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## Final Health Care Reform Package Makes Sweeping Changes to U.S. Health Care System

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The tumultuous health care reform effort of 2009 and 2010<sup>1</sup> will culminate March 30, 2010, with the president's signing of a reconciliation bill that modifies and adds to the comprehensive reform package enacted March 23, 2010. Together, the two measures make the most sweeping and fundamental changes to the U.S. health care system since the creation of Medicare and Medicaid. In the near term, the primary impact of the legislation will be to increase regulation and oversight of health insurance plans, much of which takes effect in 2010. Over the next several years, various agencies will put in place the regulations and systems for the major programmatic provisions of the legislation, which begin to take effect in 2014.

Proponents say the health care reform package will expand coverage to an estimated 32 million Americans and "bend the cost curve" to address ever-increasing health care costs. The principal law and reconciliation package seek to achieve these goals through increased regulation of the insurance industry, a carrot-and-stick (subsidies and penalties) approach to incentivize individuals to obtain and employers to provide insurance, modifications to payment systems to encourage more cost-effective care and reduction of inefficiencies and waste, including through new tools to address fraud and abuse. These activities will be paid for by new taxes and fees for the health care industry, higher taxes on high-income individuals, penalty revenues, and, according to proponents, improved efficiency and lower costs.

<sup>1</sup> Skadden has tracked the health care reform effort closely at every stage. See our analyses of the original [House- and Senate-passed bills](#), the [fraud and abuse provisions](#) of both original bills, the [White House proposal of February 2010](#), and the passage of the [Patient Protection and Affordable Care Act](#) on March 23, 2010. These memoranda also are available at <http://www.skadden.com/Index.cfm?contentID=6&viewType=2#>.

Individuals	
<b>Individual Mandate</b>	<ul style="list-style-type: none"> <li>American citizens and legal residents must have health insurance.</li> <li>After a phasing-in period, the penalty for not having insurance will be the greater of 2.5 percent household income or \$695 for each uninsured family member, up to a maximum of \$2,250 per family.</li> <li>People with financial hardship, religious objectors, American Indians, people without coverage for less than three months, undocumented immigrants, incarcerated individuals, people for whom the lowest available insurance option exceeds 8 percent of income and those with incomes below the tax filing threshold need not pay the insurance penalty.</li> </ul>
<b>Premium Tax Credits</b>	<ul style="list-style-type: none"> <li>These credits let certain low-income people pay only a small percentage of their income toward premiums for exchange-bought insurance. Eligibility is limited to those people who are below 400 percent of the federal poverty level (FPL), are American citizens or legal residents and who lack access to employer coverage (unless the plan offered by their employer lacks an actuarial value of at least 60 percent or premiums exceed 9.5 percent of income). Income and citizenship status must be verified.</li> <li>The amount of the credit depends on income and is determined via a sliding scale. For example, people with income under 133 percent FPL will pay only 2 percent of income toward premiums, while people between 300-400 percent FPL will pay 9.5 percent of income toward premiums.</li> <li>Through 2018, recipients' contributions will increase based on the amount by which premiums grow faster than incomes. Beginning in 2019, if the government is spending more than 0.54 percent of GDP on premium and cost-sharing tax credits, recipients' contributions will be increased further.</li> </ul>
<b>Cost-Sharing Tax Credits</b>	<ul style="list-style-type: none"> <li>These credits let certain low-income people pay only a small percentage of their income toward their insurance expenses. With the credits, the actuarial value (<i>i.e.</i>, percentage of expenses not paid by the individual) will be fixed to a certain level depending on income. Eligibility is limited to those who are below 400 percent FPL and are American citizens or legal residents.</li> <li>The amount of the credit is determined via a sliding scale. For example, people with incomes between 100-150 percent FPL get cost-sharing credits such that their plans have an actuarial value of 94 percent, while people with incomes between 100-150 percent FPL get credits such that their plans have an actuarial value of 70 percent.<sup>2</sup></li> </ul>
<b>Changes for Medicare and Medicaid Recipients</b>	<ul style="list-style-type: none"> <li>Provides Medicare beneficiaries with a free annual wellness visit and waives cost-sharing for preventive services. Effective 2011.</li> <li>Increases Medicaid eligibility to 133 percent FPL.</li> </ul>

