"The Patient Protection and Affordable Care Act" (Pub. L. 111-148)

Enacted on March 23, 2010; and

"The Health Care and Education Reconciliation Act of 2010" (Pub. L. 111-152)

Enacted on March 30, 2010*

Summary of Regulations Required Description of the Regulation or Rulemaking Section Number & Title **Authority** Date Title I: Quality, Affordable Health Care for All Americans Subtitle A -- Immediate Improvements in Health Care Coverage for All Americans HHS Secretary May develop guidelines to permit a group health plan and a health insurance issuer offering Not specified.** group or individual health insurance coverage to utilize value-based insurance designs. HHS Secretary Shall promulgate regulations to define the dependents to which coverage shall be made Not specified. available under section (a), extending dependent coverage of children to adult nonmarried children under 26 years of age. HHS Secretary Shall develop standards for use by a group health plan and a health insurance issuer offering Not later than 12 months group or individuals health insurance coverage, in compiling and providing to enrollees a after date of enactment. summary of benefits and coverage explanation. HHS Secretary Shall by regulation provide for the development of standards for the definitions of terms used In Not specified. health insurance coverage, including insurance related terms and medical terms. HHS Secretary In consultation with experts and stakeholders, shall develop reporting requirements for use by a Not later than 2 years group health plan, and a health insurance issuer offering group or individual health insurance after date of enactment. coverage, with respect to plan or coverage benefits and health care provider reimbursement structures, for example improving health outcomes through quality reporting or chronic disease management. HHS Secretary Shall promulgate regulations that provide criteria for determining whether a reimbursement Not later than 2 years 1001. Amendments to structure is described for purposes of the reporting requirements established. after date of enactment. the Public Health Service Act (as amended by Sec. 10101). May determine a lower percentage, by regulation, than 20%, which would be used in the Not specified. State calculation to determine the annual rebate owed to an enrollee as part of the "value for premium payments" requirement.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
8		HHS Secretary	Shall, in consultation with the National Assoc. of Insurance Commissions, establish uniform definitions for the activities reported, such as percentage of total premium revenue that the coverage expends on reimbursement for clinical services provided to enrollees.	Not specified.
9		Group health plan and health insurance issuer offering group or individual health insurance coverage	Shall implement an effective appeals process for appeals of coverage determinations and claims under which the plan or issuer shall include certain specified elements at a minimum, such as providing notice to enrollees.	Not specified.
10		National Assoc. of Insurance Commissioners	Subject to the certification of the Secretary, NAIC shall establish uniform definitions of the activities reported regarding accounting for costs, and standardized methodologies for calculating measures of activities.	Not later than Dec. 31, 2010
	1003. Ensuring that Consumers Get Value for Their Dollars.	HHS Secretary	Shall, in conjunction with States, establish a process for annual review of unreasonable increases in premiums. Secretary shall ensure public disclosure of increases and information of insurer justifications. This is subject to the monitoring requirement that begins in 2014 for the Secretary and states to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.	Annual reviews shall begin with 2010 plan year.
12		HHS Secretary	Shall establish a formula for determining the amount of any premium review grant to a State during 2010 through 2014.	Not specified.
		S	ubtitle B - Immediate Actions to Preserve and Expand Coverage	
	1101. Immediate Access to Insurance for Uninsured Individuals with a Preexisting	HHS Secretary	Shall establish a temporary high risk health insurance pool program for eligible individuals from date on which program is established until Jan. 1, 2014, and to be carried out directly or through contracts to eligible entities. The Secretary may require certain information to be submitted in the application to be eligible for a contract, determine requirements for a qualified high risk pool, shall establish criteria for determining whether issuers or plans have discouraged an individual from remaining enrolled in prior coverage, and establish criteria for when a plan is responsible for reimbursing the program for expenses incurred where an individual was encouraged to disenroll.	Not later than 90 days after the date of enactment.
	• ""	HHS Secretary	Shall establish an appeals process to enable individuals to appeal a determination under this section and procedures to protect against waste, fraud and abuse.	Not specified



