

Regulatory Update

APhA Working for You...



November 16, 2011

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News from APhA

Elections: Think About It

The next national election is only one year from now. On Tuesday, November 6, 2012 the Presidency, 33 seats in the Senate and 435 in the House will be selected by those individuals who go to the polls and cast their votes. Currently, the Democratic Party controls the Senate with 53 seats to the Republican's 47 (51 seat are needed for the majority). 23 Senate seats held by Democrats and 10 Republican seats will be voted on in the upcoming election. In the House of Representatives, Republicans hold power with 242 seats while Democrats hold 192 seats (218 seats are needed for a majority). Every two years, all seats in the House of Representatives are up for election.

The upcoming election presents either an opportunity or a threat to pharmacy. With increasing pressure to balance the federal budget and reduce spending, big decisions that can impact pharmacists and their patients will be made. Medicare, Medicaid and the Children's Health Insurance Program (CHIP) make up over 20% of the federal budget. The next Congress and President will be making these decisions.

As lawmakers look for ways to reduce national spending it is vital for lawmakers to hear the local voices and stories of motivated pharmacists. During the upcoming elections, it will be equally crucial for candidates to know that their constituents want to elect candidates that support pharmacy issues. Sign up to be an [APhA Advocacy Key Contact](#) and be a part of the growing number of pharmacists that are speaking up for their patients and their profession. If you have already signed up, help us recruit others - in politics, there is strength in numbers.

Upcoming Activities/Deadlines

11/14-20 [CDC Get Smart About Antibiotics Week](#)

11/17 [Health Care Innovation Challenge Webinar](#)

11/17-18 [ACO Accelerated Development Learning Session](#)

11/28 [Comments to FDA on Tablet Scoring Draft Guidance for Industry](#)

11/29 [Comments to CMS on National Average Drug Acquisition Cost Survey](#)

12/7 [Comments to FDA on Draft Blueprint for Opioid REMS Prescriber Education](#)

12/12 [Comments to CMS on Draft Revisions to Part D](#)

12/15 [APhA Candidate Election Application Deadline](#)

12/23 [Comments to FDA on Drug Shortage Report](#)

12/23 [Comments to FDA on Drug Shortage Workshop](#)

12/31 [Primatene Mist with CFCs No Longer Available](#)

1/3 [Comments to HHS on HIT/HIE Privacy Survey](#)

1/27 [Health Care Innovation Challenge Applications Due](#)

2/23 [Comments to FDA on Bar Coding Rule Assessment](#)

[Join APhA's Advocacy Key Contact \(AAKC\) Network:](#)

Get involved with the AAKC network and learn about opportunities to support APhA's advocacy and health care reform implementation efforts.

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APhA is seeking pharmacist members who wish to be considered for the elective offices of APhA President-elect for 2013-2014 and two Board of Trustees positions for 2013-2016. The APhA President-elect will serve as President in 2014-2015 and as Immediate Past President in 2015-2016. [Applications](#) are available now and are due December 15. [Visit APhA's Web site](#) for more information. For specific questions, contact APhA staff member, Brian Lawson, PharmD, at blawson@aphanet.org or by phone at (202) 429-7548.

Congress

Congress Considers FDA Funding Legislation

Both the House of Representatives and the Senate are preparing to pass the first appropriation legislation of the fiscal year (FY; which began October 1). The legislation, [H.R. 2112](#), consists of three appropriation bills. Agriculture, Commerce-Justice-Science, and Transportation-HUD. We expect this bill to pass within the next week.

Congress agreed to provide FDA with \$2.5 billion in FY 2012. The \$2.5 billion is \$234 million less than the Administration's request but it is about \$50 million more than in FY 2011. The bill is important to pharmacy as FDA is responsible for ensuring the safety and effectiveness of vaccines and other biological products, medications, and medical devices intended for human use.

Subcommittee Hearing on Prescription Contraceptives

On Wednesday, November 2, the House Energy and Commerce Subcommittee on Health held a hearing entitled [Do New Health Law Mandates Threaten Conscience Rights and Access to Care?](#) The witness panel, which consisted mostly of faith-based organizations, discussed [new federal rules](#), which implement provisions of the Affordable Care Act (PL 111-148), that require their organizations to offer prescription contraceptives as part of their health insurance plans. William Cox, head of the Alliance of Catholic Health Care, a California-based group of hospitals and other health care facilities, said most of the entities in his organization have been able to evade a similar state contraceptive coverage law either by dropping prescription coverage or by becoming a "self-insured" health plan, which puts it outside the reach of state mandates. The federal requirement however, leaves them no such option.

