SNMMI Comments on CMS Proposed Rules for CY2017 HOPPS and MPFS

SNMMI recently submitted comments to the Centers for Medicare and Medicaid Services (CMS) for two proposed rules for 2017. SNMMI submitted comments on its CY2017 Proposed Rule for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS) released this July.

In the HOPPS letter SNMMI commented on several important policy provisions including:

- Proposed APC restructuring for nuclear medicine services
- Reclassification and recalibration related changes
- Payment modifier for x-ray films
- Off-campus provider-based departments
- Transitional pass-through payment period
- Q9969 Code

In the MPFS letter SNMMI commented on several policy provisions including:

- Policy changes to the refinement panel
- Payment modifier for x-ray films
- Elimination of physician payment increase
- Appropriate Use Criteria

View SNMMI's HOPPS letter, here.

View SNMMI’S MPFS letter, here.

SNMMI Comments on VA Proposal to Allow Nurses to Perform Imaging Studies

On Friday, July 22, 2016, SNMMI submitted comments opposing the Department of Veterans Affairs’ (VA) proposed rule to 38 CFR 17. The VA’s proposed rule would grant advanced practice registered nurses (APRNs) the authority to, among other things, perform imaging services. Section 17.415(d)(1)(i), specifically, would allow certified nurse practitioners (CNPs) to “order, perform, supervise, and interpret laboratory and imaging studies.”

In an attempt to address criticisms over management and patient care, the VA proposed this rule to improve veteran’s access to health care services while ensuring the “VA has authority
to address staffing shortages in the future.” SNMMI applauds the VA’s efforts to provide a higher level of care for our veterans, however, the society does not believe advanced practice CNPs are qualified to “order, perform, supervise and interpret laboratory and imaging studies.”

Specifically, SNMMI commented that a CNP’s advanced-level of education does not compare to the 7-10 years of dedicated training Nuclear Medicine Physicians receive. The society also highlighted that in order for a CNP to supervise a procedure, they need to meet NRC regulations, which in this instance only physicians are qualified under. Lastly, SNMMI emphasized that CNP’s have not received any of the radiation safety training necessary to protect their patients, fellow medical personnel and themselves.

SNMMI continues to monitor the VA’s proposed amendments to 38 CFR 17, and is working at a grassroots level to oppose similar legislation.

Read SNMMI’s full comments, here.

Read the VA’s news release on this issue, here.

NAS Releases Report on Molybdenum-99 for Medical Imaging

On September 12, 2016, The National Academies of Sciences, Engineering, and Medicine (NAS) released a report on the state of molybdenum-99 (Mo-99) production, its utilization in medicine, and the progress that has been made toward eliminating the use of highly enriched uranium (HEU) during production.

In terms of progress toward eliminating the use of HEU for medical isotope production, the report states that global Mo-99 suppliers have committed to eliminating HEU use in reactor targets and in medical isotope production facilities. Additionally, financial support from the Department of Energy’s National Nuclear Security Administration (NNSA) and technical support from U.S. national laboratories are facilitating domestic production efforts of Mo-99 using non-HEU.

Despite this progress, the continued availability of Mo-99 produced with HEU is an impediment towards the transition to non-HEU technology. The NAS report points out that 75% of the global supply of Mo-99 for medical use is produced using HEU, leaving companies producing Mo-99 with non-HEU technology at a competitive disadvantage. The NNSA currently funds four projects designed to develop a domestic source of Mo-99 that does not use HEU. These initiatives are projected to supply half or more of U.S. needs.

However, the report states that substantial domestic supplies are unlikely to be available before 2018 due to technical, financial, regulatory, and market challenges. Furthermore, the NAS determined that “there is a substantial (>50 percent) likelihood of severe molybdenum-99/technetium-99m supply shortages after October 2016, lasting at least until current global suppliers complete their planned capacity expansions.”

In an attempt to mitigate any shortages that might occur, NAS recommends that the U.S. continue to work with the Canadian government to ensure there is a plan in place to resume imports if needed. Canada has said it will keep its reactor on stand-by until the end of March 2018, when it will shut down permanently. The report also recommends the U.S. government and others take additional actions to promote the wider use of non-HEU produced Mo-99/Tc-99m. Read the full report to view greater details on the NAS’ recommendations.

SNMMI President Sally W. Schwarz, MS, RPh, BCNP, professor of radiology at Washington University School of Medicine in St. Louis, agrees in general with the report’s assessment and also notes, “Development of these new, non-HEU production methods is costly, even when shared with governments. It will take time and incremental changes to reach a balance point of fair reimbursement for increased costs for all members of the supply chain including Mo-99 producers, generator manufacturers, nuclear pharmacies, hospitals, and patients.” Schwarz cautioned that the potential for short-term shortages is a real concern, but the global Mo-99 producers, processors and generator manufacturers, working with AIPES, will strive to manage any interim shortage problems that might occur.

She is optimistic overall about Mo-99/Tc-99m production through non-HEU means and the development of a domestic source of Mo-99. “The innovative, safer production methods and facilities that will be coming online over the next few years will certainly help ensure a safe, reliable supply of Mo-99.”

To read the full report, click here.
Physicians: Review Your 2015 Open Payments Data Before It’s Too Late

The Centers for Medicare and Medicaid Services (CMS) Open Payments data is now available. Mandated under the Affordable Care Act, Open Payments is a program that collects information from drug and device companies on their payments to physicians and teaching hospitals for various items including travel, research, gifts, speaking fees, and meals.

Even if you do not think any data has been collected on you, SNMMI urges all Nuclear Medicine Physicians to check the Open Payments data to ensure all data is accurately reported. If you find any inconsistencies, dispute these items quickly to ensure you have ample time to resolve the inaccuracy before the system closes in December. Disputing claims also alerts companies that you disagree with their records. Click here to register for the CMS Open Payments portal.

