Congress Adjourns for Spring Recess Without Passing SGR Legislation

On Friday, March 27, Congress adjourned for their spring recess without passing legislation that would permanently repeal Medicare's sustainable growth rate (SGR) and provide incentives for doctors to focus on value-driven care. Rep. Michael Burgess (R-TX) introduced H.R. 2, the Medicare Access and CHIP Reauthorization Act of 2015. In a rare bipartisan move, the House of Representatives easily passed H.R. 2 with a vote of 392-37. However, the Senate could not reach an agreement during their late night “vote-a-rama,” a marathon session of voting on the dozens of amendments being considered for the Fiscal Year (FY) 2016 budget.

The Senate has scheduled a vote for the SGR in April, after Congress returns to Washington. The Centers for Medicare & Medicaid Services (CMS) cannot pay electronic claims any sooner than 14 days after receipt. As a result, while the 21% pay cut will apply to claims for all services rendered after March 31, 2015 physicians will not experience any problems if the Senate passes the bill and the president signs it by April 14, 2015.

More information on the SGR can be found [here](#).

NRC Requests Information Concerning Patient Release Practices

The National Regulatory Commission (NRC) is requesting a one-time information collection regarding specific I-131 patient release procedures. Based on feedback from patients and patient advocacy groups, which questioned the availability of clear, consistent, patient friendly and timely patient release information, the NRC has been directed to work with a wide variety of stakeholders to collect additional information. The NRC intends to compile comments and input from as many stakeholders as possible. The NRC is seeking information for questions associated with:

1. existing web sites that the responders believe provide access to clear and consistent patient information about I-131 treatment processes and procedures;
2. information the responders believe represent best practices used in making informed decisions on releasing I-131 patients and stand alone or supplemental voluntary patient/licensee guidance acknowledgment forms, if available;
3. an existing set of guidelines that the responders developed or received that provides instructions to released patients; and
4. an existing guidance brochure that the responders believe would be acceptable for nationwide distribution.

The NRC intends to use the responses collected to form the basis for patient release guidance products developed in response to the NRC's April 28, 2014, Staff Requirements—COMAMM-14-0001/COMWDM-14-0001—“Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance.”
SNMMI is currently in the process of developing a response to this request and will keep members informed of any updates. Comments on patient release practices are due to the NRC by May 4, 2015 and can be submitted at regulations.gov.

SNMMI Submits Comments to CMS on Appropriate Use Criteria

On Thursday April 9, 2015, SNMMI sent a letter to CMS on imaging appropriate use criteria (AUC). The deadline for implementation of H.R. 4302 is approaching and SNMMI is concerned that this aggressive timeline is limiting the ability of professional medical societies and stakeholders to properly respond with true evidence based AUC.

SNMMI recommends that CMS further clarify how the new AUC, as well as the revisions/updates, will be included in the program on an ongoing basis. The society believes that updates and reviews should be based upon significant changes in the evidence (published scientific literature) used to develop AUC.

Additionally, SNMMI remains concerned with the possibility of multiple AUCs for a particular imaging modality, which have been developed by separate medical specialty societies using different processes and “evidence-based” criteria. If this were to occur, it is unclear whether the practitioner has a choice of which AUC they may use to order an Advanced Diagnostic Imaging Service (ADIS). In addition, there are often differences in how AUCs are defined or constructed. AUC may be categorized by specific imaging modalities, or searchable by clinical conditions which then provide rankings for the various available imaging modalities. SNMMI believes that if the AUC indicate that more than one imaging modality is appropriate for a condition, the imaging physician should have the ability to decide the imaging modality in consultation with the ordering physician.

SNMMI requests clarity from CMS on whether all approved clinical decision support mechanisms will incorporate all “deemed” or approved AUCs regardless of copyright issues. In order to provide full functionality for the free clinical decision support mechanism, the society suggests that it should have the complete list of deemed or approved AUC developed by all medical specialty societies and other provider led entities.

The society communicated these concerns during the High Country Nuclear Medicine Conference in Colorado March 2, 2015. To learn more about appropriate use criteria, clinical decision support, and the impact on nuclear medicine, view SNMMI’s presentation here.

CMS Requests Comments on Ending Data Collection for NaF-18 PET

On March 16, 2015, CMS solicited public comments regarding The National Oncology PET Registry’s (NOPR) request to end the prospective data collection requirements under coverage with evidence development (CED) for use of NaF-18 PET imaging in intended patient management. NOPR believes that the evidence-based conclusions from their analysis of the extensive NOPR NaF data set supports both the end the data collection requirement as well as the authorization for national coverage of NaF PET for bone metastasis for all oncologic indications.

