Congress passes the American Medical Isotope Production Act

The President and Congress recently affirmed their dedication to securing a sustainable, domestic supply of Molybdenum-99 (Mo-99) as they passed the American Medical Isotope Production Act of 2011 (S.99). S.99 was included in the Conference Agreement for the National Defense Authorization Act for Fiscal Year 2013 (H.R.4310). On December 21, the House of Representatives (315-107) and the Senate (81-14) voted to pass this legislation and send it to President Obama for his signature. The President then signed it into law on January 2, 2013.

The bill will establish a technology-neutral program to support the production of Mo-99 for medical uses in the United States by non-federal entities. It also calls for the United States to phase out the export of highly enriched uranium for the production of medical isotopes over a period of seven years.

Mo-99 is an isotope that decays to Technetium-99m (Tc-99m), which is used in more than 16.7 million procedures in the United States each year. Tc-99m is utilized in the detection of heart disease, detection and staging of cancer, detection of thyroid disease, study of brain and kidney function, and imaging of stress fractures.

There are currently only eight foreign producers of Mo-99 approved by the U.S. Food and Drug Administration to import the product into the United States—and there are no domestic facilities dedicated to the production of Mo-99 for medical uses. The aging foreign reactors regularly experience significant ongoing maintenance issues—frequently causing these reactors to go off-line. In 2009-2010, the United States experienced a shortage of Mo-99 that led to the disruption or delay of nuclear medicine procedures for an estimated 50,000 patients each day.

SNMMI submits letter regarding CMS’s proposed decision memo for PET

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), along with the American College of Radiology, the American College of Cardiology and the American Society of Nuclear Cardiology recently submitted a comment letter to the Centers for Medicare & Medicaid Services (CMS) regarding its proposed decision memo for positron emission tomography (PET).

CMS’s proposal would remove the national non-coverage decision for PET for U.S. Food and Drug Administration (FDA)-approved oncologic applications. The letter stated that while the group believes this to be a step in the right direction, they do not think it is comprehensive enough. SNMMI and the other societies requested that CMS modify the proposed decision and finalize that local Medicare Administrative Contractors may determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their labeled indications that are approved by the FDA.

Please find the joint society letter here.
American Taxpayer Relief Act passes, includes imaging as pay-for

On January 1, 2013, both the Senate (89-8) and the House of Representatives (257-167) passed H.R. 8, the American Taxpayer Relief Act of 2012. This legislation most notably avoids the across-the-board tax increases that were set to take effect January 1, 2013. However, H.R. 8 also blocks a scheduled 27 percent cut in reimbursements for Medicare physicians for one year. This patch will be paid for by cuts and adjustments to other provider payments.

According to the Congressional Budget Office, the cost of this one year patch will be $25.1 billion over 10 years and the Medicare offsets and other provisions would reduce spending by $25.7 billion over the same time period. In previous years, Congress has attempted to work on the Sustainable Growth Rate (SGR) and pass a permanent doc fix, but have not been able to agree on a solution. As a result they have instead relied on a series of temporary patches.

In order to help pay for the one year SGR freeze, Congress approved increasing Medicare’s equipment utilization assumption for advanced imaging services from 75 percent to 90 percent effective with the 2014 Medicare Physician Fee Schedule.

Health-related provisions in the American Taxpayer Relief Act include:

- Extending the 2012 Medicare payment rates through December 31, 2013, thereby averting the 26.5 percent reduction that had been scheduled to go into effect on January 1, 2013.
- Keeping the existing 1.0 floor on the physician work Geographic Practice Cost Index through December 31, 2013.

Additionally, the American Taxpayer Relief Act:

- Makes permanent current marginal tax rates up to $400,000 for singles, $450,000 for married couples
- Permanently extends the 15 percent top capital gains and dividends rate up to $400,000 (singles), $450,000 (married); 20 percent rate for both above threshold
- Allows the temporary payroll tax cut to expire
- Leaves in place the debt limit at $16.394 trillion
- Turns off the sequester for two months
- Extends unemployment insurance for one year

Mallinckrodt provides additional information on Dutch High-Flux Reactor

On January 9, 2013, Mallinckrodt, the Pharmaceutical business of Covidien, provided additional information regarding the operational status of the Dutch High-Flux Reactor. The Nuclear Research and Consultancy expects to provide another update due in January, and at least two weeks’ notice prior to the restart date.

The letter from Mallinckrodt, the Pharmaceuticals business of Covidien, can be viewed here.

NRC extends call for nominations on the Advisory Committee on Medical Uses of Isotopes

On December 11, 2012, The U.S. Nuclear Regulatory Commission (NRC) released a notice of extension of the call for nominations on the Advisory Committee on Medical Uses of Isotopes. The notice was previously released on October 15, 2012, for the positions of health care administrator and nuclear cardiologist on the Advisory Committee on Medical Uses of Isotopes with a due date of December 14, 2012. This NRC notice confirms a 60 day extension of the nomination period, now due on February 14, 2013.

NRC announces its licensing decision in regards to Ra-223 Cl

The U.S. Nuclear Regulatory Commission’s (NRC) staff has reviewed the radiation safety aspects of radium-223 dichloride (223RaCl2) and determined, based on available information, that licensing under Title 10 of the Code of Federal Regulations (10CFR) Part 35, Subpart E “Unsealed Byproduct Material – Written Directive Required” is appropriate. Under current regulations, physicians who are approved for the use of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV under 10 CFR 35.390 “Training for use of unsealed byproduct material for which a written directive is required” or 10 CFR 35.396 “Training for the parenteral administration of unsealed byproduct material requiring a written directive” can be authorized for the medical use of 223RaCl2.
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.

- CMS comments on the Draft Guidance for Public, Industry, and CMS Staff: Coverage with Evidence Development (CED) in the context of coverage decisions is due on January 28, 2013. SNMMI’s previous comments on CED can be found here.
- SNMMI recently submitted comments to CMS regarding the Final Rules for the FY 2013 Hospital Outpatient Perspective Payment System (HOPPS) and Medicare Physician Fee Schedule (MPFS).

Important upcoming events/deadlines

- SNMMI’s 2013 Mid-Winter Meeting will be held in New Orleans, LA, from January 23 – January 27, 2013. More information can be found here.
- CMS is holding a MEDCAC meeting entitled “Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease” on January 30, 2013, from 7:00 a.m. to 4:30 p.m. at the CMS campus in Baltimore, MD.

Contact hpра@snmмi.org to be notified by email of future newsletters.