SNMMI Holds Patient Advocacy Capitol Hill Day

On Tuesday, October 8, SNMMI’s Patient Advocacy Advisory Board (PAAB) held their Capitol Hill Lobbying Day in Washington, DC. The PAAB was created to provide SNMMI volunteer leaders, members, and staff with the patient perspective with respect to molecular imaging and nuclear medicine matters. Specifically, the PAAB helps ensure patients’ concerns, ideas, experiences, and recommendations are reflected within SNMMI.

Despite the government shutdown, which closed many congressional offices, the PAAB was successful in meeting with 13 offices from nine states, including Congressman Randy Hultgren (IL-14). The following are the main topics that were discussed:

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, the Senate has appropriated $5 million for nuclear medicine research with human application while no funding was provided in the House bill.

2. **Preventing Cuts to Medical Imaging:** Since 2006, Medicare reimbursement for medical imaging procedures has been cut 13 times. These cuts have delayed possible innovation in medical imaging which negatively affects patients who are then denied proper care. Additionally, these cuts have caused physicians to delay updating their equipment. This could lead to patients being unable to get the most appropriate treatment. The current proposal to repeal the Medicare Sustainable Growth Rate system will cost an estimated $175 billion, which will have to be paid for by cutting funds from other government budgets, most likely from within the health care system. We want to ensure that these cuts do not come from medical imaging.

The Patient Advocacy Advisory Board’s Capitol Hill Lobbying Day was a great success. Advocacy is an ongoing effort that is strengthened by the connections made between SNMMI members and their congressional representatives. We thank all those who took time out from busy schedules to participate.
Partial Government Shutdown

Due to Congress’s failure to enact legislation appropriating funds for fiscal year 2014, the United States government was forced to partially shut down on October 1. However, the crisis was finally resolved on October 16, when Congress passed H.R. 2775, the Continuing Appropriations Act of 2014, which President Obama signed into law the next day. H.R. 2775 contained a continuing resolution to fund the government until January 15, 2014, and suspended the U.S. debt ceiling until February 7, 2014.

One of the driving factors behind the shutdown was the insistence of House Republicans that any new spending bill include provisions to defund the Patient Protection and Affordable Care Act (PPACA), also known as Obamacare. While substantial debate was held on this proposal, ultimately the PPACA was not affected by the final legislation.

The government shutdown has had a direct affect of the health care industry. The Department of Health and Human Services (HHS) was forced to furlough roughly 40,000 workers, amounting to 52 percent of HHS employees. This has resulted in the delay of many services, such as federal rulemaking activities.

Following this resolution, comprehensive immigration reform once again becomes prominent issue on Capitol Hill, though it is still unclear what will be accomplished in the remaining months of 2013. While this recent shutdown has come to an end, no long term fix was put into place. As a result, similar issues will arise early in 2014. During the shutdown, more than 800,000 government workers were furloughed, and national parks, congressional offices, and more were forced to close.

CMS Delays the Release of CY 2014 HOPPS and MPFS Proposed Rules

Due to the partial government shutdown, which lasted from October 1-16, the Centers for Medicare and Medicaid Services (CMS) will be forced to delay the release of several calendar year (CY) 2014 Medicare payment regulations. The delayed regulations that will most affect SNMMI are the final rules for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS). These final rules, usually released in early November, could be delayed as late as November 27. Please be sure to visit SNMMI’s Coding Corner for any future updates.

CMS Requires CED for Coverage of Beta-Amyloid PET

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) is disappointed that the final decision on beta-amyloid positron emission tomography (PET) from the Centers for Medicare and Medicaid Services (CMS) requires coverage with evidence development (CED). Under the decision, CMS will cover one PET scan to exclude Alzheimer’s disease, but only for patients participating in specific clinical studies under a CED program, which grants conditional reimbursement upon collection of specific data.

Appropriate use criteria jointly developed by the Alzheimer’s Association and SNMMI demonstrated that more than adequate evidence exists for Medicare to cover beta-amyloid PET. CMS coverage for this imaging test would give physicians an additional tool that could change patient management, leading to better health outcomes for patients and assisting families in making care decisions.