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
15		HHS Secretary	Shall develop procedures to provide for the transition of eligible individuals enrolled in health insurance coverage offered through a high risk pool established under this section into qualified health plans offered through an Exchange.	Not specified.
16	1102. Reinsurance for Early Retirees.	HHS Secretary		Not later than 90 days after date of enactment.
17		HHS Secretary	Shall establish an appeals process to permit participating employment-based plans to appeal a determination of the Secretary with respect to claims submitted under this section.	Not specified.
18	1103. Immediate Information that allows Consumers to Identify Affordable Coverage	HHS Secretary	Shall, in consultation with the States, establish a mechanism, including an Internet website, through which a resident of any State may identify affordable health insurance coverage options in that State.	Not later than July 1, 2010.
19	Options.	HHS Secretary	Shall develop a standardized format to be used for the presentation of information relating to the insurance coverage options. Secretary may carry out this section through contracts with qualified entities.	Not later than 60 days after date of enactment.
20	1104. Administrative Simplification (as amended by Sec. 10109)	HHS Secretary	uniformity of electronic standards, and shall consider recommendations for operating rules	Not later than July 1, 2011, such that the rules are effective not later than Jan. 1, 2013.
21		HHS Secretary	transactions.	Not later than July 1, 2012, such that rules are effective not later than Jan. 1, 2014.
22		HHS Secretary	in a health plan.	Not later than July 1, 2014, such that rules are effective not later than Jan. 1, 2016.
23		HHS Secretary	Shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics (NCVHS), and shall accept and consider public comments for 60 days after the interim final rule's publication.	Not specified.
24		HHS Secretary	Secretary shall conduct audits to ensure health plans are in compliance with these rules.	Periodic.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date			
25		HHS Secretary	Shall establish a review committee to review standards, operating rules, and recommend updates and improvements.	Not later than January 1, 2014.			
26		HHS Secretary	Shall adopt through interim final rulemaking, with 60 days public comment period, any recommendations to amend the standards and operating rules approved by the review committee.	Not later than 90 days after receipt of the committee's report.			
27		HHS Secretary	Shall establish a procedure for assessment of penalty fees against a health plan.	Not specified.			
28			Shall promulgate a final rule to establish a unique health plan identifier based on input of NCVHS. May do so on an interim final basis.	Rule effective not later than Oct. 1, 2012.			
29		HHS Secretary	Shall promulgate a final rule to establish a standard for electronic funds transfers. May do so on an interim final basis such that the standard is effective not later than Jan. 1, 2014.	Not later than Jan. 1, 2012.			
30		HHS Secretary	Shall promulgate a final rule to establish a transaction standard and single set of associated operating rules for health claims attachments. May do so on an interim final basis and such that the standard is effective not later than Jan. 1, 2016.	Not later than Jan. 1, 2014.			
31		HHS Secretary	Shall task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input from stakeholders regarding the crosswalk between the 9th and 10th Revisions of the ICD.	Not later than January 11, 2011			
		S	Subtitle C - Quality Health Insurance Coverage for All Americans				
32		HHS Secretary	May establish rating areas for a state if the Secretary determines that a State's rating areas are not adequate or if the State does not establish such areas.	Not specified.			
33		HHS Secretary	Shall promulgate regulations with respect to enrollment periods, restricting enrollment in coverage to open or special enrollment periods, and establishing special enrollment periods for qualifying events.	Not specified.			
34	1201. Amendment to the Public Health Service Act.	Secretaries of HHS and Treasury	May increase the reward (up to 50% of cost of coverage) that may be available for participation in a wellness program offered by employers where any of the conditions for obtaining the premium discount or rebate or other reward for participation is based on an individual satisfying a standard related to a health status factor.	Not specified.			
35		HHS Secretary	Shall, in consultation with the Secretaries of Treasury and Labor, establish a 10-state demonstration project for employer-based wellness program; may beginning July 1, 2017, expand the demo project to include additional States.	Not later than July 1, 2014.			
36		Secretaries of HHS and Treasury	Nothing in the section shall be construed as prohibiting the Secretary from promulgating regulations to implement the provisions detailed in this section.	Not specified.			
	Subtitle D - Available Coverage for All Americans						



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
37	1301.Qualified Health Plan Defined. (as amended by Sec. 10104)	HHS Secretary	Shall permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan that meets criteria established by the Secretary.	Not specified.
38		HHS Secretary	Shall define the essential health benefits, and include at least the specified categories, including ambulatory patient services, emergency services, hospitalization, maternity newborn care, mental health and substance use disorder services, prescription drugs, rehabilitative services, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, oral and vision care.	Not specified.
39	1302. Essential Health Benefits Requirements	HHS Secretary	Shall issue regulations under which employer contributions to a health savings account may be taken into account in determining the level of coverage for a plan of the employer.	Not specified.
40		HHS Secretary	Shall develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.	Not specified.
41		HHS Secretary	Shall by regulation, establish criteria for the certification of health plans as qualified health plans using criteria described in this section, such as meeting marketing requirements, ensuring a sufficient choice of providers, and others.	Not specified.
42		HHS Secretary	Shall develop a rating system that would rate qualified health plans offered through an Exchange on the basis of quality and price.	Not specified.
43		HHS Secretary	Shall, in consultation with experts and stakeholders, develop guidelines concerning rewarding quality through market based incentives.	Not specified.
44		HHS Secretary	May establish exceptions to the quality improvement requirements for contracting with hospitals with greater than 50 beds beginning Jan. 1, 2015; Secretary may also by regulation adjust the number of hospital beds that triggers the quality improvement requirements.	Not specified.
45	1311. Affordable Choices of Health Benefit Plans (as amended by Sec. 10104)	HHS Secretary	Shall establish standards for navigators including provisions to ensure that any private or public entity that is selected as a navigator is qualified to engage in navigator activities and avoid conflicts of interest. Duties of the navigators include conducting public education activities to raise awareness of the availability of qualified health plans, facilitating enrollment in qualified health plans, and providing referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman.	Not specified.
46		HHS Secretary	Shall, in collaboration with States, develop standards to ensure that information made available by navigators is fair, accurate, and impartial.	Not specified.
	A FOLEY	Labor and HHS Secretaries	Shall jointly develop and isseu guidance on best practices of plain language writing (the Exchange shall require health plans seeking certification as qualified health plans to submit to the Exchange, the Secretary information that must be provided using plain language.)	Not specified.

