Legislation Signed to End Debt Ceiling Debate

On Tuesday, August 2, 2011, President Obama ended the nation’s debt ceiling standoff by signing legislation into law after it passed the House of Representatives on Monday night and the Senate on Tuesday morning.

The legislation, created by congressional leaders and the president, permits government borrowing into 2013, allows the debt limit to be increased by up to $2.4 trillion, sets discretionary spending caps through 2021 and creates a House-Senate “super committee” to recommend budgetary changes to reduce the deficit. It does not include any tax increases. However, a 30 percent cut in Medicare physician payments is still scheduled to take effect January 1, 2012.

The “super committee,” a 12-member congressional committee with six members coming from each chamber, evenly split between parties, will propose new deficit reduction plans that may potentially include entitlement program changes. The committee is tasked with reducing the deficit by at least $1.5 trillion through fiscal year 2021. The committee has until November 23 to vote on the proposal. The House and Senate will also have to vote on the plan by December 23, 2011, without the opportunity for amendment.

If the legislation is not enacted by January 15, 2012, or does not achieve at least $1.2 trillion in cuts, spending will be reduced automatically to ensure the combined savings are $1.2 trillion over the next nine years. However, Medicare cannot be reduced more than two percent a year, with cuts limited to providers. Three other exemptions include Medicaid, social security and veterans benefits.

SNM will continue to follow the progress of this legislation and will provide updates to members.
SNM Staff Tours Georgetown’s Nuclear Medicine Department

On July 21, 2011, Georgetown University Hospitals Nuclear Medicine Department welcomed SNM staff for a tour of the facilities. Led by SNM member Giuseppe Esposito, MD, and SNMTS member Teresa Ellmer-Buckley, CNMT, SNM staff learned about the operation and purpose of various types of equipment and observed patient testing and the reading of scans. Thank you to Georgetown University Hospital for hosting us!

PCORI Seeks Public Feedback

The Patient-Centered Outcomes Research Institute (PCORI), an independent organization created to conduct research to help guide health decisions, is seeking public feedback on eight initial topics for a series of “Tier 1” pilot projects that will help PCORI establish national priorities for research; support the development of novel methods or the collection of preliminary data that can be used to advance the field of patient-centered outcomes research; and inform the development of a future PCORI research agenda. There will be a 30-day input period on the eight topics that concludes on August 31.

PCORI is also seeking public input on the working definition of “patient-centered outcomes research.” The current working definition says “patient-centered outcomes research helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options.” There will be a 45-day input period on the definition that will conclude on September 2.

For additional information on feedback for the “Tier 1” pilot projects and working definition of “patient-centered outcomes research,” please visit the GR News section of the SNM Web site.

New FDA cGMP Guidance for Small Businesses Available

The U.S. Food and Drug Administration (FDA) has announced the availability of guidance for small business entities entitled “PET Drugs—Current Good Manufacturing Practice (CGMP); Small Entity Compliance Guide.” The guideline is intended to help small businesses better understand FDA’s thinking on compliance with the positron emission tomography drugs (PET) CGMP regulations, including appropriate resources, procedures, and documentation for PET drug production facilities.
FDA Announces PDUFA and MDUFA Fee Schedule for Fiscal Year 12

The U.S. Food and Drug Administration (FDA) has announced the fee rates and payment procedures for medical device user fees (MDUFA) for Fiscal year (FY) 2012. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), authorizes FDA to collect user fees for certain medical device submissions, and annual fees for certain periodic reports and establishments subject to registration.

These fees apply from October 1, 2011, through September 30, 2012. This document provides information on how the fees for FY 2012 were determined, the payment procedures that should be followed, and the potential to qualify for reduced small business fees.

The FDA has also announced the rates for prescription drug user fees (PDUFA) for FY 2012. The FD&C Act authorizes the FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. This document establishes the following fee rates for FY 2012 applications:

- Clinical data: $1,841,500
- Applications not requiring clinical data or a supplement requiring clinical data: $920,750
- Establishment fees: $520,100
- Product fees: $98,970

These fees are effective on October 1, 2011, and will remain in effect through September 30, 2012. Both PDUFA and MDUFA will be renewed in FY 2012.


IOM Recommends Substantial Changes to FDA’s 510(k) Process

On July 29, 2011, the Institute of Medicine (IOM) released a report recommending substantial changes to the U.S. Food and Drug Administration’s 510 (k) approval process for devices. Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA. A few policymakers and patients have expressed concern about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective.

For more information and to review the report, please click on the following: http://iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx

Bracco Diagnostics, Inc. Recalls CardioGen-82

After recently receiving reports of two patients who had received more radiation than expected due to strontium isotopes which may have been inadvertently injected due to a “strontium breakthrough” problem with CardioGen-82, Bracco Diagnostics, Inc. has asked clinicians to immediately stop using CardioGen-82. A voluntary recall was also initiated by Bracco Diagnostics, Inc.

