A continuing pharmacy education activity for pharmacists and pharmacy technicians.

Legal and Regulatory Developments Affecting Pharmacy in 2012

CPE FOR MEMBERS ONLY

APhA Pharmacy Law Matters 2012
**Pharmacy Law Matters**

**LEGAL AND REGULATORY DEVELOPMENTS AFFECTING PHARMACY IN 2012**

A continuing pharmacy education activity for pharmacists and pharmacy technicians.

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**DEVELOPMENT**

This home-study CPE activity was developed by the American Pharmacists Association.

This publication was prepared by Judy Crespi Lofton, MS, of JCL Communications, in consultation with the Government Affairs staff, on behalf of the American Pharmacists Association.

**DISCLOSURE**

Mr. Campbell, Ms. Crespi Lofton, and APhA’s Government Affairs and editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria.

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**LEARNING OBJECTIVES**

At the completion of this activity, pharmacists and technicians will be able to:

1. Describe the outcome of Supreme Court rulings in 2012 that have an impact on the practice of pharmacy.
2. Describe pending legislation and legislation that became law in 2012 that affects the profession of pharmacy.
3. Explain activities that took place in 2012 by the Centers for Medicare & Medicaid Services to implement the Affordable Care Act and other regulations that impact pharmacy.
4. Describe regulatory activities by the Food and Drug Administration affecting pharmacists, including potential revisions to the drug paradigm.
5. Discuss regulatory activities by the Drug Enforcement Administration, including those pertaining to disposal of controlled substances and the electronic prescribing of controlled substances.

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**Abstract**

**Objective:** To explain legal, regulatory, and judicial developments in 2012 that have an impact on the practice of pharmacy.

**Summary:** Key developments in 2012 included the U.S. Supreme Court’s decision to uphold most of the Affordable Care Act (ACA); activities to implement ACA, including ongoing activities to support pharmacist roles on the health care team; the 2012 reauthorization of the Prescription Drug User Fee Act; potential revisions to FDA’s paradigm of drug categories; and other activities, including those by CMS and DEA.

**Conclusion:** Laws, regulations, and judicial decisions have an important influence on the practice of pharmacy. Pharmacists involvement in advocacy efforts that communicate the value of the pharmacist to decision makers and other stakeholders is critical.

**Keywords:** Affordable Care Act, Centers for Medicare & Medicaid Services, Drug Enforcement Administration, Food and Drug Administration, health care reform, integrated care, Medicare, patient care services, pharmacy law, Supreme Court.

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**Pharmacy law matters: Legal and regulatory developments affecting pharmacy in 2012**

American Pharmacists Association

3. Which of the following provisions was included in the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA V)?
   a. New pathways for drug importation
   b. Track-and-trace provisions that track individual products to the pharmacy level
   c. Reclassification of all hydrocodone-containing products to Schedule II
   d. Provisions focused on standardizing risk evaluation and mitigation strategy (REMS) programs

4. Which of the following is a correct statement about FDA’s Nonprescription Safe Use Regulatory Expansion initiative and revisions to the drug paradigm?
   a. It would create a new category of drugs.
   b. It would allow certain drugs that would otherwise require a prescription to be sold without a prescription under conditions of safe use.
   c. Any final recommendations for modifying the drug paradigm must be voted on by Congress.
   d. The program would implement greater standardization to REMS programs.

5. Which law(s) allows FDA to create a safer process for disposing of unused controlled substances?
   a. The Affordable Care Act
   b. The Safe Doses Act
   c. The Secure and Responsible Drug Disposal Act
   d. PDUFA IV and V

The year 2012 was pivotal for many legislative and regulatory developments that affect the practice of pharmacy. The U.S. Supreme Court’s decision to largely uphold the 2010 Affordable Care Act (ACA; PL 111-148) was a critical moment for the law. The development of key components of the law required for full implementation have moved forward, and parts of the law that advance pharmacy practice continued to be implemented. These developments, along with other legislative, regulatory, and judicial activities, continue to redefine and shape the practice of pharmacy.

This article, which is current as of November 1, 2012, describes a wide range of activities that affect pharmacy practice, including implementation of ACA, new legislation, and new regulations from CMS, FDA, and DEA. Other issues affecting pharmacy are listed in Table 1.2

APhA has been integral in advocating on behalf of pharmacists regarding these activities to educate decision makers about the value of pharmacists’ services and the role of pharmacists in improving patient care.
Table 1. Other legislative and regulatory issues affecting pharmacy