The groups suggested two possible solutions. One, for the Administration to broaden the exemption in the contraception requirement, which currently allows only organizations that proselytize, primarily hire people who belong to that religion, and primarily serve only people of that religion to be exempt. The groups' second recommended solution would be for Congress to pass [H.R. 1179](#), the "Respect for Rights of Conscience Act," a bill that would exempt employers, insurers, and health care providers from providing "specific items or services... contrary to... religious beliefs or moral convictions." The legislation introduced by Representatives Jeff Fortenberry (R-NE) and Dan Boren (D-OK) has 94 cosponsors. A Senate companion bill, [S. 1467](#), introduced by Senator Roy Blunt (R-MO) has 23 cosponsors.

APhA's policy supports allowing a pharmacist to opt out of dispensing a prescription or providing a service for personal reasons and also supports the establishment of systems so that the patient's access to appropriate health care is not disrupted. [Visit APhA's Government Affairs Web site](#) to learn more about government activity concerning the conscience clause issue.

[Visit the APhA-Political Action Committee \(APhA-PAC\) Web site:](#) The APhA-PAC Web site is your one-stop shop for all information and news on the APhA-PAC.

[Read APhA2011 Issue Briefs:](#) APhA's Government Affairs Team prepared 14 issue briefs covering key legislative and regulatory issues over the past year, including health care reform (HCR).

Ask questions, share comments with the APhA Government Affairs staff at gvtaff@aphanet.org.

Senior Editor for APhA's Legislative and Regulatory Update: Jason Hansen

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Democrats on the Joint Select Committee on Deficit Reduction (Super Committee) have offered spending cuts including \$350 billion from Medicare and \$50 billion from Medicaid and other health programs as part of a larger proposal to address the federal budget deficit. The Super Committee is tasked with finding \$1.2 - 1.5 trillion in changes to revenue and/or spending by November 23. If the Super Committee cannot come to an agreement, an automatic trigger mechanism will impose cuts of 2% across-the-board, effective in 2013. Importantly, payments to providers, including pharmacists, and insurance plans in Medicare would be cut if the trigger takes effect.

According to the proposed plan, the \$50 billion in Medicaid and other health cuts would affect provider taxes (\$13 billion), disproportionate share hospitals (\$4 billion), durable medical equipment (\$5 billion), reduction of the prevention and public health trust fund (\$8 billion), and increasing the inflationary rebate for Medicaid drugs (\$20 billion). The Medicare part of the proposal would save \$250 billion from payments to Medicare providers and \$100 billion from Medicare beneficiaries. None of the cuts would go into effect until the tax reform parts of the plan that raise revenues by closing tax loopholes are enacted. Watch for additional information in the coming weeks.

Republican Letter on CMS Innovation Center

Three Republican Finance Committee Members, Ranking Member Orrin Hatch (R-UT) along with Senators Mike Enzi (R-WY) and Tom Coburn (R-OK), [wrote two letters regarding their concerns](#) about the Center for Medicare and Medicaid Innovation (CMMI). One of the letters was to HHS Secretary, Kathleen Sebelius, and the other was sent to Government Accountability Office (GAO) Comptroller General, Gene Dodaro. The Senators are concerned that the new CMMI center will place unnecessary financial strains on the nation's health care entitlement programs. They would like to see the Secretary's operating strategy and how the \$10 billion in funding allocated to CMMI is being used. The letter to Comptroller General Dodaro asks the GAO to conduct a study on the implementation of many of the new Offices and Centers created with CMS, including CMMI.

The Affordable Care Act (ACA; PL 111-148) established CMMI within CMS to test payment and service delivery models to determine their effect on program expenditures and quality of care. CMMI is important to pharmacy because Section 3021 of the ACA lists utilizing medication therapy management services among the models to test.

Programs CMMI has established that pharmacists could participate in include:

- Partnership for Patients
- Comprehensive Primary Care Initiative
- Health Care Innovation Challenge
- Innovation Advisors Program; and
- Pioneer Accountable Care Organization Model

Visit the [Innovation Center Web site](#) for more information on its programs. If you have innovative ideas also contact the APhA Foundation through the IQI Institute at IQI@aphanet.org or by phone at 800-237-2742 for help with submitting proposals. For additional information on MTM visit [APhA's MTM Central](#).

HHS

HHS Seeks Feedback on HIT/HIE Privacy Survey

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new survey entitled "Consumer Survey of Attitudes Toward the Privacy and Security Aspects of Electronic Health Records and Electronic Health Information Exchange." The proposed national survey would look at whether the number of people who are concerned with the privacy/security of electronic health records and keep part(s) of their medical history from their doctor changes over the next five years. HHS anticipates the survey will help them better understand attitudes concerning privacy and security related to the use of electronic health records and exchanges.

