SNM Submits Comments to CMS regarding the 2009 Proposed HOPPS Rule

On August 29, 2008, the SNM sent comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Hospital Outpatient Prospective Payment System (HOPPS) proposed rule for calendar year (CY) 2009.

SNM Comments to CMS address the following:
- Nuclear Medicine APC Procedures
- Diagnostic & Therapeutic Radiopharmaceuticals
- New APC for Biodistribution Imaging Procedures
- CMS Table 25 Therapeutic Radiopharmaceutical Payment Rates
- APC 307 Myocardial PET Payment Reductions
- Radiopharmaceutical Edits
- Improving Cost Reports
- New Radiopharmaceutical Pass Through and Offsets

The SNM prepares charts and spreadsheets that evaluate the impact of the proposed HOPPS rule for nuclear medicine procedures and products. The proposed 2009 charts and spreadsheets are currently available on the SNM Coding Corner.

SNM Submits Comments to CMS regarding the 2009 Proposed MPFS Rule

On August 29, 2008, the SNM sent comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year (CY) 2009.

SNM Comments to CMS address the following:
- Direct Practice Expense (PE) & Relative Value Units (RVUs)
- Independent Diagnostic Testing Facilities
- Malpractice RVUs
- MIPPA Implementation
  - Budget Neutrality
  - Accreditation and Appropriateness Criteria
  - Physician Quality Reporting Initiative (PQRI) – Selection of Measure for 2009

The SNM prepares charts and spreadsheets that evaluate the impact of the MPFS rule for nuclear medicine procedures and products. The proposed 2009 charts and spreadsheets are currently awaiting conversion factor updates and will only be available after the final rule is posted in November on the SNM Coding Corner.
Advisory Panel (MedCAC) Meets to Review Evidence to Expand PET Coverage for Oncology Indications – Results Posted

From the CMS Website: On August 20, 2008, the Centers for Medicare and Medicaid Services (CMS) convened a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting to discuss whether or not Medicare should extend PET reimbursement for the nine cancer indications currently covered through the National Oncology PET Registry (NOPR): brain, cervical, bladder, small-cell lung, ovarian, testicular, prostate, kidney, and pancreatic cancers. Representatives from SNM, the American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO), the Academy of Molecular Imaging (AMI), NOPR, and other cancer advocacy groups attended the meeting in support of broad Medicare coverage across all cancer indications using PET scans.

The meeting took place in response to NOPR's March 2008 request that CMS broaden PET reimbursement across all cancer indications including the nine cancers for which Medicare is currently reimbursing. Since 2006, Medicare has only covered patients with the above nine cancers if they were enrolled in the registry.

The meeting consisted of several presentations showing the clinical utility of PET in cancer diagnosis and treatment. NOPR Working Group Chair Bruce Hillner, MD presented the conclusions of the NOPR registry data, showing that FDG-PET is associated with a 36.5% change in the intended management of patients. These findings were published in the Journal of Clinical Oncology (JCO) in March 2008. Additionally, David Mankoff, MD, PhD presented an intersocietal consensus statement from the SNM, ACR, ASTRO, and AMI on the accuracy and impact of FDG-PET for cancers studied in the NOPR. According to Dr. Mankoff, "as clinical trial data continues to support the impact of previously covered indications, and NOPR along with other recent trials support FDG-PET accuracy and impact for a wide range of other cancers, we recommend that CMS implement broad coverage of FDG-PET for cancer diagnosis, staging, and re-staging of suspected recurrence."

The MedCAC panel consisted of eight members ranging from radiation oncologists to independent medical consultants. CMS has stated that it hopes to have a proposed decision memo by January 2009, with an expected completion date in April.

One of the outcomes of the meeting was for the MedCAC panel to vote on a series of five predetermined questions regarding the evidence for expanding FDG-PET coverage. To download the results scoresheet click here.


Effective October 1, 2008, HCPCS code C9244 (Injection, regadenoson, 0.4mg) should be used for billing Lexiscan to Medicare in the hospital outpatient setting only. This new policy will take precedence over the previous billing instructions for billing C9399 (Unclassified drugs or biologicals) in the hospital outpatient setting. Providers billing Regadenoson in the Physician office or IDTF setting continue to use J3490 (Unclassified drugs).