<table>
<thead>
<tr>
<th>Topic</th>
<th>Recent developments</th>
<th>Key issues for pharmacy</th>
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<tbody>
<tr>
<td>Fraud, waste, and abuse</td>
<td>HIPAA (PL 104-191) first established a national Health Care Fraud and Abuse Control Program. ACA increased funding for auditing activities and created greater access to pharmacy records for auditors. See the 2011 Pharmacy Law Matters for a discussion of these provisions.</td>
<td>In 2012, CMS continued its focus on data-mining efforts to identify fraud waste and abuse. More information is available from CMS at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf">www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf</a>. As of October 2012, 154 ACOs were serving more than 2.4 million Medicare patients. Pharmacists can help ACOs and other integrated models achieve quality measures by improving clinical quality and reducing costs.</td>
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<tr>
<td>ACOs and patient-centered medical homes</td>
<td>Work continues on integrated care models and shared savings opportunities. CMS is looking at potential future payment options. APhA continues to advocate for pharmacist payment within evolving models.</td>
<td>In the sequester, the Office of Management and Budget must implement across-the-board cuts in most programs, split between defense and nondefense, to reach a $1.2-trillion target. Medicare provider reimbursements could be reduced by 2%. Medicaid and Social Security are exempt from cuts. Congress is considering additional legislation to modify the mandatory cuts under the sequester. APhA is closely monitoring this activity.</td>
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<td>Compounding</td>
<td>In the wake of a fungal meningitis outbreak that originated with contaminated injectable steroids states, Congress and FDA are reevaluating regulation of compounding pharmacies.</td>
<td>In 2012, the Verifying Authority and Legality In Drug Compounding Act of 2012 (H.R. 6584) and the S.A.F.E. Compounding Drugs Act of 2012 (H.R. 6638) were introduced to address regulation of pharmacy compounding. APhA is actively engaged in ongoing dialogue with Congress and FDA as this issue evolves.</td>
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Abbreviations used: ACA, Affordable Care Act; ACO, accountable care organization; HIPAA, Health Insurance Portability and Accountability Act of 1996. Source: References 1 and 2.

ACA: Judicial update

ACA (PL 111-148) aims to expand health care coverage, improve quality, and control costs. ACA is designed to achieve these goals by reforming the health care insurance market and encouraging innovation in the provision of health care services. Examples of insurance reforms include requirements for individual health insurance coverage, essential health benefits, and expanding eligibility for Medicaid to all individuals younger than 65 years with incomes below 133% of the federal poverty level. Innovations include activities driven by the Center for Medicare & Medicaid Innovation (CMMI). The law includes numerous provisions of interest to pharmacists that affect issues such as improvements to Medicare Part D medication therapy management (MTM) programs, the Independence at Home Demonstration project, accountable care organizations, medical homes, and transitions of care.³

ACA requires individuals to purchase health insurance that meets defined standards of coverage or face a penalty—a requirement known as the “individual mandate.” Shortly after its passage, various parties challenged ACA’s individual mandate in federal court based primarily on the argument that Congress could not force individuals to purchase a product under the Interstate Commerce Clause. Challenges to the law eventually made their way to the U.S. Supreme Court, and on June 28, 2012, the Supreme Court published its long-awaited ruling. The court upheld ACA’s individual mandate as a constitutional exercise of Congress’s power to tax and only struck down a provision in the law that would strip existing Medicaid funding from states that do not comply with the law’s Medicaid expansion requirements.

The court ruled that the individual mandate provision was constitutional under Congress’s authority to tax rather than its power to regulate commerce. Concerning ACA’s expansion of Medicaid, the court ruled Congress went too far with a provision that would make states risk losing all of their Medicaid funding for not complying with ACA’s expansion of Medicaid eligibility.

Implementation of ACA and other CMS activities

Following the Supreme Court ruling on ACA’s constitutionality, there has been renewed focus on the implementation of the law’s provisions and on political opposition to the law. For example, on July 11, the House of Representatives voted 244 to
185 to repeal the law (H.R. 6079). The Senate is unlikely to vote on the issue. In the states, some governors have said that they do not plan to follow ACA’s Medicaid expansion.

APhA will continue its efforts to safeguard pharmacists’ interests in Congress and work with federal agencies and states as they consider and execute various regulations to implement the law.

Establishing state purchasing insurance exchanges
State-based health insurance exchanges will allow individuals and small businesses to compare and purchase health insurance coverage and enroll in a plan that meets their needs. Insurance plans offered through the exchanges must provide, at minimum, “essential health benefits” that have been defined by the Department of Health & Human Services (HHS). Details about the essential health benefits can be found at www.healthcare.gov/news/factsheets/2012/11/ehb11202012a.html.

In addition, exchanges will provide information and education services, such as helping patients determine whether they are eligible for tax credits for private insurance or health programs like the Children’s Health Insurance Program.

The exchanges are required to be fully operational by January 1, 2014. HHS will evaluate the readiness of the exchanges 1 year before the launch dates. States are required by ACA to submit a blueprint of their plans for developing the exchanges to HHS by November 16, 2012. These plans should address issues such as the structure of the exchange and its governance, consumer assistance and outreach, information technology infrastructure, and financing of the exchange. However, as of August 2012, only 15 states had established exchanges. Seven states declared that they would not create an exchange; others continue to evaluate their options.4

CMMI
ACA established CMMI to encourage novel payment and service delivery models to assess their effects on cost and quality of care for existing programs, such as Medicare and Medicaid. The law requires that MTM services be among the models tested. In addition, CMMI is focused on transitions of care, reducing hospital readmissions, improving quality, and reducing costs. CMMI is directed to rapidly scale up models that are demonstrated to be successful.

