In This Issue:

In this special edition of APhA’s Legislative and Regulatory Update, your Government Affairs staff have recapped the major 2010 legislative and regulatory initiatives and summarized the key issues facing the profession. Additional information on these issues is available online through APhA’s Issue Briefs, available on APhA’s Government Affairs Web page at www.pharmacist.com/GA.

Once again, the active participation by pharmacists and student pharmacists in the legislative and regulatory processes played a major role in the profession’s success this year. Thank you to all APhA members who met with their elected officials, sent letters or e-mails, made a phone call, contributed to the American Pharmacists Association – Political Action Committee (APhA-PAC) or responded to our requests for feedback.

The Year in Review is organized as follows:

- Congress in 2010, with special focus on Health Care Reform
- Department of Health and Human Services (HHS) in 2010
- Agency for Healthcare Research and Quality (AHRQ) in 2010
- Centers for Medicare & Medicaid Services (CMS) in 2010
- Food and Drug Administration (FDA) in 2010
- Health Resources and Services Administration (HRSA) in 2010
- Centers for Disease Control (CDC) in 2010
- Drug Enforcement Administration (DEA) in 2010
- White House Office of National Drug Control Policy (ONDCP) in 2010
- Internal Revenue Service (IRS) in 2010
- Department of Defense (DoD) in 2010
- Federal Trade Commission (FTC) in 2010
- Government Accountability Office (GAO) in 2010
Congress in 2010

Health Care Reform

2010 marked the first major overhaul of the healthcare system in decades. President Obama signed into law two bills that constitute health care reform (HCR). While APhA did not take a position on the overall health care reform bills (because APhA does not have policy on many of the issues addressed in the bills), the Patient Protection and Affordable Care Act (PPACA - P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (HCERA - P.L. 111-152), included several pharmacy friendly provisions that APhA worked hard to get into the legislation. These include: increased patient access to pharmacist clinical services, including medication therapy management (MTM), specifically mentioned in numerous provisions; better patient access to needed medications and services; and recognizing the role that pharmacists can play in addressing medication use issues. These two laws taken together are referred to as the Affordable Care Act (ACA).

APhA developed a summary document and a chart of the pharmacy-related provisions in the health care reform law. Much of APhA’s summary information focuses on the following key provisions:

- Integrated care models, including accountable care organizations, community-based interdisciplinary teams, and independence at home and home health programs;
- Transitional care models focused on integrated care and reducing hospital readmissions;
- Medication therapy management (MTM) delivery programs, including the MTM grant program and the new Center for Medicare and Medicaid Innovation (CMMI);
- Improvements to MTM programs in Medicare Part D; and
- Workforce issues.

Other provisions of interest to pharmacists include:

- Advance research and treatment for pain care management;
- Establish payment and approval pathway for biosimilars;
- Create a Medicare coverage gap discount program; and
- Reduce wasteful dispensing of outpatient prescription drugs in long-term care facilities.

Additional HCR information and APhA HCR Issues Briefs on many of these provisions are available on APhA’s Government Affairs Web page at www.pharmacist.com/GA.

Health Care Reform Implementation

APhA has worked diligently with the Health Care Reform Pharmacy Stakeholders (a group of 14 pharmacy organizations that APhA convened and continues to coordinate) to make sure that the key pharmacy provisions were included in the law, and that pharmacists are afforded opportunities within HCR to provide clinical services to patients. Since enactment, APhA’s and the HCR Pharmacy Stakeholders focus has shifted to implementation of the key pharmacy related provisions.

The HCR Pharmacy Stakeholders include: Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, College of Psychiatric & Neurologic Pharmacists, Food Marketing Institute, International Academy of Compounding Pharmacists, National Alliance of State Pharmacy Associations, National Association of Chain Drug Stores, National Community Pharmacists Association, Rite Aid Corporation, and Walgreen Co.
MTM Grant Program
APhA sent a letter to key Congressional committees and visited with members to solicit in support of funding the MTM grant program (Section 3503) authorized in the health care reform law. This program, within the Agency for Healthcare Research and Quality (AHRQ), allows pharmacists to access grants to test the best way to deliver MTM services. This appropriation request was supported by the HCR Pharmacy Stakeholders.

In addition, representatives of the HCR Pharmacy Stakeholders met with AHRQ and determined that AHRQ is generally supportive of the MTM grant program. The Agency strongly encouraged pharmacy to engage in AHRQ activities such as comparative effectiveness and meaningful use of electronic health records.

In August, the HCR Pharmacy Stakeholders sent a letter to AHRQ in support of research questions that had been recently submitted to AHRQ by the Pharmacy Quality Alliance (PQA). PQA, APhA and the Stakeholders asked AHRQ to consider including the following questions in the Agency’s existing research priorities. These questions address:

- Which patients benefit most from medication therapy management (MTM) services?
- What is the optimal structure and process for delivering MTM services?
- How do we enhance patient engagement in MTM services?
- What methods and performance measures are useful in evaluating MTM services?

Congressional Visits
In addition to visits by APhA staff throughout the year, in September, 28 members of the APhA Board of Trustees and the National Alliance of State Pharmacy Associations conducted 47 visits with Members of Congress and staff. The purpose of these visits was to gain support for the initiation and funding of the MTM Grant Program (Section 3503) and to educate policymakers on the key pharmacist clinical services provisions of the HCR law. APhA’s message was well-received by many policymakers, but the prospects for 2011 grant funding remains unclear.

Center for Medicare and Medicaid Innovation
One of the most important portions of the ACA is Section 3021 of the ACA which establishes a Center for Medicare and Medicaid Innovation (CMMI) within the CMS to, in Phase I, test payment and service delivery models to determine which programs are most effective in controlling costs and improving access to the quality of care. “Medication therapy management services” is among the models that must be tested under the statute. Phase II will expand the duration and scope of the best models identified through Phase I. CMS established the CMMI on November 16, 2010. Funding for the program is authorized at $5 billion in start up funds and $10 billion over 10 years for the new demonstration projects to test the models.

Short-Cycle Dispensing
(See additional information on this topic in the CMS section)
Section 3310 of the ACA directs Medicare Part D plans to utilize specific, uniform dispensing techniques (such as weekly, daily, or automated dose dispensing) to reduce waste associated with 30-day fills in LTCFs. Short cycle dispensing would require dispensing in quantities that last seven days or less. The specific dispensing techniques are to be identified by the Secretary of HHS in consultation with relevant stakeholders including representatives and residents of nursing facilities, pharmacists, retail and long-term care pharmacy, prescription drug plans and other stakeholders. This provision takes effect in plan years beginning on or after January 1, 2012. This provision was scored during the HCR debate by the Congressional Budget Office as a cost-savings measure of approximately $6 billion.
APhA and other pharmacy stakeholders met with the Centers for Medicare and Medicaid Services (CMS) to discuss the mandate within the health care reform law that directs CMS to require Medicare Part D plans to utilize specific, uniform dispensing techniques (such as weekly, daily, or automated dose dispensing) when dispensing covered Medicare Part D drugs to enrollees in long-term care facilities. The intent of the provision is to reduce waste associated with 30-day fills. While APhA supports the intent of the program to reduce medication waste, APhA and other pharmacy stakeholders continue to have concerns with the logistics, staffing and costs to pharmacy, and the challenges of short cycle dispensing in long-term care settings.

**APhA Health Care Reform Resources**
APhA developed an HCR Hub on the APhA Web site with information and resources for our members. Included on the APhA HCR Hub are:

- [APhA's Summary of the Patient Protection and Affordable Care Act (H.R. 3590 - Enrolled Version)](APhA's Summary of the Patient Protection and Affordable Care Act (H.R. 3590 - Enrolled Version))
- [APhA's chart of the HCR law's pharmacy provisions (divided by topic)](APhA's chart of the HCR law's pharmacy provisions (divided by topic))
- [APhA's 111th Congress HCR timeline](APhA's 111th Congress HCR timeline)
- [APhA's HCR template PowerPoint presentation](APhA's HCR template PowerPoint presentation)
- [CMS Health Reform Center and a chart of all of the provisions in HCR within CMS' scope](CMS Health Reform Center and a chart of all of the provisions in HCR within CMS' scope)
- [A replay of the APhA Webinar on the fraud, waste, and abuse provisions in HCR](A replay of the APhA Webinar on the fraud, waste, and abuse provisions in HCR)
- [APhA's PowerPoint presentation on the fraud, waste, and abuse provisions in HCR](APhA's PowerPoint presentation on the fraud, waste, and abuse provisions in HCR)
- [Key Issues of Interest to Pharmacy 2010-2011](Key Issues of Interest to Pharmacy 2010-2011)
- [MTM Primer Document](MTM Primer Document)
- [MTM Data Document](MTM Data Document)
- [Congressional Letter to AHRQ in Support of the MTM Grant Program](Congressional Letter to AHRQ in Support of the MTM Grant Program)
- [Pharmacy Principles for Health Care Reform](Pharmacy Principles for Health Care Reform)
- [CMMI Innovation Center Web site](CMMI Innovation Center Web site)

**Other Congressional Activity in 2010**

**DEA Nurse as an Agent of the Prescriber**
(See additional information on this topic in the DEA section)
In March, the Senate Committee on Aging held a **listening session** on the current DEA's prohibition of nurses working in long-term care facilities (LTCFs) acting as "agents" of prescribers. Panelists understood DEA's desire to curb diversion but had concerns about the impact on pain management for these this patient population. Discussion also focused on the distinctions between hospitals and LTCFs, and balancing the need to serve patients with the need to preserve the integrity of the drug distribution system.

