CMS Activates CPT Codes, Discontinues G Codes for PET

The Centers for Medicare & Medicaid Services (CMS) announced in February activation of the adoption of Current Procedural Terminology (CPT) codes for PET procedures, essentially discontinuing previously used G series Healthcare Common Procedure Coding System (HCPCS) codes. This change will be implemented April 4, will be retroactive to January 30, and will activate 3 cardiac, 2 brain, and 6 (new this year) tumor PET CPT codes for patients covered by CMS programs.

SNM President Mathew L. Thakur, PhD, hailed this action as "the first in a series of steps toward a more uniform coding system for all PET procedures." He said, "SNM has long believed that the continued use of G series HCPCS codes is administratively burdensome, creating complicated charge description masters and often requiring different codes for different payers for the same study." SNM has strongly advocated the use of CPT codes and submitted recommendations in a series of letters to CMS representatives. "CPT codes describe the PET procedures based on the resources used," agreed SNM President-Elect Peter S. Conti, MD, PhD. G codes primarily represent the indications for the uses of PET in patients for oncologic, cardiac, and neurologic diseases, whereas CPT codes represent the procedures themselves and are not tied to a specific indication. Conti, who chairs the SNM PET Center of Excellence, also noted, "While this action directly impacts physicians and physician offices, the policy decision affects all providers of PET services."

The CMS action, published as Change Request 3726, is the first of several anticipated clarifying policy statements on eliminating G codes and moving to CPT codes. The memo included the relative value units for physician services (–26) previously assigned to the CPT PET codes by CMS but did not address other reimbursement issues, such as payment for technical services.

The 53-page CMS change request, posted at www.cms.hhs.gov/manuals/pm_trans/R475CP.pdf, lists the code changes. At Newsline press time, CMS was expected to post a related Medlearn Matters provider education article online (www.cms.hhs.gov/medlearn/matters) to provide additional information on this coding issue.

Society of Nuclear Medicine

Media Cover DOE Nuclear Medicine Cuts

Under the banner headline "Nuclear Medicine Funds to Disappear Under Plan," *Newsday* writer Jamie Talan reported on March 2 on proposed budget cuts to nuclear medicine research by the U.S. Department of Energy (DOE). The author detailed the cuts, which would eliminate DOE funding of nuclear medicine research at 23 universities and 4 labs, with funding dropping from $37 million to less than $13 million in 2005 and be entirely eliminated thereafter. "We judged that the DOE was not the appropriate place for research on nuclear medicine," budget office spokesman Noam Nuesner told *Newsday*. He said the National Institutes of Health (NIH) "would be a better source." But NIH has also been hit by budget cuts and has been further constrained by increased obligations to support research related to homeland security issues.

The effects, noted *Newsday*, could be "devastating." Thomas Budinger, PhD, head of nuclear medicine and functional imaging at the Lawrence Berkeley National Laboratory (Berkeley, CA) noted that his lab would lose more than $2 million in funding for the first year. "I'm struggling now to cover that loss," he said. "This is a shock to all of us." Newsday also spoke with Joanna Fowler, PhD, director of Brookhaven's Center for Translational Neuroimaging and a frequent *Journal of Nuclear Medicine* and Newsline contributor. She said, "We need funding to take this technology into the future."

Newsday

NRC to Amend Fees

The Nuclear Regulatory Commission (NRC) announced on February 22 a proposal to amend its regulations for the licensing, inspection, and annual fees it charges applicants and licensees for fiscal year (FY) 2005. The agency is required by Congress to recover for the Department of the Treasury 90% of its appropriated budget through 2 types of fees: hourly fees for NRC services that apply to a specific license and annual fees paid by all licensees (covering generic regulatory expenses and other costs). The total amount to be recovered in FY 2005 is $540.7 million, a portion of which is recouped through annual adjustments.

Under the proposed rule, hourly rates would rise to $198 for the Nuclear Materials and Waste Safety Program. Although some annual fees have been reduced, most material users fees would rise. Categories of licenses and new fees that affect nuclear medicine-related activities include: test and research reactors (nonpower reactors), $54,400; materials users, $4,300; radiographers, $12,800; and gauge users, $2,500.

Nuclear Regulatory Commission

Former DOE Worker Screening Program Expanded

U.S. Secretary of Energy Samuel W. Bodman announced on February 9 the addition of 9 medical screening centers as part of the Department of Energy (DOE) Former Worker Medical Screening Program. Under this expansion, the program will offer all former DOE employees, contractors, and subcontractors free medical examinations to determine whether possible exposure to harmful substances, including radioactive materials, resulted in subsequent illness. The fiscal year 2005 budget provided $12.5 million for the operation of 10 screening centers around the country. The latest action adds the 9 additional sites and creates a toll-free number (888-580-1746) to guide former workers who do not live near a regional center or who prefer to see a personal physician through the program.