	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
47		Labor Secretary	Shall update and harmonize the Secretary's rules concerning the accurate and timely disclosure to participants by group health plans of plan disclosure, terms, and conditions, and periodic financial disclosure with the standards established by the Secretary.	Not specified.
48	1312. Consumer Choice.	HHS Secretary	Shall establish procedures under which a State may allow agents or brokers to enroll individuals in any qualified health plans in the individual or small group market, and to assist individuals in applying for premium tax credits and cost-sharing reductions for plans sold through an Exchange.	Not specified.
49	1321. State Flexibility in Operation and Enforcement of Exchanges and Related	HHS Secretary		As soon as practicable after date of enactment.
50	Requirements	HHS Secretary	Shall establish a process to work with a State to provide assistance necessary to assist the State's Exchange in coming into compliance with standards for approval.	Not specified.
51	1322. Federal Program to Assist Establishment and Operation of	HHS Secretary	Shall establish a program to carry out the purposes of this section, the Consumer Operated and Oriented Plan (CO-OP) program.	Not specified.
52	Nonprofit, Member-run Health Insurance Issuers. (as amended by Sec.	HHS Secretary	Shall, prior to awarding loans and grants under the CO-OP program, promulgate regulations with respect to the repayment of such loans and grants in a manner consistent with State solvency regulations and other similar State laws that may apply.	Not later than July 1, 2013.
53	10104).	HHS Secretary	May by regulations prescribe manner in which an organization must give notice to the Secretary in applying for recognition of its status as a CO-OP health insurance issuer.	Not specified.
54	1331. State Flexibility to Establish Basic Health Programs for Low- Income Individuals Not eligible for Medicaid	HHS Secretary	Shall establish a basic health program meeting the requirements of this section under which a State may enter into contracts to offer 1 or more standard health plans providing at least the essential health benefits to eligible individuals in lieu of offering such individuals coverage through an Exchange. Secretary shall conduct a review each year of each State program to ensure compliance with requirements.	Not specified.
55	1332. Waiver for State	HHS Secretary	·	Not later than 180 days after enactment.
56	Innovation.	HHS Secretary	Shall develop a process for coordinating and consolidating the State waiver processes applicable under this section and existing waiver processes.	Not specified.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
57	1333. Provisions Relating to Offering of Plans in More than One State. (as amended by Sec. 10104).	HHS Secretary	Shall, in consultation with the NAIC, issue regulations for the creation of interstate health care choice compacts under which 2 or more States may enter into an agreement and which can be entered into beginning in 2016. Under these compacts, qualified health plans may be offered in all participating States, but insurers would still be subject to the consumer protection laws of the purchaser's State.	Not later than July 1, 2013.
58	1334. Multi-State Plans (as added by Sec. 10104).	Director of Office of Personnel Management (OPM)	Shall implement the subsection on multi-state plans in a manner similar to the manner in which the Director implements the contracting provisions with respect to carriers under the Federal employees health benefit program, including through negotiating with each multi-state plan (A) a medical loss ratio; (B); a profit margin; (C) the premiums to be charged; and (D) such other terms and conditions of coverage as are in the interests of enrollees in such plans.	Not specified.
59	1341. Transitional Reinsurance Program for Individual Market in Each State (as amended by Sec. 10104).	HHS Secretary	Shall, in consultation with the NAIC, establish federal standards for determination of high-risk individuals, a formula for payment amounts, and the contributions required of insurers, which must total \$25 billion over the three years. (Note: for 2014, 2015, and 2016, States are required to establish a nonprofit reinsurance entity that collects payments from insurers in the individual and group markets and makes payments to such insurers in the individual market that cover high-risk individuals.)	Not specified.
60	1342. Establishment of Risk Corridors for Plans in Individual and Small Group Markets	HHS Secretary	Shall establish and administer a program of risk corridors for calendar years 2014-2016 under which a qualified health plan offered in the individual or small group market shall participate in a payment adjustment system based on the ratio of allowable costs of the plan to the plan's aggregate premiums.	Not specified.
61	1343. Risk Adjustment.	HHS Secretary	Shall, in consultation with States, establish criteria and methods to be used in carrying out the risk adjustment activities under this section.	Not specified.
			Subtitle E - Affordable Coverage Choices for All Americans	
62	1401. Refundable Tax Credit Providing	Secretary of Treasury	Shall, in consultation with the HHS Secretary, prescribe rules setting forth the methods to calculate family size and household income for the purpose of receiving this tax credit.	Not specified.
63	Premium Assistance for Coverage Under a Qualified Health Plan.	Secretary	Shall prescribe regulations as necessary to carry out this section, including providing for the coordination of the tax credit.	Not specified.
64	1402. Reduced Cost- Sharing for Individuals	Secretary	Shall establish procedures under which the issuer of a qualified health plan shall further reduce cost sharing in certain cases.	Not specified.
65	Enrolling in Qualified Health Plans.	HHS Secretary	Shall, in consultation with the Secretary of Treasury, prescribe rules setting forth the methods to calculate family size and household income for this section.	Not specified.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date		
66	Determination and Payment of Premium Tax Credits and Cost-Sharing Reductions	HHS Secretary	Shall provide procedures for making advance determinations on the basis of certain information.	Not specified.		
67	1413. Streamlining of Procedures for Enrollment Through an Exchange and State Medicaid, CHIP, and Health Subsidy Programs.	HHS Secretary	Shall promulgate standards governing the timing, contents, and procedures for data matching.	Not specified.		
68	1421. Credit for Employee Health Insurance Expense of	HHS Secretary	Shall, in consultation with Secretary of Labor, prescribe regulations, rules, and guidance as necessary to determine the hours of service of an employee.	Not specified.		
69		HHS Secretary	Shall prescribe regulations as necessary to carry out this section, including to prevent the avoidance of the 2-year limit on the credit period through the use of successor entities.	Not specified.		
			Subtitle F - Shared Responsibility for Health Care			
70	1511. Automatic Enrollment for Employees of Large Employers	HHS Secretary	Shall promulgate regulations whereby an employer that has more than 200 full-time employees and offers employees enrollment in 1 or more health benefits shall automatically enroll new full-time employees in one of the plans offered and continue enrollment of current employees in a health benefits plan offered through the employer.	Not specified.		
71	1512. Employer Requirement to Inform Employees of Coverage Options.	HHS Secretary	Shall promulgate regulations whereby an employer shall provide to each employee at the time of hiring (or to current employees, not later than March 1, 2013), written notice informing the employee of the Exchange and related information with respect to purchasing a qualified health plan through the Exchange.	Subsection shall take effect beginning March 1, 2013.		
72	1513. Shared Responsibility for Employers.	HHS Secretary	Shall prescribe regulations as necessary to carry out this section, including to prevent the avoidance of the 2-year limit on the credit period through the use of successor entities.	Not specified.		
	Subtitle G - Miscellaneous Provisions					
73	1554. Access to Therapies	HHS Secretary	Shall NOT promulgate any regulation that creates any unreasonable barriers to the ability of individuals to obtain appropriate care, impedes timely access to health care services, interferes with communications regarding a full range of treatment options, restricts the ability of health care providers to provide full disclosure of information, violates principles of informed consent and ethical standards, or limits availability of health care treatment for full duration of patient's	N/A.		