<sup>2</sup> The typical actuarial value of an HMO is about 93 percent, and PPOs typically range from 80-84 percent. See Chris L. Peterson, Congressional Research Service, *Setting and Valuing Health Insurance Benefits* (Apr. 6, 2009), available at [https://www.policyarchive.org/bitstream/handle/10207/19244/R40491\\_20090406.pdf](https://www.policyarchive.org/bitstream/handle/10207/19244/R40491_20090406.pdf).

<b>Changes to Personal Savings Accounts</b>	<ul style="list-style-type: none"> <li>Limits health flexible savings account (health FSA) contributions to \$2,500 per year, to be increased annually by the cost-of-living adjustment, effective 2013.</li> <li>Increases tax on health savings account (HSA) and Archer medical savings account (Archer MSA) distributions not used for qualified medical expenses to 20 percent, effective 2011.</li> <li>Bars reimbursement of over-the-counter drugs from a health reimbursement arrangement (HRA) or health FSA and taxes their reimbursement from an HSA or Archer MSA, effective 2011.</li> </ul>
<b>Temporary High-Risk Pool for People With Pre-Existing Conditions</b>	<ul style="list-style-type: none"> <li>Creates a temporary high-risk pool to cover individuals with pre-existing conditions who have been uninsured for at least six months as of the insurance pool's creation. Pool created 90 days after enactment and will expire once exchanges become operational.</li> <li>Establishes subsidized premiums, with age rating limited to 4:1.</li> <li>Cost-sharing limit will track with the HSA limit (currently \$5,950 for individuals and \$11,900 for families).</li> </ul>
<b>Employers</b>	
<b>Employers' Obligation to Provide Coverage</b>	<ul style="list-style-type: none"> <li>Employers are not required to provide health insurance to employees. However, firms with 51 or more full-time employees (<i>i.e.</i>, working more than 30 hours per week) may face penalties for providing no coverage or inadequate coverage.</li> <li>If an employer has 51 or more full-time employees and it does not offer coverage but at least one full-time employee gets an exchange credit, the firm is penalized \$2,000 per employee, exempting the first 30 workers from the payment calculation. (Example: If a firm with 75 workers faces the penalty, it pays <math>45 \times \\$2,000 = \\$90,000</math>.)</li> <li>If an employer has 51 or more full-time employees, it does offer coverage, but at least one full-time employee gets an exchange credit, the firm is penalized the lesser of \$2,000 per employee (no 30-worker exemption) or \$3,000 per credit-receiving employee. (Example: If a firm with 75 workers offers insurance but 10 workers receive exchange credits, the firm would pay the lesser of <math>75 \times \\$2,000 = \\$150,000</math> or <math>10 \times \\$3,000 = \\$30,000</math>, <i>i.e.</i>, \$30,000).</li> </ul>
<b>Automatic Enrollment in Employer Coverage</b>	<ul style="list-style-type: none"> <li>Required for firms with over 200 employees.</li> <li>Employees may opt out.</li> </ul>
<b>Prohibition on Compensation Discrimination</b>	<ul style="list-style-type: none"> <li>Prohibits employers that provide health coverage from limiting eligibility for coverage to highly compensated individuals.</li> </ul>
<b>Free-Choice Vouchers</b>	<ul style="list-style-type: none"> <li>Individuals below 400 percent FPL are entitled to a free-choice voucher from their employer when the employer offers coverage, but premiums for the individual would be between 8-9.8 percent of his or her income, and the individual instead chooses an exchange plan. The voucher amount is what the employer would have paid to cover the individual under its plan.</li> </ul>
<b>Employer Tax Credits</b>	<ul style="list-style-type: none"> <li>Tax credits will be available to small businesses with fewer than 26 workers and average wages under \$50,000. The maximum credit is available to employers with fewer than 11 employees and average wages of \$25,000 or less. The credit is scaled down as firm size and average wage increases.</li> <li>For non-tax-exempt businesses, from 2010 to 2013, the maximum credit will cover up to 35 percent of the employer's contribution to premium costs. Employers must contribute at least 50 percent of total premium costs or 50 percent of a benchmark premium to be eligible. In 2014, the maximum credit will increase to 50 percent of the employer's contribution; to be eligible, employers must contribute at least 50 percent of total premium costs.</li> <li>Tax-exempt businesses meeting the above requirements are eligible for the 2010-2013 and post-2014 tax credits but only are entitled to a maximum credit of 25 percent and 35 percent, respectively.</li> </ul>

