

Health Care Reform's Impact on Healthcare Providers and Suppliers

On March 30, 2010, the tumultuous health care reform effort culminated with the passage of H.R. 4872, the Health Care and Education Reconciliation Act of 2010 ("HCERA"), P.L. 111-152, that modifies and adds to H.R. 3590, the Patient Protection and Affordable Care Act ("PPACA"), P.L. 111-148, which passed on March 23, 2010.

Together, PPACA and HCERA are a comprehensive health care reform law:

- Addressing the transformation of the health insurance industry, implementing and investigating new models of healthcare delivery,
- Expanding financial access through employer-based health plan coverage, Medicaid and state health insurance exchanges,
- Investing in primary care physicians and a primary care workforce and
- Improving preventive care, chronic disease treatment and public health.

Healthcare providers will see changes in their Medicare reimbursements from (1) reductions in annual market basket updates and through productivity adjustments, (2) incentives from value-based purchasing programs linking payment to performance on quality measures, and (3) penalties if hospital-acquired conditions and readmission rates for certain conditions rise above targeted rates.

An Independent Payment Advisory Board will be created to recommend Medicare spending changes and extend the program's solvency. If Congress fails to act on its recommendations, the U.S. Department of Health and Human Services ("DHHS") has the authority to reduce the rate of per capita Medicare spending by the recommended targeted amounts.

A decade of investigations, audits, critical reports and Congressional hearings produced significant changes for charitable hospitals and their community benefit practices. New mandates require the conduct and implementation of a community health needs assessment and strategy, development of financial assistance policies, inclusion of audited financial statements with IRS Form 990 tax returns and review of tax-exempt status every three years.

Waste, fraud and abuse initiatives, Medicare and Medicaid program integrity requirements and transparency with respect to ownership, investment and provider interactions affect every part of the healthcare industry under the health reform law. Compliance

programs will now be mandatory, and noncompliance will result in penalties and potential disenrollment. Overpayments by federal healthcare programs must be refunded within 60 days of identification. The DHHS Office of Inspector General has been granted new authority to pursue fraud and abuse and evaluate the economy, efficiency and effectiveness of federal healthcare programs.

Recognizing that expanded health insurance coverage will require greater healthcare workforce capacity, the healthcare reform law addresses the reallocation of medical residency positions to primary care specialties. In addition to more primary care physicians, the new law directs considerable investment to primary care nursing, workforce shortages in rural and underserved areas and other education, training and development programs to meet the anticipated increased demand for healthcare workers.

Healthcare delivery system changes are emphasized in the roll-out of accountable care organizations and medical home demonstration programs. New payment models involving payment bundling, capitation and gainsharing will be tried in demonstration and pilot projects in the Medicare and Medicaid programs. Comparative effectiveness research has been renamed "patient-centered outcomes research". Evidence and findings from this research may be used in Medicare coverage determinations if implemented through a public, transparent and inclusive process, but its use in rationing healthcare is subject to various restrictions.

Personalized healthcare to combat chronic diseases is not forgotten in the reforms as proven prevention services, behavior modification programs and wellness programs are established and receive incentives.

Selected Provisions in PPACA and HCERA Impacting Healthcare Providers and Suppliers

The following chart, Selected Provisions in PPACA and HCERA Impacting Healthcare Providers and Suppliers, summarizes the provisions of PPACA and HCERA that impact, either directly or indirectly, healthcare providers and suppliers under Medicare, Medicaid and other federal healthcare laws. The chart is organized by provisions affecting:

- Hospitals
- Physicians, Nurses and Other Healthcare Professionals
- Nursing and Long Term Care Facilities
- Manufacturers and Suppliers of Drugs, Medical Equipment and Medical Devices
- Mental Health Providers
- Home Health Agencies
- Pediatric Providers
- Multiple Providers

The PPACA and HCERA section citation, United States Code citation, short description, effective date and rulemaking are provided in the chart. Rulemaking addresses provisions that require (mandatory), permit (discretionary), or contemplate regulations or

program requirements from DHHS and other federal agencies.

ACRONYMS AND ABBREVIATIONS USED IN THE CHART

BBA	-	Balanced Budget Act of 1997	IME	-	Indirect graduate medical education costs
CAH	-	Critical access hospital	IPPS	-	Inpatient prospective payment system
CHIP	-	Children's Health Insurance Program	IRS	-	Internal Revenue Service
CMP	-	Civil Monetary Penalty	LTCHs	-	Long term acute care hospitals
DHHS	-	Department of Health and Human Services	MedPAC	-	Medicare Payment Advisory Commission
DSH	-	Disproportionate share hospital	OIG	-	DHHS Office of Inspector General
EHR	-	Electronic health record	OPPS	-	Outpatient prospective payment system
FCA	-	False Claims Act	PBM	-	Pharmacy benefit manager
FY	-	Fiscal Year	PPS	-	Prospective payment system
GME	-	Direct graduate medical education costs			

This paper was prepared by Anna Kana, Associate; Lew Lefko, Shareholder; and Cheryl Camin, Shareholder, with Winstead PC. An examination of the health insurance, tax and funding provisions of healthcare reform is beyond the scope of this summary.

