President Proposes RBMs for Medicare

The budget released by President Obama in March proposed almost $634 billion to finance health care reform in 2009. The money would come from a combination of tax increases on higher-earning Americans and savings to be garnered from greater efforts at efficiency and accountability in health care. Among the proposed economies is the saving of more than $260 million over 10 y by requiring Medicare to use the services of radiology benefit management (RBM) companies. Third-party payers are increasingly turning to RBM companies that use a combination of actuarial, guideline-driven, and specific case information to approve or disapprove coverage for physician-recommended imaging studies, including nuclear medicine studies.

The imaging community reacted swiftly and negatively to the proposal that RBMs become a part of the Medicare decision-making process. The Medical Imaging and Technology Alliance (MITA), a division of the National Electrical Manufacturers Association, released a statement indicating that "the budget's proposed reliance on RBMs will deny imaging services and is an ineffective model that undermines the doctor–patient relationship in making health care decisions. If the Medicare program depends on RBMs, it will lead to further reducing seniors' access to life-saving medical services." A statement from the American College of Radiology (ACR) noted that "instead of using a for-profit entity, whose only goal is to bring down costs, physicians themselves can be responsible for ensuring that the imaging they order for patients is appropriate." Both groups, as well as other professional imaging societies, favor an appropriateness criteria approach. "We must ensure that patients have access to the right scan at the right time. The RBM model is the wrong approach and the Administration and Congress should instead build on appropriateness criteria—a successful approach that was established in last year's Medicare law, and which is used by and proven effective in many of the nation's leading health systems," said Ilyse Schuman, managing director of MITA.

According to the U.S. Government Accountability Office (GAO), the Deficit Reduction Act of 2005 resulted in $1.64 billion in Medicare cuts for imaging services in 2007 alone, the first year cuts were implemented. This amounted to 3 times more than the original dollar amount targeted by Congress. The GAO also found that utilization of advanced imaging services has slowed significantly, suggesting that additional cuts could limit the availability of these services.

Medical Imaging and Technology Alliance
American College of Radiology

Health Expenditures Expected to Slow

On February 24 the Centers for Medicare & Medicaid Services (CMS) released a report indicating that national health expenditures (NHEs) in the United States are expected to significantly outpace economic growth in 2008 and 2009 as a result of the recession but that the rate of NHE growth is expected to slow. The report was prepared by the CMS Office of the Actuary and published online in *Health Affairs* (2009;28: w346–w357).

For 2008, growth in national health expenditures was expected to be 6.1%, as health spending increased from $2.2 trillion in 2007 to $2.4 trillion in 2008, whereas growth in the economy (as measured by the gross domestic product [GDP]) was anticipated to be 3.5%. For 2009, health spending is projected to increase 5.5%, whereas the GDP is expected to decrease by 0.2%. The health share of GDP was expected to increase from 16.2% in 2007 to 16.6% in 2008 and fall to 17.6% in 2009. By 2018, national health spending is expected to reach $4.4 trillion and make up more than one-fifth (20.3%) of the GDP.

Over the projection period, average annual spending growth by public payers (7.2%) is expected to exceed that of private payers (5.3%). As a result, the public share of total health care spending is expected to rise from 46.2% in 2007 to more than 51.3% by 2018. The rate of private health spending growth, which includes private health insurance spending and out-of-pocket payments, is projected to decelerate from 5.8% in 2007 to 5.3% in 2008 and reach a 15-y low of 3.9% in 2009.

Hospital spending growth is expected to edge downward from 7.3% in 2007 to 7.2% in 2008 and to 5.7% in 2009. Prescription drug spending growth is projected to slow to 3.5% in 2008, down from 4.9% in 2007, and to rebound to 4.0% in 2009. Prescription drugs are projected to be the fastest-growing component of Medicare's spending over the projection period, with the prescription drug share of Medicare spending increasing from 10.9% in 2007 to 14.7% by 2018. Physician and clinical services spending is expected to grow 6.2% in 2008, a slowdown from 2007 (6.5%), with more slowing projected for 2009 (6.0%).

Longer-term projections in the report are based on assumptions of an economic recovery beginning in 2010 and health care demands related to Medicare eligibility of the baby boom population. These health care spending projection data are available at: www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp.

Centers for Medicare & Medicaid Services

Increase in Imaging in Pregnancy

A study published on March 17 ahead of print in *Radiology* and covered in media outlets in the United States and around the world raised concerns about increased radiation risk to pregnant women undergoing medical imaging. The study documented the utilization of radiologic imaging in pregnant patients at a single academic institution during a 10-y period, encompassing 5,270 imaging studies in 3,285 patients. During the study period radiologic exams on pregnant women more than doubled.