[Comments are due](#) to HHS January 3, 2012.

CDC Get Smart About Antibiotics Week November 14 - 20

CDC's fourth annual [Get Smart About Antibiotics Week](#) will take place November 14 - 20. Since 2008, Get Smart About Antibiotics Week helps coordinate the work of CDC's [Get Smart: Know When Antibiotics Work](#) campaign and state-based appropriate antibiotic use campaigns to raise awareness about antibiotic resistance and the importance of appropriate antibiotic use.

Antibiotic resistance is among CDC's top concerns and CDC reports that the best way to control resistance is by reducing inappropriate antibiotic use. CDC is strongly targeting parents of young children due to the high use of antibiotics in children. APhA is a part of the Get Smart campaign. Pharmacists can help the CDC in its efforts to combat and educate individuals on this public health problem by taking part in this week-long event. Visit CDC's Web site for participant [Planning](#) and [Promotional](#) Materials. See also [FDA's Consumer Update Video: Get Smart About Antibiotics](#)

CDC Issues Report on Prescription Painkiller Overdoses in the US

On November 1, [CDC released a new Vital Signs report](#) entitled [Prescription Painkiller Overdoses in the US](#) which shows deaths from prescription painkillers at epidemic levels. According to the report, these overdose deaths now exceed the deaths from heroin and cocaine combined. The report points to the nonmedical use of prescription painkillers as a large contributor to this growing problem. Vital Signs reports are used in the development and updating of the [President's National Drug Control Strategy](#).

The report encourages improving prescribing practices for painkillers to ensure continued access to for those who need them while at the same time reducing the number of people who overdose or abuse these medicines. Pharmacists can help through the recognition of potential misuse and abuse of medications. Additionally, pharmacists are encouraged to speak with their patients about the importance of proper prescription drug disposal so unused controlled substances are not available for abuse.

For more information on prescription painkiller misuse, see CDC's Web page on [Unintentional Poisoning](#) and its issue brief entitled [Policy Impact: Prescription Painkiller Overdoses](#). Visit the [SMARxT Disposal](#) Web site for more information on drug disposal. Read APhA's article [Prescription painkiller abuse an epidemic, CDC says](#).

CMS

Medicare Part D Prescriber Identifier Reporting

CMS recently announced the findings of a project that examined exclusive [National Provider](#)

to improved prescriber ID reporting rates on
pharmacy claims submitted to Medicare plans).

According to the report, recent PDE data show that approximately 90% of PDEs currently submitted to CMS contain prescriber NPIs. CMS has notified those pharmacies with high reporting rates of invalid NPI or other identifiers such as DEA numbers. These notices were also sent to the Medicare Compliance Officers of any Part D plans to which these pharmacies submitted Part D claims. CMS is encouraging pharmacies and Part D sponsors to make appropriate actions to quickly improve their NPI prescriber identifier reporting performance.

CMS is also encouraging individuals to be aware of its recently proposed [Revisions to Medicare Parts C and D for 2013](#) (76 FR 63018). As required through the Health Insurance Portability and Accountability Act of 1996 (HIPAA; PL 104-191) the proposed rule would, among other things, require PDE records to contain an active and valid individual NPI starting in 2013. This revision is part of CMS' efforts to improve reporting requirements and was discussed in the [CY 2012 Call Letter](#) through which CMS stated that it was considering limiting acceptable prescriber identifiers on claims and PDE records in 2013 to only the individual NPI. [Comments on this proposed rule](#) are due to CMS December 12, 2011.

CMS Launches New Demonstration Program to Curb Improper Payments

On November 15, [CMS announced](#) new demonstration projects aimed at reducing improper Medicare and Medicaid payments. These demonstration projects are scheduled to begin January 1, 2012. Some pharmacies may be impacted by these demonstration projects.

One demonstration project, [The Recovery Audit Prepayment Review](#) will permit Medicare Recovery Auditors (RACs) to review claims prior to payment to verify provider compliance with the Medicare payment rules. These reviews will be conducted on specified types of claims that resulted in high rates of improper payments in the past. Seven states (FL, CA, MI, TX, NY, LA, IL) that have high populations of fraud- and error-prone providers will be the subject of these reviews. These reviews will also focus on another four states (PA, OH, NC, MO) that have high claims for short inpatient hospital stays.