SELECTED PROVISIONS IN PPACA AND HCERA IMPACTING HEALTHCARE PROVIDERS AND SUPPLIERS

Provisions Impacting Hospitals				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 2202	42 U.S.C. 1396a, 1396b	Hospitals may elect to be a qualified entity for determining, on the basis of preliminary information, eligibility of an individual for Medicaid coverage under all Medicaid eligibility categories, and provide services to the individual during the period of presumptive eligibility.	Jan. 1, 2014	N/A
PPACA § 2551, HCERA § 1203	42 U.S.C. 1396r-4	Funding for Medicaid DSH program is reduced by \$18.1 billion from FY 2014-2020. DHHS must develop a methodology to implement the DSH reductions that imposes the largest reductions in DSH for states with the lowest percentage of uninsured.	Oct. 1, 2011	Mandatory methodology
PPACA § 2704	42 U.S.C. 1396	DHHS must establish a Medicaid bundled payments demonstration project, in up to eight states, to study the use of bundled payments to hospitals for services received by a Medicaid beneficiary during an episode of care involving a hospitalization, concurrent physician services and post-acute services.	Jan. 1, 2012 – Dec. 31, 2016	Mandatory program requirements beginning Jan. 1, 2012
PPACA § 2705	42 U.S.C. 1396	DHHS must establish a Medicaid global payment system demonstration project that would allow up to five participating states to adjust their current payments to safety net hospitals from a fee-for-service model to a global capitated payment structure.	FY 2010 – FY 2012	Mandatory program requirements beginning FY 2010
PPACA § 3001	42 U.S.C. 1395ww	DHHS must establish a hospital value-based purchasing program to provide value-based incentive payments each FY to hospitals that meet specified performance standards. A percentage of the hospital's Medicare payment would be tied to its performance on quality measures related to common and high-cost conditions, including, in the 1 st year, acute myocardial infarction, heart failure, pneumonia, surgical care and health-care associated conditions. Quality measures would be developed and chosen with input from external stakeholders. Hospitals may be ineligible for incentive payments in years they are (1) subject to a payment reduction because they are not a meaningful EHR user, (2) cited for serious patient health or safety deficiencies, (3) lacking a sufficient number of quality measures that apply, or (4) lack the number of necessary cases to apply the measures.	Oct. 1, 2012	Mandatory program requirements beginning Oct. 1, 2012
PPACA § 3008	42 U.S.C. 1395ww	Acute care hospitals in the top 25% of all hospitals according to a national average of hospital-acquired conditions will be subject to a Medicare payment penalty. DHHS must submit a report to Congress by January 1, 2012 on the appropriateness of establishing a healthcare-acquired condition policy related to other providers.	FY 2015	N/A

Provisions Impacting Hospitals				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA §§ 3025, 10309	42 U.S.C. 1395ww	Payments for hospitals under IPPS will be adjusted on the dollar value of each hospital's percentage of potentially preventable Medicare readmissions for heart failure, heart attack and pneumonia. DHHS must make publicly available information on all hospital readmission rates for certain conditions. In 2015, DHHS will expand the policy to include additional readmission measures.	Oct. 1, 2012; readmission program established by March 23, 2012	N/A
PPACA § 3106, 10312	42 U.S.C. 1395ww	For long-term acute care hospitals, relief from the "25% Rule" payment adjustment, limiting the proportion of patients who can be admitted to an LTCH from a co-located or host hospital, is extended for two years. The moratorium on new LTCHs and satellite facilities, and on the increase of hospital beds in existing LTCHs is extended for two years.	Dec. 29, 2010	N/A
PPACA § 3121	42 U.S.C. 13951	The existing "hold harmless" provision applying to Medicare outpatient services payments to sole community hospitals and rural hospitals under 100 beds is extended for an additional year through December 31, 2010. The 100-bed limitation for sole community hospitals is removed for 2010. This provision protects such rural and sole community hospitals so that they receive the difference between the pre-BBA payment amount for covered outpatient services and the OPPS payment.	Jan. 1, 2010	N/A
PPACA § 3122	42 U.S.C. 13951-4	Medicare reasonable cost payments for certain clinical diagnostic laboratory tests furnished in qualifying rural hospitals under 50 beds are extended for one year.	July 1, 2010 – July 1, 2011	N/A
PPACA §§ 3123, 10313	P.L. 108-173, 117 Stat. 2272	The Rural Community Hospital Demonstration Program is extended for five additional years. The number of eligible states is expanded to 20, and the number of participating rural community hospitals is expanded to 30.	Date after the last day of the initial five-year program	N/A
PPACA § 3124	42 U.S.C. 1395ww	The Medicare-dependent Hospital Program is extended for one year.	Oct. 1, 2011	N/A
PPACA §§ 3125, 10314	42 U.S.C. 1395ww	The Medicare requirements to be eligible as a "low volume" hospital are modified to include hospitals with 1,600 Medicare discharges, and hospitals located more than 15 miles from another low-volume hospital.	FY 2011	N/A
PPACA § 3128	42 U.S.C. 1395m	CAHs continue to be eligible to receive 101% of reasonable costs for providing outpatient care and ambulance services.		N/A
PPACA § 3129	42 U.S.C. 1395i-4	The Rural Health Flexibility Program is extended by providing appropriations in 2011 and 2012. The awarding of FLEX grants to rural hospitals to upgrade data systems is expanded so that hospitals may expend those funds to participate in delivery system reforms, value-based purchasing programs and accountable care organizations.	Jan. 1, 2010	N/A