New clinics will be established for former employees of the following facilities: Lawrence Berkeley National Laboratory (Berkeley, CA); Lawrence Livermore National Laboratory (Livermore, CA); Sandia National Laboratory (Albuquerque, NM); Ames (Ames, IA); National Nuclear Security Administration (Kansas City Plant; Kansas City, MO); Mound Closure Project (Miamisburg, OH); Fernald Closure Project (Fernald, OH); Brookhaven National Lab (Upton, NY); and the Pinellas Project (Pinellas, FL). Clinics currently serving former workers of the following facilities include: Hanford Project (Richland, WA); Idaho National Lab (Idaho Falls, ID); Nevada Test Site (near Las Vegas, NV); Rocky Flats Closure Project (Golden, CO); National Nuclear Security Administration's Pantex Plant (near Amarillo, TX); Paducah Gaseous Diffusion Plant (Paducah, KY); Portsmouth Gaseous Diffusion Plant (Portsmouth, KY); Oak Ridge Operations (Oak Ridge, TN); Savannah River Site (Aiken, SC); and the Iowa Army Ammunition Project (Middletown, IA)

U.S. Department of Energy

Research Protection Assurances Simplified

The U.S. Department of Health and Human Services (HHS) on February 9 released a new and simplified mechanism for all research institutions that receive HHS funding or support to obtain an assurance of compliance with HHS regulations for the protection of human subjects. A single Web-based "Federalwide Assurance" (FWA) will replace the several types of assurances under which research institutions had operated in the past. "We are pleased to provide this robust and flexible simplification to our assurance system," said Bernard A. Schwetz, DVM, PhD, director of the Office for Human Research Protection. "It reduces the burden of regulatory compliance while strengthening the research community's ability to focus on protections for research subjects."

Almost all federal departments and agencies that conduct or fund human subject research adhere to the Federal Policy for the Protection of Human Subjects, a set of identical regulations adopted by 16 departments and agencies in 1991 that is known informally as the "Common Rule." The Common Rule is based on the HHS regulations in force since 1974 and requires that federally supported research involving human subjects be covered by an assurance. Common Rule agencies will now have the option of using or directing their grantees to use the HHS FWA rather than operating their own assurance systems. A majority of the agencies are expected to rely on the FWA.

Because of the multiple types of assurances in current use, HHS will allow research institutions to transition to the new system over the next 11 months. By December 31, 2005, all institutions conducting HHS-funded human subjects research must hold an FWA approved by the HHS Office for Human Research Protections (OHRP). For more information, visit the OHRP assurance Web page at www.hhs.gov/ohrp/assurances/assurances_index.html.

U.S. Department of Health and Human Services

New NCI Gene Expression Database

Researchers at the National Cancer Institute (NCI) described in a press release on March 1 the creation of the largest open-source gene expression database for normal tissue from human organs. "Genes identified by the database as abnormally active in a particular disease could become potential targets, guiding researchers to better candidates for new drug therapies, immune-based vaccine treatments, and potential biomarkers to help with diagnosis," explained Javed Khan, MD, chief of the Oncogenomics Section of NCI's Pediatric Oncology Branch.

"These data give investigators a baseline against which to compare gene expression data obtained from tumor or other disease specimens, and should be a valuable resource for the research community," said James Jacobson, PhD, acting branch chief of the Diagnostics Research Branch in NCI's Division of Cancer Treatment and Diagnosis

The normal organ database will enable scientists and clinicians to compare gene expression results for their own tissue or genes of interest with a baseline standard that represents a generic picture of normal gene activity, organ by organ, in the human body. The new Web site contains expression profiles for 18,927 genes, which include most of the genes known to help direct basic activities of the human body.

The press release accompanying the debut of the site noted that the Human Genome Project has revealed that the total number of human genes (20,000–25,000) is much lower than previously assumed and that only a fraction of these—perhaps 10,000

genes—are actively transcribed in normal cell processes. The new database takes on the important task of "characterizing this essential backdrop." This is the first publicly available, normal human organ database to draw from so many tissue samples (158) or include samples of tissue from multiple organs and from different parts of the same organs. The very large cDNA microarray has more than 42,000 detectors built into 2 chips using verified cDNA libraries upon which many other researchers currently rely.

To illustrate the kind of useful data that can emerge from using this tool, Khan's team analyzed 100 samples of neuroblastoma. Despite the fact that the tumor samples were taken from a variety of patients with different stages of cancer, the database kicked back a list of 19 genes that were consistently overexpressed compared with normal brain tissue.

The database is available at http://home.ccr.cancer.gov/oncology/oncogenomics/, and a study validating the database was published in the March 2005 issue of *Genome Research* (2005;15:443–450).

National Cancer Institute

Joint NCI–FDA Fellowship Program Announced

In preparation for the new generation of molecular-based oncology medical products, the National Cancer Institute (NCI), part of the National Institutes of Health, and the Food and Drug Administration (FDA) announced on February 16 the creation of an NCI–FDA Research and Regulatory Review Fellowship program. The program, initiated by the joint Interagency Oncology Task Force, is designed to train a cadre of researchers to bridge the processes from scientific discovery through clinical development and regulatory review of new oncology products. Fellows will work and train primarily at FDA's offices and laboratories in the metropolitan Washington, DC, area and will learn first-hand about the regulatory requirements that must be built into the early stages of medical product development. "As new therapies are developed using the latest breakthroughs, fast progress requires that researchers understand the safety and effectiveness questions that regulators must ask, and that reviewers understand the critical details of the latest science," said Acting FDA Commissioner Dr. Lester M. Crawford. "This cross-fertilization of FDA and NCI will be invaluable in helping move the next wave of promising cancer-fighting agents through the development pipeline."

