House and Senate Pass Bills Addressing Drug Shortages

Yesterday, in a 387 to 5 vote, the House approved H.R. 5651, the Food and Drug Administration Reform Act of 2012. The bill reauthorizes the Prescription Drug User Fee Act and the Medical Device User Fee Act and creates new user fee programs for generic drugs and biosimilar drugs. The Senate approved its version of the bill – S. 3187 – on May 24.

Of particular importance to AAEM are the provisions in these bills addressing drug shortages. Current law requires sole manufacturers of certain types of drugs to notify the Secretary of Health and Human Services at least six months before discontinuing the manufacture of that drug. It also requires the Secretary to distribute discontinuation information to appropriate physician and patient organizations.

The new legislation includes reforms that amend the current law by applying the notification requirement to all manufacturers of certain drugs and requiring notification of both a permanent discontinuance and a manufacturing interruption that could lead to supply disruptions. The bills require the Food and Drug Administration (FDA) to alleviate shortages by modifying current reporting requirements and expediting the approval of drugs in need, and work to prevent a future crisis by authorizing the Government Accountability Office to conduct a study to examine the causes and make recommendations to prevent future shortages.

The report language accompanying the House bill clarifies that drugs used for treatment in emergency care situations, including resuscitation, are to be included in the FDA's drug shortage notification process. Although both bills require manufacturers to report potential shortages to the FDA at least six months in advance or as soon as possible, the House bill requires the FDA to keep a public, updated list of all drugs in shortage, while the Senate version requires a record-keeping of drug shortages, but not to make that information public.

The measures will now go to conference where their differences will need to be ironed out. Congress has to reauthorize the user fee bills by September 30, 2012 or these programs will expire.

HHS Searching for Answers to Drug Shortages

A rapidly organized meeting on The Impact of Drug Shortages on Emergency Care was held in Washington, D.C. on April 16, 2012. Hosted by the Department of Health and Human Services Assistant Secretary for Preparedness and Response, the meeting gathered key players in the emergency care community to better understand the magnitude and effect of shortages on the drugs that are available for emergencies. The meeting also sought to relate the federal efforts to reduce shortages, as well as deliberate on coping and mitigation strategies.

Providing background on the issue, the Food and Drug Administration (FDA) staff described its Drug Shortage Program. FDA studies show that the (Cont’d page 2)
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number of reported drug shortages in the United States nearly tripled between 2005 and 2010, growing from 61 to 178. Of the FDA-studied shortages in 2010-11, 80% involved drugs delivered to patients by sterile injection, including sedatives/anesthetics, toxin antidotes, antibiotics, electrolyte/nutrition drugs, and oncology drugs. The leading reasons for the reported shortages were problems at the manufacturing facility (43%), delays in manufacturing or shipping (15%), and active pharmaceutical ingredient shortages (10%). Sterile injectable medications (SIMs) have unique manufacturing and market features which make shortages of these products more likely and harder to prevent or mitigate – the top three generic injectable manufacturers hold 71% of the market by volume and that most SIMs have one manufacturer producing at least 90% of the drug.

Shortage reports may originate from manufacturers, although there is no FDA regulatory requirement for firms to report shortfalls unless the situation involves the discontinuation of “sole-source,” “medically necessary” drugs. A medically necessary product is defined as one that is “used to prevent or treat a serious or life-threatening disease or medical condition for which no other source of that product or an alternative drug is available in adequate quantities.” Even in instances of sole-source, medically necessary drugs where reporting is required, FDA has no enforcement mechanism to penalize a drug maker for failing to report potential shortages. However, when information about the interruption or discontinuation of a product was made available to the FDA, the agency avoided shortages by implementing countermeasures. The FDA successfully prevented 233 drug shortages between the beginning of 2010 and December 2011.

One panel of individuals spoke to the decisions they take in solving the “front line” issues of drug shortages. They reported needing to redistribute medications such as epinephrine and sodium bicarbonate from crash carts on in-house units to ambulances in order to ensure that high-need environments have the drugs they need. Some healthcare systems have hired compounding pharmacies to fill the void in SIMs.

Whenever substitute medications are used in place of familiar drugs, the potential for errors exists. These drugs may require education to guarantee proper administration, including patient observation for unique side effects associated with these standby drugs. This is challenging under the best circumstances, and is very stressful in highly charged emergency settings. The panelists described drug shortages resulting in pharmacy, nursing, and medical leaders working closely together, quickly implementing plans to ameliorate the immediate shortage. “Drug huddles” are used in some institutions to provide real-time information and education about the changes, allowing staff to be routinely updated on the challenges and solutions for that day. Evaluating the validity of expiration dates on medications was an issue discussed, and identified for follow-up. It seems counterintuitive to “dump” expired medications when there is a shortage of that same medication. The meeting participants asked for help in determining the safety and efficacy of using certain drugs after their expiration date to make available appropriate medications for patient needs.

