Releases Drastic Cuts

The production of $^{99}$Mo without using $^{163}$ million to support projects for the United States and gradually eliminate other medical isotopes, including $^{131}$I and $^{133}$Xe, be produced as byproducts of the $^{95}$Mo fission process.

The decision as to how these funds will be allocated to new production centers will rest with the Secretary of Energy. Both private industry and public research entities will be eligible for the funds. Criteria for selection will include evidence that the applicant can begin production for medical uses in a timely manner, that each project can supply “a significant percentage” of U.S. demand for $^{99}$Mo, and that each project is cost effective. Almost all medical isotopes are now imported from producers outside the United States, and the legislation is designed to ensure a sustainable supply of domestic medical isotopes.

U.S. House of Representatives

SGR Status Unclear; CMS Releases Drastic Cuts

At Newsline press time, the ups and downs of early fall activity on the fate of the Sustainable Growth Reform (SGR) formula for Medicare reimbursement remained unchecked, with the ultimate resolution in the hands of Congress and tied to the fate of much larger health reform legislation. Radiologists and cardiologists had rallied during the week of October 14 on Capitol Hill and in a letter writing effort to increase awareness of obstacles to access to imaging. The participants noted concerns about continued SGR-related reductions in Medicare reimbursements as well as a number of other pending cuts that would affect diagnostic imaging. The groups cited compelling data indicating that further reductions might prevent some practices from serving Medicare beneficiaries or might cause imaging centers to close.

The SGR formula requires Medicare payments to be modified annually to control health care utilization. Because of a flaw in the calculation methodology, the SGR has called for cuts annually in physician payments and must be corrected every year through Congressional action, such as the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. This year, Senator Debbie Stabenow (D-MI) introduced bill S.1776, the Medicare Physicians Fairness Act of 2009, which would have repealed the SGR formula, canceled the $240 billion associated debt, and effectively frozen reimbursement rates for a decade. On October 21, Senate Democrats failed to secure the necessary 60 votes to force floor consideration for the act.

On the same day, 3 House panels approved separate plans to discard the SGR formula and replace it with calculations that more accurately reflect physician costs. In a statement, House Democratic leaders said they were “confident that we will enact the payment reform this year.” At Newsline press time, however, it appeared that the House plan was to strip language addressing SGR repeal from national health reform legislation and to reintroduce separate legislation later in the fall session. Senate leaders had previously indicated a plan to include a 1-y “patch” in their version of the larger health reform bill.

The lack of resolution to the SGR question forced the Centers for Medicare & Medicaid Services (CMS) to release drastic proposed cuts in 2010 payment and policy changes for physicians’ services to beneficiaries under the Medicare Physician Fee Schedule (MPFS). The MPFS sets payment rates for more than 7,000 types of services in physician offices, hospitals, and other settings. Federal law requires that CMS announce these rates by November 1. In a press release that clearly indicated reluctance to institute such large cuts, CMS noted “In the absence of Congressional action for the CY 2010 physician update, the final rule with comment period will reduce the conversion factor for services on or after Jan. 1, 2010, by 21.2%” (a slight reduction from the 21.5% projected SGR calculation).

“The Administration tried to avert the pending fee schedule cut in the FY 2010 budget proposal that it submitted to Congress and remains committed to repealing the SGR,” said Jonathan Blum, director of the CMS Center for Medicare Management. “In the meantime, CMS is finalizing its proposal to remove physician-administered drugs from the definition of ‘physicians’ services’ for purposes of computing the physician fee schedule update. While this decision will not affect payments for services during CY 2010, CMS projects it will have a positive effect on future payment updates.” Several imaging media sources indicated that if these cuts are instituted, along with other pending reductions, imaging physicians could see reimbursement reduced at rates well over 30% in 2010. This issue remains in flux, and readers are advised to visit the SNM Web site at: www.snm.org for frequent updates.