DEA indicated a willingness to work with stakeholders and acknowledged the need to adjust their regulations to reflect technology and practice. For more information on this topic, go to APhA’s Issue Brief on [www.pharmacist.com/GA](http://www.pharmacist.com/GA).

**Recall of Children's Medications**
In May, the House Committee on Oversight and Government Reform held a hearing entitled, "Johnson and Johnson's Recall of Children's Tylenol and Other Children's Medicines," to explore the circumstances surrounding the voluntary recall of 6 million bottles from over 40 different types of medications widely used infant and children's medicines produced by Johnson & Johnson/McNeil Consumer Healthcare. House Government Reform Committee Chairman Towns (D-NY) and Ranking Member Issa (R-CA) opened the Committee's investigation into the
circumstances surrounding the Johnson & Johnson’s recall. For more information on the hearing, visit House Committee on Oversight and Government Reform Web site.

Prescription Drug Disposal Awareness Day
The Senate designated May 24, 2010 as Prescription Drug Disposal Awareness Day. The purpose of the Senate Resolution (S.Res. 539) was to recognize the importance of prescription drug disposal programs to reduce the supply of unused, unwanted prescription drugs in the United States; and encourage each State to establish and promote a prescription drug collection program. APhA expressed support for the responsible disposal of unused medication and encouraged the development of programs for safe medication disposal. For information on the Senate Resolution, visit APhA’s Legislative Action Center. Read APhA’s letter of support.

Medication Disposal
(See the DEA section for additional information on this topic)
In June, the Senate Committee on Aging held a hearing on problems and potential solutions of drug disposal programs. The Committee discussed various medication “take back” programs that have been implemented to help mitigate the effects of wrongful drug disposal of unused medications. They also focused on how current DEA regulations hinder expansion of existing programs or implementation of new programs, and agreed that coordination among various federal agencies is needed before implementing any national drug disposal policy or program. For additional information about hearings, visit the Senate Aging Committee Web site.

Ultimately Congress passed the Secure and Responsible Drug Disposal Act (S. 3397), a bill amended the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances. Specifically, the bill would allow the patient to deliver controlled substances to persons or locations not registered with the DEA for disposal if the person is authorized to engage in such activities, and the disposal takes place in accordance with regulations to prevent drug diversion. The legislation also authorizes long-term care facilities to dispose of a controlled substance on behalf of their patients. On October 12, 2010, President Obama signed the legislation into law, P.L. 111-273. DEA now has the authority to promulgate regulations to facilitate these disposal programs.

Medication Therapy Management (MTM)
Senators Hagan (D-NC) and Franken (D-MN) introduced, the Medication Therapy Management (MTM) Expanded Benefits Act of 2010 (S. 3543), which would expand Medicare beneficiary access to MTM services. APhA supported this legislation and strongly encouraged members to contact their Senators to co-sponsor. Additionally, Sens. Hagan and Franken sent a Senate Dear Colleague Letter to help generate additional co-sponsors for the bill by highlighting the importance of medication therapy management and pharmacist clinical services. Read the Congressional Dear Colleague letter.

Combat Methamphetamine Enhancement Act
In September, Congress passed the Combat Methamphetamine Enhancement Act of 2009 (H.R. 2923) which: requires all pharmacies that sell products used to make methamphetamine, to self-certify that they are compliant with certain requirements; and imposes civil penalties for negligent failure to self-certify as required in the bill. In October, President Obama signed the bill into law, P.L. 111-268.
Re-Labeling VA Hospital Medications for Outpatient Use
In July, the House of Representatives adopted an amendment (H. AMDT. 740) to the Military Construction and Veterans Affairs and Related Agencies Appropriations Act, 2011 (H.R. 5822). Sponsored by Rep. Peters (D-MI), the amendment would provide the Secretary of Veterans Affairs (VA) the authority to implement a prescription drug re-labeling program. In sum, prescription drugs used in VA hospitals would be re-labeled to be sent home with discharged patients for outpatient use. No action was taken in the Senate.

Diabetes Screening
In September, the House Energy and Commerce Health Subcommittee passed H.R. 6012 which would require a review of the utilization of diabetes screening benefits to identify and address any existing problems impeding utilization. The bill would also take other steps to increase awareness among seniors and providers about diabetes screening benefits. Read more information about H.R. 6012. No action was taken by the Senate.

Prescription Drug Monitoring
In September, the House of Representatives passed the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010 (H.R. 5710), which would revise and update the 2005 law to foster establishment of state-administered controlled substance monitoring systems by authorizing several funding and reporting mechanisms. These monitoring systems ensure that certain state agencies and law enforcement have access to prescription information for investigating drug diversion and prescribing and dispensing practices. For bill details Read more about H.R. 5710. No action was taken in the Senate.

Extension of Medicaid Federal Medical Assistance Percentages (FMAP) Funding for States
In August, the Education and Medicaid Funding For States (H.R. 1586) was enacted into law which provides $16.1 billion to extend Medicaid aid to states and $10 billion in funding to states for education-related jobs. The new law extends Federal Medical Assistance Percentages (FMAP) funding for states through June 30, 2011. Many states were concerned that without the aid, it would be necessary to cut their State's Medicaid program, which could potentially lead to cuts to the pharmacy program.

APhA, along with several other pharmacy organizations, supported the additional funding and cosigned a letter in support of extending the increased federal funding of FMAP. For additional information, read APhA's www.pharmacist.com article.

Department of Health and Human Services (HHS) in 2010

Regulations on Developing the Calculation of Medical Loss Ratios
Regarding health care reform implementation, APhA has done a lot of work to ensure that pharmacists’ clinical activities are included in the calculation of the medical loss ratios. The new health reform law requires health insurers spend at least 80% of insurance premiums on reimbursement for clinical services and activities that improve health care quality.

In April, HHS issue a request for information on the calculation of medical loss ratios (MLRs). APhA cosigned two letters supporting the inclusion of "activities that improve health care quality" in addition to "reimbursement for pharmacist clinical services" as categories of health care.
plan expenses that count toward meeting minimum MLRs. Read the PFCD letter and the joint letter to the National Association of Insurance Commissioners (NAIC).

In September, NAIC issued draft guidance on the procedures for calculating MLRs that include many areas of pharmacist’s clinical services including:
- Medication and care compliance initiatives;
- Activities to prevent avoidable hospital admissions;
- Education and participation in self-management programs;
- Wellness/lifestyle coaching programs; and
- Coaching or education programs and health promotion activities designed to deal with a specific chronic disease or change member behavior.

Without the inclusion of these services in the calculation, insurers may choose not to pay for them because they wouldn’t count towards the MLR.

In December, HHS released its interim final rule that adopts and certifies the recommendations from the NAIC. Read APhA’s comment letter.

Institute of Medicine (IOM) Study on Essential Health Benefits
The IOM will make recommendations on the “essential health benefits package” that health insurers will have to provide to patients. Starting in 2014, the Secretary of HHS will specify the products and services that insurance companies in the state health insurance exchanges must cover and pay for as an essential health benefit. The IOM will not define specific coverage required in the essential benefit package but will review how insurers determine covered benefits and medical necessity. IOM will also provide guidance on how qualified health plans find an appropriate balance among 10 categories of care required by the statute. APhA filed comments and testified at an IOM meeting and provided information on the need to include MTM services as part of an essential benefit. APhA expects significant activity on defining essential health benefits in 2011.

HIPAA Privacy Rule Accounting of Disclosures Under the HITECH Act
In July 2010, HHS issued a proposed rule to modify health information privacy, security, and enforcement rules issued pursuant to HIPAA, as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act (P.L. 111-5), to better understand the administrative burden imposed by requiring covered entities to account for all disclosures they make of protected health information. Specifically, this law expands an individual's right under the HIPAA privacy rule to receive an accounting of disclosures of protected health information made by HIPAA-covered entities and their business associates. If adopted, this would require pharmacies to account for disclosures of protected health information to carry out treatment, payment, and health care operations if such disclosures are through an electronic health record (EHR). APhA cosigned a comment letter to HHS as part of the Confidentiality Coalition that offered general recommendations to improve provisions of the proposed rule.

