

Washington Update – March 2009

American Economic Recovery and Reinvestment Act of 2009

On February 17, 2009, President Obama signed the \$789 billion “economic stimulus bill”, which is the largest combined spending and tax bill in American history, with a total of \$787 billion in spending and tax cuts. The bill will impact a wide range of businesses and industries from healthcare to energy to education and transportation, state and local government and other public and non-profit and educational institutions.

The bill includes more than \$130 billion in new healthcare spending, including \$87 billion in increased federal medical assistance payments to states, \$1.1 billion to the U.S. Department of Health and Human Services - National Institutes of Health, Agency for Healthcare Research and Quality, and newly formed Federal Coordination Council – to conduct comparative effectiveness research, and \$19 billion in health IT incentives.

HIT Provisions

The key goals for health information technology in the bill include an investment in HIT infrastructure and Medicare/Medicaid incentives to encourage doctors and hospitals to use certified health IT and to electronically exchange patients’ health information; places the onus on the Government to take a leadership role in developing standards that allow for the nationwide exchange and use of health information to improve quality and coordination of care; to generate \$12B savings for the government and additional savings throughout the health sector, through improvements in quality of care and care coordination and reductions in medical errors and duplicative care; and to strengthen Federal privacy and security law to protect identifiable health information from misuse as use of HIT increases.

Some of the significant health IT Provisions in the legislation include:

- Increased reimbursement through Medicare and Medicaid for hospitals that utilize certified electronic health records in a meaningful way starting in 2011. Hospitals that are not meaningful users of certified electronic health records over time will receive decreased reimbursement.
- Increased reimbursement through Medicare and Medicaid for physicians that utilize certified electronic health records in a meaningful way starting in 2011. Physicians who are not meaningful users of certified electronic health records over time will receive decreased reimbursement.
- Establishment of two federal advisory committees: the Healthcare IT Policy Committee and the Healthcare IT Standards Committee to oversee the development of standards and the strategic implementation of HIT across the US.
- Codification of the Office of the National Coordinator for Health Information Technology (ONC)
- Competitive grant programs to foster the use of healthcare IT within states and for clinical education.

Comparative Effectiveness Research (CER):

The comparative effectiveness policy is intended to facilitate the collection of meaningful data to evaluate the relative effectiveness of various medical treatment options. If done correctly, Siemens is hopeful that CER could demonstrate the value of medical imaging. The provision includes appropriation of \$1.1billion to comparative effectiveness research and designates \$400 million each to NIH and HHS, and \$300 million to AHRQ. The provision also establishes the Federal Coordinating Council (FCC) comprised of 15 federal employees chartered to guide HHS spending of their allocated funds on CER. The language further specifies that the FCC cannot mandate coverage, payment or clinical recommendations.

NIH has designated at least \$200 million in FYs 2009 - 2010 for a new initiative called the **NIH Challenge Grants in Health and Science Research**, to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research may be available to support additional grants. Projects receiving these funds will need to meet this definition of CER: “a rigorous evaluation of the impact of different options that are available for

treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy.” Such research may include the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.

This new program will support research on Challenge Topics which address specific scientific and health research challenges in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds.

Challenge Areas, defined by the NIH, focus on specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that would benefit from an influx of funds to quickly advance the area in significant ways and include several imaging related topics. Siemens has directed key academic and other customers to this NIH initiative and specifically the imaging related high-priority projects.

Information on this can be found on the NIH web site at:

http://grants.nih.gov/grants/funding/challenge_award/#topics .

For a full copy of the American Recovery and Reinvestment Act of 2009, please go to:

http://www.rules.house.gov/111/LegText/hr1_legtext_cr.pdf

http://www.rules.house.gov/111/LegText/hr1_legtext_crb.pdf

Health Provisions in the President's FY 2010 Budget Proposal

On February 26th, the White House released its budget proposal for FY 2010. The proposal included a number of broad reforms related to health care system reform, and calls for a \$634 billion “reserve fund” to expand access to health care coverage and paid for through a mix of tax increases and cuts to healthcare spending. Perhaps most notable for physician providers is the acknowledgement within the budget document of the level of funding that will be needed to address looming physician payment cuts. The budget includes \$329.6 billion to account for the additional expected Medicare physician payments. This infusion of funds would effectively eliminate the enormous deficit and scheduled Medicare physician payment cuts of 40% over the next seven years.

The savings proposals include:

- use of radiology benefits managers (RBMs) (\$260 million in savings over 10 yrs)
- competitive bidding for Medicare Advantage plans (\$176.6 b)
- bundled payments for hospitals and post-acute care services (\$17.8 b)
- reduce payments for hospital readmissions (\$8.4 b)
- reduced payments for home health services (\$37.1 b)
- increased Medicaid drug rebates (\$19.6 b)
- increased Part D drug premiums for higher income beneficiaries (\$8.1 b)
- Medicare program integrity efforts (\$2.0 b)
- restrictions on physician owned hospitals (minor savings and no policy explanation)
- incentives for physicians to administer flu vaccinations (with negligible savings and no policy explanation).

Other health-related provisions of the in the President's budget proposal include:

- \$630 billion reserve fund over 10 years to finance healthcare reform
- \$6 billion within the National Institutes of Health (NIH) to support cancer research
- Regulations to allow Americans to access drugs from other countries and establish a regulatory pathways to approve generic biologics

Documents outlining the details of the President's budget proposal are available on the Web:

- *DHHS fact sheet on FY 2010 budget proposal* - http://www.whitehouse.gov/omb/assets/fy2010_factsheets/fy10_health_human_services.pdf

- *DHHS budget document* – http://www.whitehouse.gov/omb/assets/fy2010_new_era/Department_of_Health_and_Human_Services1.pdf

March 2009 MedPAC Report to Congress

As required by Congress, the Medicare Payment Advisory Commission reviews Medicare payment policies and makes recommendations each March. There were several recommendations of interest to Siemens in the recently released 2009 report.