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
74	1561. Health Information Technology Enrollment Standards and Protocols.	HHS Secretary	Shall, in consultation with the HIT Policy Committee and the HIT Standards Committee, develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs.	Not later than 180 days after date of enactment.
			Title II - Role of Public Programs	
		Subtitle	E - New Options for States to Provide Long-term Services and Supports	
75	2402. Removal of Barriers to Providing Home and Community- based Services.	HHS Secretary	Shall promulgate regulations to ensure that all States develop service systems that are designed to allocate resources in a manner responsive to changing needs and choices of beneficiaries, provide support and coordination.	Not specified.
			Subtitle F - Medicaid Prescription Drug Coverage	
76	2503. Providing Adequate Pharmacy Reimbursement.	HHS Secretary	Shall implement a smoothing process for the calculation of average manufacturer price (AMP). Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological.	Not specified.
		s	ubtitle H - Improved Coordination for Dual Eligible Beneficiaries	
77	2602. Providing Federal coverage and Payment Coordination for Dual Eligible Beneficiaries.	HHS Secretary	Shall establish a Federal Coordinated Health Care Office within CMS; the purpose of the office is to bring together officers and employees of the Medicare and Medicaid programs to more effectively integrate benefits and improve coordination.	Not later than March 1, 2010.
		Subt	itle I - Improving the Quality of Medicaid for Patients and Providers	
78	2701. Adult Health Quality Measures.	HHS Secretary	Shall identify and publish not later than Jan 1, 2011 for comment a recommended core set of adult health quality measures for Medicaid eligible adults. Shall publish and disseminate the measures not later than Jan. 1, 2012. Shall develop a standardized format for reporting information based on the initial core set of adult health quality measures and create procedures to encourage States to use the measure and voluntarily report information.	Standardized format shall be developed not later than Jan. 1, 2013.
79		HHS Secretary	Shall establish a Medicaid Quality Measurement Program and then not later than 24 months after its establishment, and annually thereafter, shall publish recommended changes to the initial core set of adult health quality measures.	Not later than 12 months after the release of the recommended core set.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date	
80	2702. Payment Adjustment for Health Care-Acquired Conditions (HAC)	HHS Secretary	Shall identify current state practices that prohibit payment for HACs and, through regulations, incorporate the practices she determines appropriate for application to Medicaid. Regulations shall prohibit payments to States for amounts spent providing medical assistance for HACs.	Regulations effective as of July 1, 2011	
81	2703. State Option to Provide Health Homes for Enrollees with Chronic Conditions.	HHS Secretary	Shall establish standards for qualification as a designated provider for the purposes of being eligible to be a "health home." Nothing shall prevent the Secretary from establishing higher levels [than the State] as to the number or severity of chronic or mental health conditions for purposes of determining eligibility for receipt of "health home" services.	Not specified.	
	Sı	ubtitle J - Impro	vements to the Medicaid and CHIP Payment and Access Commission (MACPAC)		
82	2801. MACPAC Assessment of Policies Affecting All Medicaid Beneficiaries	MACPAC	Shall review Medicaid and CHIP regulations and may comment through submission of a report to the appropriate committee of Congress and the Secretary, on any such regulations that affect access, quality, or efficiency of health care.	Not specified.	
			Subtitle L - Maternal and Child Health services		
83	2951. Maternal, Infant, and Early Childhood Home Visiting Programs.	HHS Secretary	Shall establish criteria for evidence of effectiveness of the service delivery models and shall ensure that the process for establishing the criteria is transparent and provides the opportunity for public comment.	Not specified.	
84	2952. Support, Education, and Research for Postpartum Depression	HHS Secretary	Shall establish requirements for grants made under this section that include a limit on the amount of grants funds that may be used for administration, accounting, reporting or program oversight functions and a requirement for each eligible entity receiving a grant to submit a report to the Secretary on use of the grant funds.	Not specified.	
85	2001. Medicaid Coverage for the Lowest Income Populations. (as amended by Sec. 10201).	HHS Secretary	relating to the goals of the program to be implemented or renewed, and a process for periodic	Regulations to be promulgated not later than 180 days after the date of enactment.	
	Title III - Improving the Quality and Efficiency of Health Care				
	Subtitle A - Linking Payment to Quality Outcomes Under the Medicare Program				