U.S. Congress

Centers for Medicare & Medicaid Services
Advanced Imaging Growth Lower Than Other Areas

On October 14, the Access to Medical Imaging Coalition (AMIC), of which SNM is a member, released a Moran and Company analysis of 2008 Medicare claims data indicating that growth in the volume of advanced imaging is less than that of other physician services since the implementation of the Deficit Reduction Act of 2005 (DRA). These data confirmed a trend reported earlier this year, when Moran and Company analyses showed that Medicare spending on advanced imaging was reduced by 19.2% from 2006 to 2007 and volume of service grew by only 1.9%.

The new data indicated that: (1) Use of CT, MR, and PET and other nuclear procedures grew by only 1.1%, even more slowly than for the previous year; (2) mammography and bone-density screening (DEXA) continued to decline in volume, with screening mammography down nearly 30% and DEXA volume down 0.4%; and (3) use of MR imaging decreased by 0.3%, with the growth rate for CT volume cut almost in half (2.6% compared with 4.2%) over the previous year.

"Utilization of advanced imaging services continues to be slower in the post-DRA environment than in the prior period," said Don Moran, president of Moran and Company. "Contrary to the assumption that advanced imaging spending is rapidly increasing, the 2008 data appear to confirm the deceleration of imaging cost growth first observed in the 2007 data. Policymakers may wish to consider this trend when considering changes to imaging coverage and reimbursement."

Medical News Today
Access to Medical Imaging Coalition

CMS Asked to Reconsider Single-Scan PET

On October 19, 7 medical imaging groups, including SNM, wrote a joint letter to the Centers for Medicare & Medicaid Services (CMS) to formally request that CMS reconsider its current coverage policy for 18F-FDG PET scans used during initial treatment strategy evaluation. CMS currently covers only a single 18F-FDG PET study during initial treatment evaluation—a limitation that the groups believe is contrary to good clinical practice under certain circumstances. "It is absolutely critical for CMS to reconsider this decision," said Michael M. Graham, PhD, MD, president of SNM. "It is unacceptable to have reimbursement for only 1 scan when you may need additional scans in some patients, for example to plan radiation treatment."

The letter—which was sent jointly by the leadership of the National Oncologic PET Registry Working Group, the Academy of Molecular Imaging, the American College of Nuclear Medicine, the American College of Radiology, the American Society for Radiation Oncology, the Institute for Molecular Technologies, and SNM—presented CMS with 3 practical scenarios in which a second initial 18F-FDG PET scan would be necessary for optimal patient care: (1) when a second PET study is needed for successful radiation therapy planning; (2) when a previous PET is false-negative and subsequent findings indicate that a repeat PET is needed for initial staging before treatment; and (3) when initial treatment is delayed so that PET is needed for reevaluation after a period of time during which disease may have progressed in ways that could significantly affect management choices.

The groups presented CMS with new supporting bodies of evidence (such as studies that were not considered or were not yet available during the original consideration period), with the request that CMS open the decision for reconsideration and lift the restriction on number of 18F-FDG PET scans for initial treatment strategy evaluation.

SNM

AMA CPT Codes Released for MPI

The 2010 Current Procedural Terminology (CPT) electronic file was released by the American Medical Association (AMA) on September 29. New, deleted, and revised codes will be effective on January 1, 2010. Important changes were made to the myocardial perfusion imaging (MPI) codes as a result of action taken by the AMA Five-Year Review Identification workgroup and the Centers for Medicare & Medicaid Services (CMS), which work to identify high volume and potentially misvalued codes. They found that the MPI code CPT 78465 and the add-on codes for wall motion and ejection fraction, 78478 and 78480, respectively, were billed together by the same physician more than 95% of the time and, therefore, requested the construction of new inclusive codes to eliminate potential redundancy.

In response, new MPI code proposals were submitted jointly by the SNM, the American College of Cardiology, the American College of Radiology, and the American Society of Nuclear Cardiology. The multispecialty society team collaborated over 1 y and developed an MPI package of codes that describe the entirety of associated procedures. Providers will continue to bill separately for the electrocardiographic stress test, using the CPT 93015–93017 codes, as well as any drug and radiopharmaceutical supply codes administered.