Although the deadline to review and dispute the Open Payments records is December 31, 2016, SNMMI suggests that you review the Open Payments data on an annual basis to ensure companies are providing accurate information to CMS.

If you have questions on how Open Payments works or on how to dispute any CMS data, contact CMS’s Open Payments Help Desk at openpayments@cms.hhs.gov or 855-326-8366.

SNMMI Presents at NRC Stakeholders Meeting

On Tuesday, July 26, 2016, SNMMI presented at a high-level stakeholders meeting at the Nuclear Regulatory Commission. The NRC Chairman and Commissioners met with numerous stakeholders to discuss matters such as the efficiency and effectiveness of NRC regulatory programs, effectiveness of public engagement, and the use of risk insights in regulations and decision-making. Participants included Fred Fahey, DSc, FSNMMI, FACR, FAAPM, (representing SNMMI), states, public interest groups, nuclear power plant operators, new reactor vendors, and former NRC Commissioners.

Dr. Fahey represented the society and provided the medical perspective for NRC. Dr. Fahey's presentation highlighted the impact of radioactive materials on patients, NRC's impact on patients, inspections, resolution of stakeholder comments and regulatory analysis, as well as communication between the NRC and the medical community.

SNMMI continues to see ways to engage with regulators and communicate the value of nuclear medicine and molecular imaging.

To view Dr. Fahey’s full presentation, click here.

To view the NRC meeting materials, including all slides and transcripts, click here.

Imaging Drug Development - FDA Regulatory Issues Presentation Available to Members

The society has been given permission by the Food and Drug Administration to share the "Imaging Drug Development - FDA Regulatory Issues" presentation from SNMMI’s 2016 Annual Meeting. The FDA sponsored session took place on Tuesday, June 14, at the San Diego Convention Center in San Diego, California. SNMMI is grateful for the opportunity to share this valuable information with members. Educational objectives of the presentation include identifying CMC and compliance issues as they relate to research, IND, and NDA, describing DMIP product approvals and safety-related issues, discussing PET inspection issues as well as discussing FDA’s perspective on 68Ge / 68Ga Generators and 68Ga radiolabeled approved kit. Access the links below to view specific presentations. Access the links below to view FDA's presentations.

- Update on Product Approval
  Louis Marzella, MD, PhD

- Expanded Access to Investigational Drugs
  Phillip Davis, MD

- Peptides as Radiopharmaceuticals: CMC Perspectives
  Ravindra Kasliwal, PhD

- Compliance Update
  Krishna Ghosh, PhD
Katherine Zukotynski Chosen as Recipient of the 2016 Ursula Mary Kocemba–Slosky, PhD, Professional Relations Fellowship

SNMMI and the Education and Research Foundation for Nuclear Medicine and Molecular Imaging are pleased to announce that Katherine Zukotynski, BASc, MD FRCPC is the recipient of the 2016 Ursula Mary Kocemba–Slosky, PhD, Professional Relations Fellowship. Each year, a young professional in nuclear medicine and molecular imaging is chosen to spend a week in Washington, DC and SNMMI’s Headquarter Office in Reston, Virginia to gain direct, personal exposure to SNMMI’s professional relations activities as they relate to other medical societies, industry partners, and other organizations.

With a vision of nuclear medicine and molecular imaging leading the way in patient care, teaching and research, Dr. Zukotynski hopes to use the knowledge gained from this experience to help advance the field. Dr. Zukotynski specifically stated that “to grow the field of nuclear medicine and molecular imaging, we must go beyond understanding our own community, to understand those around us to learn how to communicate with them to promote good relations.”

Dr. Zukotynski concurrently serves as an Associate Professor at the McMaster University Departments of Medicine and Radiology in Ontario, Canada. She completed her Radiology residency in 2007 through the University of Toronto and Nuclear Medicine residency in 2009 through the Joint Program in Nuclear Medicine at Harvard Medical School.

This fellowship would not be possible without the generous contributions made by Jack Slosky, MD. Dr. Slosky established this wonderful fellowship opportunity in memory of his late wife, Ursula Mary Kocemba-Slosky.

SNMMI Comments on FDA Data Integrity and Compliance with CGMP

On July 21, 2016, SNMMI provided comments on FDA’s draft Guidance Document on Data Integrity and Compliance with CGMP. The U.S. Food and Drug Administration (FDA) released new draft guidance in April to help the pharmaceutical industry ensure data is consistent and accurate. The guidance includes 18 questions and answers on data integrity, as well as defined terms on data as they relate to current good manufacturing practice (cGMP) records, recommendations on when workflows on computer systems validation, and ensure electronic master production and control records (MPCR).

SNMMI addressed several concerns with the guidance, such as the need for FDA to delineate the difference between PET drug manufacturing and conventional drug manufacturing, allowing PET radiopharmaceutical firms to implement meaningful and effective strategies for data integrity, challenges with electronic audit systems requirements, and batch records.

To view the full comment letter, click here.
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.

- SNMMI submitted comments on the Veterans Affairs (VA) 38 CFR 17 Proposed Rule.
- SNMMI submitted comments on the FDA’s draft Guidance Document on Data Integrity and Compliance with CGMP.
- SNMMI presented at a high-level stakeholders meeting at the Nuclear Regulatory Commission on July 27, 2016.

Upcoming Events/Deadlines

- The National Academies of Sciences releases its Molybdenum-99 for Medical Imaging report.
- Save the date! SNMMI’s 2017 Mid-Winter Meeting will take place January 19-22,2017, in Phoenix, Arizona.
- Save the date! SNMMI’s 2017 Annual Meeting will take place June 10-14, 2017, in Denver, Colorado.

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