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
86		HHS Secretary	Shall select measures for purposes of the Program. Measures shall be selected from the measures specified and shall include efficiency measures.	Not later than 60 days prior to beginning of the performance period for FY involved.
87		HHS Secretary	Shall establish performance standards with respect to measures selected for a performance period for a fiscal year. Secretary shall establish the performance period for a fiscal year.	Not specified.
88	3001. Hospital Value- Based Purchasing Program	HHS Secretary	Shall develop a methodology for assessing the total performance of each hospital based on the performance standards; shall provide for an assessment for each hospital.	Not specified.
89		HHS Secretary	Shall establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards.	Not specified.
90		HHS Secretary	Shall promulgate regulations to carry out the Program, including selection of measures, methodology developed to calculate performance scores and to determine the amount of value-based incentive payments.	Not specified.
91		HHS Secretary	Shall establish a process to validate measure including auditing of randomly selected hospitals.	Not specified.
92	3002. Improvements to the Physician Quality Reporting System	HHS Secretary	Shall develop a plan to integrate reporting on quality measures under this subsection with requirements related to meaningful use of electronic health records.	Not later than January 1, 2012.
93	3003. Improvements to the Physician Feedback Program	HHS Secretary	Shall develop an episode grouper that combines separate but clinically related items and services into an episode of care for an individual.	Not later than January 1, 2012.
94	3004. Quality Reporting for LTC and Inpatient Rehabilitation Hospitals and Hospice Programs	HHS Secretary	Shall establish procedures for making data on quality measures submitted by long-term care hospitals, rehabilitation hospitals, and hospice programs to the Secretary available to the public.	Not specified.
95	3005. Quality Reporting for PPS-Exempt Cancer Hospitals.	HHS Secretary	Shall specify the form and manner that quality data shall be submitted to the Secretary. Shall establish procedures for making data submitted available to the public, ensuring that the hospital has the opportunity to review the data prior to its being made public. Shall report quality measures on process, structure, outcome, patients' perspective on care, efficiency, and cost of care.	For fiscal year 2014 and each subsequent fiscal year.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
96	3006. Plans for a BP Program for SNF and Home Health Agencies (as amended by Sec. 10301).	HHS Secretary	Shall develop a plan to implement a value-based purchasing (VBP) program for payments under Medicare for skilled nursing facilities (SNF). Shall also develop a VPB program for payments under the Medicare program for ambulatory surgical centers (ASCs).	Not specified.
97	3007. VBP Modifier under the PFS.	HHS Secretary	Shall establish appropriate measures of the quality of care furnished by a physician or group to individuals enrolled under this part, such as measures that reflect outcome.	Not specified.
98	Sec. 3013 (as amended by Sec. 10303).	HHS Secretary	Shall develop, and periodically update (not less than every 3 years), provider-level outcomes measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary. The measures shall include, the extent appropriate, outcome measurement for acute and chronic disease, including the 5 most prevalent and resource-intensive conditions, and outcome measurement for primary and preventative care.	Not specified.
99	3014. Quality and	HHS Secretary	Shall publish in the Federal Register the rationale for use of any quality and efficiency measure in Medicare that has not been endorsed.	Not specified.
100	Efficiency Measurement (as amended by Sec. 10304).	HHS Secretary	Shall establish a process for disseminating quality and efficiency measures used by the Secretary and periodically reviewing them no less than once every 3 years.	Not specified
101	3021. Establishment of Center for Medicare and	HHS Secretary	Shall ensure that the CMI is carrying out its duties, such as to research, develop, test, and expand innovative payment and delivery arrangements to improve quality and reduce cost of care.	Not later than January 1, 2011.
102	Medicaid Innovation (CMI) Within CMS	HHS Secretary	May establish requirements for States and other participating entities to collect and report information that the Secretary determines necessary monitor and evaluate such models.	Not specified.
103		HHS Secretary	Shall determine appropriate measures to assess the quality of care furnished by the accountable care organization (ACO), such as clinical processes and outcomes.	Not specified.
104	3022. Medicare Shared Savings Program.	HHS Secretary	To the state of th	Not specified.
105	3023. National Pilot	HHS Secretary	Shall develop requirements for entities to participate in the pilot program.	Not specified.
106	Program on Payment Bundling	HHS Secretary		Not later than January 1, 2016.

Subtitle B - Improving Medicare for Patients and Providers



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date		
107	3109. Exemption of Certain Pharmacies From Accreditation Requirements.	HHS Secretary	May implement by program instruction or otherwise, notwithstanding any other provision of law, the amendments made regarding an alternative accreditation requirement established if determined more appropriate for such pharmacy.	Not specified.		
108	3111. Payment for Bone Density Tests.	HHS Secretary	May implement by program instruction or otherwise, notwithstanding any other provision of law, the amendments made regarding treatment of bone mass scans, for dual-energy x-ray absorptiometry services furnished during 2010 and 2011.	Not specified.		
109	3113. Payment Adjustment of home Health Care	HHS Secretary	Shall provide for a 4-year phase in of the adjustment for 2013 and subsequent years, with adjustment being fully implemented for 2016.	Adjustment shall be fully implemented for 2016		
110	3132. Hospice Reform	HHS Secretary	Shall, by regulation, implement revisions to the methodology for determining the payment rates for routine home care and other services included in hospice care.	Not earlier than October 1, 2013.		
111	3134. Misvalued Codes Under the Physician Fee Schedule.	HHS Secretary	Shall examine codes which could potentially be misvalued; establish a process to validate relative value units under the fee schedule; notwithstanding any other provision of law, the Secretary may implement the subparagraphs of this section by program instruction or otherwise.	Not specified.		
112	3137. Hospital Wage index Improvement.	HHS Secretary	Shall develop a plan to reform the hospital wage index system under section 1886 of the Social Security Act.	Not later than December 31, 2011.		
113	3138. Treatment of Certain Cancer Hospitals.	HHS Secretary	Shall provide for an appropriate adjustment to reflect higher costs for services furnished on or after January 1, 2011.	Not specified.		
114	3139. Payment for Biosimilar Biological Products.	HHS Secretary	Amend Section 1847A to provide for unique payment for biosimilar products.	Shall apply to payments for biosimilar biological products beginning with the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary).		
	Subtitle C - Provisions Related to Part C					
115	Sec. 1102 of the Reconciliation Act. Medicare Advantage Payments.	HHS Secretary	Shall establish a method to apply to MA plans with low enrollment (as defined by the Secretary) the computation of quality rating and the rating system under paragraph (4) regarding determination of Medicare Part D low-income benchmark premium.	For 2013 and subsequent years.		