Genetic Education and Training of Health Care Professionals
In May, HHS issued a notice for feedback on its draft report, "Genetics Education and Training of Health Care Professionals, Public Health Providers, and Consumers." The report focused on the importance of educating professionals and the public on genetics, and provides recommendations to improve education and genetics/genomics literacy.

APhA commented on the draft report and highlighted the importance of preparing providers to use information technology to obtain genetic information. APhA also recommended the
recognition of pharmacists as health care providers who play an important role in providing genetic education to other health care providers to ensure that genetic technologies are used appropriately in patient care.

Medication Therapy Management (MTM) in Strategic Framework on Multiple Chronic Conditions
In June, APhA commented to HHS on the Interagency Workgroup on Multiple Chronic Conditions draft report, "HHS Strategic Framework on Multiple Chronic Conditions." APhA supported the overall direction of the framework and recommended several areas where pharmacists could be utilized to help better manage the health status of these patients. Specifically, APhA provided data and information on successful medication therapy management (MTM) programs, core elements, and APhA Foundation programs. Read APhA’s pharmacist.com article.

Healthcare.gov Web Site
In July, HHS launched a new online tool, www.healthcare.gov, to assist consumers in accessing health care coverage information. The Web site provides a single tool to aggregate consumer information on both public and private health coverage options, tailored specifically for individuals’ needs. The Web site is also intended to be a one-stop-shop for information about ACA as well as other health care resources, such as quality rankings for local health care providers. HHS also launched a Spanish version of the online tool.

Prevention Services
In September, APhA commented to HHS on its interim final rule for group health plans and health insurance issuers relating to coverage of preventive services under the ACA. This rule, effective upon its release, implements provisions that require group health plans and health insurers to offer group or individual health insurance coverage and waiver of cost-sharing requirements for recommended preventive services. These preventive services include immunizations recommended by CDC.

APhA comments focused on ensuring:
- Patients have continued access to applicable pharmacist-provided preventive care services that includes a waiver of patient cost-sharing at the pharmacy;
- Payment to all qualified healthcare providers (including providers not recognized as Medicare Part B providers, such as pharmacists), for applicable preventive services and how the cost-share waiver would be applied;
- Coverage of vaccine administration and waiver of cost-sharing in any practice setting allowed under state laws and regulations;
- Earlier coverage timeframes for both applicable and newly recommended vaccines; and
- Processes are permitted for pharmacies to submit preventive services claims directly to plans through current electronic claims payment processes and receive prompt payment for such covered services.

National Health Care Quality Strategy and Plan
In September, HHS sought public input in the development of a National Health Care Quality Strategy and Plan, The Strategy must include a comprehensive plan that identifies priorities to improve the delivery of health care services, patient health outcomes, and population health.

APhA commented to HHS and focused on the importance of safe and appropriate medication utilization and patient access to pharmacist clinical services. Specifically, APhA recommended that:
• HHS ensure that the 3 pillars of the proposed Strategy - better care, affordable care, and healthy people/healthy communities - are considered together;
• HHS consider the importance of safe and appropriate medication use as a national priority and goal, fitting into all three pillars of the Strategy HHS utilize the Pharmacy Quality Alliance’s (PQA) adherence and comprehensive medication review measures to measure progress; and
• HHS solicit input from diverse stakeholders in creating the Strategy.

Centers for Medicare and Medicaid Services (CMS) in 2010

New CMS Administrator
President Obama nominated Dr. Donald Berwick to be Administrator of the Centers for Medicare and Medicaid Services (CMS). Dr. Berwick previously served as President and Chief Executive Officer of the Institute for Healthcare Improvement, Clinical Professor of Pediatrics and Health Care Policy at the Harvard Medical School and Professor of Health Policy and Management at the Harvard School of Public Health. He is also a pediatrician. Read the White House press release, Read APhA's press release. Subsequently, approval of the appointment was not approved by the full Senate but Dr. Berwick remains on the job as acting Administrator.

NDC Non-Matched List for Medicare Prescriptions
Effective January 1, 2010, CMS will no longer reimburse Medicare Part D plans for prescription drugs that are not properly registered with the Food and Drug Administration (FDA). This means some drugs dispensed in the past may no longer be covered by Medicare plans. Drugs with National Drug Codes (NDCs) that are not properly registered with FDA should trigger a NCPDP claim adjudication reject message that the drug is not on the FDA list.

In December, CMS posted an update to the 2011 Non-matched NDC list to reflect the newest FDA NDC Directory listings. Effective January 1, 2011, CMS will use this updated list to implement prescription drug event (PDE) reject edits for dates of service. CMS expects Medicare Part D sponsors to rely on the monthly updates to the FDA NDC Directory to determine when NDCs get listed and not wait for CMS to update the Non-matched NDC list. The updated list can be found on CMS' Web site. The FDA NDC Directories are posted at:

Medicare Part D 2011 Call Letter
In February, CMS released its preliminary advanced notice and draft Call Letter information to Medicare Advantage (MA) and Medicare Prescription Drug Plans (PDP). This document outlines CMS non-payment policy changes for the upcoming 2011 plan year. APhA’s comments focused on the waste reduction provision to provide 7-14 day trial fills of prescription medications. APhA supported waste reduction efforts and recommended that CMS provide assurances on a number of issues. APhA also recommended that CMS reconsider its policy that prevents pharmacists from enrolling beneficiaries.

In April, CMS released its final 2011 Call Letter. In response to many comments received on the waste reduction issue, CMS included the following clarification in the final Call Letter:
• Any waste reduction program would be a trial program and would be strictly voluntary for the beneficiary (Note: Changes to this policy were included in the 2012 proposed rule.);
• CMS envisions the program to be driven exclusively by the beneficiary and his/her prescriber;
A trial fill would be triggered by patient request to the prescriber at the time of an initial prescription;  
If the prescriber agrees to a trial fill, the prescriber could either: a) write one prescription for a trial supply; or b) write two prescriptions (one for the initial trial supply and the second for the remainder of a 30 day supply);  
CMS expects participating plans and pharmacies to negotiate dispensing fees to appropriately reimburse for multiple dispensing events;  
CMS believes that the additional costs of both a trial supply and follow-up supply of some medications might be offset by savings associated with reduced dispensing;  
CMS recognizes that the current "partial fill" standard may not accommodate a voluntary trial fill and CMS will work with NCPDP to explore whether any changes to adjudication standards are needed;  
CMS expressed interest in meeting with pharmacy regarding the SMARxT Disposal™ program, a recommendation made by APhA (APhA partnered with the Fish and Wildlife Administration and the Pharmaceutical Research and Manufacturers of America to develop the program); and  
CMS appreciates the extensive comments it received on this provision and has been persuaded that extensive discussions with prescribers, pharmacists, pharmacies and Part D sponsors are warranted before contemplating any requirements related to trial fills.

Revisions to Medicare Part D  
On April 15, CMS issued its final rule on policy and technical changes to the Medicare Advantage and the Medicare prescription drug benefit programs for 2011. This rule finalizes a proposed rule issued in October 2009. With the final rule, CMS strengthened performance requirements, extended greater protections to beneficiaries, and eliminated duplication in drug and health plan bids in the same areas by requiring meaningful differences between those plans. APhA applauded CMS for including provisions that codify its authority to establish improved and expanded medication therapy management (MTM) program requirements under Medicare Part D for targeted beneficiaries (similar to provisions in the CMS 2010 Call Letter).

The final rule included the following provisions of interest to pharmacy:  
- Codifying expanded MTM program and service requirements under Medicare Part D as required in the 2010 Call Letter to plans;  
- Clarification on Medicare Part D fraud, waste and abuse training requirements, including an exemption for pharmacies accredited to provide durable medical equipment (pages);  
- Codifying guidance for network pharmacies to process prescription claims and to facilitate more accurate accounting of beneficiary true out-of-pocket (TrOOP) expenses; and  
- Clarification on protected drug categories and classes enacted in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (P.L. 110-275) and in the Patient Protection and Affordable Care Act (P. L. 111-148).

For additional information, please read the CMS Press Release and the CMS Fact Sheet.

Medicare Coverage Gap Discount Program and Rebate Checks  
On April 30, CMS released draft guidance for implementing the Medicare Coverage Gap Discount Program (Discount Program), which was included ACA. The guidance was issued to help Medicare Part D sponsors prepare for their 2011 bids. Effective January 1, 2011, the law authorized CMS to implement a discount program by making manufacturers provide discounts on coverage gap claims.
In general, the discount on each applicable covered Medicare Part D drug would be 50% of the negotiated price. Medicare Part D sponsors must provide discounts at the Point-of-Sale (POS) if the drug is a discountable drug; the beneficiary is eligible for the discount; the claim is wholly or partially in the coverage gap; and the amount of the discount, taking into consideration plan supplemental benefits that pay first.

