Agencies Release Final Rules on "Meaningful Use" of EHRs

Two final rules that define and support the "meaningful use" of electronic health records (EHRs) were recently released. One rule, issued by the Office of the National Coordinator for Health Information Technology, identifies the standards and criteria for the certification of EHR technology so that hospitals and physicians will know that the EHRs in which they invest can perform the required functions. A companion rule, issued by the Centers for Medicare and Medicaid Services (CMS), defines the minimum EHR meaningful use objectives that physicians and other professionals must meet to qualify for bonus programs enacted under the American Recovery and Reinvestment Act of 2009. CMS estimates that it may pay out $27 million in incentives during the next 10 years. Physicians can choose to participate in the Medicare bonus program or earn Medicaid incentives. CMS received more than 2,000 comments—including those from the American Academy of Family Physicians (AAFP)—on the proposed meaningful use rule that was issued on January 13, 2010. According to Steven Waldren, MD, director of the AAFP's Center for Health Information Technology, CMS thoughtfully reviewed the comments they received and made significant changes to the regulations. He said CMS addressed the biggest concerns of the AAFP and that family physicians will benefit from many of the changes CMS made. For more information, visit http://www.aafp.org/news-now/practice-management/20100714meaningfuluserule.html.

AAMC Report Gives Guidelines for Managing Conflicts of Interest

The Association of American Medical Colleges (AAMC) released a report that provides guidance on how academic medical centers can identify, evaluate, and disclose conflicts of interest in clinical care. It recommends that teaching hospitals establish policies to manage financial relationships between physicians and industry, and says that specialty societies and professional medical associations have a responsibility to be free of conflicts of interest because of their role in providing continuing medical education and developing clinical practice guidelines. Although the report points out that partnerships between academic medical centers and industry are essential to innovation and create powerful collaborations that benefit patients, it also acknowledges that individual or institutional financial interest in these relationships can create perceived or real conflicts of interests in patient care. The AAMC report was developed by a 20-member task force comprising senior leaders of U.S. medical schools and teaching hospitals. The report is the AAMC's third and final publication on managing financial conflicts of interest. For more information, visit http://www.aafp.org/news-now/professional-issues/20100721aamcconflictrpt.html.

ABFM Announces Further Enhancements to Maintenance of Certification for FPs

This year marks the completion of the staged, seven-year transition of all American Board of Family Medicine (ABFM) diplomates into the new recertification paradigm, Maintenance of Certification for Family Physicians (MC-FP). The ABFM announced it also will introduce major changes to MC-FP beginning in 2011. According to ABFM President and CEO James Puffer, MD, the ABFM continues to seek ways to allow diplomates more flexibility in meeting MC-FP requirements. He said one recent change that has been overwhelmingly well-received is giving ABFM diplomates the option to move from a seven-year to a 10-year MC-FP cycle, and that nearly all diplomates offered this opportunity to date have chosen the 10-year pathway. Currently, either option culminates with the administration of the cognitive examination (Part III). However, the ABFM has determined that the examination need not be given as frequently as in the past. Therefore, beginning with those who certify or recertify in summer 2011, the ABFM will unlink the examination from the MC-FP cycle, and diplomates may take it at any point in the cycle. The results of the examination will be valid for 10 years. In addition, diplomates can choose how to complete their MC-FP Part II and Part IV requirements during each three-year stage of the MC-FP cycle. For more information, visit http://www.aafp.org/news-now/cme-lifelong-learning/20100721mcfpchanges.html.

FDA Expert Panel Members Split on How to Address Rosiglitazone Safety Concerns

Two committees that advise the U.S. Food and Drug Administration (FDA) on medications have voted to recommend that the FDA remove the diabetes mellitus drug rosiglitazone (Avandia) from the market. Rosiglitazone, a member of the thiazolidinedione class of drugs, is manufactured by GlaxoSmithKline. During a joint meeting of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, the majority of

committee members indicated that available data on treatment with rosiglitazone are sufficient to raise serious safety concerns for its risk of ischemic cardiovascular events. Committee members' recommendations were split as to what regulatory action the FDA should take in regard to the marketing or discontinuation of the drug. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100720avandiarec.html and http://www.fda.gov/AdvisoryCommittees/Calendar/ucm214612.htm.