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
116	3205. Extension for Specialized MA Plans for Special needs Individuals.	HHS Secretary	Shall establish procedures for the transition of applicable individuals to a MA plan that is not a specialized MA plan for special needs individuals or the original Medicare FFS program under Medicare parts A and B.	Applicable individuals must be transitioned by not later than Jan. 1, 2013.
		Subtitle D - N	ledicare Part D Improvements for Prescription Drug Plans and MA-PD Plans	
117	3301. Medicare Coverage Gap Discount Program. (As modified by	HHS Secretary	Shall establish a Medicare coverage gap discount program by Jan. 1, 2011 and establish a model agreement for use under the program in consultation with manufacturers and allow for comment on such model agreement.	Model agreement to be established by not later than 30 days after date of enactment.
118	Sec. 1101 of the Reconciliation Act).	HHS Secretary	Shall provide for the implementation of this section, including performance of the duties described for an applicable drug manufacturer. Shall implement the program under this section by program instruction or otherwise.	Not specified.
119	3303. Voluntary de Minimis Policy for Subsidy Eligible Individuals Under Prescription Drug Plans and MA-PD Plans.	HHS Secretary	Shall establish procedures under which the Secretary shall permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.	this subsection shall
120	3305. Improved Information for Subsidy Eligible Individuals Reassigned to PDP and MA-PD Plans.	HHS Secretary	Shall, in the case of reassigned subsidy-eligible individuals, within 30 days of reassignment, provide the individual with information regarding formulary differences and a description of the individual's right to request a coverage determination, exception or reconsideration.	Not later than January 1, 2011.
121	3307. Improving Formulary Requirements for PDPs and MA-PD Plans with Respect to Certain Categories or Classes of Drugs.	HHS Secretary		Amendments made by this section shall apply to plan year 2011 and subsequent plan years.
122	3310. Reducing Wasteful Dispensing of Outpatient Prescription Drugs in LTC facilities	HHS Secretary	Shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders, when dispensing covered Medicare part D drugs to enrollees who reside in a long-term care (LCS) facility in order to reduce waste associated with a 30 day supply of prescription drugs.	Plan years beginning on or after Jan. 1, 2012.



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date	
123	3311. Improved Medicare Prescription Drug Plan and MA-PD Plan Compliant System.	HHS Secretary	Shall develop and maintain a complaint system, to collect and maintain information on MA-PD plan and prescription drug plan complaints that are received by the Secretary (including regional HHS offices, etc.), through the date on which the complaint is resolved. Shall develop a model electronic complaint form to be used.	Not specified.	
			Subtitle E - Ensuring Medicare Sustainability		
124	3401. Revision of Certain Market Basket Updates and Incorporation of Productivity Improvements into Market Basket Updates that do not Already Have Such Improvements (as amended by Sec. 10322).	HHS Secretary		Not later than October 1, 2012.	
125	Sec. 10330. Modernizing Computer and Data Systems of CMS to Support Improvements in Care Delivery.	HHS Secretary	Shall develop a plan (and detailed budget for the resourced needed) to modernize the computer and data systems of CMS; shall post the plan on the CMS website no later than 9 months after the date of enactment.	No later than 9 months after the date of enactment.	
126	Sec. 10331. Public Reporting of Performance Information.	HHS Secretary	Shall implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information for the public on quality and patient experience measures with respect to physicians enrolled in Medicare.		
127		HHS Secretary	If, with respect to a proposal year, the Board is required, but fails, to submit a proposal to the President by the deadline, the Secretary shall develop a detailed and specific proposal that satisfied the requirements. The proposal shall be transmitted to the President and a copy to MedPAC.	By not later than January 25 of the year.	
128	(as amended by Sec.	HHS Secretary	May use interim final rulemaking to implement any recommendation contained in a proposal submitted by the President to Congress pursuant to this section on August 15 of the year in which the proposal is submitted.	Not specified	
129		HHS Secretary	The Board shall submit to Congress and the President recommendations to slow the growth in national health expenditures (regarding non-federal health care program), such as those that the HHS Secretary or other Federal agencies can implement administratively.	Not later than Jan. 15, 2015, and at least once ever two years thereafter.	



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	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date		
130	3507. Presentation of Prescription Drug Benefit and Risk Information.	HHS Secretary	Shall promulgate regulations as necessary to implement such format if the Secretary determines that additional quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as table or drug facts box) to promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.	Not later than 3 years after the date of submission of the report.		
		Title IV -	Prevention of Chronic Disease and Improving Public Health			
		Subt	itle A - Modernizing Disease Prevention and Public Health Systems			
131	4001. National Prevention, Health Promotion and Public Health Council.	Chairperson of the Council	Chairperson shall develop and make public a national prevention, health promotion and public health strategy, and shall review and revise such strategy periodically. The HHS Secretary and GAO shall conduct periodic reviews, as well.	Not later than 1 year after enactment.		
132	4004. Education and	HHS Secretary	Shall provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement.	Not specified.		
133	Outreach Campaign Regarding Preventive Benefits.	HHS Secretary	Shall establish and implement a national science-based media campaign on health promotion and disease prevention.	Not later than 1 year after enactment.		
134	Denema.	HHS Secretary	Shall, through the CDC, develop and implement a plan for dissemination of health promotion and disease prevention information.	Not specified.		
			Subtitle B - Increasing Access to Clinical Preventive Services			
135	4101. School Based Health Centers (SBHC)	HHS Secretary	Shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.	Not specified.		
136	4103. Medicare Coverage of Annual	HHS Secretary	Shall establish publicly available guidelines for health risk assessments (HRAs), to be developed in consultation with relevant groups and entities and provide for the identification of chronic diseases and urgent health needs. Shall also establish interactive programs used to furnish health risk assessments.	Not later than 1 year after enactment.		
137	Wellness Visit Providing a Personalized Prevention Plan.	HHS Secretary	Shall develop and make public a health risk assessment model.	Not later than 18 months after the date of enactment.		
138	1 1575Huon Flan.	HHS Secretary	Shall issue guidance that identifies elements required to be provided to a beneficiary as part of their first visit for personalized prevention plan services and establishes a yearly schedule for appropriate provision of such elements thereafter.	Not specified.		
139	4108. Incentives for Prevention of Chronic Diseases in Medicaid.	HHS Secretary	Shall develop program criteria for initiatives under this section using relevant evidence-based research and resources.	Not specified.		