A speaker from the American Society of Health System Pharmacists explained its services to track drug shortages for the health care community. The ASHP site at http://www.ashp.org/shortages provides frequently updated lists of drug shortages, resolved shortages, and drugs no longer available. At the ASHP shortage site you may link to a page that describes the reason for the specific drug shortages, the related drugs that are affected, and the anticipated resupply dates. (Cont’d page 4)
Emergency Care for Patients with Mental Health Disorders Focus of Demonstration Project

In March, the Centers for Medicare and Medicaid Services (CMS) announced that 11 states (Alabama, California, Connecticut, Illinois, Maine, Maryland, Missouri, North Carolina, Rhode Island, Washington, and West Virginia) and the District of Columbia will participate in a $75 million demonstration project – The Medicaid Emergency Psychiatric Demonstration – aimed at enabling private psychiatric hospitals to receive Medicaid reimbursement for emergency care provided to Medicaid enrollees aged 21 to 64 who have an acute need for treatment.

CMS Acting Administrator Marilyn Tavenner said that requiring the nearest ED to care for a person who is threatening to hurt himself or someone else “may not be an efficient use of health care dollars, and may be detrimental to vulnerable patients – especially when they could immediately be treated in the setting with more appropriate care.”

Under current federal law, Medicaid is prohibited from paying for mental disease care provided in private psychiatric hospitals. Consequently, Medicaid enrollees needing emergency psychiatric treatment often go to an ED where services may not be matched to their needs. Should they go or be transferred to a private psychiatric hospital, they may receive appropriate care, but Medicaid reimbursement is not provided.

The three-year demonstration project, which is funded under the Patient Protection and Affordable Care Act (PPACA), covers Medicaid enrollees between the ages of 21 and 64. The participating states and district will be required to match nearly 45% of their federal dollars, resulting in $115 million to $120 million in total spending. At its conclusion, the project will assess whether Medicaid reimbursement for the treatment of psychiatric emergencies improves the quality of care and lowers costs. Also it will gauge whether expanding Medicaid reimbursement reduces the burden on hospital EDs.


White House Presses for Senate Vote on CMS Nominee

Despite reports that Senate Democrats have decided to forgo a confirmation hearing because of Republican opposition, the White House on May 22 urged the Senate to act on the nomination of Marilyn Tavenner, President Obama's choice to head the Centers for Medicare & Medicaid Services. According to reports published May 21, Senate Finance Committee Chair Max Baucus (D-MT) said he will not schedule a confirmation hearing for Tavenner. He expressed doubt that Tavenner could win the 60 votes needed in the Senate to overcome a likely GOP filibuster against her confirmation.

In November 2011, Obama nominated Tavenner, CMS's Acting Administrator, to replace Donald Berwick, who had held the position through a recess appointment. Berwick, who left the post in December, also failed to receive a confirmation vote in the Senate, with GOP opposition centered on remarks he made praising the British health care system.

Prior to becoming Acting Administrator, Tavenner was CMS's principal Deputy Administrator, the agency's second-ranking official. She oversaw CMS policy development and implementation, as well as management and operations. Before joining CMS, Tavenner served for four years as Virginia's secretary of health and human resources in the administration of former Governor Timothy M. Kaine (D).
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The AAEM Government Affairs Committee and the AAEM/RSA Advocacy Committee have been leveraging all possible advocacy strategies to raise the visibility of emergency medicine in solving the national drug shortage crisis. In addition to participating in the ASPR public policy discussions, since last year the organizations have conducted a “full court press” of monitoring federal actions, examining, commenting on, and endorsing congressional bills, holding visits with elected officials and their staff, and identifying and collaborating with other national organization stakeholders. Keep current with the AAEM and AAEM/RSA activities via the Critical Drug Shortage issue page at [http://www.aaem.org/emtopics/criticaldrugshortage.php](http://www.aaem.org/emtopics/criticaldrugshortage.php). Examine the relevant legislation at the AAEM Legislative Action Center at [http://capwiz.com/aaem/issues/](http://capwiz.com/aaem/issues/).

Bill Would Link Prescription Drug Monitoring Programs

A recently introduced federal bill would establish a nationwide system allowing physicians to see if a new patient has a history of drug abuse in another state before writing a prescription. According to Representative Harold Rogers (R-KY), a sponsor of the House bill, **The Interstate Drug Monitoring Efficiency and Data Sharing Act** (H.R. 4292/S. 2254), introduced by a bipartisan group of House and Senate legislators, would make it easier for law enforcement officials to track and prosecute drug dealers. The lawmakers introduced the measure in response to calls from state lawmakers, many in the southeastern United States, who have cracked down on so-called "pill mills" during the past two years.

Rogers's bill, introduced with Representative Frank Wolf (R-VA) and Senators Rob Portman (R-OH) and Sheldon Whitehouse (D-RI), would ease data sharing by creating uniform requirements for encryption and formatting. Currently there is no national standard for exchanging prescription drug monitoring information across state lines.

In a press release, Senator Whitehouse noted that prescription drug overdoses kill "more people in Rhode Island every year than car accidents. . . . By standardizing the way states share prescription data, this important legislation would help our health and law enforcement professionals to better identify patterns of distribution and abuse, and ultimately to save lives.”

Richard Kerlikowske, Director of the White House Office of National Drug Control Policy, called the system a priority, signaling that the proposal will likely win support from the Obama Administration.

Forty-eight states have prescription drug monitoring programs in some form or another.