Medicare Part D sponsors must provide the discount amount in the adjudicated claim response and payment to the pharmacy. Plan sponsors are also required to reimburse the pharmacy for the applicable discount within the applicable number of calendar days, which is consistent with current Medicare Part D prompt payment requirements. Sponsors must develop and implement processes to separately account for these amounts in order to populate prescription drug events and explanation of benefits. CMS will incorporate changes into Part D contracts for purposes of implementing the requirement for Part D sponsors to provide the discount at POS. Read APhA's comments on the draft guidance. For additional information, read the final guidance on the Medicare Part D Coverage Gap Discount Program.

**Medicare Part D 2010 Rebate Checks**
As a part of the ACA, Medicare beneficiaries, who enter the Medicare Part D coverage gap in 2010 and were not eligible for Medicare Extra Help, received a one-time, tax-free $250 rebate check from Medicare. This provision was the first of several steps authorized in the health care reform law to close the Medicare Part D coverage gap by 2020 (see APhA's pharmacist.com article). CMS also posted a "Closing the Prescription Drug Coverage Gap" brochure that includes details about rebate for Medicare beneficiaries. The program began in June and checks were mailed monthly after a beneficiary enters the coverage gap. Read the pharmacist.com article.

**Pharmacist Tip Sheet: Medicare Part D Coverage Gap ("Donut Hole") Discount Program**
On November 15, CMS released a “Information Pharmacists Can Use on: Closing the Coverage Gap” to assist pharmacists in answering questions about the Medicare Coverage Gap Discount Program, designed to close the "donut hole" beginning in January 1, 2011. The tip sheet provides information about which drugs are eligible for a 50% discount and information on how the discount will be applied by Medicare Part D plans at the point of sale.

**True-Out-Of-Pocket Facilitator for Medicare Part D**
Effective January 1, 2011, CMS implemented changes to the True-Out-Of-Pocket (TrOOP) Facilitation contractor with a new matching logic for the Medicare eligibility query (E1) to identify a Medicare beneficiary's plan enrollment information. CMS states that using enhanced matching logic will enable the TrOOP Facilitator to provide pharmacies with more accurate information by decreasing the probability of false positive matches as well as the need for pharmacy reprocessing of the claims associated with the mismatches. For additional information on the changes, read the CMS tip sheet.

**Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation**
In February, CMS issued a CMS issued a communication regarding its accreditation requirements for being reimbursed for DMEPOS under Medicare Part B. CMS' communication stated that the National Supplier Clearinghouse will notify DMEPOS suppliers who have not initiated the accreditation process or who are in the midst of accreditation process regarding their enrollment options.
In short, DMEPOS suppliers not accredited by a CMS-approved accreditation organization will discontinue furnishing accredited services on or after March 1, 2010, until they are accredited. Suppliers needed to become accredited by March 1, 2010, or elect to: (1) step down to furnish non-accredited products and services, or (2) voluntarily withdraw/terminate from the Medicare program. For DMEPOS suppliers who make the business decision to voluntarily withdraw/terminate from the Medicare DME program, these suppliers will need to reapply to furnish accredited services in the future.

Exemption Criteria
However, in March, the health care reform law extended the accreditation deadline for pharmacies that supply DMEPOS under Medicare Part B until January 1, 2011. The law also authorizes CMS to exempt certain pharmacies from being accredited. To be exempted, a pharmacy must meet the following criteria:

- Total billing by the pharmacy for DMEPOS is less than 5% of total pharmacy sales;
- The pharmacy has been enrolled as a DMEPOS supplier for at least five years during which a final adverse action has not been imposed; and
- The pharmacy attests to this information and submits supportive material.

Each pharmacy individually must meet the 3 criteria. Thus, only those pharmacies in a chain that meet the standard are exempt, meaning that chains may have both exempt and non-exempt locations. In addition, pharmacies that are new, have been purchased, or have changed tax ID numbers within the last 5 years cannot meet the second criteria so they are non-exempt. Of the exempted pharmacies, CMS stated that it will randomly choose 10% of the pharmacies to be audited.

NSC compiled a list of enrolled pharmacies who could potentially qualify for the exemption. A letter from NSC was to go out to those pharmacies by the end of October. The letter requested that the pharmacy complete an attestation that they are, in fact, exempt because they meet all three of the required criteria.

In early October, CMS strongly advised that pharmacies do not withdraw accreditation until the pharmacy has received a letter from the National Supplier Clearinghouse (NSC) stating that the pharmacy is exempt. Pharmacies billing only for Medicare Part B drugs are exempt from accreditation.

National Provider Identifier (NPI) Requirements
On June 30, APhA commented to CMS on its interim final rule related to fraud, waste and abuse requirements and changes in provider and supplier enrollment; ordering and referring; documentation requirement; and changes to provider agreements. APhA expressed support for CMS’ efforts to control fraud, waste, and abuse, and recommended limiting administrative and financial burdens on pharmacists to ensure that legitimate pharmacists and pharmacies can continue to provide services. APhA also strongly supported a soft launch of the Provider Enrollment, Chain, and Ownership System (PECOS) which took effect July 6. APhA expressed concern that pharmacists and pharmacies may not have access to all providers’ NPIs, including the exact legal name listed in the enrollment record in the PECOS verification system, or have the ability to identify and verify a provider NPI if the ordering providers are an intern, resident, or a teaching physician.

Specifically, APhA recommended:
- Delaying full implementation until January 2011;
- Requiring error codes in the claims adjudication process to indicate why claims are rejected;
• Clarifying the Agency's plans to make publically available the national file of Medicare practitioners eligible for ordering and referring and updating it daily; and
• Clarifying the logistics and processes for pharmacists and pharmacies to process intern/resident-generated orders and to identify teaching physician information.

CMS has published materials for practitioners getting started in PECOS and contact information for an External User Services (EUS) Help Desk to assist physicians and non-physician practitioners if they encounter an application navigation or access problem with Internet-based PECOS.

For addition information, read APhA’s comments. Read APhA’s pharmacist.com article.

Medicare Tobacco Cessation Proposal
In June, APhA commented to CMS on its proposed decision memo discussing the Agency’s proposal to cover two individual tobacco cessation counseling attempts per year for certain Medicare beneficiaries. APhA expressed support for expanding Medicare’s preventive services to cover counseling for tobacco cessation; and strongly recommended that the Agency include payment to all qualified health care providers, including providers not recognized as Medicare Part B providers such as pharmacists, for these counseling services. Read APhA’s comments to CMS.

Fraud, Waste, and Abuse
In September, CMS issued a proposed rule to help fight fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). The new rules, required under ACA, aim to strengthen and expand CMS’ fraud prevention efforts by requiring new provider screening and enforcement measures. HHS sought input on how to best structure and develop provider compliance programs that will ensure providers are aware of and comply with CMS program requirements. Furthermore, HHS created a Center for Program Integrity at CMS that is focused on identifying and stopping fraud.

Tools to Help Prevent Fraud, Waste, and Abuse
On September 28, CMS announced new tools and resources to help prevent fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program. The initiative reflects new fraud, waste, and abuse provisions that were established in the new health care reform, the Affordable Care Act. The tools include:
• New rules and sentences for criminals;
• Rules for suspending payment for suspected claims;
• Enhanced screening and other enrollment requirements for providers and suppliers;
• New funding resources to fight fraud;
• Sharing data to fight fraud;
• New tools to prevent fraud;
• Expanded overpayment recovery efforts;
• Enhanced penalties to deter fraud and abuse; and
• More oversight of private insurance abuses.

For more information, read the CMS Fact Sheet on New Tools to Fight Fraud or the CMS Fact Sheet on New Tools to Fight Fraud in Medicare.
Medicare Advantage and Prescription Drug Benefit Programs Revisions for 2012
On November 22, CMS published a proposed rule to implement provisions of the health care reform law related to the Medicare Advantage and Prescription Drug Benefit Programs. This proposed rule also sets forth programmatic and operational changes to these programs for contract year 2012 based on continued experience with the administration of the Medicare Parts C and D benefits. CMS stated that the provisions included in the proposed rule fall into the following five categories: Implementing provisions of the ACA, clarifying various program participation requirements; strengthening beneficiary protections; strengthening Medicare’s ability to distinguish stronger health plans for participation in Medicare Parts C and D and to remove consistently poor performers; and implementing other clarifications and technical changes.

