

SNM HPRA: A Year in Review

The SNM Health Policy and Regulatory Affairs Department has been very busy over the past year. Following are brief descriptions of our activities in 2008:

- In January, SNM sent comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Hospital Outpatient Prospective Payment System and the Medicare Physician Fee Schedule final rules for calendar year 2008. The comments addressed many areas of the rules; the most important topic concerned the bundling of diagnostic radiopharmaceuticals.
- SNM continues to monitor the U.S. Department of Energy (DOE) budget recommendations. The recommendations for fiscal year 2009 included \$13.1 million for the Radiochemistry and Instrumentation program within the Biological and Environmental Research program in the Office of Science. This amount is less than that allocated in the Omnibus Spending Bill signed by President Bush in December, which funded the program at \$17.5 million for FY 2008. SNM continues to remain focused on ensuring that: (1) the \$17.5 million restored by Congress in late 2007 for FY 2008 are awarded by DOE; and (2) FY 2009 funding appropriated by Congress for this vital research is either increased or at least maintained at the FY 2008 level approved by Congress. The latter objective is particularly important, given the reorganization of this function and the lower funding level proposed by the administration for FY 2009.
- The members of the Physicians' Consortium on Quality of the American Medical Association (AMA) voted in late February to adopt 2 bone scan measures developed by a nuclear medicine working group with significant involvement from SNM. One of the measures was included in the 2009 CMS Physician Quality Reporting Initiative program. The measure requires the interpreting physician for bone scans to indicate whether or not comparison was made to other imaging procedures at the time of interpretation. Although the process of developing quality measures continues to be a challenge, SNM is committed to working with the AMA and other stakeholders to develop the best measures possible to improve the quality of nuclear medicine practice.
- An SNM working group has been working to address the need for the production of medical isotopes in the United States. The working group has released a report that identifies the physical and intellectual resources needed to develop production capabilities, where those facilities

are located, and estimates on development/production costs.

- In October, SNM, the American College of Radiology, the Academy of Molecular Imaging, the American Society for Therapeutic Radiology and Oncology, and the National Oncologic PET Registry submitted comments to CMS regarding the national coverage analyses for ^{18}F -FDG PET for solid tumor (CAG 00181R). The letter was written in response to CMS's request for additional comments regarding whether its current framework of cancer-by-cancer coverage for oncologic ^{18}F -FDG PET imaging could be replaced by an omnibus framework. In the letter, the societies strongly supported efforts by CMS to update and modernize the current PET national coverage determination to allow for expanded coverage of PET for cancer diagnosis, staging, and restaging.
- The SNM Committee on Pharmacopeia, together with Health Policy and Regulatory Affairs staff, has posted answers to frequently asked questions about the U.S. Pharmacopeia (USP) General Chapter <797>, *Pharmaceutical Compounding—Sterile Preparations* in the Government Relations section of the SNM Web site. Questions not answered in this section can be e-mailed to USP797@snm.org.
- In September, SNM filed comments with the Nuclear Regulatory Commission (NRC) in response to a petition for rulemaking filed by the Natural Resources Defense Council (NRDC). The NRDC has requested that the NRC amend the regulations that govern domestic licensing of production and utilization facilities and special nuclear material to establish a date by which the NRC will no longer license the use or export of highly enriched uranium (HEU) except for restricted use by a few specialized facilities. The NRDC believes that the amendment is needed to protect the public from potential exposure to an improvised nuclear explosive device made with HEU.



Hugh Cannon

As always, more detailed information can be found in the Government Relations section of the SNM Web site.

Hugh Cannon
Director, SNM Health Policy and Regulatory Affairs