Currently, CMMI has many programs, including the Health Care Innovation Awards, Partnership for Patients, and Hospital Engagement Networks (HENs) (more information available at www.innovations.cms.gov).

The Health Care Innovation Awards invest up to $1 billion to support local innovation aimed at improving quality of care and lowering costs. The awards are intended to:

■ Engage a broad set of innovation partners to identify and test new care delivery and payment models that originate in the field and that produce better care, better health, and reduced cost.
■ Identify new workforce development and deployment models, including training and education to support new models.
■ Support innovators who can rapidly deploy care improvement models (within 6 months of award) through new ventures or expansion of existing efforts to new populations of patients. Wherever possible, innovators should work with other public and private sector partners.

Two rounds of Health Care Innovation Awards were announced in May and June 2012. Pharmacy and pharmacists played integral roles in at least 15 of the organizations that won awards. As the pharmacy community becomes more familiar with these projects, APhA expects to identify additional programs that integrate pharmacist services, especially related to transitions of care, medication reconciliation, adverse drug events, and reducing drug-related hospital readmissions. Each project will be monitored for measurable improvements in quality of care and cost savings.5

Launched in April 2011, the Partnership for Patients is a nationwide public–private partnership that supports physicians, nurses, pharmacists, and other clinicians working to make patient care safer and to support effective transitions of patients from hospitals to other settings. The Community-Based Care Transitions Program (a program of Partnership for Patients) tests models for improving care transitions to reduce hospital readmissions.6

As part of Partnership for Patients, hospitals across the country will have new resources and support through HENs. HENs are being developed to make health care safer and less costly by targeting and reducing the millions of preventable injuries and complications from health care–acquired conditions. In 2012, CMMI awarded $218 million to 26 state, regional, national, or hospital system organizations to develop HENs. HENs will help develop programs that are already reducing health care–acquired conditions and are increasingly focused on preventing drug-related readmissions and adverse drug events and improving transitions of care. Such work aims to share information with other hospitals and health care providers so that communities can learn from each other as part of an evolving health care system.6

APhA is actively engaged with CMMI and the initiatives described above to be a resource and increase awareness of the role that pharmacists can play in improving patient outcomes, meeting quality measures, and improving care transition activities.7,8

APhA/American Society of Health-System Pharmacists transitions of care resources. To better define pharmacists’ roles in supporting medication safety throughout transitions of care, in 2012, APhA and the American Society of Health-System Pharmacists released a white paper, Improving Care Transitions: Optimizing Medication Reconciliation (www.pharmacist.com/sites/default/files/files/2012_improving_care_transitions.pdf). The white paper provides a comprehensive overview of the medication reconciliation process during transitions in care, its effect on patient care and outcomes, and how pharmacists can contribute to the improvement of this process through MTM.

The white paper advocates that pharmacists should take a leadership role in collaborating with other health professionals in the coordination and implementation of medication reconciliation. A publication containing best practice highlights also is being developed.9
Public–private partnerships: The Million Hearts Campaign

Launched by HHS and led by CDC and CMS, Million Hearts is a national public–private partnership aimed at preventing 1 million heart attacks and strokes in the United States over 5 years. The campaign encourages the use of its ABCs mnemonic: A, aspirin for people at high risk; B, blood pressure control; C, cholesterol control; and S, stopping smoking.

APhA and other pharmacy organizations and corporations have partnered with HHS to work toward the Million Hearts goal. Numerous federal agencies are involved in the campaign to provide staff and funding. As part of the program, CDC announced the $2 million Pharmacy Outreach Project, which will enroll pharmacists to provide advice and support to patients with high blood pressure. CMS will award $485 million over 5 years to 10 states to encourage Medicaid beneficiaries to participate in chronic disease prevention programs.10–12

In support of the Million Hearts initiative, the APhA Foundation launched the Pharmacy Blood Pressure Challenge in June 2012. The challenge is a screening and education initiative that encourages pharmacists to help prevent and control high blood pressure in their patients by performing screenings and providing education. Pharmacists who engage in this program will be able to report their impact on the APhA Foundation’s Pharmacy Blood Pressure Challenge website (http://millionhearts.aphafoundation.org). Aggregated information collected through this site will help to demonstrate the impact of pharmacists in their communities.13

In addition, in September 2012, APhA and the APhA Foundation announced that they have joined the new pharmacy-based hypertension program, Team Up. Pressure Down (http://millionhearts.hhs.gov/resources/teampuppressuredown.html).14

APhA urges members, including independent pharmacists, regional and national chain pharmacists, and student pharmacists, to embrace these opportunities to help patients get screened and take action to help manage cardiovascular health.