<b>Temporary Reinsurance Program</b>	<ul style="list-style-type: none"> <li>For employers that provide health benefits for Medicare-ineligible retirees over 55, the federal government will cover 80 percent of retirees' medical claims between \$15,000 and up to \$90,000.</li> <li>Effective 90 days after enactment and will last through 2013.</li> </ul>
<b>"Simple" Cafeteria Plan</b>	<ul style="list-style-type: none"> <li>Creates a "simple" cafeteria plan by which small businesses can provide employees with a flexible array of insurance options, effective 2011.</li> </ul>
<b>Other Obligations for Employers</b>	<ul style="list-style-type: none"> <li>Requires employers to include the value of employee insurance benefits on W-2s, effective 2011.</li> <li>Requires employers to inform employees of the existence of health insurance exchanges when they become available.</li> </ul>
<b>Changes to Tax Code Affecting Employers</b>	<ul style="list-style-type: none"> <li>See "Costs and Financing" section.</li> </ul>
<b>Insurers</b>	
<b>Reforms Applicable to New Individual and Group Insurance Plans</b>	<ul style="list-style-type: none"> <li>Prohibits exclusion for pre-existing conditions. With respect to children, prohibition becomes effective six months after enactment.</li> <li>Prohibits rescission of coverage except in cases of fraud or intentional misstatement of material fact, effective six months after enactment.</li> <li>Prohibits lifetime coverage limits, effective six months after enactment.</li> <li>Prohibits unreasonable annual coverage limits. Prior to 2014, plans may only impose annual limits as permitted by the Department of Health and Human Services (HHS).</li> <li>Requires guaranteed issue and renewability.</li> <li>Requires such plans to cover adult children up to age 26 on parents' insurance, effective six months after enactment.</li> <li>Prohibits coverage waiting periods lasting more than 90 days.</li> <li>Requires an effective appeals process for coverage determinations and claims, effective six months after enactment.</li> </ul>
<b>Reforms Applicable to New Individual and Small Group Insurance Plans</b>	<ul style="list-style-type: none"> <li>Requires plans to include an essential health benefits package with a comprehensive set of services, coverage of at least 60 percent of the total benefit value and cost-sharing limited to the current HSA limits (currently \$5,950 for individuals and \$11,900 for families). HHS must define and annually update the essential health benefits package.</li> <li>Prohibits rating variation except based on age (up to 3:1 ratio is permitted), premium rating area, family composition and tobacco use (up to 3:2 ratio is permitted).</li> </ul>
<b>Deductible Cap for New Small Group Insurance Plans</b>	<ul style="list-style-type: none"> <li>Limits deductibles to \$2,000 (individuals) or \$4,000 (families) unless the plan offers contributions to offset deductible amounts in excess of these limits.</li> </ul>
<b>Reforms Applicable to Grandfathered Individual and Group Insurance Plans</b>	<ul style="list-style-type: none"> <li>Prohibits rescission except in cases of fraud or intentional misstatement of material fact, effective six months after enactment.</li> <li>Prohibits lifetime coverage limits, effective six months of enactment.</li> <li>Requires all group plans and individual plans that cover children to cover adult children up to age 26 on parents' insurance, effective six months after enactment.</li> <li>Prohibits coverage waiting periods lasting more than 90 days, effective six months after enactment.</li> </ul>