"Imaging utilization has not been previously studied in the pregnant population," said Elizabeth Lazarus, MD, first author of the study and an assistant professor of diagnostic imaging at the Warren Alpert School of Medicine at Brown University and a radiologist at Rhode Island Hospital (Providence, RI). "This population may be vulnerable to the adverse effects of radiation."

The authors conducted a retrospective review of nuclear medicine, CT, fluoroscopy, and plain-film imaging examinations performed at Rhode Island Hospital and Women and Infants' Hospital from 1997 through 2006 to determine how often these imaging exams were performed on pregnant women and the estimated radiation dose to the fetus. Data were then compared with the number of infant deliveries per year for that same time period. Over the 10-y focus period, the total number of imaging studies performed on pregnant women increased by 10.1% per year, but the number of CT exams increased by 25.3% per year. The majority (about 75%) of CT examinations in the study were performed in areas of the mother's body outside the abdomen.

"Women should know that imaging is generally safe during pregnancy and is often used to detect potentially life-threatening problems," Lazarus said. "However, this study should raise awareness about imaging trends in pregnant patients and help us continue in our efforts to minimize radiation exposure."

Over the course of the study, the number of patients imaged per year increased from 237 to 449, and the number of exams per year increased from 331 to 732. This represented an 89% increase in patients and a 121% increase in examinations. During the same 10 y, however, the number of deliveries increased by only 7%, from 8,661 to 9,264. Imaging utilization rates (exams per 1,000 deliveries) increased 107%. Use of plain-film x-rays increased an average of 6.8%/y, and the number of nuclear medicine examinations rose by approximately 11.6% annually. Fluoroscopy and CT utilization increased by 10.6% and 25.3%/y, respectively. The average estimated fetal radiation exposure per exam for CT was 4.3 mGy, compared with 2.91 mGy for fluoroscopy, 0.40 mGy for nuclear medicine, and 0.43 mGy for x-rays.

The authors concluded that although radiologic imaging in pregnancy remains safe, physicians should be aware of the trend toward increased imaging and of the need to image conservatively.

Radiological Society of North America

UK Expert Calls Attention to Isotope Shortage

In a press release issued on March 19, a University of Nottingham (UK) expert called on the British government to provide substantial new investment in the production of medical isotopes or "face a dangerous shortage that threatens to compromise patient health care." Alan Perkins, PhD, a professor of medical physics at the university and president-elect of the British Nuclear Medical Society, told the BBC's *Material World* that a series of setbacks in the worldwide production of radionuclides had caused disruptions to clinical services. Despite resolution of these disruptions, Perkins cited the need to "plan for failure" to ensure the future provision of essential diagnostic imaging procedures for thousands of UK patients. "The medical use of radionuclides is probably the single most beneficial application of atomic and nuclear sciences to mankind," he said. "I am advocating further investment in alternative means for producing medical radionuclides for the benefit of patients who desperately need them." He reviewed the series of maintenance issues and unexpected failures at key commercial nuclear reactors that caused sporadic shortages of ^{99}Mo in 2007 and 2008. "Supply disruptions at the end of 2008 and early 2009 have adversely affected patient services in many countries, including the UK, the majority of Europe, the USA and Canada and beyond," he added. In the UK, the supply of ^{99}Mo to some hospital departments was down to 30% of normal levels. As a result, these departments had to prioritize to make the most effective and efficient use of limited supplies and ensure that tests were provided for those patients most in need. Perkins said, "However, with pressure on hospitals in England to provide tests within 6 weeks, there has been concern that this may not have happened in all cases and that priority would be decided based on waiting lists and not clinical judgment." He concluded that Britain should seriously consider investing in its own production facilities to reduce its reliance on foreign reactors, which are all more than 40 y old and approaching scheduled decommissioning.

University of Nottingham

Insect Life at Chernobyl

In an article e-published on March 18 ahead of print in *Biology Letters*, Møller and Mousseau from the Université Paris-Sud (Orsay, France) reported on a study on the numbers of insects at the Chernobyl site 20 y after the nuclear accident. The authors conducted standardized counts of bumblebees, butterflies, grasshoppers, dragonflies, and spider webs at forest sites around Chernobyl with differing levels of background radiation. They found that the abundance of invertebrates decreased with increasing radiation, even after controlling for the effects of soil type, habitat, and height of vegetation. These

and other results suggested that the the ecological effects of radiation from Chernobyl on fauna are greater than previously assumed.