Provisions Impacting Hospitals				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA §§ 3141, 10324, 10317	42 U.S.C. 13951, 1395w-4, 1395ww	Medicare is required to apply the budget neutrality requirements associated with the effect of the imputed rural floor on the area wage index through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.	Oct. 1, 2010	N/A
PPACA § 3505	42 U.S.C. 300d-41	DHHS must establish programs to award grants to public, nonprofit and other trauma centers to defray their substantial uncompensated care costs, further their core missions, and provide emergency relief to ensure future availability of trauma centers. DHHS must also make funds available to states to award grants to trauma centers in order to promote universal access to trauma care services and trauma-related physician specialties.	Authorizes appropriations for FY 2010 - FY 2015	Mandatory program requirements beginning FY 2010
PPACA § 5503	42 U.S.C. 1395ww	DHHS must redistribute unfilled medical residency positions for the training of primary care physicians. In distributing the residency slots, special preference will be given to programs located in states with a resident-to-population ratio in the lowest quartile and with the highest ratio of population living in a health professional shortage area relative to the general population.	July 1, 2011	Mandatory action beginning July 1, 2011
PPACA § 5504	42 U.S.C. 1395ww	Any time spent by an intern or resident in an approved medical residency training program in a non-provider setting that is primarily engaged in furnishing patient care in non-patient care activities shall be counted toward direct graduate medical education and indirect medical education costs of hospitals paying the resident's stipend during the nonprovider rotations.	July 1, 2009	N/A
PPACA § 5505	42 U.S.C. 1395ww	DHHS must permit hospitals to claim non-patient care didactic time in nonprovider settings for GME purposes and in the hospital for IME purposes. Hospitals may also claim residents' vacation and sick time as part of the IME and GME resident count.	Retroactive to various years but DHHS not required to reopen settled cost reports.	Mandatory regulation amendments
PPACA § 5506	42 U.S.C. 1395ww	DHHS must redistribute residency positions from a hospital that closes on or after March 25, 2008.		Mandatory action
PPACA § 5508	42 U.S.C. 293k et seq.	DHHS may establish a grant program to support new or expanded primary care residency programs at teaching health centers. DHHS must provide payments to teaching health centers for direct and indirect costs related to training primary care residents in certain expanded or new programs.	Authorizes appropriations beginning FY 2010 for grant program and FY 2011 for training programs	Discretionary program requirements beginning FY 2010; mandatory program requirements beginning FY 2011
PPACA § 5509	42 U.S.C. 1395	DHHS must establish a graduate nurse education demonstration under which hospitals may receive payment for the provision of qualified clinical training to advance practice nurses.	Authorizes appropriations for FY 2012 – FY 2015	Mandatory program requirements beginning FY 2012

Provisions Impacting Hospitals				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6001	42 U.S.C. 1395 nn	The use of the Stark whole hospital and rural provider exceptions for physician-owned hospitals is ended if the hospital does not have a Medicare provider agreement by December 31, 2010. The percentage of physician investment interests in a physician-owned hospital cannot increase. The number of operating rooms, procedures rooms and beds for a licensed physician-owned hospital cannot increase after March 23, 2010, subject to an exceptions process to be implemented prior to February 1, 2012. Conversions of ambulatory surgery centers to physician owned hospitals using the whole hospital or rural provider exceptions are prohibited. Physician-owned hospitals must meet certain patient safety and ownership disclosure requirements within 18 months of the date of enactment.	Various	Mandatory regulations
PPACA § 9007	26 U.S.C. (501)(r)	At least every three years, tax exempt hospitals must conduct a community health needs assessment and implementation strategy. Tax-exempt hospitals must have written financial assistance policies including eligibility criteria, whether care will be free of charge or at a discount, the basis for calculating charges, the method for applying for financial assistance, a billing and collections policy addressing actions taken upon nonpayment and measures to widely publicize the policy. Limitations are imposed on patient charges and collection practices regarding individuals qualifying for financial assistance. Form 990 submissions must include audited financial statements. The tax-exempt status of hospitals will be reviewed every three years.		

