CMS Sets New Deadline for Implementation of Sunshine Act

According to a provision in the Patient Protection and Affordable Care Act, any gift or payment of more than $10 to physicians from a pharmaceutical or medical device company must be declared publicly. Reporting requirements have been limited to drugs or biologics that require a prescription; over-the-counter (OTC) drugs and Class I and II devices (e.g., tongue depressors, elastic bandages) are excluded. Types of payments to be reported include consulting fees, honoraria, entertainment, education, and charitable contributions. Originally, the Centers for Medicare and Medicaid Services (CMS) had set the implementation deadline for January 1, 2012. CMS has now proposed a rule that would delay the start of mandatory reporting to March 31, 2013, pending timing of the final rule. Once the reports have been submitted, physicians and other entities (e.g., teaching hospitals) have 45 days to review the data and contest any claims they disagree with. CMS is accepting comments on the proposed rule until February 17, 2012. For more information, visit http://www.aafp.org/news-now/government-medicine/20120105sunshinedelayed.html and https://www.cms.gov/apps/media/press/release.asp?Counter=4220.

HHS Adopts First of Electronic Health Care Transaction Standards

In accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the U.S. Department of Health and Human Services (HHS) has adopted the first of a series of standards enabling health information to be exchanged more efficiently and uniformly. These standards are designed to streamline health care administrative transactions, encourage greater use of standards by physician practices and hospitals, and make existing standards function more efficiently. The purpose of the first two new regulations, involving electronic funds transfers and remittance advice transactions, is to initiate operating rules, making it easier for health care professionals to determine whether a patient is eligible for coverage and to monitor the status of health care claims submitted to a health insurer. Once implemented by health plans, these regulations are expected to save physicians and hospitals $3 to 4.5 billion over the next 10 years. Future regulations will address a standard unique identifier for health plans, a standard for claims attachments, and requirements that health plans certify compliance with all HIPAA standards and operating rules. For more information, visit http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4242.

FDA Approves Single Risk Evaluation and Mitigation Strategy for Fentanyl Drugs

The U.S. Food and Drug Administration (FDA) has approved a single shared-system risk evaluation and mitigation strategy (REMS) for the transmucosal immediate-release fentanyl prescription medications. It is the first to cover a complete class of opioids. Starting in March 2012, this program will replace the individual REMS programs currently in place. Those already enrolled in product-specific REMS programs will automatically be transferred to the new program. For physicians prescribing these medications only in an inpatient setting, there is no requirement to enroll in the program. Physicians who want to enroll must review an education program, complete a knowledge assessment, and fill out an enrollment form. According to the FDA, the REMS is intended to mitigate misuse, abuse, addiction, overdose, and serious complications (e.g., preventing inappropriate conversion between fentanyl products, preventing accidental exposure to children and others for whom the drugs were not prescribed) associated with these medications. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20120109tirfrems.html.

Center for the History of Family Medicine Seeks Fellowship Applicants

The Center for the History of Family Medicine has announced its second annual fellowship and is inviting all interested family physicians, other health care professionals, historians, scholars, educators, and scientists to apply. The application deadline is March 30, 2012. The fellowship recipient will receive a grant for up to $1,500 to support travel, lodging, and incidental expenses relating to conducting research on a project that focuses on any aspect on the history of general practice, family practice, or family medicine; its practitioners; and their role in health and health care in the United States. The proposed project must lead to a durable product in any format (e.g., written report, manuscript, CD/DVD, audio or video recording) of the applicant's choosing. The funds will go to the individual rather than the institution where the applicant is employed. For more information, visit http://www.aafp.org/news-now/news-in-brief/20120105wklynewsbrfs.html#NewsArticleParsys69492.

IOM Releases Report on Reducing Risk of Developing Breast Cancer

The Institute of Medicine (IOM) has released a report stating that women can reduce their risk of breast cancer by limiting exposure to certain environmental factors. According to the report, *Breast Cancer and the Environment: A Life Course Approach*, women may be able to lower the risk of developing breast cancer by avoiding unnecessary medical radiation, not using combination estrogen-progestin menopausal hormone therapy, limiting alcohol consumption, maintaining a healthy weight, exercising regularly, and not using tobacco. The report concludes that further research is needed regarding breast cancer prevention. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20111221iomrptbreastca.html.

SAMHSA Releases Report on Admissions to Substance Abuse Treatment Programs

A new report from the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that overall substance abuse treatment admissions among patients 12 years and older remained steady from 1999 to 2009, but that there was a 430 percent increase in admissions for abuse of prescription pain relievers during this period. SAMHSA has released a comprehensive action plan to address this epidemic. The plan includes support for the expansion of state-based prescription drug monitoring programs, more convenient and environmentally responsible disposal methods to remove unused medications from the home, education for patients and health care professionals, and support for law enforcement efforts that reduce the prevalence of pill mills and doctor shopping. For more information, visit http://www.samhsa.gov/newsroom/advisories/1112074117.aspx.

HHS Awards Bonuses for Expansions of State Medicaid and CHIP Coverage

HHS is awarding more than $296 million to states that have expanded health care coverage for children through Medicaid and Children's Health Insurance Programs (CHIPs). To receive funding, states must surpass a specified Medicaid enrollment target and adopt procedures that make it easier for children to enroll and retain coverage. These performance bonus payments are intended to help states offset the costs of enrolling lower-income children. Also, ensuring that the states streamline enrollment and renewal procedures makes it easier for the programs to adopt long-term improvements. For more information, visit http://www.aafp.org/news-now/news-in-brief/20120105wklynewsbrfs.html#NewsArticleParsys69170.

MEDWATCH: Novartis Closes Production Facility, Issues Recall of OTC Medications

Novartis Consumer Health Inc. has shut down its Lincoln, Neb., plant because of manufacturing problems, and has issued a recall of some commonly used OTC medications. Novartis is voluntarily recalling all lots of Bufferin, Excedrin, Gas-X Prevention, and NoDoz after receving reports of chipped and broken pills. The FDA also issued a warning about several opiate products produced at the plant. The recall was prompted by concerns about inconsistent bottle packaging that could result in the bottles containing foreign tablets, caplets, or capsules. The possibility of mixed product in the bottles poses a risk of overdose, adverse interaction with other medications, or allergic reaction. According to the FDA warning, pills, tablets, or caplets of oxycodone and acetaminophen (Percocet), oxycodone and aspirin (Percodan), and seven other opiate medications may have carried over into the packaging of other products. Patients and physicians are advised to examine opiate medications to ensure that all the tablets are the same. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20120111novartisrecall.html and http://www.fda.gov/Safety/Recalls/ucm286240.htm?source=govdelivery.

FDA Alert: Similarity in Drug Names Poses Serious Risk of Injury

The FDA has issued an alert to pharmacists and other health care professionals about the potential for injury caused by confusion between an FDA-approved eye medication, difluprednate ophthalmic emulsion (Durezol), and an unapproved topical salicylic acid wart remover (Durasal). The agency has had one report of serious injury and several cases of confusion between the two drugs, including complaints from health care professionals about the similarity of the drug names. Because Durasal did not undergo the drug approval process, the FDA did not evaluate the name for potential conflicts. The manufacturer has not recalled the product in response to the FDA's inquiry into the risk to patients. For more information, visit http://www.aafp.org/news-now/news-in-brief/20120105wklynewsbrfs.html#NewsArticleParsys29427 and http://www.fda.gov/Drugs/DrugSafety/ucm285235.htm.

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