



Health Care Reform Legislation Summary

Device Manufacturers

Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (“PPACA”)
Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (“Recon”)

PROVISION	DESCRIPTION	EFFECTIVE DATE(S)	CBO 10-YEAR SCORE
Reimbursement for Medical Devices			
Payment for Imaging Services Recon § 1107; PPACA § 3135(b)	Amends 42 U.S.C. § 1395w-4(b)(4)(c) to change the utilization rate assumption for calculating the payment for advanced imaging equipment to 75 percent starting in 2011.	Utilization rate assumption – fee schedules established beginning in 2011	Saves \$2.3 billion
Payment for Power-Driven Wheelchairs PPACA § 3136	Amends 42 U.S.C. § 1395m(a)(7)(A) to change the payment rate for rental of power-driven wheelchairs to 15 percent of the statutorily recognized purchase price for the first three months of the rental period and six percent for the remaining months.	January 1, 2011	Saves \$800 million
Revision of Market Basket Updates PPACA § 3401(m), (n)	Amends 42 U.S.C. § 1395m(a)(14) to make the market basket increase for certain durable medical equipment (DME) in 2011 and each subsequent year the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) for the previous year, reduced by the productivity adjustment in 42 U.S.C. §1395ww(b)(3)(B)(xi)(II).	January 1, 2011	Savings of \$156.6 billion bundled into score of all market basket updates (excluding home health)

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Reimbursement for Medical Devices			
	Amends 42 U.S.C. § 1395m(h)(4) to make the market basket increase for prosthetic devices, orthotics and prosthetics in 2011 and each subsequent year the percentage increase in the CPI-U for the previous year, reduced by the productivity adjustment in 42 U.S.C. §1395ww(b)(3)(B)(xi)(II).		
DMEPOS Competitive Acquisition Program PPACA § 6410(a)	Amends 42 U.S.C. § 1395w-3(a)(1) to increase the number of participating metropolitan statistical areas in Round 2 of the competitive bidding program. Delays requirement for Secretary of HHS to implement competitive bid areas or use competitive bid prices until January 1, 2016.	Round 2 extension – 2011 Competitive bidding – January 1, 2016	Saves \$1.4 billion

PROVISION	DESCRIPTION	EFFECTIVE DATE(S)	CBO 10-YEAR SCORE
Fraud and Abuse (see also Fraud and Abuse Summary)			
Physician Payment Sunshine Act PPACA § 6002	Creates new 42 U.S.C. § 1320-7(g), requiring medical device manufacturers (and pharmaceutical and biologics manufacturers) to report annually to the HHS payments and transfers of value furnished to “covered recipients” (including physicians and teaching hospitals); excludes certain transactions from requirement to report (e.g., product samples for patient use, discounts and rebates, items provided under contractual warranty); requires physicians and group purchasing organizations to report ownership or investment interests in manufacturers; and preempts state sunshine laws.	March 31, 2013	\$0

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Fraud and Abuse (see also Fraud and Abuse Summary)			
Documentation of Referrals PPACA § 6406	Amends 42 U.S.C. § 1395u(h) to allow Secretary of HHS to revoke physician's enrollment for failure to maintain and provide, upon request, access to documentation relating to orders or requests for payment for DME.	Orders or requests dated on or after January 1, 2010.	\$0
Face-to-Face Encounters PPACA § 6407	Amends 42 U.S.C. § 1395m(a)(11)(B) to allow Medicare and Medicaid payment for DME only if a written order documents that a physician, physician assistant, nurse practitioner or clinical nurse specialist has had a face-to-face (including telehealth) encounter with the patient during the six months preceding the order.	Date of enactment (March 23, 2010).	\$0
90-Day Increased Oversight for Initial DME Claims Recon § 1304	Amends 42 U.S.C. § 1395cc(j) to allow Secretary of HHS to withhold payment to a DME supplier within 90 days of initial enrollment if the Secretary determines that there is a significant risk of fraudulent activity among that category or geographic area of DME suppliers.	January 1, 2010	Savings of \$900 million bundled into all Program Integrity Provisions in Recon §§ 1301-04, 1308

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Taxation			
Excise Tax on Medical Device Manufacturers Recon § 1405	Imposes excise tax equal to 2.3 percent of the sales price on any "taxable medical device" sold by a manufacturer, producer or importer. The term "taxable medical device" does not include eyeglasses, contact lenses, hearing aids, and any other medical device that the Secretary of HHS determines to be of a type that is generally purchased by the general public at retail for individual use.	Sales after December 31, 2012	\$20 billion increase in revenue

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