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	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
			Subtitle C - Creating Healthier Communities	
140	4202. Healthy Aging, Living Well; Evaluation of Community-based Prevention and Wellness Programs for Medicare Beneficiaries.	HHS Secretary	Shall conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries.	Not specified.
41	4203. Removing Barriers	Architectural and	In consultation with FDA, shall promulgate regulatory standards setting forth the minimum	Not later than 24 months
	and Improving Access to	Transportation Barriers Compliance Board	technical criteria for medical diagnostic equipment used in (or in conjunction with) physician's offices, clinics, emergency rooms, hospitals, and other medical standards. Standards issued for medical diagnostic equipment shall apply to equipment listed in the subsection (b).	after date of enactment.
42	4205. Nutrition Labeling of Standard Menu Items at Chain Restaurants	HHS Secretary	Shall promulgate regulations to carry out this clause.	Not later than 1 year after date of enactment.
43	4302. Understanding Health Disparities: Data Collection and Analysis.	HHS Secretary	Shall ensure through promulgation of regulations or otherwise that all data collected is protected under privacy protections, and from all inappropriate internal use, and all appropriate information safeguards are used in the collection, analysis, and sharing of data.	Not specified.
			Title V - Health Care Workforce	
		Subtitle	e F - Strengthening Primary Care and Other Workforce Improvements	
144	5508. Increasing Teaching Capacity.	HHS Secretary	Shall promulgate regulations to expand hospital teaching capacity in primary care fields.	Not specified.
			Subtitle G Improving Access to Health Care Services	
	5602. Negotiated Rulemaking for Development of Methodology and Criteria for Designating Medically Underserved Populations and Health Professional Shortage Areas.	HHS Secretary		Target date of July 1, 2010.
4	HOAG		17 of 23	4/5/2010

	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date			
	Title VI - Transparency and Program Integrity						
	Subtitle A - Physician Ownership and Other Transparency						
146	6001. Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals. (as modified in Sec. 10601(a)).	HHS Secretary	Shall promulgate regulations to carry out the process under which an applicable hospital may apply for an exception from the requirement limiting expansion of facility capacity.	Not later than Jan. 1, 2012.			
147	6002. Transparency Reports and Reporting of Physician Ownership or Investment Interests.	HHS Secretary	Shall establish procedures for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary regarding payments or other transfers of value.	Not later than October 1, 2011.			
148	6003. Disclosure Requirements for In- Office Ancillary Services Exception to the Prohibition on Physician Self-Referral for Certain Imaging Services.	HHS Secretary	Shall specify a form and manner in which each manufacturer and authorized distributor of record of an applicable drug shall submit information relating to drug samples to the Secretary.	Submission shall be not later than April 1 of each year (beginning with 2012).			
149	6005. Pharmacy Benefit Managers Transparency Requirements.	HHS Secretary	Shall specify the form and manner in which a health benefits plan or any entity that provides pharmacy benefit management services (i.e. PBMs) that manage prescription drug coverage shall provide the information required to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with at such time.	Not specified.			
	Subtitle B Nursing Home Transparency and Improvement						



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
150	6101. Required Disclosure of Ownership and Additional Disclosable Parties Information.	HHS Secretary	Shall promulgate final regulations requiring, effective 90 days after date of publication in the Federal Register, a facility to report information regarding facility ownership to the Secretary in a standardized format. Secretary shall provide guidance and technical assistance to States on how to adopt a standardized format.	Not later than 2 years after date of enactment.
151	6102. Accountability Requirements for Skilled Nursing Facilities and Nursing Facilities.	HHS Secretary	Shall promulgate regulations for effective compliance and ethics program for SNFs and other nursing facilities.	2 years after date of enactment.
152	6103. Nursing Home	HHS Secretary	Shall include various patient safety and performance data on the Nursing Home Compare Medicare website.	Not specified.
153	Compare Medicare Website.	HHS Secretary	Shall provide guidance to states on how states can establish electronic links to inspection reports for SNFs and other nursing facilities.	Not specified.
154	6111. Civil Money Penalties	HHS Secretary	Shall issue regulations specific to each time it imposes a civil money penalty to allow the aggrieved party the opportunity to appeal.	Not specified.
			Subtitle D Patient-Centered Outcomes Research	
155	6301. Patient-Centered Outcomes Research	Patient Centered Outcomes Research Institute	Patient Centered Outcomes Research Institute (for comparative effectiveness research) shall establish procedures to ensure transparency, credibility and access are met with regard to Institute functions. After release of draft findings, the Institute shall also provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption of national priorities, research project agenda, the methodological standards developed and peer review process provided.	Not specified.
			Subtitle E Medicare, Medicaid & CHIP Program Integrity Provisions	
156	6401. Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP.	HHS Secretary	Shall establish procedures for screening providers who participate in Medicare, Medicaid and CHIP to reduce risk of fraud, waste, and abuse; Secretary may, but need not, promulgate an interim final rule to carry out the provision.	180 days after enactment.
157	6402. Enhanced Medicare and Medicaid Program Integrity	HHS Secretary	Shall promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items and services that qualify for provider identifier to include their national provider identifier on all applications to enroll in programs.	Not specified.
158	Provisions.	HHS Secretary	Shall promulgate regulations to suspend Medicare and Medicaid payment to providers subject to investigation for fraud.	Not specified.
159	6403. Elimination of Duplication Between the Healthcare Integrity and	HHS Secretary	Shall promulgate regulations to maintain a national health care fraud and abuse data collection program for reporting certain adverse actions taken against health care providers.	Not specified.