Provisions Impacting Physicians, Nurses, and Other Healthcare Professionals

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA §§ 3002, 10327	42 U.S.C. 1395w-4	Bonus payments under the Physician Quality Reporting Initiative are extended through 2014. Beginning in 2014, a penalty will be assessed for failure to submit quality information. An additional bonus payment will be available for eligible professionals who report quality measures through a Maintenance of Certification Program with their specialty board. DHHS is required to develop an appeals and feedback process.	2011	Mandatory program requirements by Jan. 1, 2011
PPACA § 3003	42 U.S.C. 1395w-4	The Physician Feedback Program is expanded to provide for development of individualized reports. Reports will compare the per capita utilization of physicians to other physicians who see similar patients. Reports will be risk-adjusted and standardized to take into account local healthcare costs.	By Jan. 1, 2012	N/A
PPACA §§ 3007, 10327	42 U.S.C. 1395w-4	DHHS must develop and implement a budget-neutral payment system that will adjust Medicare physician payments based on the quality and cost of the care they deliver. Quality and cost measures will be risk-adjusted and geographically standardized.	Implementation begins in 2013	Mandatory program requirements beginning Jan. 1, 2012
PPACA § 3024	42 U.S.C. 1395	DHHS must conduct a demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes physician and nurse practitioner directed home-based primary care teams aimed at reducing expenditures and improving health outcomes.	By Jan. 1, 2012	Mandatory program requirements by Jan. 1, 2012
PPACA § 3102, HCERA 1108	42 U.S.C. 1395w-4	A new method for the physician practice geographic practice cost indices is established. DHHS must analyze and evaluate data and make adjustments to the practice expense geographic adjustment.	2010 and 2011.	Adjustments by January 1, 2012.
PPACA § 3108	42 U.S.C. 1395f	Physician assistants may order Medicare post-hospital extended care services.	Jan. 1, 2011	N/A
PPACA §§ 5301-5317	42 U.S.C. 202 et seq., 256f et seq., 280g et seq., 293 et seq., 294 et seq., 296j et seq., 297 et seq.	DHHS may/must make various grants to eligible entities for the purpose of education and training in family medical, general internal medicine, general pediatrics and dentistry, and for physician assistants.	Authorizes appropriations as early as 2010	Mandatory and discretionary program requirements
PPACA § 5402, 5404	42 U.S.C. 293b, 296m	Loan repayment, scholarship, and grant programs are expanded for minority and disadvantaged healthcare professionals	Authorizes appropriations for FY 2010-FY 2014	N/A
PPACA § 5405	42 U.S.C. 280g et seq.	DHHS must establish a Primary Care Extension Program to educate and provide assistance to primary care providers about evidence-based therapies, preventive medicine, health promotion, chronic disease management, and mental health.	Authorizes appropriations for FY 2010-FY 2014	Mandatory and discretionary program requirements

Provisions Impacting Physicians, Nurses, and Other Healthcare Professionals				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 5501	42 U.S.C. 13951	Primary care practitioners and general surgeons practicing in health professional shortage areas will receive a ten percent bonus with each Medicare payment.	Jan. 1, 2011 - Jan. 1, 2016	N/A
PPACA § 6003	42 U.S.C. 1395nn(b)(2)	As a condition of using the Stark in-office ancillary services exception, a physician must inform a patient in writing that the patient may obtain radiology and other imaging services from another supplier outside the physician's group practice. The physician must provide a written list of radiology and other imaging suppliers in the area in which the patient resides.	January 1, 2010	
PPACA §§ 6405, 10604	42 U.S.C. 1395m(a)(ii), 42 U.S.C. 1395n(a)(2), 42 U.S.C. 1395(a)(2)	Physicians or other eligible professionals who order or certify durable medical equipment or home health services for beneficiaries must be enrolled in the Medicare program. DHHS is given the authority to extend this requirement to other categories of Medicare items and services, including Part D drugs, if DHHS determines that it would help reduce fraud, waste and abuse.	July 1, 2010	Interim Final Rule, May 5, 2010, 42 CFR 424.507
PPACA §§ 6407, 10605	42 U.S.C. 1395f, 1395m 1395n	Physicians must document that they (or a nurse practitioner, a clinical nurse specialist, a certified nurse-midwife, or a physician assistant) have had a face-to-face encounter with the Medicare or Medicaid beneficiary prior to issuing a certification for home health services. Documentation of a face-to-face encounter is also required for a written order for durable medical equipment and may be required for other Medicare items and services as determined by DHHS.	Jan. 1, 2010	Discretionary regulations
PPACA § 10331	42 U.S.C. 1395w-4	DHHS must develop and implement a Physician Compare Internet website on physician performance and quality.	Website by January 1, 2011. Public disclosure of physician performance by January 1, 2013	Mandatory program requirements

Provisions Impacting Nursing and Long-Term Care Facilities				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 10325		Implementation of the revised case-mix classification methodology (RUG-IV) in the skilled nursing facility prospective payment system is delayed until October 1, 2011.		N/A