An SNM press release on October 5 called attention to words in the code description that are important in selecting the proper code, including a special informational table. No dollar impact is anticipated for providers billing the technical rates in the hospital outpatient payment system (HOPPS) for 2010, because CMS had packaged payment for the add-on wall motion and ejection fraction codes. However, SNM staff noted that it is critically important for hospitals to account for the added work when performing wall motion and ejection fraction studies when they set their rates for the new 2010 MPI codes. Specifically, when establishing charges for the new MPI codes, hospitals should add the charges they had typically billed (charged) for wall motion and ejection fraction studies to the new
Value of In-Patient Diagnostic Imaging

Hospitals that make greater use of inpatient diagnostic imaging exams achieve lower in-hospital mortality rates with little or no impact on costs, according to a peer-reviewed study of more than 1 million patient outcomes in more than 100 hospitals nationwide published in the November issue of the Journal of the American College of Radiology (JACR). “The results of our in-depth study would indicate that greater use of imaging does, in fact, lead to better patient outcomes in terms of lower in-hospital death rates with no significant impact on overall cost,” said David W. Lee, PhD, lead author of the article and senior director of health economics and outcome research at GE Healthcare. “This study dealt only with imaging provided in hospitals but would seem to confirm what many have long suspected—that medical imaging exams save lives.”

Lee’s comments were included in an October 28 press release from the American Roentgen Ray Society.

Researchers examined data from the Thomson Reuters Drug Database (HDD) exploring the association between utilization of diagnostic imaging services and 2 key hospital outcome measures: mortality and costs. The analysis examined data from inpatient admissions in 2007 in the 102 hospitals in the HDD that provided sufficiently detailed data to support assessment of utilization of inpatient diagnostic services. The study included all clinical conditions treated in-hospital and assessed the experiences of patients with private, commercial, and government-sponsored insurance. “Because use of imaging procedures grew rapidly in the early parts of this decade, payers and policymakers have questioned whether more diagnostic imaging use is associated with better health outcomes. Based on our research, the answer would appear to be yes,” said Lee.

Journal of the American College of Radiology

OIG to Review Radiology Payments and Appropriateness

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) in October released its Fiscal Year 2010 Work Plan, which includes plans to initiate new studies focusing on Medicare Part B imaging payments and on appropriateness of many emergency department scans. The OIG functions under a Congressional mandate to review health care–related programs and operations. The work plan outlines upcoming investigations, audits, and reports and focuses on areas that the OIG has determined may be too costly or may violate federal fraud and abuse laws.

Under the heading “Payments for Diagnostic X Rays in Hospital Emergency Departments,” the document indicates that OIG will “review a sample of Medicare Part B paid claims and medical records for diagnostic x rays performed in hospital emergency departments to determine the appropriateness of payments.” The reasons given for this scrutiny include 2005 Congressional testimony from the Medicare Payment Advisory Commission on the increasing cost of imaging services for Medicare beneficiaries and potential overuse of diagnostic imaging services and 2007 data indicating that Medicare reimbursed physicians approximately $207 million for imaging interpretations performed in emergency departments. Although the document indicates that the OIG “will determine the appropriateness of payments for diagnostic x rays and interpretations,” the implication is that all types of imaging performed in emergency departments will be under scrutiny.

In a second area of investigation, OIG will focus on the “practice expense” components of imaging reimbursement, including the equipment utilization rate to “determine whether Medicare payment reflects the actual expenses incurred and whether the utilization rate reflects current industry practices.” The OIG is already conducting an ongoing examination of services and billing patterns in locations with a high density of independent diagnostic testing facilities.


