CMS Creates MedCAC from MCAC

The Centers for Medicare & Medicaid Services (CMS) announced on December 13 that the Medicare Coverage Advisory Committee (MCAC) has been rechartered through 2008 and that the agency has updated the committee's role in the Medicare national coverage process. The new charter redesignates the group as the Medicare Evidence Development & Coverage Advisory Committee (MedCAC). MedCAC now has an explicit responsibility to advise CMS as part of its "coverage with evidence development" (CED) activities. The CED initiative involves the issuance of national coverage determinations that include, as a condition of payment, requirements for developing additional clinical data on specific medical technologies, including clinical indications for PET and other molecular imaging technologies.

"We see enormous potential in working with the MedCAC to expand the coverage process to include additional data collection that will ensure appropriate provision of care, while also developing data of direct clinical relevance to Medicare beneficiaries and the doctors who treat them," said Acting CMS Administrator Leslie V. Norwalk, Esq. "And by renaming the Committee the MedCAC, we are acknowledging its new role in our evidence development initiatives."

The new charter also formalizes the permanent role of patient advocates on the committee. Since 2005, each committee meeting has included a patient advocate as a voting member on each expert panel. As permanent members, these advocates now will identify issues most important to patients, communicate patient perspectives, and vote on the committee's recommendations.

CMS has relied on the expertise of this committee since 1998 to develop recommendations about specific issues of Medicare coverage and to review and comment upon proposed or existing Medicare coverage policies. The Committee consists of up to 100 appointed members, who are selected for their expertise in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, medical ethics, and other related disciplines. Up to 88 members are at-large standing voting members, with 12 nonvoting members (6 representing consumer interests and 6 representing industry interests). The Committee reviews and evaluates medical literature and technology assessments and examines other available data and information on the effectiveness and appropriateness of medical items and services under evaluation at CMS. The Committee conducts several public meetings each year to review the submitted evidence, listen to testimony, deliberate, and provide CMS with recommendations as to the strength of the evidence reviewed.

To accompany the changes in the MedCAC charter, CMS issued a guidance document, *Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee*, available at www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=10. Details about the newly renamed and rechartered committee are available at www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf.

Centers for Medicare & Medicaid Services

NIH Licensing Opportunities for Rare Disease Technologies

The National Institutes of Health (NIH) launched a new Web site on December 11, offering technologies available for commercial licensing that are related to rare diseases or conditions. The listing can be found at www.ott.nih.gov/rarediseases and currently consists of more than 500 such technologies, including drugs, biologics, and devices, available to be transferred from the NIH and the U.S. Food and Drug Administration (FDA) to the private sector for further research and development and potential commercialization.

The new resource was developed by the Office of Rare Diseases (ORD) and the Office of Technology Transfer (OTT) at NIH. "By making it much easier for pharmaceutical companies and academic institutions to identify licensing opportunities, this new site will help facilitate the transfer of research advances from bench to bedside where the interventions can ultimately benefit patients," said NIH Director, Elias Zerhouni, MD.

A rare disease is defined as one with prevalence less than 200,000 in the United States. An estimated 25–30 million people in the United States have one of the more than 6,500 diseases classified as rare. Although technically "rare," some of these diseases are familiar, such as meningitis and amyotrophic lateral sclerosis. Stephen Groft, PharmD, Director of ORD, explained that, "Because relatively few people are affected by any one rare disease, finding therapies for each poses unique challenges and requires innovative approaches." He added, "We're excited about this new mechanism to foster collaboration with the private sector and the potential to make a real difference for patients."

The Web site module was designed to provide a more collaborative, consolidated, and systematic approach to the development of products for rare diseases and conditions. "In addition to the technologies already available on the site, we encourage not-for-profit organizations, academic research centers,

and foundations in the U.S. and abroad to submit technologies available for licensing from their institutions," said Mark Rohrbaugh, PhD, JD, Director of OTT. Parties interested in licensing will be directed to the institution owning the technology. More information about submitting additional technologies can be found at www.ott.nih.gov/rarediseases/submit.

National Institutes of Health

Proposed Changes to Radiology Resident Education

Writing in the January issue of the *American Journal of Roentgenology* (2007;188:3–4), David B. Larson, MD, of the University of Colorado at Denver Health Sciences Center, reviewed proposed major revisions to the Program Requirements for Diagnostic Radiology Resident Education as detailed by the Diagnostic Radiology Residency Review Committee (RRC) of the Accreditation Council for Graduate Medical Education (ACGME). The 11-member Diagnostic Radiology RRC is made up of representatives from the American Board of Radiology (4 members), the American College of Radiology (3 members), and the American Medical Association (3 members), and has 1 resident member. The RRC issued its proposed changes on October 26, with an effective date of July 1, 2007. The 25-page document containing the proposed revisions can be viewed at the ACGME Web site at www.acgme.org/acWebsite/reviewComment/rev_420pr10_26_06.asp.

