



## **SNMMI-ACNM JOINT GOVERNMENT RELATIONS COMMITTEE**

Committee Report

January 2015

### **Committee Charges for 2014-2015:**

The Government Relations Committee is charged with reviewing federal regulations and congressional legislation that could possibly affect the nuclear medicine community as such policy issues arise. To that end, we deal with the following federal agencies:

Nuclear Regulatory Commission (NRC)  
Food and Drug Administration (FDA)  
Center for Medicare and Medicaid Services (CMS)  
Environmental Protection Agency (EPA)  
Department of Energy (DOE)  
Department of Transportation (DOT)  
Department of Health and Human Services (HHS)

To accomplish our goals, we lobby directly with contractors. Additionally, we have established good communication and working alliances with industry partners and professional organizations associated with nuclear medicine. This includes, but is not limited to CORAR, ACR, AMI, ASNC, and NEI.

### **Current Working Objectives/Goals:**

- Provide the lead on legislative and regulatory issues where appropriate.
- Work with Coding & Reimbursement Committee leaders to appropriately address policy/GR needs in the area of CMS and related Medicare legislation.
- Support the CARE legislative efforts by and for the SNMMITS.
- Continue to work toward cooperative working partnerships with the NRC, FDA, and other regulatory agencies. Monitor and appropriately respond to the emerging and continuing issues at NRC and FDA. Assist the Center for Molecular Imaging Innovation and Translation (CMIIT) in advocating for change in the FDA imaging agents' review/approval processes.
- Work with the Commission on Radiopharmaceuticals on government relations issues surrounding isotope production, domestic supply of Mo-99, etc.
- Continue to support basic and translational research at DOE Office of Science. Advocate in Congress for FY 2015 appropriations for DOE nuclear medicine research. Continue to advocate for the initiatives in the NAS "Advancing Nuclear Medicine Through Innovation" study.
- Work together with the SNMMITS Advocacy Committee and other relevant committees to enhance the grassroots advocacy programs and initiatives of SNMMI.
- Continue to monitor the ACO proposed rule.
- Coordinate HPRA activity with other societies to ensure a consistent message such as ACR, ASTRO, ASNC and the Academy of Radiology Research.

## Progress of Charge/Objectives/Goals to Date:

### REIMBURSEMENT

- SNMMI continues to work with CMS on issues of coverage and payment for nuclear medicine procedures.
- Working with other imaging societies to reverse proposed reimbursement cuts in cardiac imaging and nuclear medicine procedures in general.
- On April 1, President Obama signed H.R. 4302, the Protecting Access to Medicare Act of 2014. This legislation makes permanent changes to how physicians who perform advanced imaging services are paid by connecting it to appropriate use criteria. These permanent changes were included as part of the temporary one year patch to the Sustainable Growth Rate system.
- The Committee continues to watch the status of the one year patch to the Sustainable Growth Rate, which is currently set to expire on March 1, 2015.
- The Government Relations Committee will provide assistance, when appropriate, to the Coding & Reimbursement Committee's recently formed APC Remodeling Task Force

### LEGISLATIVE

- At the end of their 112<sup>th</sup> session, Congress passed S. 99, American Medical Isotopes Production Act of 2011, as part of the National Defense Authorization Act for fiscal year 2013. The Committee must now stay focused on the proposed conversion from HEU-non-HEU isotopes. President Obama's FY 2015 budget cuts funding for the Global Threat Reduction Initiative by 24.6%. The GTRI program is tasked to work with domestic and international civilian research reactors and isotope production facilities to assist in converting technology from highly enriched uranium (HEU) to non-highly enriched uranium (non-HEU) by 2020. SNMMI has met with Congress to discuss our lack of confidence in GTRI meeting its goal the budget's timeframe.
- Congress passed H.R. 3204, The Drug Quality and Security Act, which deals with compounding issues, and President Obama signed it into law on November 27, 2013. SNMMI continues to follow up on this new law and meet with individuals at the FDA to discuss its implementation.

### REGULATORY

- Continued dialogue with the FDA regarding various regulatory issues. Specifically, the FDA Task Force, in conjunction with the Government Relations Committee, is working on a White Paper to be submitted to the FDA regarding a new regularity pathway for the approval of biomarkers. The White Paper comes out of the FDA Stakeholders Meeting that was held in October.
- Continued work with NRC to mitigate any regulatory changes that affect nuclear medicine, including developing comments on the proposed changes to Part 35 and Part 20 as well as monitoring NRC activities related to regulations for patient release after treatment with I-131.

### MISCELLANEOUS

- Continue to work with the SNMMI Isotope Availability Task Group to address domestic isotope supply issues in the wake of the Mo-99 and other fission product supply crisis. Also now working on avenues to increase Tl-201 production that has been unable to meet demand when Tc-99m is in short supply.