Another demonstration project, [Prior Authorization for Certain Medical Equipment](#) will require Medicare beneficiaries living in seven states (CA, FL, IL, MI, NY, NC and TX) to receive prior authorization for specified medical equipment. These states are noted by CMS for having high populations of fraud- and error-prone providers. Through this demonstration project, CMS is attempting to ensure it is paying appropriately for specified medical equipment that has a high error rate. Additionally, CMS intends for the project to help ensure a beneficiary's medical condition warrants their medical equipment under existing coverage guidelines.

In this announcement, CMS also reported a [composite improper payment error rate](#) for the Medicare Part D prescription drug program. According to the announcement, based on payment year 2009, the improper payment rate is 3.2 percent, or \$1.7 billion. Of interest to pharmacy, this rate is generally lower than other provisions of the Medicare and Medicaid programs. This is the first time this error rate has been reported. The rate combines five component payment error measures:

- Medicare Advantage prescription drug payment system error;
- Payment error related to low income subsidy status;
- Payment error related to incorrect Medicaid status;
- Payment error related to prescription drug event data validation; and
- Payment error related to direct and indirect remuneration.

Visit the [CMS Web site](#) for more information on specific error rates reported. See also APhA's

CMS Innovation Center Launches Health Care Innovation Challenge

On November 14, [CMS announced the Health Care Innovation Challenge](#). The Innovation Challenge will make available \$1 billion in grants to applicants that can implement new ideas on delivering better health, improved care and lower costs to Medicare, Medicaid and Children's Health Insurance Program (CHIP) enrollees. Innovation Challenge awards will range from approximately \$1 million to \$30 million for a three-year period. According to the announcement, applicants are encouraged to include new models of workforce development and deployment that efficiently support their service delivery model proposal. Letters of Intent are due to the Innovation Center December 19, 2011 and applications are due January 27, 2012. Pharmacists are encouraged to team with other health care providers and apply.

More information is available on the [Innovation Center Web site](#). CMS innovation staff will also host an informational webinar November 17 from 2:00 pm to 3:00 pm ET. Visit the [webinar site](#) or to listen only dial 888-567-1602 or 201-604-5049 and request "Center for Medicare & Medicaid Innovation Webcast" (no passcode).

Medicare Adds Additional Preventive Services to Reduce Cardiovascular Disease

On November 8, [CMS announced Medicare would expand coverage](#) for a number of preventive services to reduce cardiovascular disease (CVD). These new and free services contribute to the [Million Hearts initiative](#) which is led jointly by CMS and the Centers for Disease Control and Prevention in partnership with private sector partners such as APhA. The goal of the initiative is to prevent 1 million heart attacks and strokes, over the next five years.

As part of this expanded coverage, Medicare beneficiaries are eligible for one free face-to-face CVD risk reduction visit each year. The visit must be provided by a primary care practitioner and in a primary care setting.

Pharmacists can play a significant role in the prevention and management of cardiovascular disease. As partners in Million Hearts initiative, pharmacists are encouraged to share this latest coverage decision with their Medicare patients. More information about this new benefit is available on the [CMS Web site](#). Read also APhA's articles [APhA joins Million Hearts campaign](#) and [Cardiovascular care: Evidence strong for pharmacist role](#).

DEA

DEA Hosts Third National Prescription Drug Take-Back Day

On October 29, DEA, in partnership with state, local and tribal law-enforcement and community partners, hosted its third [National Prescription Drug Take-Back Day](#). DEA reports that individuals taking part in this event turned in more than 377,086 pounds (188.5 tons) of unwanted or expired medications for safe and proper disposal. Over 5,000 take-back sites were available in all 50 states and US territories. Previous Drug Take-Back Days in 2010 and 2011 collected more than 309 tons of medicines. DEA expects additional take-back days in the future until final regulations are in place to improve options for disposing of controlled substances.

Pharmacists are encouraged to share information concerning future Prescription Drug Take-Back Days with their patients to help address prescription drug abuse among Americans

use of medications.

See DEA's [Web site](#) for more information from the event. In addition, visit the [SMARxT Disposal](#) Web site for more information on drug disposal. Read also APhA's article [Next DEA drug take-back day is October 29](#).

FDA

FDA Announces Draft Blueprint for Opioid REMS Prescriber Education

On November 7, [FDA announced](#) the availability of a draft document entitled [Blueprint for Prescriber Education for the Long-Acting/Extended-Release Opioid Class-Wide REMS \(Blueprint\)](#). According to the announcement, the draft Blueprint contains core messages intended for use by continuing education (CE) providers to develop educational materials to train prescribers of long-acting and extended-release opioids under the required REMS for these products (Opioid REMS).