Report Ranks U.S. Last in Health System Performance Among Seven Countries

Despite much greater per capita expenditures on health care, the United States again ranked last overall among seven industrialized countries in measures of health system performance in a new report from the nonprofit Commonwealth Fund. The U.S. health system ranked last or next to last on five performance measures when compared with health systems in Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom. The Netherlands ranked first overall, followed by the United Kingdom and Australia. The measures examined were quality; efficiency; access to care; equity; and the ability for persons to lead long, healthy, productive lives. However, the report said the newly enacted U.S. health care reform law may lead to improvements in these measures, especially in Americans' access to care. For more information, visit http://www.aafp.org/news-now/professional-issues/20100709commonwealthfund.html.

MedWatch: FDA Warns Against Off-Label Quinine Use, Leflunomide Liver Damage

Off-label use of the malaria drug quinine (Qualaquin) has resulted in reports of serious adverse events, including deaths. The FDA has responded by approving a Risk Evaluation and Mitigation Strategy for the medication. From April 2005 to October 1, 2008, the FDA received 38 reports of serious adverse effects associated with its use, and only one of those patients was taking quinine for the treatment of malaria, which is the only FDA-approved use of the drug. Most patients were taking quinine to prevent or treat leg cramps or restless legs syndrome. There were serious and life-threatening reactions in 24 patients, including thrombocytopenia. Some patients had permanent kidney impairment and required hospitalization, and two patients died. The FDA says physicians should discuss the warning signs of thrombocytopenia with patients. In addition, the FDA recently identified 49 cases of severe liver injury—14 of which were fatal—in patients taking the rheumatoid arthritis drug leflunomide (Arava). The FDA responded by adding information about severe liver injury to the boxed warning on the drug's package label. Although many of the patients were taking other drugs associated with liver injury or had preexisting liver disease, the FDA concluded that the use of leflunomide was associated with the development of severe liver injury in the affected patients. The FDA advises physicians to consider leflunomide therapy only for patients in whom the anticipated therapeutic benefit is expected to outweigh the risk of severe liver injury. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100712fdamalaria.html and http://www.aafp.org/news-now/health-of-the-public/20100714leflunomidewarning.html.

MedWatch: McNeil Again Expands Recall to Add 21 Lots of OTC Medications

McNeil Consumer Healthcare has added 21 lots of over-the-counter (OTC) medications to its recall list as a precautionary measure after a review determined that packaging materials used in those lots had been shipped and stored on the same type of wooden pallet as in earlier recalled lots. Their first in a series of recalls was in January 2010, when McNeil recalled more than 500 lots of its OTC products—including Benadryl, Rolaids, Motrin, and Tylenol—after receiving consumer reports of moldy, musty, or mildew-like odor. The odor was linked to trace amounts of 2,4,6-tribromoanisole, a pesticide and flame retardant used to treat the wooden pallets. McNeil said it has stopped accepting shipments of materials from its suppliers on that type of pallet. For more information, visit http://www.aafp.org/news-now/health-of-the-public/20100713newmcneilrecall.html and http://www.mcneilproductrecall.com/page.jhtml?id=/include/news_july.inc.

CMS Creates Online Medicare Enrollment Resources to Help Physicians

CMS is offering guidance to help physicians through the process surrounding new Medicare enrollment requirements. The online resource refers to a "specific set of physicians" who will need to enroll in the Medicare program for the sole purpose of certifying or ordering services for Medicare beneficiaries. The CMS document also answers questions about how to verify current enrollment in CMS' Provider Enrollment, Chain, and Ownership System. For more information, visit http://www.aafp.org/news-now/practice-management/20100720cmsmedicarehelp.html and https://www.cms.gov/MedicareProviderSupEnroll/Downloads/SpecialEnrollmentFactsheetInfrequentPhysicianReimbursement.pdf.

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