<b>Reforms Applicable to Grandfathered Group Insurance Plans</b>	<ul style="list-style-type: none"> <li>Prohibits exclusions for pre-existing conditions. With respect to children, plans must eliminate such exclusions within six months of enactment.</li> <li>Prohibits annual coverage limits. Prior to 2014, plans may only impose annual limits as permitted by HHS.</li> </ul>
<b>Mandated Medical Loss Ratio (MLR)</b>	<ul style="list-style-type: none"> <li>Requires insurers to report MLR as of 2010.</li> <li>Starting in 2011, when MLR reaches 85 percent (large group market) or 80 percent (small group and individual markets), plans must provide rebates. Applies to all plans, including grandfathered plans but excluding self-insurance plans.</li> <li>Nonprofit Blue Cross Blue Shield plans must maintain MLR of 85 percent or higher to take advantage of special tax status. Effective 2010.</li> </ul>
<b>Rate Review</b>	<ul style="list-style-type: none"> <li>Orders HHS to establish a process for reviewing premium rate increases and requires insurers to justify rate increases, beginning in 2010.</li> <li>Provides grants to states to support efforts to review and approve premium increases.</li> </ul>
<b>Offering Plans Across Multiple States</b>	<ul style="list-style-type: none"> <li>Allows states to form interstate compacts starting in 2016. Insurers may then offer plans in any participating state. Insurer chooses which state's laws to apply except for rules pertaining to market conduct, trade practices, network adequacy and consumer protections. Compacts must result in coverage that is at least as comprehensive and affordable as exchange coverage.</li> </ul>
<b>Abortion</b>	<ul style="list-style-type: none"> <li>Private plans may choose whether to cover elective abortion.</li> <li>People receiving premium or cost-sharing tax credits may choose a health plan that covers elective abortion if offered, but the federal funds may not be used to purchase the coverage and must be kept segregated.</li> <li>States may pass laws prohibiting exchange plans from covering elective abortion.</li> <li>The president also issued an executive order affirming the continued prohibition on using public funds for elective abortion.</li> </ul>
<b>Temporary Reinsurance Program</b>	<ul style="list-style-type: none"> <li>Creates a temporary reinsurance program, to be financed by mandatory payments from insurers in the individual and group markets, to provide payments to plans in the individual market that cover high-risk individuals. Effective 2014 through 2016.</li> </ul>
<b>Merging Insurance Markets</b>	<ul style="list-style-type: none"> <li>States may merge the individual and small group insurance markets.</li> </ul>
<b>Antitrust Exemption</b>	<ul style="list-style-type: none"> <li>Retained for insurers.</li> </ul>
<b>Health Insurance Exchanges</b>	
<b>Structure of Exchanges</b>	<ul style="list-style-type: none"> <li>Creates two types of state exchanges in each state: individual and small business.</li> <li>Funding is available for creating the exchanges within one year of enactment and through 2014.</li> <li>Requires exchanges to submit financial reports to HHS and comply with oversight investigations.</li> </ul>
<b>Access to Exchanges</b>	<ul style="list-style-type: none"> <li>Nonincarcerated American citizens and legal residents are eligible to purchase insurance on the exchanges.</li> <li>Small businesses with fewer than 101 employees may obtain insurance for their employees through an exchange. Until 2016, states may opt to cap the size limit at 50 employees. Starting in 2017, states may allow large employers to purchase exchange insurance.</li> </ul>