Larson discussed varying and divergent viewpoints about the most significant proposed changes. Among these changes are:

- A requirement for 12 months (rather than the current 6 months) of training before taking independent call ("making an interpretation available to patient care providers prior to review of the examination by faculty or senior resident").
- A change in the wording of the requirement for radiologic/pathologic education to include this training in a bulleted list of 9 general didactic content items that include such topics as "appropriate imaging utilization", "fundamentals of molecular imaging", and "professionalism and ethics". This change in wording is viewed by some as a threat to the viability of the radiologic pathology course at the Armed Forces Institute of Pathology in Washington, DC.
- Several changes are targeted at more carefully tracking residents' educational progress, bolstering resident scholarly activity, and increasing residents' accountability. These also include new requirements about institutional teaching file maintenance, the structure of the didactic curriculum, and the availability of Internet access to major journals.
- The current 1-to-1 faculty-resident ratio requirement would be removed and changed to a requirement for at least 1 full-time subspecialty-trained faculty member for each of the 9 major subspecialties.

Of special note to Newsline readers are enhanced requirements for education in nuclear medicine, with most changes pertaining to additional education in radionuclide safety, as recently mandated by the Nuclear Regulatory Commission.

The entire 25-page document containing the proposed revisions can be viewed at the ACGME website at the following address: www.acgme.org/acWebsite/reviewComment/rev_420pr10_26_06.asp.

Accreditation Council for Graduate Medical Education
American Journal of Roentgenology

Extended Hours Tied to Errors for Medical Trainees

First-year doctors-in-training reported that working 5 extra-long shifts (≥24 hours without rest) per month led to a 300% increase in the chance of making "fatigue-related, preventable adverse events that contributed to the death of a patient" according to a study published online in the December issue of *PloS Medicine*. The study, by Barger et al. from the Brigham and Women's Hospital and Harvard Medical School (Boston, MA), was funded by the Department of Health & Human Services Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health.

The study carries significant implications for the way first-year residents/interns are trained in the United States. Unlike previous studies on interns and fatigue that have suggested but not proven a link between work hours and medical errors, this study had a sufficiently large sample size to demonstrate that the rate of preventable adverse events grows when interns work shifts of 24 or more hours. According to the study, interns were 3 times more likely to report at least 1 fatigue-related preventable adverse event during months in which they worked between 1 and 4 extended-duration shifts. In months in which they worked more than 5 extended-duration shifts, the doctors were 7 times more likely to report at least 1 fatigue-related preventable adverse event and were also more likely to fall asleep during lectures, rounds, and clinical activities, including surgery. "Given the number of extended-duration work shifts that interns routinely put in, these findings are very troubling," said AHRQ Director Carolyn M. Clancy, MD. "These findings underscore the urgency of focusing on both high-quality learning and high-quality patient care."

Laura Barger, PhD, the study's first author, and her colleagues analyzed the results of a national, Web-based survey in which 2,737 first-year residents/interns completed 17,003 monthly reports. Researchers assessed the association between the number of extended-duration shifts worked in the month and the reporting of significant medical errors, preventable adverse events, and attentional failures. The findings are significant because, although the total hours of work are now capped for first-year residents/interns, guidelines for graduate

medical education in the United States still allow up to 9 "marathon" shifts (up to 30 hours each) per month. "It is clear that sleep deprivation takes its toll over time on physicians," Barger said. "While tradition holds that forcing young doctors to work extended-duration shifts teaches them to become better doctors, the evidence shows that this method of education is dangerous to patients." The study builds on previous research and the growing awareness that sleep-deprived interns working 24-hour shifts make many more serious medical errors while working in intensive care units and crash their cars more often than those whose work is limited to 16 consecutive hours; that most interns are working hours that exceeded the limits of a 2003 national standard implemented by the Accreditation Council for Graduate Medical Education; and that interns are more likely to injure themselves mistakenly with a needle or another sharp instrument when working in a hospital more than 20 consecutive hours or at night.

"Considered as a whole, the evidence demonstrates that academic medicine is failing both doctors and patients by routinely requiring exhausted doctors to work marathon 30-hour shifts. The human brain simply does not perform reliably for 30 consecutive hours without sleep." said Charles A. Czeisler, MD, PhD, senior author of the study.