Part D–related provisions for 2013

ACA codified into law more robust MTM program requirements for Medicare Part D plans. Building on current programs, requirements in ACA offer a set of MTM services to targeted Medicare beneficiaries that include, at minimum, strategies to improve adherence to prescription medications or other goals. Specifically, Part D MTM programs and strategies must include an annual comprehensive medication review (CMR) delivered person to person or using telehealth technologies by a licensed pharmacist or other qualified provider and follow-up interventions as indicated by findings of the annual medication review or the targeted medication enrollment. Services may be provided person to person or using telehealth technologies.

Part D plan sponsors also must assess, at least quarterly, medication use by individuals who are at risk but not enrolled in the MTM program, including individuals who have experienced a transition in care (e.g., a hospitalization or stay in a skilled nursing facility), if the drug plan sponsor has access to that information. They also must automatically enroll targeted beneficiaries in the MTM program, including beneficiaries identified in the quarterly assessment, and permit beneficiaries to opt out of enrollment in the MTM program.

CMS’s 2013 call letter to Part D plans included several additional requirements, including:15,

- Offering to provide targeted beneficiaries a CMR as soon as possible after enrollment into the MTM program. The rate of targeted beneficiaries who complete CMRs will be used as a quality measure for Part D plans. In 2013, information about CMR completion will be available as a display measure for beneficiaries to view, and it’s anticipated that in 2014, this measure will be used in the plan’s overall quality STAR rating. (STAR ratings are information about a Part D plan’s quality that are provided to beneficiaries.)
- Using more than one approach to reach all eligible targeted beneficiaries.
- Expanding beneficiary targeting to include Alzheimer disease, end-stage renal disease, and atrial fibrillation, as well as target at least five of nine core chronic conditions
- Leveraging effective MTM programs to improve plan STAR ratings.

ACA also directed CMS to develop a standardized format for CMR documentation for beneficiaries enrolled in Part D MTM programs. The standardized documentation includes three components: a beneficiary cover letter, a medication action plan, and a personal medication list (PML). The format of these documents is similar to MTM forms currently in use (i.e., those included in the core elements model from APhA and the National Association of Chain Drug Stores Foundation). For example, the PML is similar to the patient medication record described in the core elements model.16,17 Medicare Part D plans will be required to use the standardized format beginning January 1, 2013.

The standardized format’s written summary requires certain activities during the CMR to complete the documentation. These include discussion of beneficiaries’ concerns regarding their drug therapy; collection of the purpose and instructions for using their medications; review of their medications, including prescription drugs, nonprescription drugs, and supplements; and engaging beneficiaries in managing their drug therapy.18 For a more complete review of the Part D information and revisions for 2013, see APhA’s issue brief on www.pharmacist.com.

Issues affecting long-term care facilities

Citing concerns about potential conflicts of interest, in October 2011, CMS proposed a Medicare rule that would require long-term care consultant pharmacists to be “independent” from long-term care pharmacies and drug manufacturers and distributors. Under the proposal, long-term care facilities (LTCFs) also would be prohibited from contracting for consultant pharmacy services, with a long-term care pharmacy subsidiary created to provide reorganized services.18

CMS published a final rule in April 2012 that differed substantially from the initial proposal. In the final rule, CMS decided against requiring long-term care consultant pharmacists to be “independent” and instead requested comments to help CMS determine a more comprehensive approach to address inappropriate formulary decisions and the use of chemical restraints in long-term care. CMS encouraged the long-term care industry to voluntarily adopt the following changes to increase transparency and specifically requested feedback on them:19.
Separate contracting for long-term care consulting services from dispensing and other pharmacy services
Pay a fair market rate for consultant pharmacist services
Require consultant pharmacists to disclose any potential conflicts of interest to LTCFs or execute an integrity agreement to increase transparency

CMS delayed the implementation of short-cycle dispensing in LTCFs by 1 year to January 1, 2013. After that date, dispensing will be limited to 14-day increments for solid oral doses of covered brand-name drugs, with some exclusions. The reporting requirement for unused drugs in increments of 7 days or less will be waived. Also, total cost sharing for copayments cannot be more than what would be imposed without the provision (additional information available at www.pharmacist.com/cms-releases-medicare-revisions-2012).

Legislative developments in 2012
A number of legislative actions in 2012 will have an important influence on the practice of pharmacy, including Prescription Drug User Fee Act (PDUFA) reauthorization, the Safe Doses Act, and MTM legislation.

PDUFA reauthorization
On July 9, 2012, President Barack Obama signed the Food and Drug Administration Safety and Innovation Act (PL 112-144), which included the fifth reauthorization of PDUFA (PDUFA V). PDUFA allows FDA to collect fees from drug manufacturers to help fund the drug application review process and must be reauthorized every 5 years. PDUFA V also creates new user fee programs for generic drugs, biosimilars (generic biologics), and medical devices. The user fee program for biosimilars would apply to products approved under the abbreviated pathway created by ACA.