Imaging specific recommendation – There was one imaging specific recommendation included in the report that if implemented could have significant impact on reimbursement of advanced imaging services:

- Congress should direct the Secretary to increase the equipment use standard for expensive imaging machines from 25 hours per week (50%) to 45 hours per week (90%). This change would redistribute RVUs from expensive imaging to other physician activities.

MedPAC defines expensive imaging equipment as imaging machines that cost at least \$1 million. Within the report MedPAC advises Congress to explore applying this standard to imaging equipment that costs less than \$1 million.

This recommendation is based on MedPAC's belief that the recent volume growth in advanced imaging services is a signal that these services are mispriced under the fee schedule. Medicare's current methodology assumes that machines are operated 25 hours per week. MedPAC believes that there is evidence that usage for these machines is higher. If CMS assumes the machines are used more frequently, practice expense (PE) RVUs for advanced imaging services (CT and MRI most likely) would decrease. Since PE RVUs are established in a budget neutral manner, at the same time CT and MRI PE RVUs decrease, PE RVUs for other services on the physician fee schedule would increase.

MedPAC has acknowledged that the utilization rate formula change requires a legislative change because the recommendation is not based on actual data about imaging use. Siemens is working with MITA member companies to collect data on the actual use of advanced imaging to counter MedPAC's recommendation.

Other recommendations – There was also a number of other recommendations made by MedPAC of interest to Siemens:

- *Physician and Ambulatory Surgical Centers*
 - The Congress should update payments for physician services in 2010 by 1.1 percent
 - The Congress should establish a budget neutral payment adjustment for primary care services billed under the physician fee schedule and furnished by primary-care-focused practitioners. Primary-care-focused practitioners are those whose specialty designation is defined as primary care and/or those whose pattern of claims meets a minimum threshold of furnishing primary care services. The Secretary would use rulemaking to establish criteria for determining a primary-care-focused practitioner.
 - The Congress should increase payments for ambulatory surgical centers (ASC) services in calendar year 2010 by 0.6 percent. In addition, the Congress should require ASCs to submit to the Secretary cost data and quality data that will allow for an effective evaluation of the adequacy of ASC payment rates.
- *Hospitals*
 - The Congress should increase payment rates for acute inpatient and outpatient prospective payment systems in 2010 by projected rate of increase in the hospital market basket index, concurrent with implementation of a quality payment program.
 - The Congress should reduce the indirect medical education adjustment (IME) in 2010 by 1 percentage point to 4.5 percent per 10 percent increment in the resident-to-bed ratio. The funds obtained by reducing the IME adjustments should be used to fund a quality incentive payment program

The complete report is available on the MedPAC website:
http://www.medpac.gov/documents/Mar09_EntireReport.pdf.

CMS Releases Proposed Decision Memo on CT Colonography Screening Coverage

CMS released a proposed National Coverage Decision (NCD) on the issue of coverage of CTC for colorectal cancer (CRC) screening denying coverage of CTC. In reaching its proposed decision the Agency came to two main conclusions: 1) the evidence was not sufficient to determine that CTC is a valuable screening test for colorectal cancer for average risk Medicare beneficiaries compared to optical colonoscopy and 2) the evidence was not sufficient to conclude that the use of CTC for CRC screening for average risk Medicare beneficiaries improves net health outcomes compared to optical colonoscopy. These conclusions were reached principally because the current available evidence is not generalizable to the Medicare population.

Comments on the proposed decision memo were due on Friday, March 13 and a final decision is expected in May 2009. Siemens, along with MITA, GE and Philips, met with the agency to voice concerns about the proposed decision, and filed comments on the decision memo.. Specifically, CMS was informed of additional analyses currently being completed on the ACRIN study data to respond to their concerns of applicability to the Medicare population. Additionally, Siemens and MITA worked with patient and provider groups, including the Colon Cancer Alliance, on a coordinated regulatory and legislative response. As a result, on March 13th, Representatives Granger and Kennedy, along with 40 other members of Congress, sent a letter to CMS urging the agency to cover CT colonography. Congressman Danny Davis also sent another letter to CMS urging coverage for CTC citing lower levels of screening among African Americans.

The proposed decision memo, public comments and other details are available on the CMS coverage website: http://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=220&basket=nca:00396N:220:Screening+Computed+Tomography+Colonography+%28CTC%29+for+Colorectal+Cancer:Open:New:9

California Technology Assessment Forum (CTAF) Consider CT Colonography

The California Technology Assessment Forum (CTAF) conducts evidence-based reviews of new and emerging medical technology. These assessments can be considered by private insurers as part of their coverage decision process. CTAF recently posted a draft assessment on CT colonography for colorectal cancer screening for average risk individuals. They concluded, "Thus, despite its diagnostic accuracy, because the impact of the potential harms is not currently known, CTC is not currently recommended for screening asymptomatic individuals for CRC." This draft assessment was considered and open for public comment at the March 11 CTAF meeting. A final assessment based on input from this meeting is expected.

The draft assessment is available on the CTAF website: http://www.ctaf.org/UserFiles/File/March%2011_2009/CT%20Colonography%20final%20draft%202.pdf