health care settings. Return via mail or through boxes in pharmacies or other settings should be available year-round to maximize the disposal of potentially harmful medicines in the home. Extensive dialogue with key stakeholders such as boards of pharmacy, state and national pharmacy organizations, federal agencies (including FDA, DEA, ONDCP, EPA, and the Department of Transportation), state legislatures, the public, and environmental protection groups is imperative to the creation of sustainable and appropriate mechanisms for the safe disposal of medicines. Any program implemented must focus on patient safety and public health and engage all stakeholders—law enforcement, health professionals (including pharmacists), and consumers.
References

Current Relevant APhA Policy

2012 Controlled Substances Regulation and Patient Care
1. APhA encourages the Drug Enforcement Administration (DEA) and other regulatory agencies to recognize pharmacists as partners that are committed to ensuring that patients in legitimate need of controlled substances are able to receive the medications.

2. APhA supports efforts to modernize and harmonize state and federal controlled substance laws.

3. APhA urges DEA and other regulatory agencies to balance patient care and regulatory issues when developing, interpreting, and enforcing laws and regulations.

4. APhA encourages DEA and other regulatory agencies to recognize the changes occurring in health care delivery and to establish a transparent and inclusive process for the timely updating of laws and regulations.

5. APhA encourages the U.S. Department of Justice to collaborate with professional organizations to identify and reduce (a) the burdens on health care providers, (b) the cost of health care delivery, and (c) the barriers to patient care in the establishment and enforcement of controlled substance laws.

2012 Counterfeit Medication and Unit-of-use Packaging
APhA encourages the continued development, distribution, and use of unit-of-use packaging as the industry standard to enhance patient safety, patient adherence, and efficiencies in drug distribution and to reduce potential for counterfeiting.

2009 Medication Disposal
1. APhA encourages appropriate public and private partnerships to accept responsibility for the costs of implementing safe medication disposal programs for consumers. Further, APhA urges DEA to permit the safe disposal of controlled substances by consumers.

2. APhA encourages provision of patient appropriate quantities of medication supplies to minimize unused medications and unnecessary medication disposal.

( JAPhA NS49(4):493 July/August 2009)

2006/2003 Unit-of-Use Packaging
1. APhA encourages the continued development, distribution and use of unit-of-use packaging as the industry standard to enhance patient safety, patient compliance, and efficiencies in drug distribution.

2. APhA shall collaborate with the pharmaceutical industry, third party payors, and appropriate federal agencies to affect the changes necessary for the adoption of unit-of-use packaging as the industry standard.

3. APhA encourages the enactment of legislation and regulations to permit pharmacists to modify prescribed quantities to correspond with commercially available unit-of-use packages.


2004 Protecting the Integrity of the Medication Supply
1. APhA encourages pharmacists to enhance their role in protecting the integrity of the medication supply, including careful consideration of the source and distribution pathways of the medications they dispense.

2. APhA recommends that all individuals and entities of the pharmaceutical supply system, including manufacturers, wholesalers, pharmacies, pharmacists, and other, adopt appropriate technology, tracking mechanisms, business practices, and other initiatives to protect the integrity of the drug supply.

3. APhA supports public education about the risk of using medications whose production, distribution, or sale does not comply with US federal and state laws and regulations.

4. APhA urges pharmacists and other health care professionals to report suspected counterfeit products to the Food and Drug Administration.

2004 Medication Disposal
1. APhA encourages the Environmental Protection Agency and other appropriate entities to continue research exploring any connection between the disposal of discarded prescription and OTC medications and contamination of the water supply.
2. APhA encourages the development of programs for safe medication disposal.
3. APhA encourages appropriate government entities to accept responsibility for implementation and associated costs of safe medication disposal programs for consumers.

1985 Registration of Facilities Involved in the Storage and Issuing of Legend Drugs to Patients
APhA supports enactment of state and federal laws and regulations which would require registration with the state boards of pharmacy of all facilities involved in the storage and issuing of legend drugs to patients, provided that such registration does not restrict the pharmacist from providing professional services independent of a facility.

2004/1992 Drug Product Packaging
1. APhA supports the role of the pharmacist to select appropriate drug product packaging.
2. APhA supports the pharmaceutical industry’s performance of compatibility and stability testing of drug products in officially defined containers to assist pharmacist selection of appropriate drug product packaging.
3. APhA supports the value of unit-of-use packaging to enhance pharmaceutical care, but recognizes that product and patient needs may preclude its use.
4. APhA encourages the pharmaceutical industry to ensure that all unit-of-use packaging will accommodate a standard pharmacy label.