As required by PDUFA IV (which was passed in 2007), in 2010 and 2011, FDA held numerous public meetings and conducted discussions with pharmaceutical manufacturers and stakeholder groups to develop recommendations for PDUFA V, and Congress based the reauthorization process on FDA’s recommendations. APhA worked with FDA, Congress, and other stakeholders throughout the regulatory and legislative process to educate stakeholders about provisions important to pharmacists. At the same time, APhA worked to exclude potential items that would have been harmful to pharmacists. For example, APhA was involved in activity on multiple fronts urging senators to vote against any drug importation amendments; in the end, one drug importation amendment was voted on but did not pass the Senate. 19,20

PDUFA V addresses many aspects of the drug development, review, and approval process. Issues of the greatest interest to pharmacy included enhancing and modernizing FDA’s drug safety system. Several important PDUFA provisions build on the stakeholder feedback that gathered during the reauthorization process, including input from APhA focused on improving and standardizing risk evaluation and mitigation strategy (REMS) programs. APhA’s recommendations to improve REMS programs are outlined in the 2009 and 2011 REMS white papers available on www.pharmacist.com. REMS program improvements and other important activities that support FDA’s efforts are outlined in the FDA and manufacturer PDUFA V agreement that was submitted to Congress in January 2012. Additional provisions include using FDA’s postmarket surveillance and Sentinel Initiative to evaluate drug safety issues and ensuring that resources are in place to manage pharmacogenic information. Specific information in the agreement is available at www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

Other key provisions of the law that affect pharmacy include20:

- Requirements related to drug shortages, including early notification of FDA by manufacturers of potential shortages and an HHS-maintained public list of all drugs experiencing shortages.
- Authorization for HHS to develop guidance on interoperability standards for prescription drug monitoring programs.
- Increased manufacturer-level track-and-trace provisions. Provisions that were considered but not included in the final bill include20:
- Track-and-track provisions that would reach the pharmacy level.
- Reclassification of all hydrocodone-containing products from Schedule III to Schedule II.

In addition, the law authorizes the development of guidance for standards for interoperability of prescription drug monitoring programs and a study on drug labeling by electronic means.

Progress of MTM legislation introduced in 2011
Congress continues to consider legislation introduced in 2011 that would increase patient access to MTM services: the Medication Therapy Management Benefits Act of 2011 (H.R. 8) and its companion bill, the Medication Therapy Management Empowerment Act of 2011 (S. 274). Either bill would make several improvements to the Medicare Part D MTM program. Improvements would include increasing the number of diseases for which beneficiaries may be targeted for services, requiring plan sponsors to offer any willing pharmacy in its network the opportunity to provide services, and providing additional quality-based incentive payments to pharmacies that deliver MTM services.

Although no significant action has been taken on the bills since they were introduced in 2011, they do offer an avenue to continue dialogue with Congressional staff about the value that pharmacists provide to the health care team. In addition, as of October 2012, there were 61 cosponsors in the House and 17 cosponsors in the Senate.

APhA believes that it is crucial that pharmacists continue their advocacy efforts to communicate the value of pharmacy services. Pharmacists are encouraged to communicate with their legislators and to join APhA’s key contact network. See www.pharmacist.com/advocate for more information on how to advocate on behalf of pharmacists and www.pharmacist.com/advocacy-key-contacts-sign to sign up as a key contact.
The Safe Doses Act

On September 25, 2012, Congress passed the Safe Doses Act, and it became law in October (PL 112-186). The bill seeks to fight medical theft and protect patients from receiving stolen and mishandled medical products that have been resold into the marketplace, typically through gray- or black-market channels.22

Before the Safe Doses Act, federal law did not distinguish the theft of medication from the theft of other products. The law creates a distinction and provides:

- Increased sentences for robbing pharmacies of controlled substances.
- Increased sentences for those who steal medical products.
- Enhanced penalties for the “fences” who knowingly obtain stolen medical products for resale into the supply chain.
- Increased sentences when harm occurs (i.e., instances in which injury or death results from using a stolen substance or the defendant is used by an organization in the supply chain).
- Application of the Racketeer Influenced and Corrupt Organizations (RICO) law, which helps equip law enforcement with additional tools, to the theft of medical products.
- Restitution to victims injured by stolen medical products.

Other regulatory activities

Other 2012 regulatory activities that affect pharmacy practice include those from FDA, CMS, DEA, and the White House Office of National Drug Control Policy (ONDCP).

FDA potential revisions to drug paradigm

In February 2012, FDA announced that it is considering revisions to nonprescription drug classification. In the proposed new paradigm, FDA would approve certain drugs for nonprescription use under “conditions of safe use.” Similar to REMS programs, this new paradigm concept fits into the overall drug safety continuum by allowing more flexible access to drugs that otherwise would remain prescription only (Figure 1).

