

EPSTEIN BECKER & GREEN P.C.

How will Health Care Reform in the United States Impact Medical Device Manufacturers?

MarketReach America



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Outline

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- Federal Health Reform Update - Status of the Legislation
- Key Provisions on Health Benefits Reform
- Key Provisions on Entitlement Reform – Medicare/Medicaid/CHIP

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Status of the Legislation

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- House passed bill November 7, 2009
- Senate passed bill at 7:00 AM on December 24, 2009
- Leadership of both chambers are merging the two bills – expect Senate views to dominate
- Initial goal of having legislation to President Obama before State of the Union (late January or early February) may be unachievable – House does not reconvene until January 11 and the Senate does not reconvene until January 20

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Access Expansion

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- The share of nonelderly residents with insurance coverage would rise from 83% to 94% by 2019
 - Individual mandate requiring residents to obtain insurance begins in 2014
 - Employer mandate that generally requires employers with more than 50 workers to offer coverage or pay a penalty of \$750 per full-time worker
 - Subsidies available for those with income between 133% and 400% of the Federal Poverty Level
 - Most residents with income below 133% of the Federal Poverty Level would be eligible for Medicaid
 - Beginning in 2014, states would receive higher federal reimbursement for CHIP beneficiaries, increasing from an average of 70% to 93%
 - Medicare coverage for individuals exposed to environmental health hazards (i.e., Montana)

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Device Manufacturer Tax

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- Senate Bill Sec. 9009: Each manufacturer of medical devices shall pay a fee to the Secretary
 - Exemption for small manufacturers (less than \$5,000,000 in annual sales)
 - Fee proportionate to share of industry's total "gross receipts"
 - Total industry fee for the years 2011 to 2017 is \$2 billion. Beginning in 2018, fee is \$3 billion

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Physician Payment Sunshine Act

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- Beginning March 31, 2013, and quarterly thereafter, drug, device, biological, and medical supply manufacturers must report to the Secretary transfers of value made to a physician, physician medical practice, or teaching hospital
 - Exceptions include:
 - Nominal items with a value of less than \$10, unless the aggregate amount transferred during the calendar year exceeds \$100
 - Product samples
 - Educational materials
 - The loan of a device for a short-term trial period, not to exceed 90 days, to permit evaluation
 - Discounts (including rebates)
 - Preemption of duplicative state laws, but preemption would not occur of laws requiring reporting of data in excess of what is required by federal law
- Beginning March 31, 2013, and quarterly thereafter, drug, device, biological, and medical supply manufacturers, as well as GPOs, must report to the Secretary all physician ownership or investment interest in the company

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Key Medicare Reform Provisions

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A Closer Look at Certain Key Medicare Provisions

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Encouraging Development of New Patient Care Models

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- Center for Medicare and Medicaid Innovation: Purpose is to test new payment and delivery models that reduce costs while increasing quality
- National Pilot Program on Payment Bundling: Voluntary program whereby participants will receive one payment for an "episode of care" relating to one of up to eight conditions the Secretary deems appropriate for inclusion in the program
 - An episode of care includes the three days before a hospitalization, the length of stay in the hospital, and thirty days following the hospitalization
- Independence at Home Demonstration Program: Testing a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams
 - Seeks to reduce preventable hospitalizations, prevent hospital readmissions, reduce emergency room visits, improve the quality of care, and reduce the cost of care
 - Incentive payments possible if actual expenditures per beneficiary is lower than expected expenditure per beneficiary for Medicare Parts A and B covered services

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Hospital Payments

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- Reduction of annual market basket updates
- Reduction in Disproportionate Share Hospital payments beginning in 2015 to reflect lower uncompensated care costs relative to increases in the number of insured
- Reduce Medicare payments for hospitals with excessive preventable readmissions
- Reduce Medicare payments to hospitals with high rates of hospital-acquired conditions