On January 11, APhA commented to CMS on the proposed rule. APhA comments focused on recommendations to:

- Modify the enrollment election period to end on December 7;
- Hold further discussions on the implementation of 7-day or less dispensing (short-cycle) in long-term care facilities (LTCFs), including the implementation deadline, dispensing fee, pharmacy dispensing transactions, excluded medications, and return and reuse of medications;
- Develop education materials on uniform exceptions and appeals forms and on claims messaging/printing;
- Ensure coverage for preventive services includes services provided by pharmacists;
- Consider adding a “Welcome to Medicare, Medication Check-up” as a covered preventive service for all Medicare beneficiaries;
- Revise existing Part D medication therapy management (MTM) regulations related to a standardized medication plan, telehealth, and quarterly assessments for at risk beneficiaries;
- Ensure that systems are in place to comply with required separate documentation for the distinct MTM and medication regimen review in LTCFs;
- Revise the proposal to indicate that a contractual relationship should be between the Medicare Part D plan and the LTCF’s pharmacist/pharmacy;
- Continue to provide information to stakeholders on coverage gap information;
- Update the definition of pharmacists; and
- Implement electronic transactions standards that allow for payment of compounded medications.

A final rule should be released in the spring of 2012.

Accountable Care Organizations (ACOs)
Throughout 2010, CMS worked to develop its rule for establishing accountable care organizations (ACOs), which were authorized in the health care reform law. ACOs are groups of providers and suppliers that, if they meet certain quality and cost performance standards, are eligible to receive payments in the form of shared savings. On November 17, CMS published a request for information regarding ACOs and the Medicare Shared Savings Program. CMS sought information on policies and standards of ACOs as the Agency prepares to develop its ACO regulations and to develop potential ACO models for the CMS Innovation Center (Section 3021).
On December 3, APhA provided comments to CMS that focused on the importance of medication management and the need to utilize pharmacists on the health care team. Specifically, APhA’s comments addressed:

- The need for CMS to adopt criteria that require and assess medication use activities through patient-centered, pharmacist-provided services;
- Lack of Medicare Part B payment for pharmacist services should not preclude pharmacist participation on the care team or in an ACO model; and
- Pharmacist-provided patient care services should be considered a core activity of an ACO.

Additionally, in October, the National Committee for Quality Assurance (NCQA), an accreditation organization, sought input on its Draft 2011 Accountable Care Organization (ACO) Criteria. NCQA’s Draft 2011 ACO Criteria were grouped into the following categories:

- Program structure operations;
- Access and availability;
- Primary care;
- Care Management;
- Care coordination and transitions;
- Patient rights and responsibilities; and
- Performance reporting.

APhA worked with the HCR Pharmacy Stakeholders to provide feedback to NCQA.

**Medicaid Average Manufacturer Price (AMP)**

In September, CMS published a proposed rule to withdraw the determinations that define average manufacturer price (AMP), multiple source drug, and upper limits for multiple source drugs used to calculate the reimbursement rates for generic medications in Medicaid. These AMP definitions, which were included in a 2007 final rule, have been the subject of a lawsuit. In 2008, CMS published a final rule revising the definition of multiple source drug. And, most recently, the ACA made significant changes to the definition of AMP and made modifications to the methodology for calculating federal upper limits (Section 2305). APhA supported these AMP revisions in ACA.

The proposed rule states that the Agency expects to develop a regulation to implement the ACA provisions and advises manufacturers to calculate AMP based on the definitions set forth in the statute, instead of using the AMP and AMP-related definitions provided in existing regulations and guidance.

On November 15, CMS published a final rule to withdraw the determinations that define average manufacturer price (AMP), multiple source drug, and federal upper limits (FULs) for multiple source drugs. The rule was effective December 15, 2010. Read the final rule.

**CMS Announces Plans for the CMS Innovation Center & New Initiatives**

In November, CMS formally announced the establishment of the Center for Medicare and Medicaid Innovation (CMMI), which was established in the health care reform law to test new delivery and payment models. CMS stated that the Innovation Center will replicate successful programs in communities across the country. Among the models to test, “utilizing medication therapy management services” is listed in ACA (P.L. 111-148, Section 3021). In addition to announcing the establishment of the Innovation Center, CMS also announced new initiatives with potential opportunities for pharmacists, including:
• Expansion of the Multi-Payer Advanced Primary Care Practice Demonstration;
• Announcement of the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration; and
• Launch of the Medicaid Health Home State Plan Option.

Furthermore, the Innovation Center announced demonstration projects that will focus on providing fully integrated care for dual-eligibles. States may apply for resources to support the demonstration projects they design beginning in December; and the CMMI will award up to 15 state program design contracts for care for dual-eligibles up to $1 million each.

APhA is leading the Health Care Reform Pharmacy Stakeholders’ efforts on the Innovation Center, a group of 14 pharmacy organizations and plans to actively engage the CMMI throughout the development and implementation process of these programs. For more information, please read the CMS fact sheet and the CMS press release.

CMS Publishes Proposed Rule on Recovery Audit Contractors for Medicaid
In November, CMS published a proposed rule that provides guidance to states related to federal/state funding of state start-up, operation and maintenance costs of Medicaid Recovery Audit Contractors (Medicaid RACs), and the payment methodology for state payments to Medicaid RACs. Additionally, this rule proposes:

• Requirements for states to assure that adequate appeal processes are in place for providers to dispute adverse determinations made by Medicaid RACs; and
• That states and Medicaid RACs coordinate with other contractors and entities auditing Medicaid providers, and with state and Federal law enforcement agencies.

The health care reform law (P.L. 111-148, Section 6411) required states to establish programs to contract with 1 or more Medicaid RACs by December 31, 2010 for the purpose of identifying underpayments, and overpayments and recouping overpayments.

CMS Special Open Door Forum on Independence at Home Demo
In December, CMS held a Special Open Door Forum to solicit stakeholder input for the design and development of the Independence at Home demonstration program established in the health care reform law (P.L. 111-148, Section 3024). Slated to begin in 2012, this demo, which APhA supported in the health care reform debate, will test a payment incentive and service delivery model that utilizes physicians, nurse practitioners and other health care providers, including pharmacists, in home-based primary care teams designed to reduce expenditures and improve health outcomes. Read more information at the demo Web site.

Transition of Care Public Conference
In December, CMS hosted a public conference on the upcoming Community-based Care Transitions program. The goal of the meeting was to provide a forum for healthcare providers to receive guidance on the Community-Based Care Transitions Program outlined in the health care reform law (P.L. 111-148, Section 3026). Various models of care transition interventions that have been implemented were presented. Of interest to pharmacy:

• The program began in January and will receive rolling applications;
• Per the law, preference is focused on area agencies on aging;
• Pharmacy or other group wishing to engage at the local level in these programs must identify and engage with the local groups applying for these monies;
• Program eligibility will be based on what the systems have in place to meet the goals of the program, rather than requiring specific provider participation.
Finally, APhA’s Kristina Lunner, Vice President of Government Affairs, attended the meeting and asked about the role of pharmacists in these models. CMS Administrator Berwick responded that nothing is more important than team-based care, everyone needs to be part of the team, and pharmacists are central to the team. Furthermore, Berwick noted that in all of his work on safety, pharmacists on the hospital floor often were the team member to identify and address a safety problem. When asked by Lunner about inpatient transitions of care programs and their engagement of community pharmacy, most panelists responded very positively about the role of pharmacists in their programs. A Web cast of the meeting and other meeting materials are available on the CMS Care Transitions Web site.

CMS Publishes Final Rule on Medicare Part B Revisions
In November, CMS published a final rule on the payment policies for the physician fee schedule and other revisions to Medicare Part B for 2011. Effective January 1, 2011, the final rule implements several provisions of the health care reform law (P.L. 111-148) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA – P.L. 110–275). The key provisions covered in the final rule include:

- Medicare coverage of annual wellness visit providing a personalized prevention plan;
- Removal of barriers to preventive services in Medicare;
- Telehealth services;
- Adjustments to durable medical equipment (DME) Metropolitan Statistical Areas for purposes of competitive bidding;
- Payment for intentional overfill of drugs and biologics;
- Average manufacturer price (AMP) threshold and price substitution;
- Final qualification requirements for electronic health record (EHR) vendors and their products;
- 2011 measures for EHR-based reporting;
- 2011 Electronic Prescribing Incentive Program and 2012 Electronic Prescribing adjustments; and
- Durable medical equipment, prosthetics, orthotics, supplies (DMEPOS) including provisions on diabetes test strips.

Food and Drug Administration (FDA) in 2010

FDA Safety Updates
In February, the FDA issued several Drug Safety Communications and other information for healthcare providers and consumers related to certain decisions and activities. APhA appreciates FDA’s efforts to increase communications to stakeholders and in providing new tools for delivering such information on safety issues. FDA communications included information for health care professionals on how these decisions impact practice and information to help address patients’ questions.