Such conditions could include intervention by a pharmacist or use of innovative technologies before purchase of the product. FDA posed more than 20 questions for feedback and accepted comments until May 7, 2012. APhA is a leader in the dialogue on this issue and has highlighted eight key focus areas for discussion regarding the new drug paradigm (Table 2).23

FDA has regulatory authority to continue the discussion on this issue. The agency continues to evaluate comments received from public hearing and engage in dialogue with stakeholders. Ongoing developments with a potential new paradigm may have important implications for the roles of pharmacists in supporting patient self-care.24 As of October 2012, FDA is moving forward with this effort through the

![Figure 1. Potential new drug regulation paradigm being considered by FDA: Creating more flexibility on the drug safety continuum to benefit patients and public health](image-url)

Abbreviation used: REMS, risk evaluation and mitigation.
Source: Reference 23.
Nonprescription Safe Use Regulatory Expansion (NSURE) initiative and aims to clarify misinformation and questions about what is being considered. FDA is working with the Brookings Institution to explore a variety of NSURE topics.

**CMS rule on medical staff privileges**

A CMS final rule that was published in May 2012 and effective as of July 2012 broadens the concept of hospital medical staff to allow hospitals to grant privileges to nonphysicians (including pharmacists) in accordance with state law and within their state scope of practice.

In the rule’s executive summary, CMS notes, “This change will clearly permit hospitals to allow other practitioners (e.g., APRNs [advanced practice registered nurses], PAs [physician assistants], pharmacists) to perform all functions within their scope of practice.” The impact of this rule’s expansion of the medical staff concept eventually may be widespread, and pharmacy is looking at potential opportunities that may result.25

**CMS issues stage 2 “meaningful use” criteria**

CMS “meaningful use” criteria are requirements for the use of electronic health records with which eligible health care providers must comply to earn incentive payments as a provision of “the stimulus” law of 2009. Although pharmacists are not included within the definition of eligible professionals, through the Pharmacy e-Health Information Technology Collaborative (www.pharmacyhit.org), APhA continues to advocate the importance of pharmacists being connected and how pharmacists can help physicians and hospitals meet meaningful use requirements. Integration of pharmacists in the EHR infrastructure is critical for pharmacists throughout the health care system.

The program is divided into three stages. Stage 1, which began in 2011, set the basic functionalities that must be included in electronic health records. Stage 2 increases health information exchange between providers and promotes patient engagement by giving patients secure online access to their health information. Stage 3 will continue to expand meaningful use objectives to improve health care outcomes.

Criteria for stage 2 were released in September 2012 and became effective in November 2012.26 The final rule for stage 2 included the following:

- Providers have more time to meet stage 2 criteria (until 2014 instead of 2013).
- Nearly all of the stage 1 core and menu objectives are retained for stage 2. The “exchange of key clinical information” core objective from stage 1 was reevaluated in favor of a more robust “transitions of care” core objective in stage 2, and the “provide patients with an electronic copy of their health information” objective was removed and replaced by a “view online, download, and transmit” core objective.
- A new core objective for hospitals was included: requiring automatic tracking of medications from order to administration using assistive technologies in conjunction with an electronic medication administration record. Release of the final stage stage 2 rule sets the stage for continued dialogue as CMS considers stage 3 requirements.

### Table 2. APhA’s key focus areas for a new drug paradigm

<table>
<thead>
<tr>
<th>Area</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence and clinical experience</td>
<td>As currently described, APhA agrees that the approval of any product in the new paradigm would need to be based on science, clinical evidence of efficacy, and patient safety in actual use.</td>
</tr>
<tr>
<td>Public input</td>
<td>An opportunity must exist for public input on any sponsor’s proposal for a product with conditions of safe use.</td>
</tr>
<tr>
<td>Consistent definitions and processes</td>
<td>The process for drug availability through conditions of safe use must be defined in a uniform and standardized process.</td>
</tr>
<tr>
<td>Communication technology</td>
<td>Pharmacist–patient care activities could be communicated through phone calls and faxes. However, expanding use of health information technology infrastructure and electronic health records would be more efficient and effective.</td>
</tr>
<tr>
<td>Use of practice algorithms</td>
<td>A pharmacist–patient intervention as part of conditions of safe use to determine appropriate dispensing should be built upon consensus-based, best-practice algorithms for pharmacists to implement and communicate with other providers.</td>
</tr>
<tr>
<td>Ability to bill for services</td>
<td>Clinical services required to dispense products with conditions of safe use must be valued by the sponsors, payers, or consumers who derive the benefit of those services. APhA encourages FDA to maintain a system that incorporates such mechanisms. Billing initiated by pharmacists and administrative processes must be straightforward and use standardized mechanisms.</td>
</tr>
<tr>
<td>Provider education</td>
<td>Education about a new paradigm must focus on the availability of a product, targeted patient population, processes and logistical requirements of the program, and resource materials for the pharmacist.</td>
</tr>
<tr>
<td>New paradigm authority</td>
<td>APhA supports pursuing broad and general authority through appropriate legislative and/or regulatory processes.</td>
</tr>
</tbody>
</table>

Source: Reference 23.
DEA activities
Disposal of unused controlled substances. The Secure and Responsible Drug Disposal Act of 2010 (PL 111-273) became law in October 2010 to create a safer process for disposing of unused controlled substances. This law amends the Controlled Substances Act to allow the attorney general to develop drug disposal programs and allows LTCFs to dispose of drugs on behalf of their residents. DEA continues to work on proposed regulations to implement this law. Until regulations are in place, DEA will continue to sponsor National Prescription Drug Take-Back Days. These take-back days are intended to improve options for medication disposal and reduce the amount of unused medications that could be misused, abused, or diverted.