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Physician Payments

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- No permanent Sustainable Growth Rate (“SGR”) fix in legislation
 - Facing 21.2% cut, physicians received a temporary freeze of current rates until March 2010 when Congress is expected to address a permanent fix
- Simplified interaction for physician offices with health insurers through standardized eligibility verification and claim status checks, electronic funds transfers and health care payment and remittance, and health claim format
 - Insurers not in compliance with standards would face a penalty of no more than \$1 per covered life

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National Pilot Program on Payment Bundling

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- Voluntary pilot program to encourage physicians, hospitals, and post-acute care providers to improve patient care and establish savings through bundled payment models for “applicable conditions” during an “episode of care”
 - Applicable Conditions – Eight conditions chosen by the Secretary
 - Episode of Care – The three days prior to the hospitalization through the thirty days following discharge from the hospital
 - Program to be established by January 1, 2013
 - Program shall be conducted for five years
 - Participants will submit quality data
 - No later than January 1, 2016, the Secretary shall submit a plan for the expansion of the program if she determines such an expansion would result in reduced spending and would not reduce the quality of care

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Improving Payment Accuracy

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- Starting in 2013, rebasing of home health payments based on an analysis of the current mix of services and intensity of care provided to home health patients
 - Establishment of 10% cap on the amount of reimbursement a home health provider can receive from outlier payment
 - Reinstatement of add-on payment for rural home health providers from April 1, 2010 through 2015

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Ensuring Medicare Sustainability

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- Establishment of the Independent Payment Advisory Board
 - Purpose is to reduce the per capita rate of growth in Medicare spending
- Years in which Medicare costs are projected to be unsustainable, the Board's proposals will take effect unless Congress passes an alternative measure that achieves the same level of savings
- Board is prohibited from rationing care, raising taxes or premiums, or changing benefits, eligibility or cost-sharing standards
- Beginning in 2015, the Board, at least biannually, shall submit to Congress and the President recommendations to slow the growth of national health expenditures, exclusive of recommendations regarding Medicare spending, while preserving or enhancing the quality of care

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Health Care Quality Improvements

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- Secretary to create program to provide grants or enter into contracts with eligible entities to create community-based interdisciplinary teams ("health teams") to support primary care providers and provide capitated payments to primary care providers
- The health teams shall support the patient centered medical home care model

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Patient-Centered Outcomes Research and the Federal Coordinating Council for Comparative Effectiveness Research

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- Establishes the Patient-Centered Outcomes Research Institute
 - Identifies priorities for and provides for the conduct of comparative outcomes research
 - Prohibition on findings being construed as mandates on practice guidelines or coverage decisions
 - AHRQ shall disseminate the research
- Upon enactment of the bill, the Federal Coordinating Council for Comparative Effectiveness Research is terminated

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Medicare, Medicaid, and CHIP Program Integrity Provisions

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- Beginning in January 2010, the maximum period for Medicare claim submission is reduced to no more than 12 months
- Face-to-face encounter with patient now required before physician certifies eligibility for home health services or durable medical equipment
 - Secretary may apply this requirement to other items and services based upon finding that doing so would reduce the risk of fraud, waste, or abuse
- Competitively bid pricing to be used throughout the country by 2016 for those products defined in the competitive bidding project
- Requires states to contract with at least one Recovery Audit Contractor ("RAC") to identify underpayments and overpayments and to recoup overpayments made for services provided under the state's Medicaid plan
 - Also expands the RAC program to Medicare Parts C and D

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Conclusions

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- General Observations about Medicare Program Decisionmaking in the Next Five Years
- Greater challenges with Coverage and Payment Issues, More Transparency, Greater Focus on Quality, and New Decisionmakers

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Recommended Websites to Watch

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- Kaiser Health News: <http://www.kaiserhealthnews.org/>
- WSJ Health Blog: <http://blogs.wsj.com/health/>
- National Journal Expert Blogs – Health Care: <http://healthcare.nationaljournal.com/>
- White House Health Reform: <http://www.healthreform.gov/>
- Health Affairs Blog: <http://healthaffairs.org/blog/>
- EBG's Website: <http://www.ebglaw.com>


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Questions/Discussion

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