Provisions Impacting Nursing and Long-Term Care Facilities				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6101	42 U.S.C. 1320a-3	Nursing facilities must make available, on request by DHHS, the Inspector General, the States, and the States long-term care ombudsman, information about ownership, including a description of the governing body and organizational structure of the facility. Within two years, DHHS must issue regulations requiring such information to be reported in a standard format.	March 23, 2010	Mandatory regulations by March 23, 2012
PPACA § 6102	42 U.S.C. 1301 et seq.	Nursing facilities must implement compliance and ethics programs to be followed by the facility's employees and its agents.	By March 23, 2013	N/A
PPACA § 6111	42 U.S.C. 1395i-3	DHHS may reduce civil penalties by up to 50 percent for facilities that self-report and promptly correct a deficiency within ten calendar days. DHHS must develop an independent formal dispute resolution process that generates a written record within 30 days of imposition of a civil penalty and prior to collection of the penalty	March 23, 2011	Mandatory and discretionary regulations
PPACA § 6113	42 U.S.C. 1320a-7	The administrator of a closing nursing facility must provide written notification of such closing to the residents, legal representatives of residents or other responsible parties, the state, DHHS, and the long-term ombudsman program in advance of the closure by at least 60 days. Closing facilities must prepare a plan for closing the facility, and such plan must be approved by the state.	March 23, 2011	N/A
PPACA § 6121	42 U.S.C. 1395i-3	Nursing facilities must include dementia management and abuse prevention training as part of pre-employment initial training for permanent and contract or agency staff, and if DHHS determines appropriate, as part of ongoing in-service training.	March 23, 2011	Discretionary regulations
PPACA § 6201		DHHS must establish a nationwide program for national and State background checks on direct patient employees of certain long-term services facilities or providers.	Authorizes appropriations for FY 2010 – FY 2012	Mandatory program requirements
PPACA § 6703	42 U.S.C. 1397 et seq.	The Elder Justice Act authorizes DHHS to make grants to long-term care facilities for the purpose of assisting such entities in offsetting the costs related to electronic health record technology, to adopt electronic standards for the exchange of clinical data by long-term care facilities, and to carry out activities to incentivize employment in direct care at long-term care facilities. Each individual owner, operator, employee, manager, agent, or contractor of a long-term care facility that receives \$10,000 in federal funds must report annually to DHHS and one or more local law enforcement entities any reasonable suspicion of a crime against anyone who is receiving care from the facility.		Mandatory and discretionary program requirements

Provisions Impacting Manufacturers and Suppliers of Drugs, Medical Equipment and Medical Devices				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 3109	42 U.S.C. 1395m	Until January 1, 2011, all pharmacies are exempt from the accreditation requirements for durable medical equipment, prosthetics, orthotics and suppliers. Certain pharmacies are exempt until DHHS develops an alternative accreditation requirement that is more appropriate.		Discretionary regulations
PPACA § 3139	42 U.S.C. 1395w-3a	The Medicare Part B payment for a "biosimilar" biological product is the average sales price plus 6 percent of the reference/brand biological product.	First day of the second calendar quarter after the enactment of legislation providing for a biosimilar pathway	N/A
PPACA § 3301	42 U.S.C. 1395w-101 et seq.	Manufacturers of applicable drugs, which generally includes branded drugs and biological products that are on a Part D plan's formulary, must provide a discount equal to 50% of the negotiated price of such drugs when dispensed to a Part D plan enrollee who is not entitled to low-income subsidies during the Part D coverage gap (the "donut hole").	July 1, 2010	N/A
PPACA § 4204	42 U.S.C. 247b	DHHS and states may contract directly with manufacturers for the purchase and delivery of adult vaccines. A demonstration program is established which will provide grants to states to improve immunization coverage among high-risk populations.	Authorizes appropriations for program FY 2010 – FY 2014	Mandatory program requirements beginning FY 2010
PPACA § 10409	42 U.S.C. 282b	The National Institutes of Health must establish a Cures Acceleration Network to conduct and support revolutionary advances in basic research. The Network will award grants to entities such as biotechnology companies and pharmaceutical companies to promote innovations that support advanced research and development of high-need cures.	Authorizes appropriations beginning FY 2010	Mandatory program requirements
PPACA § 6002	42 U.S.C. 1301	Drug, device, biological and medical supply manufacturers of Medicare-covered items that make a payment or another transfer of value to a physician or a teaching hospital must report annually, in electronic form, specified information on such transactions. Excluded from reporting requirements are payments/transfers of \$10 or less (unless the aggregate annual payments/transfers exceed \$100), samples intended for patient use, patient educational materials and loans of a covered device for a short-term time period. Manufacturers and group purchasing organizations must report annually certain information regarding an ownership or interest held by a physician (or immediate family members). Penalties apply for failure to submit such reports and the information from the reports will be publicly available.	March 31, 2013 and annually thereafter	Mandatory program requirements

Provisions Impacting Manufacturers and Suppliers of Drugs, Medical Equipment and Medical Devices				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6005	42 U.S.C. 1301 et seq.	Health benefits plans and pharmacy benefits managers that manage prescription drug coverage under contract with health plans under Medicare or a state's exchange must provide specific information related to prescription and drug dispensing to DHHS and, in the case of a PBM, to the plan with which it contracts.		N/A
PPACA § 6410	42 U.S.C. 1395w-3	Under the durable medical equipment, prosthetics, orthotics, and supplies competitive bidding program, the number of areas to be included in Round Two will increase. DHHS must use information regarding payments determined under competitive bidding to adjust payments in areas outside of competitive bidding areas beginning in 2016.		Mandatory program requirements beginning 2011
HCERA § 1304	42 U.S.C. 1395cc	DHHS may hold Medicare claims for up to 90 days for suppliers of durable medical equipment where there is a significant risk of fraud.	Jan. 1, 2011	N/A

