## Issue No. 2
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### SNM Joins Effort in Renewing Battle to Halt Imaging Payment Cuts

On Wednesday, February 28, 2007, several Members of Congress announced that new legislation is being introduced to delay further implementation of the deep payment cuts in medical imaging services for Medicare patients, which went into effect January 1, 2007. The Access to Medical Imaging Act of 2007, sponsored by Representative Carolyn McCarthy (D-NY), along with her colleagues Rep. Joseph Pitts (R-PA) and Rep. Gene Green (D-TX), would direct Medicare to halt further implementation of the Deficit Reduction Act (DRA) imaging payment reductions for two years. During that time, the Government Accountability Office (GAO) would be directed to evaluate the impact of the DRA payment reductions on patient access and service issues, with special attention to seniors living in rural and medically underserved areas. Joining as original co-sponsors of the legislation were more than 20 other Members of the House.

Along with news of the new legislation, the Access to Medical Imaging Coalition (AMIC) released a study by The Moran Company which shows that—as a result of the Deficit Reduction Act of 2005 (DRA)—total reimbursement for imaging services in physician offices and imaging centers will fall some 18-19 percent below total reimbursement for similar services provided in hospital outpatient departments. The report serves as further proof that issues such as patient access and patient care must be assessed prior to further implementation of the cuts.

Throughout 2006 and 2007, SNM has served as a member of AMIC. Since its formation, AMIC has worked tirelessly with Congress and CMS in efforts to alleviate the payment cuts physicians will and have experienced from the imaging provisions within the DRA.

To learn about AMIC or to read a full copy of the new report, go to [www.imagingaccess.org](http://www.imagingaccess.org).

### FDA CDER DMIHP Update

Dr. George Mills’s current replacement at FDA CDER is Dr. Rafel (Dwaine) Rieves, a hematologist and published poet. Dr. Rieves was the Deputy Director under Dr. Mills prior to accepting his new position as Acting Director of the Division of Medical Imaging and Hematology Products (DMIHP).

Because Dr. Rieves has a background in hematology and not nuclear medicine, Dr. Libero (Lou) Marzella, Acting Deputy Director of DMIHP and previous Medical Officer Team Leader, will be the primary handler of nuclear medicine-related issues.
CARE Legislation, February Alliance Meeting

On February 26, the Alliance for Quality Medical Imaging and Radiation Therapy—a group of 20 radiologic science organizations representing more than 350,000 imaging technologists, radiation therapists and medical physicists—held their Winter/Spring meeting to discuss the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill (CARE bill) and work on potential draft regulations to propose to the U.S. Department of Health & Human Services should the CARE bill be enacted. As you know, the CARE bill would require personnel performing medical imaging and radiation therapy procedures to meet federal minimum education and credentialing standards in order for the procedures to be eligible for Medicare reimbursement.

Last month, the CARE bill (H.R.583) was introduced in the U.S. House of Representatives by Representative Mike Doyle (D-PA 14th) and referred to the House Committee on Energy and Commerce. Congressman Doyle recently distributed a “Dear Colleague” letter to his colleagues in the House to gain support and increase awareness for H.R.583.

In addition to the House bill efforts, the Alliance anticipates the Senate will reintroduce their version of the CARE bill (known as RadCARE in the Senate) within the next month or so. Due to the unanimous passage of the Senate RadCARE bill in the 109th Congress, the RadCARE legislation should receive a relatively swift and positive consideration in the 110th (if all goes well). Fast passage through the Senate will mean more time and resources for Alliance members to focus on moving the legislation through the House.

The SNM-Technologist Section (SNMTS) is a co-founding member of the Alliance and longtime supporter of the CARE / RadCARE legislation.

IAEA and ISO Introduce International Supplemental Radiation Symbol

On February 15, 2007, the International Atomic Energy Agency (IAEA) and the International Organization for Standardization (ISO) launched a new ionizing radiation warning symbol to supplement the traditional international symbol for radiation, the three cornered trefoil, which has no intuitive meaning and little recognition beyond those educated in its significance.

The new symbol was developed by human factor experts, graphic artists, and radiation protection experts, and was tested by the Gallup Institute on a total of 1,650 individuals in Brazil, Mexico, Morocco, Kenya, Saudi Arabia, China, India, Thailand, Poland, Ukraine and the United States.

The symbol is intended for IAEA Category 1, 2 and 3 sources defined as dangerous sources capable of death or serious injury, including food irradiators, teletherapy machines for cancer treatment and industrial radiography units. The symbol is to be placed on the device housing the source, as a warning not to dismantle the device or to get any closer. It will not be visible under normal use, only if someone attempts to disassemble the device. The symbol will not be located on building access doors, transportation packages or containers.

Many source manufacturers plan to use the symbol on new large sources. Strategies to apply the symbol on existing large sources are being developed by the IAEA.