Lexiscan is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. The recommended dose of Lexiscan is 5 mL (0.4 mg regadenoson) by rapid intravenous injection; followed immediately by saline flush and radiopharmaceutical. NDC for Lexiscan is 0469-6501-89 (syringe).
CMS Reopens Public Comment Period Addressing Oncologic FDG PET Imaging

On September 16, 2008, the Centers of Medicare and Medicaid Services (CMS) posted an announcement seeking additional public comment on the use of FDG PET imaging for other solid tumors. The CMS states, “We have received public input indicating that the current coverage framework which required cancer by cancer consideration of diagnostic, staging, restaging and monitoring response to treatment should be replaced by a more omnibus consideration.” Additionally, the announcement mentions that the CMS is open to public comments that the current policy be abandoned and that a general policy could be developed and implemented for oncologic FDG PET imaging. To accommodate the expanded scope of this analysis, the tracking sheet is renamed as follows: NCA Tracking Sheet for Positron Emission Tomography (FDG) for Solid Tumors (CAG-000181R). The new public comment period opens September 16, 2008 and ends October 16, 2008. In response to this announcement, the SNM and the National Oncologic PET Registry (NOPR) are developing comments to the CMS and will post these comments after submission.

The following sections of the National Coverage Determination Manual currently address solid tumors:

- 220.6.2 – Lung cancer
- 220.6.3 – Esophageal cancer
- 220.6.4 – Colorectal cancer
- 220.6.5 – Lymphoma
- 220.6.6 – Melanoma
- 220.6.7 – Head and neck cancers
- 220.6.10 – Breast cancer
- 220.6.11 – Thyroid cancer
- 220.6.12 – Soft tissue sarcoma
- 220.6.14 – Brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers
- 220.6.15 – All other cancer indications not previously specified

Public commenters are encouraged to provide additional feedback on the use of FDG PET imaging for other solid tumors listed above and possible alternatives to the current coverage framework. To submit comments and view additional information regarding the NCD on FDG PET click here and use the orange “Comment” button at the top of the page. To download the Coverage Education Document for PET facilities, please click here. To download the Coverage Education Document for Referring Physicians, please click here.

ACMUI Announces October 27-28 Meeting

The Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) has announced a meeting on October 27th and 28th to discuss issues related to 10 CFR Part 35 Medical Use of Byproduct Material. A sample of agenda items includes: (1) ACMUI subcommittee reports on cesium chloride (CsCl), permanent implant brachytherapy rulemaking, and fingerprinting; (2) Y–90 microsphere brachytherapy licensing guidance; (3) potential changes to 10 CFR Parts 20 and 35; (4) patient needs, concerns, and rights in radiation medicine; (5) infiltration of fluorine-18 (F–18) and therapeutic radiopharmaceuticals as medical events; (6) status of recommendations for modifying training and experience attestation requirements; (7) status of technical basis for the Petition for Rulemaking (PRM) 35–20 (Ritenour) and follow-up; (8) Potential rulemaking and associated Regulatory Issue Summary (RIS) regarding multiple RSOs on a medical-use license; (9) status of current and future 10 CFR Part 35 rulemaking; and (10) medical isotope shortages.

NRC Announces New Members to the Advisory Committee on Medical Uses of Isotopes

The Nuclear Regulatory Commission (NRC) has announced two new members of the Advisory Committee on Medical Uses of Isotopes (ACMUI): Steven R. Mattmuller and Debbie B. Gilley. The ACMUI was established in 1958 and advises the NRC on policy and technical issues related to the regulation of the medical use of radioactive material.
NRC Further Revises Licensing Guidance for Therasphere and SIRSphe rses Yttrium-90 Microspheres

The Licensing Guidance for Therasphere and SIRSphe rses Yttrium-90 Microspheres has been further updated by the Nuclear Regulatory Commission (NRC). For more information, see the NRC Public Medical Uses Licensee Toolkit website.

SNM Files Comments to NRC Regarding Natural Resources Defense Council Petition for Rulemaking

On September 24th, SNM filed comments with the Nuclear Regulatory Commission (NRC) in response to a petition for rulemaking filed by the Natural Resources Defense Council (NRDC). The NRDC has requested that the NRC amend the regulations that govern domestic licensing of production and utilization facilities, and special nuclear material to establish a date when the NRC will no longer license the use or export of highly enriched uranium (HEU) except for restricted use by a few specialized facilities. The NRDC believes that the amendment is needed to protect the public from potential exposure to an improvised nuclear explosive device made with HEU and used by terrorists.

In its comments, SNM asked that the petition be denied and recommended that the NRC possibly re-open the comment period and also delay its decision until there has been time to fully assess the recommendations put forth in the National Academy of Sciences' (NAS) report on "Medical Isotope Production Without Highly Enriched Uranium", due to be released this fall.

NRC Grants Extension of Comment Period for the Security and Continued Use of Cesium-137 Chloride Sources

The Nuclear Regulatory Commission (NRC) has granted an extension for comments described in the Notice on the Security and Continued Use of Cesium–137 Chloride Sources. NRC staff recognizes that the public and other stakeholder comments may be impacted by the discussions that will occur during the two-day public meeting which concludes on September 30, 2008, and therefore agrees to extend the comment period an additional 15 days. Comments are now due by October 15, 2008.