Pharmacists are encouraged to share information about the drug take-back days with their patients and work with local law enforcement to increase awareness of these events in their community. The DEA National Take-Back Initiative website provides information on upcoming events. In addition, more information on drug disposal is available at the SMARxT Disposal website (www.smarxtdisposal.net/index.html).

e-Prescribing of controlled substances. On March 31, 2010, DEA issued an interim final rule for the e-prescribing of controlled substances (EPCS). Beginning June 1, 2010, appropriately credentialed prescribers were able to e-prescribe Schedule II through V controlled substances. On August 1, 2012, DEA identified three entities that may certify e-prescribing systems as meeting DEA security standards. To date, a limited number of prescribers and pharmacies have been certified to issue and process e-prescriptions for controlled substances. DEA provided answers to frequently asked questions regarding the development and implementation of the EPCS rule.

ONDCP 2012 strategy update
The Obama Administration’s first National Drug Control Strategy, published in 2010, provided new direction for efforts to reduce illicit drug use and its negative effects in the United States. The strategy established and promoted evidence-based public health and safety initiatives focusing on key areas such as substance abuse prevention, treatment, and recovery.

The 2012 National Drug Control Strategy, released on April 17, builds on the 2010 plan and provides a review of the progress made since the original strategy was released and continues to promote a balanced national drug control policy. Key activities include:

- Strengthening efforts to prevent drug use.
- Seeking early intervention opportunities in health care. This activity includes initiatives that may affect pharmacy, such as (1) expanding prescription drug monitoring programs and promoting links among state systems and to electronic health records and (2) increasing prescription return/take-back and disposal programs.
- Integrating treatment into mainstream health care.
- Breaking the cycle of drug use and crime, delinquency, and incarceration.
- Disrupting drug production and trafficking.
- Strengthening international partnerships.
- Improving information systems.

Supreme Court decision: Douglas v. Independent Living Center of Southern California
In 2008, the California Pharmacists Association, pharmacies, other health care providers, and patients in California filed suit in federal court to argue that steep California Medicaid reimbursement cuts violated federal law. They argued that the drastic cuts would effectively force pharmacies and other providers out of the Medicaid program, harming Medicaid patient access to quality care in violation of the federal patient access law.

The lawsuit, captioned Douglas v. Independent Living Center of Southern California, reached the Supreme Court in 2012. The court was not asked to rule on the merits of the suit but rather to decide whether private citizens such as providers and Medicaid patients could sue a state for actions inconsistent with federal law under the Supremacy Clause. (The Ninth Circuit Court had previously ruled that providers had standing to sue over reimbursement rate cuts and blocked the Medicaid cuts.) In February 2012, the Supreme Court sent the case back to the Ninth Circuit Court to reconsider its decision in light of new information described in the Supreme Court’s opinion.

APhA and several other pharmacy associations supported the Supreme Court’s actions because it preserves health care providers’ ability to challenge Medicaid reimbursement cuts.

Conclusion
This article presents an overview of legislative, regulatory, and judicial actions in 2012 that affect pharmacy practice. The Supreme Court decision to uphold ACA played an important role in stimulating regulatory implementation of the law. Other legislative and regulatory developments at FDA, CMS, and DEA continue to shape the practice of pharmacy. At all levels, it is critical for pharmacists to become involved in efforts to educate policy makers about the value pharmacists provide to patient outcomes, health care teams, and the overall health care system.

APhA helps pharmacists, student pharmacists, pharmacy technicians, and pharmaceutical scientist members and other stakeholders remain aware of and engaged in a variety of ongoing national developments that are important to the pharmacy profession and pharmacists’ role on the health care team. APhA offers a comprehensive review of legislative and regulatory issues and provides numerous tools and resources for pharmacists who wish to advocate on behalf of their profession. Visit www.pharmacist.com/advocate for more information and ideas for taking action.

