SNMMI-ACNM Health Policy & Regulatory Affairs Newsletter

SNM MI 
SOCIETY OF 
NUCLEAR MEDICINE 
AND MOLECULAR IMAGING

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Contact Us
1850 Samuel Morse Drive
Reston, VA 20190
hpra@snmmi.org
(703) 708-9000

Sue Bunning
Director
sbunning@snmmi.org
Ext. 1322

Jesse Schoolnik
Government Affairs Manager
jschoolnik@snmmi.org
Ext. 1246

Caitlin Kubler
Regulatory Affairs Manager
ckubler@snmmi.org
Ext. 1323

Kendall Horvath
Associate Manager
khorvath@snmmi.org
Ext. 1025

Election Update

Following the November 4 midterm elections, Senate Republicans have gained at least seven seats for a total of 52. This gives control of the Senate to the Republicans for the first time since 2006. Republicans held the House of Representatives, which has been Republican-controlled since 2010.

While there are two races that have not been officially called, it seems as though Senator Mark Warner (D-VA) will win re-election in Virginia while Alaska Senator Mark Begich (D-AK) will lose to challenger Dan Sullivan. To further complicate the Senate map, Louisiana will hold a runoff election between incumbent Senator Mary Landrieu (D-LA) and challenger Rep. Bill Cassidy on December 6. Once these outstanding election results are finalized, there is a high probability that the Republicans will hold a majority with 54 seats.

Changes to the power structure in the Senate also mean changes to committee leadership, including those that affect nuclear medicine and molecular imaging. Longtime Senator Orrin Hatch (R-UT) is expected to become Chairman of the powerful Senate Finance Committee, where he is currently Ranking Member. Additionally, Senator Lamar Alexander is expected to become Chairman of the Health, Education, Labor & Pensions (HELP) Committee, where he also currently serves as Ranking Member. Previous Chair, Senator Tom Harkin, is retiring at the end of this year. Finally, while the outcome of the LA Senate race remains uncertain, leadership of the Senate Energy Committee will go to current Ranking Member Lisa Murkowski.

SNMMI's FDA Stakeholder Meeting

On October 27, 2014, SNMMI hosted a broad stakeholder meeting which brought in more than 40 experts from the field of nuclear medicine and molecular imaging. Longtime Senator Orrin Hatch (R-UT) is expected to become Chairman of the powerful Senate Finance Committee, where he is currently Ranking Member. Additionally, Senator Lamar Alexander is expected to become Chairman of the Health, Education, Labor & Pensions (HELP) Committee, where he also currently serves as Ranking Member. Previous Chair, Senator Tom Harkin, is retiring at the end of this year. Finally, while the outcome of the LA Senate race remains uncertain, leadership of the Senate Energy Committee will go to current Ranking Member Lisa Murkowski.

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benefit/utility between FDA and CMS. Individuals felt that clearly defining these terms would reduce ambiguity for all stakeholders involved in the drug development process. SNMMI is already in progress of developing a detailed white paper, set to be released in the coming months, which will identify the outcomes of each breakout group. The white paper will also lay out the action items, recommendations, and strategies SNMMI will implement. Currently there are plans to make this meeting an annual event.

SNMMI Patient Advocacy Capitol Hill Day

On Tuesday, September 30, SNMMI’s Outreach department, in conjunction with the Health Policy and Regulatory Affairs department, held the 2014 Patient Advocacy Advisory Board (PAAB) Capitol Hill Lobbying Day. The PAAB was created to provide SNMMI volunteer leaders, members, and staff with the patient perspective regarding nuclear medicine and molecular imaging matters. Specifically, the PAAB helps ensure patients’ concerns, ideas, experiences, and recommendations are reflected within SNMMI. The participants discussed continued Department of Energy funding for nuclear medicine research and ensuring a stable domestic source of Molybdenum-99.

