# ISSUES The

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## ACCC Submits Comments on Proposed Definition of EHR "Meaningful Use"

On Dec. 31, 2009, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) issued two proposed regulations that will help implement the EHR incentive programs enacted under the American Recovery and Reinvestment Act of 2009 (ARRA). The ARRA established programs to provide incentive payments to eligible professionals and eligible hospitals participating in Medicare and Medicaid that adopt and make "meaningful use" of certified EHR technology. Incentive payments may begin as soon as Oct. 2010 to eligible hospitals. Incentive payments to other eligible providers may begin in Jan. 2011.

CMS issued a proposed rule that includes a definition for "meaningful use" of EHR technology. ONC issued an interim final regulation (IFR) that sets initial standards, implementation specifications, and certification criteria for EHR technology. CMS provided a 60-day comment period on the proposed rule.

CMS's proposed regulation defines and specifies how to demonstrate "meaningful use" of EHR technology. "Meaningful use" is a prerequisite for receiving the Medicare EHR incentive payments under the ARRA. The proposed rule also outlines the payment methodologies for the Medicare and Medicaid EHR incentive programs.

The IFR issued by ONC describes the standards that must be met by certified EHR to exchange healthcare information among providers and between providers and patients. The IFR will go into effect 30 days after publication, with an opportunity for public comment and refinement over the next 60 days. A final rule will be issued in 2010.

The proposed rule calls for a phased approach to implement the proposed requirements for demonstrating meaningful use. This approach would initially establish reasonable criteria for meaningful use based on currently available technological capabilities and providers' practice experience. Over time, the agency will establish stricter and more extensive criteria for demonstrating meaningful use.

After careful review, the Association of Community Cancer Centers (ACCC) believes that the proposed meaningful use criteria for Stage 1 are far too ambitious and, therefore, urges CMS to re-examine its plans for Stages 2 and 3. Overall, ACCC believes that CMS needs to have more reasonable expectations with respect to the ability of eligible professionals and hospitals to adopt and meaningfully use certified EHR technology. ACCC submitted its comments to the agency the first week in March. The full comments are available on ACCC's website at: *www.accc-cancer.org.*

In the proposed rule, "meaningful EHR user" is defined as an eligible professional or eligible hospital that, during the specified reporting period, demonstrates meaningful use of certified EHR technology in a form and manner consistent with certain objectives and measures presented in the regulation. These include use of EHR technology in a manner that:

- Improves quality, safety, and efficiency of healthcare delivery;
- Reduces healthcare disparities;
- Engages patients and families;
- Improves care coordination;
- Improves population and public health; and
- Ensures adequate privacy and security protections for personal health information.

The rule proposes one definition for "meaningful use" that would apply to eligible professionals participating

### ACCC Submits Comments to CMS on Proposed NCD on PET to Identify Bone Metastasis

On Dec. 29, 2009, ACCC submitted comments to CMS regarding the proposed national coverage decision (NCD) on positron emission tomography (PET) (NaF-18) to identify bone metastasis of cancer. The agency concluded that NaF-18 PET is "promising," but "the evidence of clinical benefit is not yet conclusive and is not generalizable to the Medicare patient population."

ACCC agreed with CMS that the evidence is promising, but ACCC suggested "that the evidence is sufficient to cover the test as prescribed by physicians, however, without coverage with evidence development (CED). ACCC believes that Medicare should allow patients and physicians to select the most appropriate imaging methods for each patient." ACCC encouraged CMS to cover NaF-18 PET to ensure that patients have a choice of effective imaging modalities.

In its proposed NCD, CMS states, "there is inconsistent evidence that the results of NaF-18 PET scans are used to alter recommended treatment strategy." The agency also reports that it found "no conclusive evidence of improved patient oriented health outcomes related to NaF-18 PET studies for routine follow-up or monitoring of suspected bone metastases, except for the diagnosis of bone metastases in patients with symptomatic evidence of bone pain and with no other imaging findings of bone metastasis."

in the Medicare fee-for-service and the Medicare Advantage EHR incentive programs, as well as a proposed definition that would apply to eligible hospitals and critical access hospitals. These definitions also would serve as the minimum standard for eligible professionals and eligible hospitals participating in the Medicaid EHR incentive program.

### New FDA Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

On Feb. 9, 2010, the FDA announced an initiative to reduce unnecessary radiation exposure from three types of medical imaging procedures: computed tomography (CT), nuclear medicine studies, and fluoroscopy. These procedures have led to early diagnosis of disease, improved treatment planning, and image-guided therapies that help save lives every day. However, like all medical procedures, these procedures pose risks, including exposing patients to ionizing radiation, a type of radiation that can increase a person's lifetime cancer risk. Accidental exposure to very high amounts of radiation also can cause injuries, such as skin burns, hair loss, and cataracts. Healthcare decisions made by patients and their physicians should include discussions of the medical need and associated risks for each procedure. While some disagreement exists concerning the extent of the cancer risk associated with exposure to radiation from medical imaging, there is broad agreement that steps can and should be taken to reduce unnecessary radiation exposure.

The FDA is advocating the adoption of two principles of radiation protection: 1) appropriate justification of the radiation procedure and 2) optimization of the radiation dose used during each procedure. The FDA initiative will promote the safe use of medical imaging devices, support informed clinical decision-making, and increase patients' awareness of their own exposure.