Biology Letters

Fox Foundation Awards Neuroimaging Grants

The Michael J. Fox Foundation for Parkinson's Research announced on February 19 the award of $1.9 million in grants to develop neuroimaging techniques for visualizing the clumping of the α-synuclein protein in the living human brain. The program was funded with a lead gift from the Edmond J. Safra Foundation and will provide grants to 6 teams, including: Brian Bacskai, PhD, and Pamela McLean, PhD, of Massachusetts General Hospital (Boston) for "Development and Screening of Contrast Agents for In Vivo Imaging of Parkinson's Disease"; Yvette Bordelon, PhD, of the University of California, Los Angeles, for "Utility of the Amyloid Ligand ^{18}F-FDDNP in Human PET Imaging in Parkinson's Disease"; Franz Hefti, PhD, of Avid Radiopharmaceuticals (Philadelphia, PA) and Alan Snow, PhD, of ProteoTech (Seattle, WA) for "^{18}F-Labeled α-Synuclein Ligands for PET Imaging of Lewy Bodies"; Poul Henning Jensen, PhD, of the University of Aarhus (Denmark) for "Generation of α-Synuclein Conformation-Specific Aptamers for In Vivo Bioimaging of α-Synuclein Pathology"; Kenneth Marek, PhD, of the Institute for Neurodegenerative Disorders (New Haven, CT) and Omar El-Agnaf, PhD, of the United Arab Emirates University (Al Ain) for "A Strategy to Develop a Radiotracer Targeting α-Synuclein"; and Michael Sierks, PhD, of Arizona State University (Tempe) for "In Vivo SPECT Imaging of Synuclein Aggregation with Morphology-Specific Antibody-Based Ligands."

Michael J. Fox Foundation for Parkinson's Research

FDA Partners with Alliance for NanoHealth

The U.S. Food and Drug Administration (FDA) announced on March 10 a new collaboration initiative with the Houston (TX)-based Alliance for NanoHealth and its 8 member institutions to speed development of safe and effective medical products in the emerging field of nanotechnology. Under a memorandum of understanding, the initiative will work to expand knowledge of the ways in which nanoparticles behave and affect biologic systems and to facilitate the development of tests and processes that might mitigate risks associated with nanoengineered products. All outcomes from this public–private partnership will be placed in the public domain.

"FDA's Nanotechnology Initiative with the Alliance for NanoHealth is an effort to engage resources and technical expertise in this rapidly advancing field and is a clear example of leveraging science and scientists to advance the public good," said FDA Acting Commissioner Frank M. Torti, MD, MPH. "Nanotechnology holds great promise for the advancement of novel medical products."

The 8 academic institutions include Baylor College of Medicine, the University of Texas M.D. Anderson Cancer Center, Rice University, the University of Houston, the University of Texas Health Science Center at Houston, Texas A&M Health Science Center, the University of Texas Medical Branch at Galveston, and the Methodist Hospital Research Institute.

U.S. Food and Drug Administration

FDA Requirements for PET Radiopharmaceuticals

On March 26, SNM and the International Partnership for Critical Markers of Disease announced the scheduling of an in-depth meeting examining U.S. Food and Drug Administration (FDA) requirements for manufacturing PET radiopharmaceuticals. The meeting was to be held on May 1 at the Natcher Auditorium on the campus of the National Institutes of Health (NIH) (Bethesda, MD).

"We are pleased to collaborate with the International Partnership for Critical Markers of Disease on this important meeting," said Michael Graham, MD, PhD, SNM president-elect and director of nuclear medicine at the University of Iowa Carver College of Medicine (Iowa City). "New developments in molecular imaging technologies are dramatically improving the ways in which cardiovascular disease, neurological disorders, and cancer are diagnosed and treated. It is essential that we work together as a scientific community to facilitate personalized medicine through the development of advanced imaging techniques and new radiopharmaceuticals that will enable physicians to determine early on the precise location of disease, and evaluate and monitor the effectiveness of therapy."

The 2 partnering groups "share a common interest in accelerating scientific research to bring the best in health care to patients today," said Thérèse Heinonen, DVM, executive director of the International Partnership for Critical Markers of Disease. "With an active interest in the evaluation of potential cardiovascular biomarkers and their appropriate application in clinical trials, a partnership with SNM is a natural fit."

Slated to appear first on the program were Don Black, MD, head of research and development at GE Healthcare's Medical Diagnostics; Dwaine Rieves, MD, director of medical imaging at the FDA; and Graham from SNM. Dennis Swanson, RPh (University of Pittsburgh, PA), and Sally Schwarz (Washington University, St. Louis, MO) were to survey the regulatory history of PET and review current regulations for PET compounding. Joseph Hung, PhD (Mayo Clinic, Rochester, MN), along with other speakers, was to address the critical necessity for developing new tracers and radiopharmaceuticals in compliance with FDA's current good manufacturing practice and chemistry, manufacturing, and control regulations. Experts were also scheduled to address the need for harmonization and standardization across multiple imaging sites, the concept of a centralized Investigational New Drug approval process, and SNM's new Clinical Trials Network.