Provisions Impacting Mental Health Providers				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 2707		DHHS must establish a three-year Medicaid demonstration project in up to eight states, which would require reimbursement to certain institutions for mental health for services provided to Medicaid beneficiaries between the ages of 21 and 65, who need medical assistance in order to stabilize an emergency psychiatric condition.	Authorizes appropriations for FY 2011	Mandatory program requirements
PPACA § 3107	P.L. 110-275	The fee schedule add-on of five percent for mental health services is extended through December 31, 2010.	Jan. 1, 2010	N/A
HCERA § 1301	42 U.S.C. 1395x	Community mental health centers that provide Medicare partial hospitalization services must provide at least 40% of services to individuals who are not eligible for benefits under Medicare.	First quarter that begins after March 30, 2010	N/A
PPACA § 10322		DHHS will establish a quality reporting program for inpatient psychiatric facilities.	July 1, 2013	Mandatory requirements by October 1, 2012

Provisions Impacting Home Health Agencies				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 3103		The outpatient therapy services exceptions process for therapy caps is extended through December 31, 2010.	April 1, 2010	
PPACA §§ 3131, 3401, 10315	42 U.S.C. 1395fff, P.L. 108-173, 117 Stat. 2283	The market basket update payment rate for home health agencies is reduced by one percentage point. DHHS must impose a productivity adjustment on payment rates and rebase payments by a percentage amount based on an analysis of the current mix of services and intensity of care provided to home health patients. The amount of outlier payments each home health agency can receive is capped at 10%, and rural home health providers will receive a 3% add-on. DHHS must submit a plan to Congress to include home health agencies in a Medicare, value-based purchasing program.	Payment adjustments phased in from 2014 through 2017; plan must be submitted by Oct. 1, 2011	Mandatory payment adjustments

Provisions Impacting Pediatric Providers				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 2706		DHHS must establish a demonstration project that allows qualified pediatric providers to be recognized and receive payments as accountable care organizations under Medicaid.	Jan. 1, 2012 – Dec. 31, 2016	Mandatory program requirements beginning Jan. 1, 2012

Provisions Impacting Multiple Providers				
<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 2703	42 U.S.C. 1396	States have the option of providing medical assistance to Medicaid recipients with chronic conditions who seek treatment in a "health home," which is a designated provider, a team of healthcare professionals, or a health team who provide health home services for eligible Medicaid recipients. States who develop this health home plan must outline their methodology for determining payment for health home services and must require hospitals to outline procedures for referrals of eligible individuals with chronic conditions and require state coordination with other agencies.	Jan. 1, 2011	N/A

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA §§ 3004-3005, 10322	42 U.S.C. 1395ww	"Pay for reporting" provisions are established for previously exempt providers including LTCHs, inpatient rehabilitation facilities, psychiatric hospitals, and hospices. For each type of provider, DHHS will specify the quality measures for which the provider must submit data. Providers that fail to report will be subject to a reduction in their annual market basket update. DHHS must establish quality reporting programs for exempt cancer hospitals (does not provide a penalty for failure to report).	Rate year 2014	Mandatory program requirements by Oct. 1, 2012
PPACA §§ 3006, 10301	42 U.S.C. 1395i-3	DHHS must submit a plan to Congress outlining how to effectively move skilled nursing facilities and home health agencies into a value-based purchasing payment system. DHHS must also develop a plan to reimburse ambulatory surgery centers based on the quality and efficiency of care delivered.	By Oct. 1, 2011	Mandatory program requirements by Oct. 1, 2011
PPACA § 3021		DHHS shall establish a Center for Medicare and Medicaid Innovation for testing of innovative payment and service delivery models to reduce Medicare program expenditures.	No later than Jan. 1, 2011	Mandatory program requirements
PPACA §§ 3022, 10307	42 U.S.C. 1395	DHHS must establish a Medicare shared savings program in which accountable care organizations that meet quality-of-care targets and reduce the costs of their patients relative to a spending benchmark are rewarded with a share of the savings.	By Jan. 1, 2012	Mandatory program requirements by Jan. 1, 2012
PPACA §§ 3023, 10308	42 U.S.C. 1395	DHHS must establish a five-year national, voluntary pilot program that will encourage hospitals, doctors, and post-acute care providers to improve patient care and achieve savings for the Medicare program through bundled payment models. DHHS may expand the payment bundling pilot if it is found to improve quality and reduce costs. DHHS shall test bundled payment arrangements involving continuing care hospitals within the program.	By Jan. 1, 2013	Mandatory program requirements by Jan. 1, 2013
PPACA § 3026		DHHS will establish a five year Community Care Transitions Program to fund eligible high admission rate hospitals, or certain community based organizations with continuum of care arrangements through certain hospitals, to furnish improved care transition services to high risk Medicare beneficiaries.	Jan. 1, 2011	Mandatory program requirements
PPACA § 10326		DHHS must conduct a pilot program establishing value-based purchasing programs for psychiatric hospitals and units, LTCHs, inpatient rehabilitation facilities, PPS-exempt cancer hospitals, and hospice programs.	By Jan. 1, 2016	Mandatory program requirements by Jan. 1, 2016
PPACA § 10333	42 U.S.C. 254b	DHHS may award grants to develop networks of providers to deliver coordinated care to low-income populations.	Authorizes appropriations for FY 2011- FY 2015	Discretionary program requirements