HHS Office of Inspector General

Thyroid Cancer After Childhood Cancer Treatment

In an article in the November 15 issue of the International Journal of Cancer (2009;125:2400–2405), a group of researchers from the University of Birmingham (UK) reported on results from the British Childhood Cancer
NRG to Build New Reactor

The Nuclear Research and Consultancy Group (NRG), which operates the High Flux Reactor (HFR) in Petten, The Netherlands, announced in October developments in its plans to build a new reactor to produce medical isotopes. The HFR, which has been in operation since 1963, is “reaching the end of its economic life,” according to the NRG Web site, and the new Pallas reactor could be in full-scale isotope production at the end of 2016. The new Pallas reactor, named after the Greek goddess of wisdom and knowledge, will be built by an international consortium.

Juliette van der Laan, the NRG spokesperson, told media sources that “The most important characteristic of Pallas will be its operational flexibility, which will make it possible to respond immediately to the fluctuating demands for isotopes. Operational power for Pallas will be adjustable and in a range of 30–80 MW power. Pallas has the capacity to be the world’s largest producer of medical isotopes.” She added that Pallas will be a tank-in-pool type reactor and operate on low-enriched uranium fuel, with high annual availability and irradiation capacity optimized for both isotope production and research for fission and fusion reactors. “The next phase of the Pallas project—the development of the detailed design—will be funded by the regional government. For the construction phase, NRG foresees a public–private investment,” van der Laan said. Two Netherlands locations are being investigated for the new reactor: on the North Sea Coast in Petten, where the HFR and current medical processing facilities are located; and at Borssele, in the Zeeland Province, where a nuclear power plant and the national nuclear waste management organization are located.

Centralized Review Process and Clinical Trials

A Central Institutional Review Board (CIRB) for cancer clinical trials created by the National Cancer Institute (NCI) in 2001 helps trials start more quickly (just over 1 mo faster, on average) and thus expedites the time from concept to completion of crucial investigational research, according to findings highlighted by NCI. The information comes from a study of the CIRB performed by scientists at the Veterans Affairs Palo Alto Health Care System (VAPAHCS) and Stanford University School of Medicine (Palo Alto, CA) with assistance from NCI. The study appeared online on October 19 in the Journal of Clinical Oncology.

Over the past 40 y, more than 1,700 institutions in the United States have enrolled up to 20,000 patients annually in phase 3 clinical trials coordinated by NCI and have used separate IRBs to monitor research involving patients. To determine whether a new treatment is safe and more effective than current treatments using clinical trials is a lengthy process that can take up to 10 y and cost more than $1 billion. Many researchers have complained that administrative requirements, including IRB oversight, are delaying the release of new treatments. One solution NCI proposed was to form a CIRB to conduct IRB review of large, multisite oncology trials.

“Mounting a CIRB that is nationwide in scope has been challenging for NCI due to the complexity involved in assuring high-quality protection for study participants while attempting to speed the process,” said Jeffrey Abrams, MD, associate director of the NCI Cancer Therapy Evaluation Program. “For all the volunteer reviewers and participating sites, this study provides objective confirmation that a centralized approach significantly improves the overall process for participants in multisite trials.”

The study assessed whether use of the NCI CIRB was associated with decreased effort, time, and cost in processing adult phase 3 oncology trials. Early phase trials (phase 1 and 2) and pediatric trials were not included in the analysis. Researchers compared clinical trial reviews at sites affiliated with the NCI CIRB with reviews at unaffiliated sites that used local IRBs. Oncology research staff and IRB staff were surveyed. CIRB affiliation was associated with faster local review (about 34 d faster) and about 6 h less in research staff effort. Affiliation with the NCI CIRB was also associated with a savings of $717 per initial review, of which about half was associated with time savings for research staff and the remainder was associated with savings for the IRB staff.

National Cancer Institute
NIH Expands Rare Diseases Clinical Research Network

The National Institutes of Health (NIH) announced on October 5 a second phase of the Rare Diseases Clinical Research Network (RDCRN), including funds for 19 research consortia. The Rare Diseases Clinical Research Consortia and a Data Management Coordinating Center (DMCC) will be awarded a total of more than $117 million over the next 5 y. The research conducted with the new funding will explore the natural history, epidemiology, diagnosis, and treatment of more than 95 rare diseases.