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Recanalization of Plaques with Photothermal Microbubbles

In the March issue of *Lasers in Surgery and Medicine* (2009;41:240–247), Lukianova-Hleb et al. from the A.V. Lykov Heat and Mass Transfer Institute (Minsk, Belarus) reported on a method for disruption and recanalization of atherosclerotic plaques in coronary vessels using photothermal microbubbles generated around gold nanoparticles. For the studies, the authors used 3 in vitro models: a layer of living fibroplast, epoxy layers, and human arteries and plaques. Photothermal microbubbles were generated around 30–250-nm gold spheres within each of these models, and 10-nanosecond laser pulses were used to propel the microbubbles into the model obstructions. Complete removal of all obstructive material was seen after 1–10 single pulses, with resulting cleared areas measured at 500–1,000 times larger than the nanoparticle sizes used. Generation of the microbubbles did not increase the temperature in the model microenvironments, nor was any debris of significant size noted. The authors concluded that this method for nonthermal mechanical and localized removal of plaque tissue can provide "safe and rapid canalization of totally occluded and calcified arteries without collateral damage."

Lasers in Surgery and Medicine

Quantum Dot Imaging of Pancreatic Cancer

In an article e-published on February 25 ahead of print in *ACS Nano*, Young et al. from the State University of New York (Buffalo) and the Johns Hopkins University School of Medicine (Baltimore, MD) described the use of noncadmium-based quantum dots as efficient and nontoxic optical probes for imaging live pancreatic cancer cells. They detailed the preparation and design of these quantum dots, the surfaces of which were functionalized with mercaptosuccinic acid to make them highly dispersible in aqueous media. The resulting constructs were functionally bioconjugated with pancreatic cancer–specific monoclonal antibodies to allow in vitro targeting of pancreatic cancer cell lines. Targeted delivery of the bioconjugates was confirmed by optical imaging and additional experiments. The authors concluded that the described quantum dots have great promise as "noncadmium-based safe and efficient optical imaging nanoprobes in diagnostic imaging, particularly for early detection of cancer."

ACS Nano

Biodegradable Luminescent Silicon Nanoparticles

Park et al. from the University of California, San Diego (La Jolla) reported on February 22 ahead of print in *Nature Materials* on the development of luminescent porous silicon nanoparticles that can carry a drug payload and that can be monitored with photoluminescent imaging in vivo from accumulation through subsequent degradation. In mouse studies, the particles were found to self-destruct into renally cleared components in a short period of time and with no noted toxicities. The authors also reported on preliminary in vivo applications in tumor imaging, using dextran-coated particles. They concluded that these results "demonstrate a new type of multifunctional nanostructure with a low-toxicity degradation pathway for in vivo applications."

ACS Nano

Imaging Tissue-Specific mdr1a Gene Expression

Gu et al. from the Beckman Research Institute at City of Hope (Duarte, CA) reported on March 12 ahead of print in the *Proceedings of the National Academy of Sciences of the USA* on the creation of a unique mouse model that allows noninvasive bioimaging of mdr1 gene expression in vivo and in real time, with specific promise for elucidating the role of mdr1 expression in multidrug resistance. The authors described the creation of an mdr1a firefly luciferase gene construct (mdr1a.fLUC) that was shown to be a reliable reporter for mdr1a expression in vivo in mice. Additional studies validated xenobiotic-inducible regulation of mdr1a.fLUC expression in real time, providing a more detailed understanding of the kinetics of mdr1a gene induction. The authors concluded that this "represents a unique tool with which to study the magnitude and kinetics of mdr1a induction under a variety of physiologic, pharmacologic, genetic, and environmental conditions."

Proceedings of the National Academy of Sciences of the USA

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SNM and the International Partnership for Critical Markers of Disease report plans to host other collaborative symposia and forums dedicated to accelerating biomarker and radiopharmaceutical development for patient care, including the 7th annual Critical Markers of Disease Biomarkers and Surrogate Endpoints Symposium, October 19–21, in Bethesda. This symposium, with the theme "Streamlining to Promote Innovation and Efficiency," will also be held in collaboration with representatives from the FDA, NIH, Centers for Disease Control and Prevention, U.S. Agency for Healthcare Research and Quality, Canadian Institutes for Health Research, Radiological Society of North America, and other public and private research organizations. Registration for the fall symposium is available at www.cmod.org.

SNM