News from Federal Health and Medical Agencies

CMS to Make Coverage Determination on CTA

The Centers for Medicare & Medicaid Services (CMS) is considering whether a national coverage determination is warranted for computed tomographic angiography (CTA) to diagnose coronary artery disease.

The agency will also consider coverage with evidence development, it said.

Proponents say the use of cardiac CTA will lead to better health outcomes and a reduction in cardiac catheterization, the current standard for diagnosis of coronary artery disease, according to the CMS. But the agency said it is concerned about the procedure's rapid adoption despite the lack of evidence demonstrating improved patient health outcomes.

The public has until July 13 to submit comments on the agency's national coverage analysis on the use of CT for angiographic study.

CTA is a noninvasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high-resolution, high-speed CT, the agency said. CTA, which includes helical (spiral) CT and multislice CT angiography, has potential uses as a substitute for invasive coronary angiography and for evaluation of chest pain in the urgent care or ED setting. ■

FDA Accepting Comments on Electronic Collection of Adverse Event Forms

The FDA has announced a public comment period on the continuation of a pilot project evaluating the electronic collection of the 3500A form for device adverse events. The project is intended to obtain data from user facilities participating in the Medical Product Safety Network (MedSun).

Additionally, the electronic form will include hospital profile information and several other questions related to the use of medical products. A portion of the MedSun software, called Device Safety Exchange, is a moderated site on which MedSun members may share information with each other.

Written comments must be submitted by Aug. 13. Submit electronic comments on the collection of information to *www.fda.gov/dockets/ecomments.* ■

Online Database of Bioequivalence Study Guidelines Considered

Information on designing bioequivalence studies for various types of products would be available online under a draft guidance issued by the FDA's Office of Generic Drugs.

To receive approval for an abbreviated new drug application (ANDA), a generic drugmaker must prove that the generic product is absorbed at the same rate as the comparator drug (bioequivalence), according to the FDA.

Currently, drugmakers can submit requests for assistance in bioequivalence study design to the Office of Generic Drugs, and the agency responds to individual companies in written form, according to the guidance.

In addition, the FDA recently published a report detailing many of the scientific issues that impede the development of generic drugs, including the need for improved bioequivalence testing methods. ■

Security Update Part of Fed Agenda

The federal government is getting ready to tighten the HIPAA security rule in the wake of several incidents of compromised patient data involving laptops and other mobile computing devices.

The Centers for Medicare and Medicaid Services expects this month to propose a rule "intended to provide a more prescriptive set of remote security requirements designed to reduce the likelihood of unauthorized uses and disclosures of sensitive health information," according to a notice published the *Federal Register*.

The notice is the Department of Health and Human Services' semi-annual agenda identifying regulatory actions it intends to take. Deadlines for anticipated action are not always accurate. The regulatory agenda, however, gives a look at what issues are getting attention in the department.

Amendments to the HIPAA security rule are one of at least a dozen upcoming regulatory actions of interest to the healthcare information technology industry.

The complete regulatory agenda in the *Federal Register* is available at *gpoaccess.gov/fr/index.html.* ■