Update on CMS MPFS and Policies

On January 3, the SNM Government Relations staff published an in-depth update on the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2011, including information on a December 31 emergency update to the CY 2011 MPFS database amending MPFS policies, payment indicators, relative value units (RVUs), and payment rates. Of special importance was CMS publication of an updated Conversion Factor for CY 2011 at $33.9764, down 8% from CY 2010.

The SNM release summarized important final CMS policies affecting nuclear medicine, including: the Medicare Sustainable Growth Rate; physician work RVUs; practice expenses; malpractice RVUs for new and revised services; rolling 5-y review criteria; expanded Multiple Procedure Payment Reduction; payments for drugs, contrast agents, and biologicals; payments for radiopharmaceuticals; and information on the Physician Quality Reporting System. The complete press release is available at: www.snm.org/index.cfm?PageID=10283.

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Conditional Nod to Florbetapir

On January 20, in a unanimous decision, the U.S. Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs Advisory Committee voted to conditionally recommend approval of Amyvid (florbetapir), the Eli Lilly PET imaging agent for detecting β-amyloid plaque as a clinical marker for potential early-stage diagnosis of Alzheimer disease. The committee had previously voted to reject the application because available data "did not warrant approval." The final conditional approval recommendation included stipulations that a training program be made available for readers of PET images acquired with Amyvid to reduce inconsistent interpretations. The FDA may or may not accept the recommendation. Amyvid is the first β-amyloid imaging compound to be studied in multicenter, investigational new drug clinical studies in the United States and was originally developed by Avid Radiopharmaceuticals, acquired by Eli Lilly in December 2010. Other clinical studies are currently being carried out in Europe, South America, Australia, and Asia.

On January 20 SNM released a statement including praise from molecular imaging leaders for the FDA's recommendation on florbetapir. "For many years, the in vivo diagnosis of Alzheimer's disease has been a process of exclusion of other disorders that may affect cognition," said Karl Herholz, MD, president of the SNM Brain Imaging Council. "Now, for the first time, PET scans utilizing florbetapir will provide disease-specific *inclusion* criteria in the in vivo diagnosis of the disease."

"This recommendation of florbetapir is a huge step forward for the field of molecular imaging," noted Carolyn J. Anderson, PhD, president of the SNM Center for Molecular Imaging Innovation and Translation. "Researchers are continually working to advance the adoption of emerging molecular imaging technologies and probes in preclinical and clinical applications. It's wonderful to see molecular imaging playing such an important role in the molecular characterization of Alzheimer's disease. We are hopeful that this sets the stage for the approval of the many other molecular imaging agents for cancer, cardiovascular disease, and other neurological diseases that are currently in clinical trials." The press release noted that SNM and its Brain Imaging Council, in collaboration with other professional societies, are committed to developing PET imaging procedure guidelines and diagnostic scan interpretation educational tools to ensure that nuclear medicine physicians and radiologists will be proficient in performing and interpreting PET imaging in the diagnosis of Alzheimer disease.

U.S. Food and Drug Administration
SNM

NM Tech Programs Enrollment Up

The American Society of Radiologic Technologists (ASRT) released on January 20 the results of a survey indicating that although the number of first-year students enrolled in radiologic technology programs decreased for the third year in a row, nuclear medicine technology programs saw a 5.3% increase in 2010. The report, *2010 Enrollment Snapshot of Radiography, Radiation Therapy, and Nuclear Medicine Technology Programs*, was compiled from the results of an e-mail survey of more than 1,000 directors of programs listed by the American Registry of Radiologic Technologists. Survey results indicated that an estimated 15,948 radiography students, 1,462 radiation therapy students, and 1,534 nuclear medicine technology students enrolled in educational programs in 2010, representing a 4.8% decrease for radiography programs and a 2.9% decrease for radiation therapy programs compared with 2009 numbers.

Survey results noted that these training programs remain popular: a total of 18,012 qualified students were turned away because program directors limited enrollment or programs were at full capacity. However, 56% of radiography programs, 51% of radiation therapy programs, and only 21% of nuclear medicine programs reported being at full capacity. "Radiologic science programs seem to be responding to the low vacancy rate in the current job market by decreasing enrollment numbers," said Myke Kudlas, MEd, RT, ASRT chief academic officer. "In addition, with the number of qualified candidates applying, programs can be more selective in who they admit."

Survey results also indicated that nearly 82% of radiography students, 77% of radiation therapy students, and 71% of nuclear medicine technology

students were able to obtain employment in their respective disciplines within 6 mo of graduating in 2009. The report, which is available at www.asrt.org/Media/pdf/Research/EnrollmentSnapshot10.pdf, also included a summary of longitudinal enrollment trends from 2001 to 2010.