The fellowships are viewed as part of a pilot program and as a possible model for future training programs. The NCI–FDA Research and Regulatory Review Fellowships will consist of 4 different programs, each with its own curriculum: (1) Clinical Oncology Product Research/Review for Oncology Fellows (designed for MDs or MD/PhDs); (2) Clinical Oncology Product Research/Review for Board-Certified Oncologists; (3) Oncology Product Research/Review Fellows (designed for MDs, PhDs or MD/PhDs); and (4) Cancer Prevention Fellows (designed for MDs, PhDs,or scientists with equivalent doctoral degrees).

For more information about the NCI–FDA Research and Regulatory Review Fellowship program, see http://iotftraining.nci.nih.gov.

National Cancer Institute
Food and Drug Administration

Bone Quality Assessment Meeting Scheduled

The National Institute of Arthritis and Musculoskeletal and Skin Diseases and the American Society for Bone and Mineral Research, with cosponsors from the National Institute of Biomedical Imaging and Bioengineering and the French Institute of Health and Medical Research, will be offering a scientific meeting and symposium on "Bone Quality: What Is It and Can We Measure It?" on May 2 and 3 in Bethesda, MD. Topics to be covered by internationally recognized experts in the field will include identification of needs and future directions in this area; basic science, clinical, regulatory, and pharmaceutical perspectives; assessment of which established and newly developed methodologies for measurement of bone fragility are ready for inclusion into large clinical trials and ways to facilitate their inclusion; and discussion of "novel" mechanisms to bring together research efforts on bone quality to move the field forward.

For more information, see the meeting Web site at www.asbmr.org/bonequality.cfm.

National Institute of Biomedical Imaging and Bioengineering

Bangladesh Nuclear Medicine Conference

The opening ceremony of the 10th National Conference and International Symposium of the Bangladesh Society of Nuclear Medicine highlighted the ways in which previously out-of-reach medical technologies are being made accessible here and in other developing nations. "Poor people are getting free services from the country's nuclear medicine centers, and the government is going to set up a new center at Rangamati district to help the poor community of that area get services for free," said Dr. Abdul Moyeen Khan, MP, Bangladesh Minister for Science and Information and Communication Technology. Kamaluddin Ahmed, a former member of the Bangladesh Atomic Energy Commission (BAEC) and a special guest at the symposium, said, "BAEC is providing services to the people of the country through the Nuclear Medicine Institute as well as its 14 centers. Poor people are getting services free of cost and only a token amount is charged from the other patients, in spite of the fact that these tests and treatment procedures are rather costly because of the expensive instruments and radioisotopes."

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He added that many patients who previously might have gone outside the country for nuclear medicine diagnostic and therapeutic procedures now opt to remain in Bangladesh. Experts from Japan, Singapore, and India also attended the symposium, which was held at the Dhaka Sheraton Hotel.

Society of Nuclear Medicine, Bangladesh

Stokes, Lithium Pioneer, Dies

Peter E. Stokes, MD, a Cornell Medical College endocrinologist and psychiatrist and a pioneer in the use of lithium to treat manic depression, died January 22 at St. Luke's-Roosevelt Hospital Center in New York City. In addition to his work in psychiatry, Stokes also trained in neuroendocrinology and nuclear medicine.

In 1965, at the Payne Whitney Clinic in Manhattan, Stokes and colleagues began their work on the effects of lithium salts in controlling bipolar disease and manic depression, publishing positive results in *The Lancet* in 1971, a year after U.S. Food and Drug Administration approval. He also published early studies on neurotransmitters, brain deoxyglucose uptake in animal models, and selective serotonin reuptake inhibitors in the treatment of depression.

Stokes was born in Haddonfield, NJ, attended Trinity College, and earned his medical degree from Cornell in 1952. He was appointed an instructor in medicine at Cornell Medical College in 1957 and remained there for his entire career, retiring as an emeritus professor of medicine and psychiatry in 1998.

New York Times

(Continued from page 19N)

- Publication of education-focused articles; and
- Conduct of education-focused research.

The Outstanding Technologist Award seeks to acknowledge an SNMTS member who has demonstrated outstanding service and dedication to the field and who has exhibited commitment to advancing nuclear medicine technology in his or her workplace and through involvement with the Society. Nominees must be involved with the Society at the local, regional, and/or national level and have at least 5 years of experience in nuclear medicine technology. Some of the characteristics that define an outstanding technologists may include:

- Contributing significantly to the profession as a leader;
- Receiving local, national, or international recognition;
- Enhancing the image of nuclear medicine technologists in the workplace, for the Society, and/or elsewhere;
- Mentoring others to make an impact on the field;
- Conducting and publishing original research; and
- Exemplifying excellence in patient care.

Applications for both awards are now being accepted and must be received at SNM headquarters by April 15 to be considered for 2005. For more information and application materials, see www.snm.org/grants.