CMS Releases Updated RVUs for 2007 DRA Affected Codes

The Centers for Medicare and Medicaid Services (CMS) has released an update to the 2007 Medicare Physician Fee Schedule Relative Value Units (RVUs). Codes subject to the Deficit Reduction Act (DRA) imaging provisions were revised in order to closely match their payment amounts with the Hospital Outpatient Prospective Payment System (HOPPS) amounts to which they are capped.

CMS Transmittal 1161, dated January 24, 2007, CR5498 instructs carriers to update the HOPPS CAP file with those posted in the RVU07A4 files. These changes must be implemented by February 27, 2007. Carriers are not required to make any automatic or retroactive adjustments to claims, but, if notified by providers, they must make adjustments to payments. Contractors are required to re-publish fees for those codes subject to the DRA HOPPS CAP payments.

To locate your exact local DRA HOPPS CAP rate, please visit this website and download the local RVU file. CMS has calculated all local payments for codes affected by the DRA and put the payment amounts in this file.
All national payment rates may be found on the SNM Coding Corner.

**FDA/FDG Industry Survey**

In January 2007, SNM and the Nuclear Medicine Industry Leaders Working Group (NMLILWG) compiled a survey to determine the range of specifications for $^{18}$F/FGD across the industry for submission to the Food & Drug Administration (FDA). The FDA has acknowledged receipt and stated that the survey will be useful in understanding QC information from commercial FDG suppliers.

Upon the release of the PET Drug current Good Manufacturing Practice (cGMP) final rule, the Prescription Drug User Fee Act (PDUFA) would require the submission of marketing applications for PET drugs. The survey is an attempt to help establish a potential alternative filing strategy to the costly New Drug Application (NDA) pathway for $^{18}$F/FGD producers by giving the FDA a general knowledge of formulations across the industry that may be eligible for Abbreviated New Drug Application (ANDA) status.

**NAS Studies on State of the Science and Isotope Production Without HEU**

The National Academy of Sciences (NAS) “State of the Science in Nuclear Medicine” committee held their sixth and final meeting on February 19-20, 2007, in Washington, DC. The final report from the 13-month project will likely be completed in late Spring or Summer 2007.

The NAS committee on “Medical Isotope Production Without Highly Enriched Uranium” held their first meeting on February 15, 2007. The 24-month study was mandated by Congress in Section 630 of the Energy Policy Act of 2005, and will determine the commercial feasibility of isotope production without HEU.

**NRC IN Regarding Sodium Iodide I-131 Capsules Remaining in Vials After Administration**

The U.S. Nuclear Regulatory Commission (NRC) issued an information notice (IN) (.Pdf file) to alert addressees about events in which patients were administered dosages of sodium iodide iodine-131 (I-131) that were less than the prescribed dosages, because of sodium iodide I-131 capsules that remained in vials, containing multiple capsules, after administration. These occurrences resulted in “medical events” because the patients did not receive the prescribed dosages.

The NRC requested that recipients review the IN for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. Note that the suggestions contained in the IN are not new NRC requirements; therefore, no specific action or written response is required from stakeholders.

**NRC Announces Appointment of New Member to the ACMUI**

The Nuclear Regulatory Commission announced the appointment of Darrell R. Fisher, Ph.D., as the patient’s rights advocate on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The ACMUI was established in 1958 and advises the NRC on policy and technical issues related to the regulation of the medical use of radioactive material.

Dr. Fisher, a medical physicist with experience in the dosimetry and health effects of radionuclides and radiopharmaceuticals used for diagnosing and treating cancer, is currently a senior scientist with 28 years experience at the Pacific Northwest National Laboratory in Richland, Wash. He leads the radioisotopes research program and serves as scientific director of the Department of Energy’s isotope production program.

**Quick Notes**

**CMS**

CMS posted a new website for the Physician Quality Reporting Initiative, which contains preliminary program information.

**NRC**

The NRC final rule on naturally occurring and accelerator produced radioactive material (NARM) has been delayed until approximately Summer 2007.

**CARE Action Alert**

The ACNP-SNM Legislative Action Center has draft text and a simple electronic communication tool for contacting the Hill to support H.R.583.

**Reimbursement Roadshow**

The February 23 Boston “Reimbursement Roadshow” marked a successful end to the 2007 series of Roadshow seminars on nuclear medicine coding practices. The Reimbursement Roadshow Workbook used in the seminar will be available soon for purchase on the SNM website.

**CRCPD**

The 2007 edition of the Conference of Radiation Control Program Directors (CRCPD) Directory of Personnel Responsible for Radiological Health Programs will be available on the SNM website within the month. The 2006 edition is freely available for download by SNM members.

**Coming in March…**

3/08: NRC Commission briefing on Nuclear Materials Safety and Safeguards (NMSS) programs, performance, and plans.

3/18-3/20: Annual ASRT “RT in DC” fly-in of radiologic and nuclear medicine technologists to support the CARE/RadCARE legislation.