Resources
- APhA. Advocacy: www.pharmacist.com/advocate; key contacts sign-up: www.pharmacist.com/advocacy-key-contacts-sign
- Brookings NSURE workshop: www.brookings.edu/events/2012/11/08-nsure-initiative-event
References

CPE assessment

Instructions: This exam must be taken online; please see “CPE information” for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. The Supreme Court upheld all of the Affordable Care Act, except for which provision?
   a. Medical loss ratios
   b. A requirement for states to expand Medical eligibility or lose federal funding
   c. Penalties for individuals who fail to maintain health insurance
   d. Requirements for essential health benefits

2. State-level health insurance exchanges are required by the Affordable Care Act to:
   a. Utilize a standardized national information technology infrastructure.
   b. Be fully operational by January 1, 2014.
   c. Automatically enroll individuals who do not have insurance through their employers.
   d. Issue tax credits.

3. Which of the following Partnership for Patients programs are intended to improve transitions of care and reduce hospital readmissions?
   a. The Community-based Care Transitions Program and Hospital Engagement Networks (HENs)
   b. The Community-based Care Transitions Program and STAR ratings
   c. HENs and expanded medical staff privileges
   d. STAR ratings and expanded medical staff privileges

4. Why should pharmacists who participate in the APhA Foundation’s Pharmacy Blood Pressure Challenge report their outcomes to the program?
   a. It will allow for aggregation of data that demonstrate the value of pharmacy services.
   b. Reporting will improve their pharmacy’s scores on quality measures for certain third-party payers.
   c. They must report outcomes for this program to be eligible for future APhA Foundation grants.
   d. CMS is tracking outcome reporting for STAR ratings.

5. Which of the following was a requirement of CMS’s 2013 call letter to Part D plans?
   a. Completion of a comprehensive medication review (CMR) within 90 days of a targeted beneficiary’s enrollment
   b. Addition of the CMR completion rate as a display measure in 2013 for beneficiaries to view
   c. Decreasing diseases for which beneficiaries can be targeted for medication therapy management (MTM) services
   d. Part D plan assessment of beneficiary eligibility on a monthly basis

6. In a final rule regarding long-term care consultant pharmacists, CMS is requiring that:
   a. Pharmacists be “independent” from the long-term care pharmacies.
   b. Industry voluntarily adopt changes to increase transparency.
   c. Long-term care facilities (LTCFs) are prohibited from contracting with long-term care pharmacy subsidiaries.
   d. LTCFs must separate consulting services from dispensing services.

7. Which of the following provisions was included in the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA V)?
   a. New pathways for drug importation
   b. Track-and-trace provisions that track individual products to the pharmacy level
   c. Reclassification of all hydrocodone-containing products to Schedule II
   d. Provisions and agreement focused on standardizing risk evaluation and mitigation strategy (REMS) programs

CPE instructions

1. Log in or create an account at pharmacist.com and select LEARN from the top of the page; select Continuing Education, then Home Study CPE to access the Library.
2. Enter the title of this article or the ACPE number to search for the article and click on the title of the article to start the home study.
3. To receive CPE credit, select Enroll Now from the left navigation and successfully complete the Assessment (with randomized questions), Learning Evaluation, and Activity Evaluation. You must be an APhA member to claim credit.
4. To get your Statement of Credit, click “Claim” on the right side of the page. You will need to provide your NABP e-profile ID number to obtain and print your Statement of Credit.
   Live step-by-step assistance is available Monday through Friday from 8:30 am to 5:00 pm ET at APhA Member Services at 800-237-APhA (2742) or by e-mailing education@aphanet.com.
8. The pending Medication Therapy Management Benefits Act of 2011 would require which of the following activities?
   a. Expansion of MTM program requirements under Medicare Part D to state Medicaid programs
   b. Provide pharmacies that deliver MTM services with additional quality-based incentives
   c. Require a minimum number of follow-up MTM visits annually for all patients who have a comprehensive MTM review
   d. Establish credential requirements for pharmacists who provide MTM services

9. Which of the following is a correct statement about FDA’s Nonprescription Safe Use Regulatory Expansion initiative and revisions to the drug paradigm?
   a. It would create a new category of drugs.
   b. It would allow certain drugs that would otherwise require a prescription to be sold without a prescription under conditions of safe use.
   c. Any final recommendations for modifying the drug paradigm must be voted on by Congress.
   d. The program would implement greater standardization to REMS programs.

10. Which law(s) allows DEA to create a safer process for disposing of unused controlled substances?
    a. The Affordable Care Act
    b. The Safe Doses Act
    c. The Secure and Responsible Drug Disposal Act
    d. PDUFA IV and V

11. Criteria for stage 2 of the electronic medical records meaningful use requirements for earning incentive payments include:
    a. Adding pharmacists to the definition of an eligible professional.
    b. More robust focus on “transitions of care.”
    c. Focus on the impact of the use of electronic medical records on patient outcomes.
    d. An accelerated timeline for meeting the stage 2 criteria.

12. The Supreme Court ruling in Douglas v. Independent Living Center of Southern California has the result of:
    a. Increasing the rate that California’s Medicaid program must pay pharmacists.
    b. Reducing patient access to pharmacy services.
    c. Preventing private citizens from suing states under the supremacy clause.
    d. Preserving health care providers’ ability to challenge Medicaid reimbursement cuts.