The FDA intends to issue targeted requirements for manufacturers of CT and fluoroscopic devices to incorporate important safeguards into the design of their machines to develop safer technologies and to provide appropriate training to support safe use by practitioners. The agency intends to hold a public meeting on March 30-31, 2010, to solicit input on what requirements to establish.

In addition, the FDA and CMS are collaborating to incorporate key quality assurance practices into the mandatory accreditation and conditions of participation survey processes for imaging facilities and hospitals.

The FDA recommends that healthcare professional organizations continue to develop, in collaboration with the agency, diagnostic radiation reference levels for medical imaging procedures, and increase efforts to develop one or more national registries for radiation doses.

For more information, go to: *www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM199904.*

### CMS Names Three National Organizations to Accredit Suppliers of Advanced Imaging Services

On Jan. 28, 2010, CMS designated three national accreditation organizations—the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and The

Joint Commission (TJC)—to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging procedures. The accreditation requirement will apply only to the suppliers furnishing the imaging services, and not to the physician's interpretation of the images.

MIPPA (Medicare Improvements for Patients and Providers Act of 2008) requires that all suppliers of the TC of advanced imaging be accredited by an accreditation organization designated by the Secretary of Health and Human Services by Jan. 1, 2012. The accreditation requirement applies to physicians, non-physician practitioners, and physician and non-physician organizations that are paid for providing the technical component of advanced imaging services under the Medicare Physician Fee Schedule.

MRI, CT, and PET scans are among the services to be affected. MIPPA excludes certain imaging services from the accreditation requirement, including X-rays, ultrasound, and fluoroscopy procedures. The law also excludes from the CMS accreditation requirement diagnostic and screening mammography, which are subject to oversight by the FDA under the Mammography Quality Standards Act.

CMS will issue further guidance to suppliers about meeting the accreditation requirements and plans to undertake a provider education outreach program. For more information, go to: *www.cms.hhs.gov/medicareprovidersupenroll*.

## FDA Announces New Safety Plan for Agents Used to Treat Chemotherapy-Related Anemia

On Feb. 17, 2010, the FDA approved a risk management program to inform healthcare providers and their patients about the risks of a class of drugs called erythropoiesis-stimulating agents (ESAs). For patients with cancer, the program is also designed to help ensure the appropriate administration of these drugs, which they receive to treat anemia that can occur as a result of chemotherapy.

ESAs, which include epoetin alfa (marketed as Procrit and Epogen) and darbepoetin alfa (marketed as Aranesp), are manufactured by Amgen Inc. In April 2008, the FDA required Amgen Inc. to establish a risk management program based on studies that found that ESAs caused tumors to grow faster and resulted in earlier deaths in some cancer patients. The company's risk management program, referred to as a Risk Evaluation and Mitigation Strategy (REMS), requires healthcare professionals to provide their patients receiving an ESA with a medication guide that explains the risks and benefits of ESAs and how to safely use the ESA.

In addition, the company's ESA APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe Use of ESAs) Oncology Program, which is part of the REMS, requires specific training and certification of healthcare professionals who administer chemotherapy to patients with cancer and counseling of their patients. It does not apply to patients being treated with an ESA for anemia due to other circumstances. The ESA APPRISE Oncology Program will be launched on Mar. 24, 1010. Through the risk management program, Amgen must ensure that healthcare professionals who treat patients with cancer do the following three actions:

- Register and maintain active enrollment in the ESA APPRISE program
- Complete a special training module on how to use ESAs in patients with cancer
- Discuss the risks, benefits, and FDA-approved uses of ESAs with patients who have cancer before beginning a course of ESA treatment and document this discussion with a written acknowledgement from the patient.

Amgen is also required to oversee and monitor healthcare professionals and hospitals that use ESAs for patients with cancer to ensure that these caregivers are fully compliant with all aspects of the overall risk management program. For more on the FDA approval, go to: *www.fda.gov/AboutFDA/CentersOffices/CDER/ucm091745.htm*. For information on Amgen's REMS program log onto: *wwwext.amgen.com/media/amgen_esa_risk_evaluation.html*.

## Study Finds that Medicare Covers Only Half the Cost of Administering Chemotherapy

A comprehensive study of the delivery of modern-day cancer care in community oncology practices revealed that Medicare covers only 56 percent of the actual costs of administering chemotherapy and providing related infusion room services to seniors with cancer. The remaining costs—for essential services such as treatment planning, care coordination, and follow-up care planning—are not reimbursed by Medicare, causing many oncology practices to struggle to continue to provide care under the Medicare program.

The study by Avalere Health, a strategic healthcare advisory firm, collected detailed qualitative and quantitative data from 76 community oncology practices across the nation, representing 499 oncologists, in order to quantify the full range of services performed by community oncology practices, including those currently reimbursed by Medicare and private insurers, as well as many of the services that are unrecognized and thus uncompensated by payers. The study includes data regarding the time physicians and staff spend on each component of care, as well as financial information about the actual capital and expense costs necessary for operating a community oncology practice.

In addition to underpayments for chemotherapy infusion-related services reported in the study, the average oncology practice reported annual bad debt of $500,178.

Medicare has already severely cut payments for cancer drug infusion room services—over 25 percent since 2004. In addition, CMS will implement even more cuts, reducing payment for drug infusion room services an additional 5 percent annually, up to 20 percent by 2013. Other cuts have been made for cancer diagnostic imaging and physician consultation services.