Sodium Fluoride F-18 (NaF-18) is a radioisotope commonly used in oncologic PET imaging procedures to detect bone metastasis in cancer and is the focus of this national coverage analysis. The rate of NaF-18 uptake provides information on the tissues being studied. NaF-18 PET evaluation can indicate the probable presence or absence of bone metastasis based upon observed differences in biologic activity of adjacent tissues.

SNMMI submitted comments on April 8, 2015. View the comment letter here.

Public comments are due no later than April 15, 2015. Comments may be submitted here.

Keys to an effective CMS comment letter can be found here.

SNMMI Submits Comments on Compounding

On March 24, 2015, SNMMI submitted comments to FDA regarding the distinction between nuclear pharmacy and manufacturing. The society’s comments are part of ongoing efforts on to ensure radiopharmaceutical products be given adequate consideration in the policymaking process. SNMMI believes there is a need for public guidance on how the FDA will exercise enforcement discretion of radiopharmaceutical compounding.
The Society submitted comments and met with FDA in September 2014. As follow up to the FDA discussions in September 2014, SNMMI’s Joint Compounding Task Force has worked with other medical societies and industry to more specifically define radiopharmaceutical compounding and preparation and sent a final report to the FDA in late November 2014. How the FDA defines “radiopharmaceutical compounding” and “radiopharmaceutical preparation” will become very important in our guidance. SNMMI defines “radiopharmaceutical preparation” to mean either activities performed in accordance with the instructions in the FDA-approved labeling, or minor deviations from those instructions. Nuclear pharmacies are an essential link in patient care, as they provide patient-specific unit dose radiopharmaceutical products to hospitals and clinics throughout the U.S. SNMMI continues to monitor this situation closely.

**Ge/Ga-68 Decommissioning Funding Plan Regulatory Relief Needed**

On Thursday March 19, 2015, the Advisory Committee on the Medical Use of Isotopes (ACMUI) recommended that the Nuclear Regulatory Commission (NRC) provide regulatory relief from the decommissioning funding plan (DFP) requirements for the use of a Germanium-68/Gallium-68 (Ga-68) generator. ACMUI member Steve Mattmuller stressed that the NRC act quickly as this diagnostic is desperately needed in the US. Ga-68-labeled somatostatin analogs are important imaging agents to detect and manage neuroendocrine tumors (NETs). The ACMUI meeting handouts can be viewed here.

At the recent Third Theranostics World Congress on Ga-68 held on March 12-14, leading world experts addressed the current limitations and shared their insights and expertise on how the field has evolved over the years—from advances in radiochemistry to new research in innovative applications for Ga-68 PET radiopharmaceuticals, including PSMA and CXCR4-targeted imaging. There, many patients asked why they needed to travel to Europe for their Ga68-labelled somatostatin receptor imaging. Although Ga-68 imaging agents have been used around the world for more than a decade, these agents are not yet approved in the United States and are available only through investigational pathways. In the US, this diagnostic is only available at 11 centers under IND.

SNMMI believes it is the responsibility of the NRC to provide regulatory relief soon from the DFP requirements for a Ga-68 generator, to avoid an unnecessary burden on patient access and care. The Society believes the NRC needs to act swiftly to avoid the consequences of an unintentional omission in the regulations from becoming a burden on patient care.

**SNMMI’s Annual Capitol Hill Lobbying Day**

SNMMI will hold its annual Capitol Hill Lobbying Day on Monday, April 27, 2015. Currently, 39 participants plan on attending the event and meeting with more than 50 Congressional offices. SNMMI plans on discussing the need for appropriate reimbursement of radiopharmaceuticals as well as the need to ensure a stable supply of Molybdenum-99.

This year’s Capitol Hill Lobbying Day coincides with SNMMI’s Spring Board Meeting and the Industry Forum Reimbursement Committee Meeting. Many Industry Forum stakeholders are remaining in Washington, DC through Monday to join SNMMI members in congressional meetings.

**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 March 2, 2015, SNMMI presented at the High Country Nuclear Medicine Conference on AUCs and clinical decision support.
- On March 24, 2015, SNMMI submitted comments to FDA on Compounding
- On Thursday April 9, 2015, sent a letter to CMS on appropriate use criteria
Upcoming Events/Deadlines

- Comments to CMS on Ending Data Collection for NaF-18 PET are due by April 15, 2015 and can be submitted [here](#).
- Capitol Hill Day will be April 27, 2015. If you are interested in participating, please contact Jesse Schoolnik at jschoolnik@snmmi.org.
- NRC is accepting comments on patient release practices. Comments are due by May 4, 2015 and can be submitted at [regulations.gov](#).
- SNMMI Annual Meeting in Baltimore, MD, June 6-10, 2015.
- NRC is accepting nominations for the position of Nuclear Pharmacist on the Advisory Committee on the Medical Use of Isotopes. Nominations are due on or before June 8, 2015.

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