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AFP Edition

Policy and Health Issues in the News

Several States Report Spike in Pertussis Activity, Need for Vaccination Emphasized

An outbreak of pertussis (i.e., whooping cough) has been declared an epidemic by the California Department of Public Health, and the South Carolina Department of Health and Environmental Council has issued a public health advisory saying reported pertussis cases are above the epidemic threshold. According to the Centers for Disease Control and Prevention (CDC), several states have reported significant increases in pertussis activity. The CDC's Advisory Committee on Immunization Practices and the American Academy of Family Physicians (AAFP) recommend that children receive five doses of diphtheria, tetanus, and pertussis (DTaP) vaccine. The CDC says that many infants are infected by older siblings, parents, or other caregivers who do not realize they have the disease, which is difficult to diagnose. A single dose of tetanus, diphtheria, and pertussis (Tdap) vaccine is recommended for adolescents 11 to 18 years of age and adults 19 to 64 years of age. The protection received from DTaP, the childhood vaccine, fades over time, so adolescents and adults should receive Tdap even if they were vaccinated as children. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100706pertussis-spikes.html.

Obama Uses Recess Appointment to Name Berwick as New CMS Administrator

President Obama has used a recess appointment to make Donald Berwick, MD, the new administrator of the Centers for Medicare and Medicaid Services (CMS), thereby circumventing a contentious confirmation process for the nomination in the Senate. Although some in the Senate have criticized the use of a recess appointment, Obama said in a prepared statement that it would allow Berwick to "get to work on behalf of the American people right away." As CMS administrator, Berwick will serve as a key player in overhauling the nation's health care system by overseeing a variety of major tasks associated with the new health care reform law, such as expanding Medicaid coverage, writing new rules and regulations, and establishing pilot projects to test different models of care and payment policies. The AAFP has praised the appointment of Berwick, saying that his medical expertise and commitment to ensuring high-quality care for all will serve America well. For more information, visit http://www.aafp.org/news-now/government-medicine/20100707berwickappointed.html.

Dosing Error Risk Increased with Shortage of Prefilled Epinephrine Syringes

The American Society of Health-System Pharmacists (ASHP) and the Institute for Safe Medication Practices (ISMP) issued a joint alert on June 16, 2010, regarding a shortage of prefilled epinephrine syringes that creates the potential for serious and possibly fatal dosing errors. According to an ASHP bulletin, Hospira Inc. is the only remaining U.S. manufacturer of epinephrine 0.1 mg per mL emergency syringes after Amphastar Pharmaceuticals Inc. discontinued its emergency drug syringes in December 2009. The U.S. Food and Drug Administration (FDA) says that unexpected demand created the shortage and that Hospira is trying to increase production to meet that demand. The Hospira product is used for heart attacks, drownings, electrocutions, and other emergency situations when a patient's heart is stopped, said Bona Benjamin, director of medication use, quality, and improvement for the ASHP. Benjamin said the shortage does not include self-administered 0.3 and 0.15 mg epinephrine injection products (Epipen), which are used to treat severe allergic reactions. Although the shortage is expected to resolve this summer, the ASHP and the ISMP say that physicians should be aware of the risk of medication errors created by the shortage. For more information, visit http://www.aafp.org/news-now/clinical-care-research/20100702epinephrineshortage.html.

FDA Warns of Potential for Overdose on Infant Vitamin D Supplements

The FDA is warning consumers about the risk of overdosing infants with liquid vitamin D supplements. In 2008, the American Academy of Pediatrics doubled the recommended daily intake of vitamin D for infants and children from 200 international units (IU) per day to 400 IU. Linda Katz, MD, MPH, interim chief medical officer in the FDA's Center for Food Safety and Applied Nutrition, says that some liquid vitamin D products come with droppers that can hold significantly more than the recommended amount of vitamin D. In a June 15, 2010, letter to manufacturers, the FDA recommended that 400 IU be clearly and accurately marked on droppers packaged with vitamin D supplements. It also recommended that products intended specifically for infants have droppers that hold no more than 400 IU. Although vitamin D overdose is a serious issue, a study published April 4, 2010, in *Pediatrics* found that most U.S. infants do not receive enough vitamin D.

For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100622vitamin-d.html and http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm214343.htm.

Federal Government Says Physicians Can Waive Medicare Coinsurance

The federal government has waived a Medicare regulation that would require physicians and other Medicare providers to bill patients for additional coinsurance (i.e., cost-sharing amounts) relative to the recently passed 2.2 percent Medicare physician payment increase. The payment increase went into effect on June 25, 2010, but is retroactive for covered Medicare services with dates of service from June 1 through June 24, 2010. Medicare policy dictates that physicians must collect full coinsurance from Medicare beneficiaries as part of the U.S. Department of Health and Human Services' (HHS') efforts to combat fraud and abuse in the Medicare system. However, on June 25, 2010, HHS' Office of Inspector General (OIG) issued a policy statement assuring physicians and other Medicare providers that they "will not be subject to OIG administrative sanctions if they waive retroactive beneficiary liability" subject to the conditions noted in the policy statement. General guidance about the federal anti-kickback statute is available on the OIG Web site (http://oig.hhs.gov/). For more information, visit http://www.aafp.org/news-now/practice-management/20100630oigcoinsurance.html.

HHS Launches National Program to Improve Health Literacy

Nearly nine out of 10 English-speaking U.S. adults have limited health literacy skills, which research has shown is associated with poor health outcomes. In response, HHS has issued a national action plan designed to make health information and services easier to understand and use. The plan includes the following goals: develop and disseminate health and safety information that is accurate, accessible, and actionable; promote changes in the health care system that improve information, communication, informed decision making, and access to services; incorporate accurate, standards-based, and developmentally appropriate health and science information and curricula in child care and education through the university level; support and expand local efforts to provide adult education, English language instruction, and culturally and linguistically appropriate health information services in the community; build partnerships with organizations and government agencies and work with them to develop guidance and change policies; increase basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy; and increase the dissemination and use of evidence-based health literacy practices and interventions. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100701healthliteracy.html.

FDA to Report on Drug Safety Monitoring Activities and Postmarketing Summaries

The FDA is making more safety-related information available to consumers and physicians about recently approved drugs and biologic products. The FDA is required to prepare safety summaries within 18 months after it approves a product or after a product has been used by 10,000 patients, whichever is later. Such summaries now will be posted online. The FDA said in a June 15, 2010, news release that summaries are based on reports to its Adverse Event Reporting System and the Vaccine Adverse Event Reporting System maintained by the FDA and the CDC. Summaries also are based on periodic safety information submitted to the FDA by manufacturers, information contained in the medical literature, and data from ongoing studies on approved drugs and biologics, and will include information about steps the FDA is taking to address safety issues. Postmarket summaries may include information on potentially serious and previously unidentified risks and known adverse events that occur more often than they did during clinical studies. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100629fdasafety.html.

ACGME Releases Updated Proposals on Duty Hours for Residents

The Accreditation Council for Graduate Medical Education (ACGME) released a draft of proposals that provide more supervision of first-year residents, reduce first-year residents' duty periods to no more than 16 hours a day, and set stricter requirements for duty hour exceptions. The ACGME said in a June 23, 2010, press release that the proposals build on recommendations made by the Institute of Medicine in 2008. The proposals maintain work hours at a maximum of 80 per week, averaged over a four-week period, but call for significant changes in training, especially for first-year residents. The proposed standards are available for comment until August 9, 2010, on the ACGME Web site (http://acgme-2010standards.org/proposed-standards.html). For more information, visit http://www.aafp.org/news-now/resident-student-focus/20100707dutyhours.html.

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