To learn more on this issue, please visit http://www.snm.org/index.cfm?PageID=10891
Second ACO Accelerated Learning Session Now Open for Registration

The second Accountable Care Organization (ACO) Accelerated Development Learning Session, to be held September 15-16 in San Francisco, Calif., is now open for registration.

The ACO Learning Session has been specifically created and designed to teach providers interested in becoming ACOs what steps they can take to improve care delivery and how to successfully develop an action plan to move toward providing better coordinated care.

To register for the ACO Learning Session, please go to https://acorestiger.rti.org. The registration for this session is open for teams of between two and four senior leaders from health care delivery organizations interested in forming an ACO or from an existing ACO. The plenary sessions will also be available on the above ACO Learning Sessions Web site.

NRC Directs Staff to Evaluate the Feasibility and Need for a Study to Determine Radiation Doses to Members of the Public

The Nuclear Regulatory Commission (NRC) issued a notice on July 13, 2011 that it has directed agency staff to determine the need for a study to determine radiation doses to members of the general public from patients released after being treated with medical isotopes.

Current NRC regulations allow patients treated with medical isotopes to be released if the expected radiation dose to other individuals is not likely to exceed 500 millirem.


SNM’s Advocacy Committee Restructures the SHPL Program

SNM’s Advocacy Committee has decided to restructure the State Health Policy Liaison SHPL program and has renamed the new group the State Technologist Advocacy Group, or the TAG Team. The TAG Team will consist of technologists in each state and will focus on state regulations. In the coming months, the SHPL Web site will transition to the TAG team and will include helpful information regarding each state. Advocacy will continue at the federal level with a group of SNM members who live or work in key Congressional districts, that is, those districts that have a Member of Congress who sits on a key Congressional Committee, is in the leadership, or has a particular specialty (e.g. is a physician).
CMS Issues 2012 Rules for HOPPS, MPFS & Medicare Payment Policies

On July 1, the Centers for Medicare & Medicaid Services (CMS) issued calendar year (CY) 2012 proposed rules for the Hospital Outpatient Perspective Payment System (HOPPS) and Medicare Physician Fee Schedule (MPFS).

The proposed rule for HOPPS would update payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and ambulatory surgical centers. The MPFS rule would update payment policies and rates for physicians and non-physician practitioners for services paid under the Medicare Physician Fee Schedule. Both updates would go into effect January 1, 2012.

CMS will accept comments on the proposed rule until August 30, 2011, and will review and respond to all comments in a final rule to be issued by November 1, 2011.

Additionally, on August 1, CMS issued a fiscal year (FY) 2012 final rule that will update Medicare payment policies and rates. This rule will affect Medicare payments to general acute care hospitals and long-term care hospitals for inpatient stays. The final rule will apply to about 3,400 acute care hospitals and 420 long term care hospitals and will be effective for discharges occurring on or after October 1, 2011, unless otherwise stated.

More details about the rules for the Hospital Outpatient Perspective Payment System, Medicare Physician Fee Schedule, and Medicare Payment Policies can be found at the SNM Web site.

If you have any questions about this announcement, please contact the CMS Office of Legislation at (202)690-8220.
SNM Weighs In

SNM provides comments to government stakeholders on a multitude of issues. For more information, please visit the SNM Web site or contact the HPRA department directly.

- On Tuesday, July 26, The HPRA department met with the Economic Policy Department at the American College of Radiology (ACR) for a tour. SNM staff learned about issues the department works on and discussed how to effectively work together with ACR. SNM staff also met with the ACR Guidelines and Appropriateness Criteria staff to better understand their development/revision process and how the evidence is scored for both. Ongoing efforts to improve communication and collaboration with ACR staff will increase our understanding of what will be needed for SNM to undertake the development of evidence-based guidelines.
- A letter was sent to Dr. Farzar Mostashari, National Coordinator for Health IT at the Health and Human Services Department regarding the need for imaging information to be included in Stage 2 Meaningful Use recommendations.
- Comments were sent by SNM to the NRC on proposed revisions to Part 35.
- As part of the Coalition for PET Drug Approval, a letter was sent to Jane Axelrad at the FDA seeking an update on guidance documents promised during the March 2 public meeting.

Important Upcoming Events/Deadlines

- NRC Public Workshop, August 11-12, Houston, Texas
- HIT Policy Committee, Meaningful Use Workgroup on August 22 from 9am to 11 am ET, webcast only
- FDA public meeting on the proposed Generic Drug User Fee Program, August 25, Silver Spring, Maryland

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