SNMMI appreciates that in its final decision, CMS included CED with short-term outcomes related to changes in management. A test that can rule out Alzheimer’s disease can result in patients being taken off powerful medications that can be costly and are not indicated for their condition. That is a positive outcome. Although Alzheimer’s disease is the leading cause of memory loss, several other factors—such as other neurodegenerative diseases, strokes, thyroid problems or medications—can cause similar symptoms. Ruling out Alzheimer’s disease also has significant outcomes for a patient’s family and caregivers. SNMMI looks forward to working with all stakeholders to establish an appropriate method to meet the required CED process so that we can offer this valuable test to our patients.

SNMMI will continue its work to ensure that dementia patients have access to the best care possible. The society will soon be launching a comprehensive education program for physicians who will be referring patients and those who will be reading the scans. Additionally, SNMMI is developing technical procedure guidelines for ensuring quality in the performance of the scans.
SNMMI Issues a Statement on Regadenoson

As you may know, the U.S. Food and Drug Administration (FDA) has placed regadenoson—a commonly used cardiac imaging agent—on its quarterly list of drugs to monitor. Regadenoson is a coronary vasodilator that produces maximal hyperemia quickly and maintains it for an optimal duration that is practical for radionuclide myocardial perfusion imaging. The drug was placed on this list due to potential signs of myocardial infarction and death.

Placing it on the watch list does not mean that FDA has concluded that the drug has the listed risk. According to the FDA, “The listing of a drug and a potential safety issue on [our] Web site does not mean that FDA is suggesting prescribers should not prescribe the drug or that patients taking the drug should stop taking the medication.”

The Society of Nuclear Medicine and Molecular Imaging is monitoring the situation and will advise members when there is further information. For additional details, click here.

Avoid PQRS Penalties: Report One Measure, on One Patient, One Time!

The physician quality reporting system (PQRS) is part of a long-term Centers for Medicare and Medicaid Services (CMS) initiative intended to, among other things, obtain information on the quality of care across the health care system. It is an incentivized voluntary reporting program to report data on quality measures for covered services provided to Medicare part B fee for service (FFS) beneficiaries. Physicians that do not voluntarily report measures in 2013 will be penalized 1.5 percent of their Medicare payments in 2015. An incentive payment (0.5 percent) is provided to those who successfully report three measures on a 50 percent sample of their applicable FFS patients for each measure. For program year 2013, to avoid the penalty physicians can simply report one measure, on one patient, one time! This can be done by submitting the CMS-1500 claims form. Consider reporting on one of the measures found in the graph located here (measure 147 is related to bone scans).

Update Regarding Shortage of DRAXIMAGE® MAA Kits

SNMMI has continued to track the supply of macroaggregated albumin (MAA). We are pleased to report that the shortages that occurred as a result of manufacturing improvements to automate the production process have been resolved. On October 11, 2013, Jubilant DraxImage Inc. (JDI), the sole supplier of MAA, reported to the U.S. Food and Drug Administration (FDA) that multiple MAA shipments were occurring. This prompted the FDA to remove MAA from its drug shortages list on October 17, 2013.

JDI’s new automated production process has proved successful. The company has been able to increase production to fully replenish MAA inventory. As a point of reference, JDI began fulfilling customers’ backorders on October 5, 2013. This was followed by another batch on October 10, 2013. Additional shipments also occurred the week of October 21, 2013, and more are to follow.

SNMMI will remain in contact with JDI. Should the situation change we will inform the nuclear medicine and molecular imaging community and other stakeholders. If you have any questions or concerns, contact your radiopharmaceutical supplier or JDI. JDI’s customer service can be reached at 1-888-633-5343 or 514-630-7080.
**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 September 24, SNMMI submitted comments to The Joint Commission on their proposed changes to diagnostic imaging services. While the comments provided reference the “Hospital Accreditation Program” standards, they are intended to be utilized for ambulatory care and critical access hospital accreditation program, when like areas are repeated.

**Important Upcoming Events/Deadlines**

- SNMMI will be presenting at the Nuclear Regulatory Commission regarding the proposed rule for Title 10 of the Code of Federal Regulations Part 35. The meeting has been rescheduled and a new date will be determined in the future.

*Contact hpra@snmmi.org to be notified by email of future newsletters.*