NRC Issues Regulatory Guide 10.7 (Revision 2): "Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material"

The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 2 of the Regulatory Guide 10.7: "Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material". This guide directs the reader to the type of information needed by the NRC staff to evaluate an application for a specific license for laboratories and industries to use megabecquerel (MBq) (millicurie (mCi)) quantities of byproduct material (reactor- or accelerator-produced radionuclides). The regulatory framework that the NRC has established for laboratory and industrial use of small quantities of byproduct material is in Title 10, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," of the Code of Federal Regulations (10 CFR part 30).

This regulatory guide endorses the methods and procedures for applying for a license for laboratory and industrial use of small quantities of byproduct material contained in the current revisions of NUREG–1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" and NUREG–1556, Volume 12, "Consolidated Guidance about Material Licenses: Program-Specific Guidance About Possession and Licenses for Manufacturing and Distribution," as a process that the NRC staff finds acceptable.
NRC Issues Regulatory Guide 10.8 (Revision 3): "Guide for the Preparation of Applications for Medical Use Programs"

The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 3 of the Regulatory Guide 10.8: "Guide for the Preparation of Applications for Medical Use Programs." This regulatory guide directs the reader to the type of information acceptable to the NRC staff for review of an application for a medical use license. Title 10, Part 35, "Medical Use of By-product Material," of the Code of Federal Regulations (10 CFR Part 35) regulates the medical use of byproduct material. In addition to the requirements of 10 CFR Part 35, medical use licensees may be subject to those portions of 10 CFR Part 20, "Standards for Protection Against Radiation," that relate to radiation safety and the sections of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," that relate to licensing and the noncommercial transfer of specific radioactive drugs to medical use licensees within a consortium.

This regulatory guide endorses the methods and procedures for medical licensing applications contained in the current revision of NUREG–1556, Volume 9, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Medical Use Licenses," as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

NRC Issues Regulatory Guide 10.9 (Revision 2): "Guide for the Preparation of Applications for the Use of Self-Contained Dry Source-Storage Gamma Irradiators"

The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 2 of the Regulatory Guide 10.9: "Guide for the Preparation of Applications for the Use of Self-Contained Dry Source-Storage Gamma Irradiators". This regulatory guide directs the reader to the type of information acceptable to the NRC staff for review of an application for the use of a self-contained dry source-storage gamma irradiator. Title 10, Part 36, "Licenses and Radiation Safety Requirements for Irradiators," of the Code of Federal Regulations (10 CFR Part 36) contains the licensing, design, and radiation safety requirements for irradiators. In addition, licensees and applicants may be subject to portions of the requirements in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 20, "Standards for Protection Against Radiation."

This regulatory guide endorses the methods and procedures describing how to apply for a license to use a self-contained dry source-storage gamma irradiator contained in the current revision of NUREG 1556, Volume 5, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

FDA Issues Final Rule Regarding Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

The Food and Drug Administration (FDA) has amended certain of its regulations on current good manufacturing practice (CGMP) requirements for finished pharmaceuticals as the culmination of the first phase of an incremental approach to modifying the CGMP regulations for these products. This rule revises CGMP requirements primarily concerning aseptic processing, verification of performance of operations by a second individual, and the use of asbestos filters. The FDA is amending the regulations to modernize or clarify some of the requirements as well as to harmonize them with other FDA regulations and international CGMP standards. This rule is effective December 8, 2008.
FDA Announces Public Workshop on FDA Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates (SoCRA), has announced a workshop on FDA Clinical Trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, November 19, 2008, from 8 a.m. to 5 p.m. and Thursday, November 20, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Westin Crown Center, 1 East Pershing Rd., Kansas City, MO 64118, 816-474-4400, FAX: 816-391-4438.

Update on Medical Isotope Availability

In the August issue of the HPRA Newsletter we reported SNM's reaction to the shortage of medical isotopes due to the shutdown of the HRF reactor in Petten, The Netherlands. The following documents are intended to provide further updates on the shortage:

- 8/27/2008 Covidien Customer Letter
- 8/29/2008 GE Healthcare Customer Letter
- 9/4/2008 Lantheus Customer Letter
- 9/10/2008 Covidien Customer Letter
- 9/12/2008 GE Healthcare Customer Letter

HPRA Staff News

The HPRA Department is pleased to announce the arrival of Erin Haberman, HPRA Assistant. She will be responsible for various administrative duties, as well as helping with the administration of the Phantom Program. Erin is a recent graduate of James Madison University.

Contact hpra@snm.org to be notified by email of new newsletters.