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 3127		MedPAC must conduct a study on the payments for suppliers and providers serving rural areas under the Medicare program and must submit a report to Congress with the results and suggestions.	Report due by Jan. 1, 2011	N/A
PPACA § 3135, HCERA § 1107	42 U.S.C.1395w-4	The utilization rate of advanced imaging equipment priced at \$1 million or more is increased to 75 percent for applying practice expense revenue value units to payments for imaging services. The discount for the technical component of additional imaging studies performed on the same Medicare patient in the same day is increased to 50 percent.	Jan. 1, 2010	N/A
PPACA §§ 3401, 10319, HCERA § 1105	42 U.S.C. 1395f, 1395l, 1395m, 1395u, 1395rr, 1395ww, 1395yy, 1395fff	Medicare market basket updates for inpatient hospitals, inpatient psychiatric facilities, LTCHs, inpatient rehabilitation facilities, home health agencies, skilled nursing facilities, hospice providers, ambulatory surgery centers, dialysis facilities, and certain Part B providers and suppliers will be adjusted to reflect productivity gains in delivering healthcare services and to encourage more efficient care.	Effective date depends on the type of provider	CMS Fact Sheet, May 21, 2010, 42 CFR Parts 412 and 413, Expected Publication Date: June 2, 2010
PPACA §§ 3403, 10302	42 U.S.C. 1395	The Independent Payment Advisory Board is established to develop and submit detailed proposals to Congress and the president to reduce Medicare per-capita spending when projected spending growth exceeds a target. IPAB's proposals will go into effect automatically unless Congress enacts specific legislation with alternative provisions to achieve the required level of savings. IPAB is prohibited from making proposals that ration care; raise taxes or Part B premiums; change Medicare standards for benefits, eligibility, or cost-sharing; reduce Medicare payments prior to December 31, 2019, for providers scheduled to receive a reduction in their payment updates in excess of a reduction because of productivity. IPAB's proposals must not increase Medicare spending over the initial 10-year period.		N/A
PPACA § 3502		DHHS must make grants to or enter into contracts with states to create "health teams" which will contract with primary care providers to provide primary care support services.		Mandatory program requirements
PPACA § 3503	42 U.S.C. 299 et seq.	DHHS must establish a program to make grants to or enter into contracts with entities that will be used to implement medication management services for targeted individuals who take four or more prescribed medications, take high-risk medications, or otherwise have a high risk for medication-related problems	By May 1, 2010	Mandatory program requirements by May 1, 2010

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 3506	42 U.S.C. 300	DHHS must contract with the National Quality Forum to support "preference sensitive care" (defined as medical care for which clinical evidence does not clearly support one treatment option, and therefore must be based on patient values, preferences, and the risks and benefits associated with treatment alternatives) and to establish consensus-based standards and a certification process for patient decision aids (defined as educational tools to assist patients and caregivers with making "preference sensitive care" decisions).	As soon as practicable	Mandatory contract as soon as practicable
PPACA § 4203	29 U.S.C. 791 et seq.	The Architectural and Transportation Barriers Compliance Board must establish standards that promote access to and usability of medical diagnostic equipment for disabled individuals.	By March 23, 2012	Mandatory regulations by March 23, 2012
PPACA § 5502	42 U.S.C. 1395m	DHHS must develop and implement a prospective payment system for Medicare-covered services, including preventive services, furnished by federally qualified health centers.	For cost reporting periods beginning on or after Oct. 1, 2014	Mandatory program requirements beginning Oct. 1, 2014
PPACA §§ 5606, 10501		States may award grants to support healthcare providers who treat a high percentage of medically underserved populations. DHHS must by regulation define "underserved rural community."		Mandatory regulation by May 22, 2010
PPACA § 6401	42 U.S.C. 1395cc	DHHS must establish procedures for providers and suppliers enrolling in Medicare, Medicaid, and CHIP. The enrollment process is required to include provider screening, enhanced oversight measures, disclosure requirements, enrollment moratoriums and requirements to developing compliance programs. At a minimum, providers will be subject to licensure checks, and additional screening items could include fingerprinting, criminal background checks, multi-state database inquiries, and surveys/site visits. Providers and suppliers will be required to disclose current or previous affiliations with providers or suppliers that have uncollected debt, have had their payments suspended, have been excluded from participating in a federal healthcare program, or have had their billing privileges revoked. Certain providers and suppliers must establish compliance programs.	Disclosure requirements effective March 23, 2011	Mandatory program requirements by Sept. 19, 2010
PPACA § 6402(a)	42 U.S.C. 1320a-7h	Medicare and Medicaid overpayments must be reported and returned within 60 days from the date of identification or by the date that the corresponding cost report is due.		N/A
PPACA § 6402(a)	42 U.S.C. 1320a-7h	DHHS must promulgate regulations that require providers to include national provider identifier on all enrollment applications.		Interim Final Rule, May 5, 2010, 42 CFR 424.506