<b>Benefits to Be Offered Through Exchanges</b>	<ul style="list-style-type: none"> <li>• Four principal suites, all but one of which include an essential benefits package and which cover 60-90 percent of benefit costs. Out-of-pocket limits track with HSA limits (currently \$5,950 for individuals and \$11,900 for families).</li> <li>• On the individual exchanges only, a catastrophic plan lacks the essential benefits package. Available only to individuals under age 31 or exempt from the individual mandate.</li> </ul>
<b>Out-of-Pocket Limits on Exchanges</b>	<ul style="list-style-type: none"> <li>• Has lower out-of-pocket limits for people up to 400 percent FPL, ranging from one-third to two-thirds of HSA limits.</li> </ul>
<b>Regulations on Insurers Participating in Exchanges</b>	<ul style="list-style-type: none"> <li>• Plans must meet marketing requirements, maintain adequate provider networks, contract with essential community providers and “navigators,” be accredited with respect to performance on quality measures and use a standardized enrollment form and presentation form for plan information.</li> <li>• Plans must comply with generally applicable insurance regulations.</li> </ul>

### Hospitals, Physicians and Providers

<b>Medicare Payment Reforms and Programs</b>	<ul style="list-style-type: none"> <li>• Establishes a value-based payment modifier to increase reimbursements for Medicare physicians that deliver high-quality care at low cost and decrease reimbursements for low-value physicians, effective 2015.</li> <li>• Reduces Medicare payments to account for preventable hospital readmissions, effective 2012.</li> <li>• Allows accountable care organizations to share in savings they produce, effective 2012.</li> <li>• Reduces market basket updates for inpatient hospital, home health, skilled nursing facility, hospice and other Medicare providers and adjusts for productivity. Effective dates vary.</li> <li>• Establishes a hospital value-based Medicare purchasing program to incentivize enhanced quality outcomes for acute care hospitals, effective 2012.</li> <li>• Creates a pilot to test payment-bundling arrangements for acute Medicare inpatient hospital services, physician services, outpatient hospital services and post-acute care services for an episode of care spanning 30 days, effective 2013.</li> <li>• Creates a demonstration program to allow certain home-care providers to share in savings from reducing preventable hospitalizations, preventing hospital readmissions, improving health outcomes, improving care efficiency, reducing the cost of services and achieving patient satisfaction. Effective 2012.</li> <li>• Requires HHS to implement quality measure reporting programs for providers including including ambulatory surgical centers, long-term care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, PPS-exempt cancer hospitals and hospice providers and pilot value-based purchasing for these providers.</li> <li>• Requires HHS to submit a plan to Congress by 2011 on how to move home health and nursing home providers into a value-based purchasing payment system.</li> <li>• Reduces Medicare disproportionate share hospital (DSH) payments.</li> <li>• Increases reimbursement rate for certain imaging services, like bone density scans.</li> </ul>
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<b>Medicaid Payment Reforms and Programs</b>	<ul style="list-style-type: none"> <li>• Tracks Medicaid fee-for-service and managed care primary care services payment rates with Medicare payment rates. Applies only for 2013 and 2014; federal government will pay for the additional financing.</li> <li>• Creates demonstration program to test payment bundling from 2012 through 2016.</li> <li>• Creates demonstration program to allow pediatric accountable care organizations to share in cost savings from 2012 to 2016.</li> <li>• Reduces Medicaid DSH payments.</li> </ul>
<b>Directed Allocations to Providers</b>	<ul style="list-style-type: none"> <li>• Provides \$400 million to hospitals in counties with the lowest quartile Medicare spending for 2011 and 2012.</li> <li>• Provides a 10 percent bonus payment from 2011 to 2016 primary care physicians and to general surgeons practicing in areas with a shortage of health professionals.</li> </ul>
<b>Medical Malpractice Tort Reform</b>	<ul style="list-style-type: none"> <li>• Does not make or impose substantive changes in tort law.</li> <li>• Establishes a voluntary grant program to incentivize states to implement litigation alternatives, from 2011 to 2016. States would develop, implement and evaluate alternatives.</li> </ul>
<b>Nonprofit Hospitals</b>	<ul style="list-style-type: none"> <li>• Requires nonprofit hospitals to conduct a community needs assessment, adopt an implementation plan and limit collection from needy patients, with a \$50,000 penalty for noncompliance, effective 2011.</li> </ul>
<b>Physician-Owned Hospitals</b>	<ul style="list-style-type: none"> <li>• Prohibits physician-owned hospitals that lack a provider agreement as of August 1, 2010, from participating in Medicare. Those with a provider agreement could participate under certain requirements addressing conflict of interest, bona fide investments, patient safety issues and expansion limitations.</li> </ul>
<b>Professional Training</b>	<ul style="list-style-type: none"> <li>• Allows unused medical education training slots to be redistributed for purposes of increasing primary care training at other sites, effective 2011.</li> <li>• Provides loans and scholarships for aspiring public health, primary care and other professionals, effective 2010.</li> <li>• Appropriates funding for nurse training, effective 2010.</li> </ul>
<b>Drug and Device Manufacturers</b>	
<b>Closing the Part D Coverage Gap</b>	<ul style="list-style-type: none"> <li>• Phases down the beneficiary coinsurance rate in the coverage gap from 100 to 25 percent by 2020. For brand-name drugs, manufacturers must provide a 50 percent discount for drugs in the gap, starting 2011. The federal government will phase in subsidies, starting 2013, that will ultimately equal 25 percent of cost.</li> <li>• Within six months of enactment, HHS must issue a model agreement by which drug manufacturers agree to provide the discount as a condition of having their drugs covered under Part D. Manufacturers must sign the agreement within 30 days of the model agreement's unveiling, and the agreement must be effective by January 1, 2011.</li> <li>• For generic drugs, the federal government will phase in subsidies that will ultimately equal 75 percent of cost, starting 2011.</li> <li>• As a temporary measure, provides a \$250 rebate to Medicare beneficiaries who hit the coverage gap in 2010.</li> </ul>