Prescription Drug User Fee Act Reauthorization (PDUFA)
In April, FDA held a public meeting on the reauthorization of PDUFA. Specifically, FDA was interested in receiving input on: 1) what features FDA should propose to Congress in the PDUFA V reauthorization; 2) what provisions should be retained, changed, or discontinued; and 3) Stakeholder assessments of the PDFUA IV program.
APhA’s Marcie Bough, PharmD, Senior Director of Government Affairs, participated in a healthcare provider panel presentation at the FDA public meeting and focused her comments on APhA’s support for PDUFA reauthorization and expanded scope throughout the life-cycle of a drug. Regarding improvements to the program, APhA recommended that FDA:

- Continue outreach and communications to stakeholders;
- Ensure opportunities for pharmacists involvement in post-market surveillance activities;
- Continue with the drug name review program and the review of direct-to-consumer advertising;
- Increase education and outreach on personalized medicine activities;
- Improve the risk evaluation and mitigation strategies (REMS) development and approval process;
- Recognize the clinical role that pharmacists can play in addressing medication use issues; and
- Continue with efforts to improve patient information dispensed through medication guides and consumer medication information.

In June, FDA announced its plan to host monthly public stakeholder meetings on the reauthorization of PDUFA. During reauthorization negotiations with manufacturers, FDA is required to hold continued discussions with stakeholders including patient and consumer groups, health care professionals, and scientific and academic experts. APhA has been a regular attendee of these monthly FDA PDUFA Stakeholder meetings.

**Reopening of Comment Period**

In November, FDA published a notice that the Agency is reopening the comment period on the reauthorization of PDUFA for the expected duration of the public part of the PDUFA reauthorization process. FDA stated that the reopening of the comments is to ensure that all interested stakeholders have the opportunity to share their views.

**Compounding**

In March, FDA convened a meeting of pharmacy compounding stakeholders for the purpose of discussing quality pharmacy compounding. In addition to the approximate dozen FDA staff, attendees included representatives from APhA, the International Academy of Compounding Pharmacists, the American Society of Health-System Pharmacists, the National Community Pharmacists Association, the International Journal of Pharmaceutical Compounding, the United States Pharmacopeia, and the National Alliance of State Pharmacy Associations.

FDA noted the increasing number of products being compounded in addition to the increase in globalization of the drug product and ingredient supply chain (related to sources of bulk products for compounding) has led to an increased patient exposure to potential risk. Consequently, FDA is seeking opportunities to work collaboratively with the pharmacy community to protect the quality of compounded products.

The discussion touched on FDA’s: communications to industry (such as their Tamiflu compounding guidance for pharmacies), FDA’s desire for feedback on areas that they should focus, helping pharmacies identify registered and recently inspected chemical suppliers, ensuring that pharmacies verify the certificate of analysis of bulk products, creating an FDA advisory committee to capture information from various practice sites, helping to prioritize the United States Pharmacopeia’s (USP) potential expansion of compounding monographs, and FDA’s desire for more safety information and reporting from pharmacy (the need for more MedWatch reporting).
The positive meeting demonstrated FDA’s appreciation for traditional pharmacy compounding and their willingness to work collaboratively with the pharmacy community to ensure that patients receive quality compounded products. FDA and pharmacy stakeholders plan to have ongoing dialogue on compounding issues.

**Phase-Out of CFC Inhaler**

In April, the FDA announced that 7 metered-dose inhalers (MDIs) containing chlorofluorocarbons (CFCs) would be phased out of use in the U.S. The Agency took this action in accordance with U.S. obligations under the Montreal Protocol on Substances That Deplete the Ozone Layer, which took effect in 1989. The inhalers use CFCs, which depletes the ozone, as a propellant. Patients using these inhalers need to be switched to one of the several alternative treatments or formulations currently available.

The following seven products, used to treat asthma and chronic obstructive pulmonary disorder (COPD), will be phased out of the U.S. market by the indicated deadline:

- **Tilade Inhaler** (nedocromil—King), June 14, 2010
- **Alupent Inhalation Aerosol** (metaproterenol—Boehringer Ingelheim), June 14, 2010
- **Azmacort Inhalation Aerosol** (triamcinolone—Abbott), December 31, 2010
- **Aerobid Inhaler System** (flunisolide—Forest), June 30, 2011
- **Combivent Inhalation Aerosol** (albuterol/ipratropium—Boehringer Ingelheim), December 31, 2013
- **Maxair Autohaler** (pirbuterol—Graceway), December 31, 2013

Information for pharmacists to share with patients on the phase-out of these MDIs is available on FDA’s Web site. Read APhA’s pharmacist.com article. APhA will continue to work with FDA and other stakeholders on implementation of the phase-out and will provide additional information in the future.

**Transparency Activities**

In 2010, FDA increased efforts to improve transparency in its interactions with the regulated industry as part of the final phase of its transparency initiative. The Agency formed an internal Transparency Task Force to develop recommendations for making information about FDA activities and decisions more useful, understandable, and readily available, while appropriately protecting confidential information.

For more information on the FDA’s Transparency Initiative, visit FDA’s Transparency Web page and their FDA Basics Web resource. Additional information include resources on FDA Basics, read FDA’s press release. Read APhA’s comment letter to the FDA Transparency Task Force.

**H1N1 Vaccine Safety**

In January, FDA sent a letter to America’s health care professionals thanking them for their efforts during the 2009 H1N1 influenza outbreak and providing information on safety monitoring of the 2009 H1N1 vaccines. Specifically, the letter detailed the additional systems being used to determine whether any adverse events can be attributed to H1N1 influenza vaccines, including the Vaccine Adverse Event Reporting System (VAERS) and the Centers for Disease Control’s (CDC) Vaccine Safety Datalink (VSD). FDA and CDC assessed H1N1 vaccine safety on a continuing basis and published a detailed report describing the safety profile of H1N1 vaccines in the United States.
In 2010, APhA also expanded its Web resources related to immunizations as a way to further dispense information from FDA, CDC, and other government activities. See APhA’s Pharmacist Immunization Center for additional information.

Tobacco and Smoking Cessation
In 2010, FDA has been engaged in the following tobacco and smoking cessation related activities:

- **Smoking Cessation Products Information**
  As part of efforts to implement the Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31), in early 2010, the FDA released a consumer information tool and an on-line educational resource for patients who are using smoking cessation products to quit smoking. These resources focused on information on the products; the benefits of quitting; information on nicotine replacement products; and information on products not containing nicotine. For more information, visit FDA’s Center on Tobacco Products.

- **Tobacco Guidance for Retailers**
  In July, FDA issued draft guidance for tobacco retailers regarding training programs. While the Act did not require retailers to implement training programs, it does provide for lower civil money penalties for violations of access, advertising, and promotional restrictions if they implement a program. In the Federal Register notice, FDA stated that it intends to establish standards for approved retail training programs in the future.

- **Draft Guidance on Penalties and No-Tobacco-Sales Orders for Retailers**
  In August, FDA released draft guidance on “Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers” that were established in the Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31). For more information, read the draft guidance.

- **Public Workshop on Nicotine Replacement Therapy**
  On October 26-27, FDA held a public workshop on the risks and benefits associated with the long-term use of nicotine replacement therapy (NRT). Currently, no NRT product is approved for use beyond 12 weeks to relieve acute withdrawal symptoms experienced when quitting smoking. Read the meeting notice.

"Bad Ad Program" for Misleading Drug Ads
On May 11, FDA launched "Bad Ad Program" designed to educate health care providers about their role in ensuring that prescription drug advertising and promotion is truthful, not misleading. Previously, FDA’s regulatory activities for monitoring prescription drug promotion primarily relied on reviews of promotional pieces submitted to the Agency by manufacturers, industry complaints, and field surveillance at large medical conventions. FDA plans to roll out the new program in three phases. In Phase 1, FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) will engage health care providers at specifically-selected medical conventions and partner with specific medical societies to distribute educational materials. Phases 2 and 3 will expand FDA’s collaborative efforts and update the educational materials developed for Phase 1.

Health care professionals are encouraged to report potential violations in drug promotions by sending an email to badad@fda.gov or calling 877-RX-DDMAC. Reports can be submitted anonymously; however, FDA encourages providers to include contact information so that DDMAC officials can follow-up, if necessary.
FDA Joint Advisory Committee Meeting on Avandia
On July 13-14, the FDA hosted a joint meeting of the Endocrinologic and Metabolic Drugs Advisory Committee & Drug Safety and Risk Management Advisory Committee. The committees focused primarily on the cardiovascular safety of Avandia (rosiglitazone maleate) tablets and specific data presented on the results from the Rosiglitazone Evaluated for Cardiac Outcome and Regulation of Glycemia in Diabetes (RECORD) trial, observational data, health claims data, and a meta-analysis of controlled clinical trials. For more information, read the meeting notice.