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	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date		
160	Protection Data Bank an the National Practitioner Databank.	HHS Secretary	Shall establish a process to terminate, by the end of the transition period, the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in the HIPDB is transferred to the NPDB (National Practitioner Data Bank).	Not specified.		
161	6411. Expansion of the Recovery Audit Contract (RAC) Program	HHS Secretary	Shall, through CMS, promulgate regulations to expand the RAC program to Medicaid and Medicare Parts C and D.	Not specified.		
			Subtitle F - Additional Medicaid Program Integrity Provisions			
162	6506. Overpayments	HHS Secretary	Shall promulgate regulations that require States to correct Federally identified claims overpayments, of an ongoing or recurring nature, with the new Medicaid Management information System (MMIS) edits, audits, or other corrective action.	Not specified.		
163	6507. Mandatory State Use of National Correct Coding Initiative	HHS Secretary	Shall implement certain provisions of the National Correct Coding Initiative.	Effective for claims filed on or after October 1, 2010.		
			Subtitle G - Additional Program Integrity Provisions			
164	6604. Applicability of State Law to Combat Fraud and Abuse	HHS Secretary	May adopt regulatory standards or issue an order relating to a specific person establishing standards for the purpose of identifying, preventing or prosecuting fraud and abuse.	Not specified.		
165	6605. Enabling the DOL to Issue Administrative Summary Cease and Desist orders Against Plans	HHS Secretary	May promulgate such regulations or other guidance as may be necessary or appropriate to carry out this section.	Not specified.		
	Subtitle H - Elder Justice Act					
166	6701, 6702, 6703. Elder Justice.	HHS Secretary	Shall promulgate regulations to carry out certain portions of the Elder Justice Act to prevent elder abuse.	Not specified; funds appropriate for Elder Justice Act FY2011- FY2014.		
	Title VII - Improving Access to Innovative Medical Therapies					



	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date			
	Subtitle A Biologics Price Competition and Innovation						
167		HHS Secretary	May, after opportunity for public comment, issue guidance with respect to the licensure of biosimilar products and such guidance may be general or specific. If class-specific guidance is issued, it must meet certain enumerated criteria.	Not specified.			
168	7001, 7002, 7003.	HHS Secretary	and MDUFMA.	Recommendations to be implemented Oct. 1, 2012.			
169	Approval Pathway for Biosimilar Biological Products.	HHS Secretary	review of biosimilar biological product applications, the Secretary shall consult with others, such as committees of Congress, experts, and industry. Secretary shall present recommendations to specified Congressional committees and publish the recommendations in the Federal Register.	Development of recommendations beginning not later than Oct. 1, 2010; Transmittal of recommendations not later than Jan. 15, 2012.			
		Subtitle	B More Affordable Medicines for Children and Underserved Communities				
170	7102. Improvements to	HHS Secretary	Shall promulgate regulations to improve program integrity and oversight of expanded 340B programs, including imposition of sanctions in the form of civil monetary penalties.	180 days after enactment.			
171	340B Program Integrity (as modified by Sec. 2302 of the Reconciliation Act)	HHS Secretary	Shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, including appropriate procedures for provision of remedies and enforcement. Regulations shall include enumerated deadlines and procedures.	Not specified.			
			Title VIII - Class Act				
172	8001, 8002. Establishment of National Voluntary Insurance Program for Purchasing	HHS Secretary	Shall promulgate regulations regarding requirements for minimum earnings to be eligible to purchase CLASS Act services.	Not specified.			
173	Community Living Assistance Services and Support (CLASS Act).	HHS Secretary		Not later than October 1, 2012.			
174		HHS Secretary and Treasury Secretary	Shall establish procedures to enable certain individual to enroll in the CLASS Act through their employers; also shall promulgate regulations to ensure individuals are not automatically enrolled by more than one employer.	Not specified.			



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	Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date	
175		HHS Secretary	Shall promulgate regulations to make eligibility determinations for individuals apply for the CLASS Act, including whether individuals are eligible for cash benefits under the CLASS Act.	1/1/2012.	
176		HHS Secretary	May promulgate any regulations necessary to implement the CLASS Act, including provisions to protect against fraud and abuse.	Not specified.	
			Title IX Revenue Provisions		
			Subtitle A Revenue Offset Provisions		
177	9001. Excise Tax on High Cost Employer- Sponsored Health Coverage (as amended by Sec. 10901).	Treasury Secretary	health coverage.	Amendments made by this section shall apply to taxable years beginning after Dec. 31, 2012.	
178	9006. Expansion of Information Reporting Requirements.	Treasury Secretary	May prescribe regulations and other guidance as may be appropriate or necessary to implement the expanded reporting requirements to corporations.	Not specified.	
179	9007. Additional Requirements for Charitable Hospitals. (as amended by Sec. 10903).	Treasury Secretary	related to the community health needs assessment, and including guidance relating to what constitutes reasonable efforts to determine the eligibility of a patient under a financial assistance policy.	Amendment made by this section shall apply to taxable years beginning after the date of enactment.	
180	9008, 9009, 9010. Titles related to imposition of annual fees /excise tax on various industries. (as amended by Sec. 10904, 10905, 10906, 10907).	Treasury Secretary	1 ' ' '	Implementation dates vary by industry.	
181	9014. Limitation on Excess Remuneration Paid By Certain Health Insurance Providers.	Treasury Secretary	Permits the Secretary to prescribe any guidance, rules, or regulations necessary to limit tax deductions available to health insurance officials.	Not specified.	



Section Number & Title	Authority	Description of the Regulation or Rulemaking	Date
provisions take effect or	es that there is no n a certain date, r	Reconciliation Act. specified date by which the regulation must be promulgated. Note, however, that many egardless of whether required regulations have been promulgated. Thus, even when n of regulations, the provision itself may take effect on a certain date.	