“The progress made by researchers through the network over the past 6 years is important and impressive,” said NIH Director Francis S. Collins, MD, PhD. “We have shown that this approach can be a catalyst for progress in meeting the challenge of rare diseases, and we are eager to launch this next phase of the program.” A rare disease is defined as a disease or condition affecting fewer than 200,000 persons in the United States. Approximately 6,500 such disorders have been identified, affecting an estimated 25 million Americans. Initially created in 2003, the RDCRN is unique in its approach to addressing rare diseases as a group. NIH institutes and centers previously funded research on individual rare diseases in their respective disease-type or organ domains. The RDCRN is the first program that aims to create a specialized infrastructure to support rare diseases research.

Since its creation, the RDCRN has enrolled more than 5,000 patients in 37 clinical studies in rare diseases. “Collaboration is a critical element of rare diseases research, and the partnerships represented in this program have tremendous potential to make great strides in understanding these diseases,” said Stephen C. Groft, PharmD, director of the NIH Office of Rare Diseases Research (ORDR). Funds and scientific oversight for the RDCRN will be provided by ORDR and 7 participating NIH institutes, each of which will also contribute considerable administrative support to the network. Several consortia will also receive financial support from their associated patient advocacy groups.

In the RDCRN’s first phase, the network’s Data and Technology Coordinating Center (DTCC) developed a management system for the collection, storage, and analysis of RDCRN data and additional systems to address needs of individual studies, such as a laboratory data collection system, a specimen tracking system, and a pharmacy management system (to support blinded distribution of study agents and placebos). The DTCC also created RDCRN’s central public Web site, developed as a diverse portal for all members of the rare diseases community (http://rarediseasenetwork.epi.usf.edu/). RDCRN DTCC also developed a unique voluntary patient registry that provides ongoing contact with approximately 5,000 individuals from more than 60 countries representing 42 diseases, alerting them when new studies are opened in the network or when ongoing studies expand to new sites.

In this second phase of the RDCRN, the University of South Florida will continue these data management efforts as the Data Management Coordinating Center (DMCC). The DMCC will develop uniform investigative clinical research protocols for data collection in collaboration with the RDCRN Steering Committee, monitoring protocol adherence, data collection and data submission, and work with the each consortium’s Data and Safety Monitoring Boards to establish protocols for adverse events notification and reporting.

National Institutes of Health

NIH Creates Stem Cell Research Consortium

The National Heart, Lung, and Blood Institute (NHLBI), one of the National Institutes of Health (NIH), announced on October 7 the award of $170 million to be paid over 7 y to 18 teams of research scientists to develop the high-potential field of stem and progenitor cell tools and therapies. The awards create the NHLBI Progenitor Cell Biology Consortium, which will bring together researchers from the heart, lung, blood, and technology research fields. The consortium comprises 9 research hubs with multidisciplinary teams of principal investigators (PIs) and an administrative coordinating center to focus on progenitor cell biology. The goals of the consortium are to identify and characterize progenitor cell lines, direct the differentiation of stem and progenitor cells to desired cell fates, and develop new clinical strategies to address the unique challenges presented by the transplantation of these cells. Almost all of the research projects have or will have imaging arms. The consortium’s administrative coordinating center will be led by Michael Terrin, MD, at the University of Maryland, Baltimore. The consortium was introduced at the NIH International Symposium on Cardiovascular Regenerative Medicine on October 14 and 15 in Bethesda, MD.

“NHLBI is committed to stimulating stem cell research that will lead to the development of regenerative therapies for the treatment of heart, lung, and blood diseases,” said NHLBI Director Elizabeth G. Nabel, MD. “Important gaps remain in our understanding of stem and progenitor cells, and this consortium holds great promise to expand our knowledge and uncover therapeutic applications of great public impact.”

National Heart, Lung, and Blood Institute

Newsline 19N