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6402(d)	42 U.S.C. 1320a-7	Permissive exclusion and CMPs of up to \$10,000 are added for ordering or prescribing during a period when the prescriber was excluded from a federal or state healthcare program and the person knows or should have known that a claim for an item or service will be made to the program.		N/A
PPACA § 6402(d)	42 U.S.C. 1301	A new permissive exclusion and CMPs up to \$50,000 are added for entities that make false statements on enrollment applications, bids or contracts to participate as a provider or supplier, or insurers, providers or suppliers that apply to participate in Medicare Advantage plans, prescription drug plan sponsors and Medicaid manage care organizations.		
PPACA § 6402(d)(2)(B)	42 U.S.C. 1301	The definition of "remuneration" under CMPs is amended to exclude remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs; the offer or transfer for free or less than FMV if the items or services are not offered as part of any advertisement or solicitation, are not related to any reimbursable items or services under federal or state healthcare programs, and there is a reasonable connection between the items or services and the medical care furnished by the provider or supplier after determining in good faith that the individual is in financial need; and waivers of copayments by prescription drug plan sponsors, or a Medicare Advantage Plan offering a prescription drug plan for the initial filling of a covered Part D generic drug prescription.		
PPACA § 6402(f)	42 U.S.C. 1320a-7b	A violation of the Anti-Kickback Statute constitutes a per se violation of the federal FCA and to commit an Anti-Kickback violation, a person does not need to have actual knowledge of the law or specific intent to commit a violation.		N/A
PPACA § 6402(g)	42 U.S.C. 1395m	DHHS is directed to consider the volume of billing for a supplier of durable medical equipment or home health agency when determining the size of the surety bond required. DHHS may impose the surety bond requirement on other providers and suppliers, depending on the level of risk presented by provider or supplier.		Discretionary imposition of surety bonds
PPACA § 6402	42 U.S.C. 1395y	DHHS may suspend payments to a provider or supplier pending a fraud investigation.		N/A

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6403	42 U.S.C. 1320a	A national healthcare fraud and abuse data collection program is established to report certain adverse actions taken against healthcare providers, suppliers, and practitioners to the National Practitioner Data Bank.	Later of March 24, 2010 and the first day after the effective date of the regulations promulgated under this section	N/A
PPACA § 6404	42 U.S.C. 1395f	The maximum period for submission of Medicare claims is reduced to not more than 12 months from the date of service.	Jan. 1, 2010	Medicare Transmittal CR6960/R6970TN; MM6960
PPACA § 6405	42 U.S.C. 1395m	Physicians who prescribe durable medical equipment or home health services must be enrolled in the Medicare program.	July 1, 2010	N/A
PPACA § 6406	42 U.S.C. 1395u	DHHS may revoke the enrollment of a physician or supplier for up to one year from Medicare for failure to maintain and provide access to written orders or requests for payment for durable medical equipment, certification for home health services, or referrals for other items and services.	Jan. 1, 2010	N/A
PPACA § 6408	42 U.S.C. 1320a-7	Civil penalties are increased for failure to grant the OIG timely access to documents and for knowingly making false statements to a federal healthcare program.	Jan. 1, 2010	N/A
PPACA § 6408	42 U.S.C. 1320a-7a	Permissive exclusions and CMPs are imposed for failing to report and return a known overpayment or for failing to grant timely access, upon reasonable request, to the OIG for its audits, investigations, evaluations or other functions.	January 1, 2010	N/A
PPACA § 6408	42 U.S.C. 1320a-7a	A permissive exclusion and up to \$50,000 CMP is imposed for knowingly making or using, or causing to be made or used, a false record or statement for payment for items or services furnished under a federal healthcare program.	September 25, 2010	Mandatory
PPACA § 6409		DHHS must establish a self-disclosure protocol for violations of section 1877 of the Social Security Act (the Stark physician self-referral law).	By September 25, 2010	Mandatory protocol by September 25, 2010
PPACA § 6411	42 U.S.C. 1396a	The Recovery Audit Contractor program, which is aimed at identifying improper payments to Medicare providers and suppliers, is extended to Medicaid and all parts of the Medicare program.	December 31, 2010	
HCERA § 1302	42 U.S.C. 1395w-3	Provider and supplier protections against random governmental audit and review are eliminated.		N/A

Provisions Impacting Multiple Providers

<u>Public Law Citation</u>	<u>U.S. Code Citation</u>	<u>Description</u>	<u>Effective Date</u>	<u>Rulemaking</u>
PPACA § 6501	42 U.S.C. 1396a(a)	States must terminate the enrollment of individuals or entities from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.	Jan. 1, 2011	N/A
PPACA § 6502	42 U.S.C. 1396a	Medicaid agencies must exclude entities from participating in Medicaid if the individual or entity owns, controls, or manages an entity that has failed to repay overpayments during the period as determined by DHHS; is suspended, excluded, or terminated from participation in any Medicaid program; or is affiliated with an individual or entity that has been suspended, excluded or terminated from Medicaid participation.	Jan. 1, 2011	N/A