Agency for Healthcare Research and Quality

House Adjourns Without Acting on CARE Bill

The U.S. House of Representatives adjourned in the predawn hours of December 9 without taking action on the Consumer Assurance of Radiologic Excellence bill. The bill, S.2322 (Senate version), supported by 18 cosponsors, passed the full Senate on December 6 as part of a unanimous consent calendar. The House bill, H.R.1426, netted 134 cosponsors with 31% of the House endorsing the bill. This is the closest to full passage that the legislation has come in the 4 previous sessions of Congress. Despite the best efforts of members of the Alliance for Quality Medical Imaging and Radiation Therapy—a coalition of 20 participating organizations focused on medical imaging and radiation therapy and representing more than 350,000 members—time ran out before the bill could come to a vote in the House. The Alliance was started in 1998 by the American Society of Radiologic Technologists (ASRT) and SNMTS. Each organization in the Alliance has pledged to support the initiative to establish nationwide education and credentialing standards for medical imaging and radiation therapy professionals.

"It all came down to the short amount of time left for the House to take action," said Christine Lung, ASRT director of government relations. "The House received the Senate version of the bill less than 72 hours before it adjourned, on top of an agenda that was already overflowing. It's important to note that the bill moved through the Senate unanimously. That leaves us very well positioned when we reintroduce the bill next year. Lawmakers understand the need to set standards for medical imaging and radiation therapy personnel."

The Aliance planned to reintroduce the CARE bill when the 110th session of Congress convened in January. Lyn Mehlberg, BS, CNMT, chair of the SNMTS Advocacy Committee, said, "We should be proud of our collective efforts and of the milestones achieved by the CARE/RadCARE legislation in the 109th Congress. I would like to thank everyone who supported the CARE/RadCARE bills and personally worked toward this initiative. We need everyone's full support to make the CARE/RadCARE legislation a reality in 2007."

American Society of Radiologic Technologists

Society of Nuclear Medicine

FDA Proposes Overhaul of Regulations on Experimental Drugs

The Food and Drug Administration (FDA) announced on December 11 a proposal for significant regulatory changes to make experimental drugs more widely and easily available to seriously ill patients with no alternative treatment options and to clarify the charges that manufacturer can make for such drugs. Under the proposed rule, expanded access to experimental drugs would be available to individual patients, small patient groups, and larger populations under a treatment plan when there is no satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. "This proposed reform is carefully designed to balance several objectives," said Dr. Andrew C. von Eschenbach, Acting FDA Commissioner. "One goal is to enable many more patients who lack satisfactory alternatives to have access to unapproved medicines, while balancing the need for safeguarding the individual patient. Another equally important goal is to ensure the continued integrity of the scientific process that brings safe and effective drugs to the market."

"FDA hopes this proposal will increase awareness in the healthcare community of the range of options available for obtaining experimental drugs for seriously ill patients," added Dr. Janet Woodcock, FDA's Deputy Commissioner for Operations. "By clarifying and streamlining the processes, FDA also hopes to encourage companies to make such drugs available, and reduce barriers for health care practitioners in obtaining them."

FDA has allowed many types of access to experimental therapies since the 1970s, including, among other programs, those governed by Investigational New Drug (IND) regulations. However, the existing regulations did not adequately describe the full range of programs available, explicitly recognizing only emergency use for individual patients and widespread treatment use access for large groups of patients. According to a press release about the proposed changes, the FDA "believes it is important that its regulations clearly reflect the full range of treatment use programs available to ensure broad and equitable access to experimental drugs

for treatment use." The regulations covering charges for an experimental drug also required revision because they "fail to account for the full range of circumstances in which charging should be permissible and because they have proven difficult to interpret in practice, resulting in confusion over what costs could be recovered." The proposal would revise the current regulation regarding manufacturers' recovery of the costs of an experimental drug to clarify that such charges are permissible in a clinical trial only to facilitate development of drugs that promise significant advantages over existing therapies and might not otherwise be developed because of their high cost, and to clarify that allowing charging for treatment use of an experimental drug is intended to facilitate and encourage access to drugs that might not be made available for treatment use unless a manufacturer is able to recover its costs. The proposal also would simplify the cost recovery calculation by making clear that charges for an experimental drug used in a clinical trial may include only direct costs associated with the drug's development and that charges for experimental drugs for treatment use may also include administrative costs of making the drug available for intermediate patient populations and under large-scale treatment INDs.

The proposed rules, which will remain open for comment until mid-March, are described in detail at www.fda.gov/cder/regulatory/applications/IND_PR.htm.

U.S. Food and Drug Administration