Risk Evaluation and Mitigation Strategy (REMS)
REMS for Certain Opioid Analgesics
On July 22-23, 2010, FDA’s Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee met jointly to discuss REMS for long-acting and extended release opioids. In preparation for the meeting FDA released its draft REMS for this class of medications. The Agency solicited feedback on the draft from the advisory committees and the public at the July meeting. FDA’s proposal included the following components:

- REMS Goal: Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of long-acting and extended release opioids while maintaining patient access to these medications. Adverse outcomes of concern include addiction, unintended overdose, and death.
- Elements of the FDA proposed REMS included:
  - Voluntary education for prescribers with no verification at the point of dispensing;
  - Medication Guide (text to focus on safe use of all opioid drugs and include product specific information);
  - Development of patient education sheet to be provided to prescribers;
    - Materials to include appropriate patient selection, dosing and patient monitoring;
    - Materials to include training on patient counseling on the safe use, storage, and disposal of opioids;
  - FDA-approval of training or educational materials (prescribers and patient)

In addition, FDA noted that it continues to undertake other non-REMS actions to address abuse and misuse of opioids through FDA’s Safe Use Initiative and partnering with other Federal agencies and private sector activities.

APhA provided a statement during the public comment period on July 23 supporting FDA’s efforts to gather input from stakeholders as it drafted the proposal and efforts to limit burden on the health care system. To strengthen the program, APhA recommended: 1) ensure that pharmacists receive outreach and educational materials about the REMS program as pharmacists often discuss REMS information with prescribers and patients and need to be aware of program elements; and 2) recognize the role that pharmacist play as the medication expert in safe medication use, in patient care, and as an important part of the health care team.

FDA REMS Public Meeting
On July 27-28, FDA held a public meeting to obtain input on issues and challenges associated with the development and implementation of Risk Evaluation and Mitigation Strategies (REMS) programs for drugs and biological products. APhA’s Marcie Bough provided a statement at the meeting that focused on issues related to elements to assure safe use (ETASU) and evaluating the effectiveness of REMS programs.
Bough provided specific recommendations during the presentations, including:

- Developing a standardized, system-based approach that works for any REMS;
- Designing the REMS system with input from front-line pharmacists and prescribers early in the development process;
- Integrating REMS with existing electronic technologies and infrastructures in pharmacy and medical practice systems;
- Recognizing the role pharmacists can play in safe medication use through REMS programs;
- Pilot testing any program prior to a nation-wide launch;
- Ensuring that REMS do not prevent or delay patient access to necessary medications;
- Ensuring that programs are flexible to adjust to data showing successes or failures of certain components; and
- Utilizing accredited continuing education materials from accredited providers that include specific information on safety, risks the REMS is designed to mitigate, and outcomes measures that capture practice changes.

To read the complete list of APhA’s recommendations, read APhA's statement. For information on the FDA’s Public Meeting, visit the FDA REMS meeting Web site. In addition to a statement at the public meeting, APhA submitted information and answers to questions asked by FDA at the public meeting. For more information, read APhA’s supplement comment letter. For a list of all approved REMS, go to FDA’s Web page.

APhA REMS Stakeholder Meeting
In October 2010, APhA hosted a two-day REMS Stakeholder Meeting that built on themes from the 2009 meeting and White Paper. The 2010 meeting included 34 representative experts from Participants included national health care provider associations, including representatives for physicians, physician assistants, nurses, nurse practitioners, and all pharmacy organizations; patient advocates; drug distributors; community chain pharmacies; drug manufacturer associations, including representatives from brand, generic, and biologic organizations; health information technology, standards, and safety organizations. In addition, representatives from FDA observed the meeting. The purpose of the meeting was to discuss the future of REMS programs, including such issues as the provider’s role, ways to standardize REMS programs, how to utilize technology in REMS implementation, and the business model for REMS.

Key issues discussed included:

- Utilizing effective provider interventions while limiting burden on the health care system
- Developing standardized REMS elements/processes
- Utilizing existing technology in provider workspace for implementation
- Ensuring sustainable REMS business models for REMS-related provider activities
- Improving access to program information through a central clearinghouse
- Improving awareness and communications about REMS implementation and logistics

APhA plans to publish in 2011 a summary of the proceedings from the meeting as a white paper to serve as additional guidance to the FDA, manufacturers and other interested stakeholders.

Drug labeling and Packaging
On June 24-25, the FDA held a public workshop entitled "Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors" to initiate dialogue and share information about the design of drug and therapeutic biologic container labels, carton labeling, product packaging, and practices to develop testing of proprietary names to reduce medication errors.
errors. The input from this workshop will be used to develop draft guidance for industry in these areas. Recommendations included having the manufacturers standardize the format of labels and the development of testing of proprietary names as they relate to reducing medication errors. For more information, visit FDA’s Web site. Read APhA’s article.

Public Hearing on Patient Information
On September 27-28, FDA held a two-day public hearing to gather input from stakeholders on patient medication information (PMI). PMI is the next step in FDA’s effort to combine medication guides (MedGuides), consumer medication information (CMI), and patient package inserts (PPIs) into a single, easy-to-read document for patients about their prescription medications. APhA’s Marcie Bough, PharmD, Director of Federal Regulatory Affairs, testified on behalf of APhA and expressed APhA’s strong support for a single document solution and appreciation for FDA’s continued effort to find a workable solution. Read APhA’s statement. Read APhA’s pharmacist.com article. Additional information is available on FDA’s meeting Web page.

Dextromethorphan
In September, the FDA’s Drug Safety and Risk Management Advisory Committee met to discuss the abuse potential of DXM and the public health benefits and risks of DXM when used as a cough suppressant in prescription and nonprescription drug products. HHS received a request from DEA for a scientific and medical evaluation and scheduling recommendation for DXM in response to the increased incidence of abuse, especially among adolescents. For more information in the meeting, visit FDA’s Web site.

Clarification on Pancreatic Enzyme Products
In 2010, the FDA released questions & answers for health care professionals and the public on the use of an approved Pancreatic Enzyme Product (PEP). In accordance with the April 2004 regulation requiring manufacturers to obtain FDA approval of their PEPs, FDA announced that April 28 was the last day that FDA exercised enforcement discretion for unapproved PEPs. FDA considers all distributors (including wholesalers) subject to the Federal Register notices concerning these products. Firms distributing unapproved PEPs after April 28 are at risk of regulatory action.

Biosimilars
On November 2-3, FDA held a public hearing to obtain input on specific issues and challenges associated with the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which was part of the health care reform law, the Affordable Care Act (P.L. 111-148, Sections 7001-7002). The BPCI Act establishes an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to, or "interchangeable" with, an FDA-licensed biological product. For information on the meeting, visit FDA’s Web site.

Agency for Healthcare Research and Quality (AHRQ) in 2010

Pharmacy Quality Alliance (PQA) Research Questions
On August 30, APhA and the Health Care Reform Pharmacy Stakeholders, a group of 14 pharmacy stakeholders, sent a letter to Carolyn Clancy, Director of AHRQ, in support of research questions recently submitted to AHRQ by the Pharmacy Quality Alliance (PQA). PQA,
APhA and the Stakeholders asked Dr. Clancy to consider including these questions in the Agency’s existing research priorities. These questions address:

- Which patients benefit most from medication therapy management (MTM) services?
- What is the optimal structure and process for delivering MTM services?
- How do we enhance patient engagement in MTM services?
- What methods and performance measures are useful in evaluating MTM services?

Centers for Disease Control

NIOSH Publishes Hazardous Drug List
On September 17, the CDC’s National Institute for Occupational Safety and Health (NIOSH) announced the publication of the final “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010.” This new list updates 21 drugs from the original list in the 2004 Alert. NIOSH will provide ongoing opportunities to provide feedback on future proposed revisions to this list.

Health Resources and Services Administration (HRSA) in 2010

Guidance for Contract Pharmacy Arrangements
On March 5, HRSA published a notice to finalize guidelines that clarify the requirements that must be met when utilizing contract pharmacy arrangements and will permit 340B Covered Entities to contract with more than one pharmacy to provide pharmacy services. The notice finalizes guidelines that were initially proposed on January 12, 2007. The new guidelines were effective on April 5, 2010. At that time, 340B covered entities were permitted to add more than one pharmacy to the Office of Pharmacy Affairs database. For additional information, the guidelines may be found at the HRSA Office of Pharmacy Affairs (OPA) Web site and the HRSA Pharmacy Services Support Center (PSSC) Web site.