1. Continued Funding from the Department of Energy (DOE): For nearly 60 years, the DOE has funded essential, fundamental nuclear medicine research in the areas of biomedical imaging and radiotherapy that has facilitated technological breakthroughs. Only the federal government funds basic nuclear medicine research, so this DOE program is critical for training and education. Currently, neither appropriations bill has included funding for nuclear medicine research with human application.

2. A reliable domestic supply of Molybdenum-99 (Mo-99): While the United States uses 50 percent of the world’s Mo-99, our supply comes from reactors in other countries, primarily Canada and the Netherlands. However, the Canadian facility will be phased out of commercial isotope production beginning in 2016. Additionally, President Obama’s FY 2015 budget proposed cutting funding for the Global Threat Reduction Initiative (GTRI) by 24.6 percent. 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 supports the program, but opposes the funding cut.

Proposed Changes to TJC Imaging Standards

On September 3, The Joint Commission (TJC) released Proposed Revisions to Diagnostic Imaging Services. These revisions would change the standards that are essential to nuclear medicine and, if approved, could have a detrimental effect on the industry as a whole. TJC’s Proposed Revisions (Standards 19 and 21):

- Would remove technologists certified by the Nuclear Medicine Technology Certification Board (NMTCB) from the list of technologists qualified to perform stand-alone diagnostic computed tomography (CT) exams; and
- Could result in problems with being allowed to perform single photon emission computed tomography (SPECT) combined with CT and PET combined with CT

SNMMI’s comments to The Joint Committee can be found here.

CMS Releases CY 2015 HOPPS and MPFS Final Rule

On Friday, October 31, CMS released the Calendar Year (CY) 2015 Final Rules for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS). The public comment period will close for both rules on December 30, 2014.

The HOPPS rule updates Medicare payment policies and rates for hospital outpatient department and ambulatory surgical center services. In CY 2015, HOPPS payments are estimated to increase by 2.3 percent. The increase is based on the projected hospital market basket increase of 2.9 percent minus both a 0.5 percentage point adjustment for multi-factor productivity and a 0.2%
percentage point adjustment required by law and includes other payment changes, such as increased estimated total outlier payments. CMS has also adopted a C-APC payment policy, which is an APC with a high cost primary service (generally includes the implantation of a device) that accounts for a higher percentage of the total costs of the hospital encounter.

The MPFS rule pays for covered physicians’ services furnished to a person with Medicare Part B. In the final rule, CMS has adopted a new process for establishing payment rates that will be more transparent and allow for greater public input prior to payment rates being set. Under the new process beginning with 2017, public comments will be considered for the vast majority of payment changes before they take effect. The final rule also makes some changes to quality reporting initiatives such as the Physician Quality Reporting System (PQRS). Finally, the rule continues the phased-in implementation of the physician value-based payment modifier (Value Modifier), created by the Affordable Care Act, that would affect payments to physicians and physician groups, as well as other eligible professionals, based on the quality and cost of care they furnish to beneficiaries enrolled in the traditional Medicare fee-for-service program.

The CY 2015 Hospital Outpatient Prospective Payment System Final Rule can be found here.

The CY 2015 Medicare Physician Fee Schedule Final Rule can be found here.

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**SNMMI Weighs In**

SNMMI provides comments to government stakeholders on a multitude of issues. For more information, please visit the [SNMMI website](#) or contact the HPRA department directly.

- On October 17, 2014, SNMMI’s submitted comments to The Joint Commission regarding released Proposed Revisions to Diagnostic Imaging Services.

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**Upcoming Events/Deadlines**

- Comments on the [proposed rule](#) for Part 35: Medical Use of Byproduct Material must be submitted to NRC no later than 5p.m. ET on November 18, 2014.

- Comments on the [proposed rulemaking](#) for Part 20: Radiation Protection must be submitted to NRC no later than 5p.m. ET on November 24, 2014.

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*Contact* [hpra@snmmi.org](mailto:hpra@snmmi.org) *to be notified by email of future newsletters.*