FDA is requiring manufacturers to develop prescriber educational materials but it is voluntary for prescribers to complete. Manufacturers will have to report back to FDA on prescriber utilization/completion of the material. The draft Blueprint suggests that the CE should be part of a basic 2-3 hour educational module.

While this particular education material is being developed for prescribers (physicians, physician assistants, and nurse practitioners), there is still reason for pharmacy to be interested as there may be pharmacies who wish to have their pharmacists complete the education material, or there may be pharmacists who voluntarily wish to review/complete the material. In addition, the Blueprint sets the stage for future REMS that may include a pharmacist-specific requirement to complete educational materials through CE.

Pharmacists are encouraged to participate in FDA's request for provider input into the document. After comments have been received, FDA will update the document as appropriate and post it on its Web site for use by CE providers. [Comments are due to FDA](#) December 7, 2011.

FDA Announces New Web site on Needles / "Sharps" Disposal

On November 7, [FDA launched a new Web site](#) for caregivers and patients on the proper disposal of needles and other sharps at the workplace, home and while traveling. The Web site details the importance of proper used needle disposal, explains the dangers of putting used sharps in public or household trash/recycling bins or flushing them down the toilet, and offers instruction on what to do if stuck by a used needle.

Pharmacists are encouraged to share this Web site with patients and parents of children that have exposure to sharps. Read [FDA's announcement](#) on its Web site. See also, the [Coalition for Safe Community Needle Disposal](#). APhA is a member this group which seeks to increase awareness of and solutions for safe sharps disposal.

FDA Seeks Comment on Product Shortage Report

On November 7, [FDA announced the availability](#) of its new report entitled [A Review of FDA's Approach to Medical Product Shortages](#). FDA requests feedback on the report which discusses the Agency's approach to product shortages. Pharmacists are encouraged to review the report's recommendations and offer comments. [Comments are due](#) to FDA December 23, 2011.

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...ue, read APhA's article [Obama executive
in Society of Health-System Pharmacists](#)
[web sites](#) also have information and resources on drug shortages.

FDA Updates

- [Drug Recalls](#)
- [Drug Safety Communications](#)
- [Current Drug Shortages](#)
- [FDA Drug Info Rounds](#)
- [Upcoming FDA Meetings](#)
- [Medication Guides](#) (updated)
- [FDA Releases Report on FY 2011 Innovative Drug Approvals - 35 New Drugs in 2011](#)
- FDA Consumer Updates:
 - [Don't Be Fooled By Health Fraud Scams](#)
 - [Lock it Up: Medicine Safety in Your Home](#) (Video)
 - [Get Smart About Antibiotics](#) (Video)

Other News

Supreme Court to Hear Arguments on the Affordable Care Act

On November 14, the US Supreme Court agreed to hear arguments on certain provisions within the Affordable Care Act (ACA; PL 111-148). The most notable provision of the new law that the Justices will consider is the ACA's requirement that beginning in 2014 individuals must have health insurance or pay a penalty. This requirement is also known as the [Individual Mandate](#) and is found at [ACA Section 1501\(b\)](#); [26 U.S.C. Section 5000A](#).

This provision could be important to pharmacists as the ACA requires health benefits plans, with certain exceptions, to include at a minimum an essential health benefits (EHB) package that will be defined through regulation by HHS. Prescription drugs are required to be covered but not in full. The list of benefits is expected to be released via a HHS proposed rule within the next several months. APhA has been encouraging HHS to include pharmacist-provided medication therapy management (MTM) in the list of essential benefits.

After considering the individual mandate, as well as other ACA related questions, the Supreme Court will have a number of options which include continuing the law in its current form, striking down the entire law or individual sections of the law (such as the individual mandate) or it could wait until after the individual mandate has become effective and rule at that time.

The outcome of this case could be very important to pharmacy. APhA will monitor this case and report developments in upcoming editions of Leg/Reg.

New Survey Finds Better Communication Leads to Improved Medication Adherence

On November 2, the National Consumers League (NCL) [released a new national survey](#) as part of its [Script Your Future campaign](#). The survey found patients who do not take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of medication adherence. According to the announcement, communication between health care professionals and their patients is very important to improving medication adherence. The survey found that additional tools for improving adherence include automatic refills, reduced co-pays and pill



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Pharmacists should note the survey's emphasis on the relationship between communication and medication adherence. Pharmacists are encouraged to engage their patients when discussing proper medication use and employ techniques that prompt the patient to ask about their medications. APhA is a member of the Script Your Future campaign. A wealth of information and tools is available on the [Campaign's Web site](#). Pharmacists are encouraged to use this information and tools to help engage their patients.

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