Drug Enforcement Administration (DEA) in 2010

Electronic Prescribing of Controlled Substances
In March, the DEA issued its interim final rule authorizing the electronic prescribing of controlled substances. To assist with implementation, DEA created a Web site with links to information and resources, including:

- Letter to Electronic Application Providers and Pharmacy Application Providers
- DEA letter to affected associations
- Questions and Answers For Pharmacies
- General Questions and Answers
- For Prescribing Practitioners
- For Providers of Electronic Prescription Applications, Pharmacy Applications, and Intermediaries

Beginning June 1, the interim final rule permitted appropriately credentialed prescribers to voluntarily transmit Schedules II-V controlled substance prescriptions electronically to pharmacies. However, due to needed changes in technology systems, certification, and other requirements, e-prescribing of controlled substances is not yet functional.
The key pharmacy-related areas in the rule include:
- Proofing prescriber identity, access control to electronic prescribing systems, two-factor authentication, and approving electronic controlled substance prescriptions;
- Transmitting controlled substance prescriptions;
- Electronic prescription system requirements;
- Audit requirements;
- Refill authorizations and transferring electronic prescriptions;
- Partial filling of prescriptions;
- Transmission failures;
- Permissibility of printing copies of prescriptions; and
- Recordkeeping requirements.

APhA worked with the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, and the National Community Pharmacists Association on a joint comment letter to DEA. The pharmacy letter highlighted support for revisions made to the proposed rule and offered recommendations to better ensure that pharmacists have the needed information to implement and comply with the final rule. Read the joint comment letter.

Dispensing Controlled Substances in Long-Term Care Facilities (LTCFs)
In June, the DEA sought information on the dispensing of controlled substances to residents in long-term care facilities (LTCFs). DEA’s goal is to make it easier for residents of LTCFs to receive controlled substance medications and to see if revisions were needed and feasible on regulations implementing the Controlled Substances Act.

APhA’s comments to DEA recommended DEA revise regulations to allow nurses to act as the agent of the prescriber, allow charts orders to serve as a valid prescription order, and create a new DEA registration for LTCFs. For additional information, read APhA’s comments and read APhA’s www.pharmacist.com article.

In October, DEA published a statement of policy to provide guidance on the role of authorized agents in communicating controlled substance prescriptions to pharmacies. In a reversal of its previous interpretation, the DEA’s new policy allows agents of the prescriber, such as nurses working in long-term care facilities, to communicate via facsimile prescription information to the pharmacy for Schedules II through V medications and orally for Schedules III through V. The new policy statement also included information on the definition of an agent, the required elements of a prescription, and the rules pertaining to faxing prescriptions. However, challenges remain and there may be additional regulatory or legislative activity in 2011.

White House Office of National Drug Control Policy (ONDCP)

President Obama’s 2010 National Drug Control Policy
On May 11, President Obama and Director R. Gil Kerlikowske of the Office of National Drug Control Policy (ONDCP) announced the release of the Obama Administration’s first National Drug Control Strategy. The goal of the 2010 Strategy is to use a comprehensive approach to reduce drug use and its consequences through a balanced policy of prevention, treatment, recovery, enforcement, and international cooperation. The Strategy was developed with input from law enforcement, health care professionals and associations, drug treatment providers and corrections professionals, individuals in recovery, parents and support groups.
The Strategy focuses on the following key objectives:
- Strengthen efforts to prevent drug use in communities;
- Seek early intervention opportunities in health care;
- Integrate treatment for substance disorders into health care and expand support for recovery;
- Break the cycle of drug use, crime, delinquency, and incarceration;
- Disrupt domestic drug trafficking and production;
- Strengthen international partnerships; and
- Improve information for analysis, assessment, and local management.

APhA provided comments to ONDCP in September 2009 and is pleased that ONCDP referenced APhA and pharmacy in the report. Specifically, the following action steps are of interest of pharmacy:
- Educate physicians about opiate painkiller prescribing (page 30);
- Expand prescription drug monitoring programs and promote links among state systems and to electronic health records (APhA is referenced as a stakeholder to include in this process, page 31);
- Increase prescription return/take-back and disposal programs (community pharmacies are referenced, page 32);
- Assist states to address "doctor shopping" and "pill mills" (page 32);
- Drive illegal Internet pharmacies out of business (page 32);
- Crack down on rogue pain clinics that do not follow appropriate prescription practices (page 33); and
- Inform public health systems on implementation of needle exchange programs (page 40).

For additional information, read press statements, highlights, and the complete report on the 2010 Strategy Web site.

**Internal Revenue Service in 2010**

**Guidance on Flexible Spending Accounts (FSAs)**
In September, the IRS issued guidance on a provision of the health care reform law, the Affordable Care Act (P.L. 111-148, Section 9003), which prohibits the use of Flexible Spending Accounts (FSAs) to pay for over-the-counter (OTC) products unless a prescription is obtained. This provision was effective January 1, 2011. The IRS guidance clarified the following:
- In order to be reimbursed for a prescribed OTC, a beneficiary must provide an independent third party a copy of the prescription and the receipt to verify that the OTC was prescribed.
- Plans must ensure that a FSA card is reprogrammed no later than January 15, 2010 so that the card can no longer be used to purchase OTCs.
- A beneficiary using left over money in the FSA from 2010 must still meet new policy requirements and have a prescription for OTCs.
- The new FSA policy does not apply to insulin or prescribed drugs.
APhA, working in a coalition lead by the Consumer Healthcare Products Association (CHPA), cosigned a letter in support of delaying or repealing the implementation of this provision due to concerns over limiting patient access to needed medications, reducing the cost-efficiencies associated with these medicines and implementation challenges. As a result of stakeholder input, on December 23, the IRS issued a revised guidance. The updated guidance further states that starting January 15, 2011, FSA debit cards can be used to pay for prescribed OTCs as long as the required prescription is processed and dispensed through the pharmacy’s prescription process and identified with a prescription number at point-of-sale. For additional information, please read the IRS press release and the updated IRS FAQ Web page.

Department of Defense (DoD) in 2010

TRICARE Pharmacy Refund
On October 15, the DoD published a final rule on the inclusion of the TRICARE pharmacy program in federal procurement of pharmaceuticals. The National Defense Authorization Act for Fiscal Year 2008 (P.L. 110-181) authorized the TRICARE retail pharmacy program to be treated as an element of DoD for purposes of procuring drugs. This provision ensures that pharmaceuticals paid for by DoD are provided by network retail pharmacies to eligible covered beneficiaries that are subject to pricing standards using the Federal Ceiling Price (FCP). In March 2009, DoD issued a final rule implementing the Act; however, in November 2009, the U.S. District Court for District of Columbia remanded the March 2009 final rule back to DoD to decide whether to maintain the current rebate/refund program or implement another mechanism for obtaining the FCP. After seeking public comment, DoD has decided to continue the existing refund program, finding that the current program is in harmony with the statue, best business practices, and is practical to administer.

Federal Trade Commission (FTC) in 2010

Identity Theft Red Flags Rule
In 2009, the Federal Trade Commission (FTC) planned to implement "red flag rule" designed to protect consumers from identity theft under the Fair and Accurate Credit Transactions Act of 2003 (P.L. 108-159). The Act requires “creditors” and “financial institutions” all such entities that have "covered accounts" to develop and implement written identity theft prevention programs to help identify, detect, and respond to patterns, practices, or specific activities – known as "red flags" – that could indicate identity theft. Since 2009, FTC delayed the implementation date of the red flag rule several times. In May, FTC announced a further delay until December 31, 2010.

Congressional intervention and changes to the law have resulted in additional delays in the enforcement of the red flag rules for certain businesses. In December 2010, President Obama signed the Red Flag Program Clarification Act of 2010 (P.L.111-319) that exempts certain businesses that do not act as a creditor from compliance with the law. Pharmacies and other businesses that meet the requirements for a creditor must have been in compliance by January 1, 2011. For additional information, read FTC guidance or read FTC's press release.
U.S. Government Accountability Office (GAO) in 2010

Appointments to Two Boards Established in Affordable Care Act (ACA)
In September, the GAO announced appointments to the Patient-Centered Outcomes Research Institute (PCORI) Board of Governors, the new entity that will conduct comparative effectiveness research, and the National Health Care Workforce Commission, which will serve as the national resource for policymakers regarding America’s health care workforce. Both of these groups were created in the health care reform law, the Affordable Care Act (ACA). APhA, in collaboration with other pharmacy stakeholders, submitted nominations for these positions. While no pharmacist was selected for the PCORI Board of Governors, Dr. Brian Isetts, Professor, Department of Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy, was appointed to the National Health Care Workforce Commission. For more information on the PCORI Board of Governors, read the National Pharmaceutical Council’s PCORI Resource Guide. For more information about National Health Care Workforce Commission, read GAO’s press release.

APhA’s Government Affairs Resources
www.pharmacist.com/GA