American Society of Radiologic Technologists

FDA Medical Device Review Path

The U.S. Food and Drug Administration (FDA) on January 18 released the details of a plan containing 25 actions to be implemented during 2011 to improve the 510(k) process, the most common path to market for medical devices. Key actions will include: streamlining the "de novo" review process for certain innovative, lower risk medical devices; clarifying when clinical data should be submitted in a premarket submission; and establishing a new Center Science Council of senior FDA experts to ensure timely and consistent science-based decision making. These actions will result in "a smarter medical device program that supports innovation, keeps jobs here at home, and brings important, safe, and effective technologies to patients quickly," said Jeffrey Shuren, MD, JD, director of the FDA Center for Devices and Radiological Health. Additional information is available at: www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm.

U.S. Food and Drug Administration

Cancer Costs to Top $158 Billion in 2020

Based on growth and aging of the U.S. population, medical expenditures for cancer in the year 2020 are projected to reach at least $158 billion (in 2010 dollars)—an increase of 27% over 2010, according to a National Institutes of Health analysis released online in the January 19 issue of the *Journal of the National Cancer Institute*. If newly developed tools for cancer diagnosis, treatment, and follow-up continue to be more expensive, medical expenditures for cancer could reach as high as $207 billion, according to the study's authors. Projections were based on the most recent data available on cancer incidence, survival, and costs of care. In 2010, medical costs associated with cancer were projected to reach $124.6 billion, with the highest costs associated with breast cancer ($16.5 billion), followed by colorectal cancer ($14 billion), lymphoma ($12 billion), lung cancer ($12 billion), and prostate cancer ($12 billion).

"Rising health care costs pose a challenge for policy makers charged with allocating future resources on cancer research, treatment, and prevention," said study author Angela Mariotto, PhD, from the National Cancer Institute Surveillance Research Program. "Because it is difficult to anticipate future developments of cancer control technologies and their impact on the burden of cancer, we evaluated a variety of possible scenarios." To project national cancer expenditures, researchers combined cancer prevalence (current number of people living with cancer) with average annual costs of care by age (<65 or ≥ 65 y). According to prevalence estimates, 13.8 million cancer survivors were alive in 2010, 58% of whom were age 65 y or older. If cancer incidence and survival rates remain stable, the number of cancer survivors in 2020 will increase by 31%, to about 18.1 million. Because of the aging of the U.S. population, researchers expect the largest increase in cancer survivors over the next decade to be among Americans age 65 y and older.

These new cost projections are higher than previously published estimates, largely because the researchers used the most recent data available—including Medicare claims data through 2006, which include payments for newer, more expensive, targeted therapies. In addition, analyzing costs according to phase of care revealed the higher costs of care associated with the first year of treatment and last year of life (for those who die from their disease). More information about these cost projections is available at: http://costprojections.cancer.gov.

National Institutes of Health

γ/Scintillation Market to Increase

Global Industry Analysts, Inc. (San Jose, CA) announced on January 20 the release of a forecast report on the international γ/scintillation camera markets. The market for γ/scintillation cameras and accessories is projected to reach US $820 million by 2015, driven by sustained efforts for developing newer radiopharmaceuticals, the advent of advanced product technologies, and the industry's focus on creation of integrated products. The reported noted that although global economic challenges have adversely affected the medical imaging equipment market, this will be balanced by rapid advancements in molecular imaging, an aging global population, and emergence of image-guided interventions, particularly in cardiac diseases, oncology, organ dysfunctions, and neurologic disorders.

The research report, titled *Gamma/Scintillation Cameras: A Global Strategic Business Report,* provided a review of the industry, key market trends, recent product launches, strategic corporate initiatives, and profiles of key market participants, with annual sales estimates and projections through 2015 by 7 geographic markets: United States, Canada, Japan, Europe, Asia–Pacific, Latin America, and the rest of the world. Key segments analyzed included γ cameras, collimators, gantries, nuclear medicine patient tables, computerized video display consoles, and computer workstations.

Europe and the United States now account for the majority of sales in the global γ/scintillation camera market, with the cost of equipment and the process of reimbursement determining levels of technologic penetration. The report cited Asia–Pacific and Latin America as the fastest growing regional markets, with steady economic growth, improving health care services, and rising consumer awareness and incomes. More details about this market research report are available at: www.strategyr.com/Gamma_Scintillation_Cameras_Market_Report.asp.

Global Industry Analysts, Inc.