<b>Medicaid Drug Reimbursement</b>	<ul style="list-style-type: none"> <li>• Requires HHS to calculate Federal Upper Limits (FULs) of pharmacy reimbursement for multisource drugs at a level no higher than 175 percent weighted average manufacturer price (AMP) of pharmaceutically and therapeutically equivalent, nationally available, multisource drugs, effective 2010.</li> <li>• Removes smoking cessation drugs, barbiturates and benzodiazepines from the list of drugs excludable from Medicaid coverage.</li> <li>• Requires Medicaid coverage for counseling and pharmacotherapy to pregnant women for cessation of tobacco use, effective 2011.</li> </ul>
<b>Medicaid Drug Rebates</b>	<ul style="list-style-type: none"> <li>• Increases minimum rebate for single-source and innovator multisource drugs purchased through Medicaid to 23.1 percent AMP, except for clotting factors and exclusively pediatric drugs, which go to 17.1 percent AMP. Increases basic rebate for non-innovator multisource drugs from 11 percent AMP to 13 percent AMP.</li> <li>• Extends rebates to drugs supplied to enrollees of Medicaid managed-care organizations.</li> <li>• Caps the Medicaid rebate for an innovator drug at 100 percent AMP.</li> <li>• For a line extension of an innovator, oral solid dosage form of a drug, the rebate is the greater of the new formulation's AMP or the highest additional rebate of any strength of the original drug (calculated as a percentage of AMP).</li> <li>• All changes are retroactively effective January 1, 2010.</li> </ul>
<b>Redefining AMP</b>	<ul style="list-style-type: none"> <li>• Amends the statutory definition of AMP to include only sales to wholesalers for drugs distributed to retail community pharmacies and direct sales to retail community pharmacies. Effective October 1, 2010.</li> <li>• Excluded from definition are prompt pay discounts, bona fide service fees, reimbursement for unsalable returned goods, and direct sales and rebates to any entity that does not conduct business as a wholesaler or retail community pharmacy. However, rebates, discounts, payments and other financial transactions that are received by or passed through to retail community pharmacies are included in AMP.</li> <li>• Wholesalers are exclusively considered entities engaged in wholesale distribution to retail community pharmacies. Mail order pharmacies and long term care pharmacies are not considered retail pharmacies.</li> </ul>
<b>AMP Public Disclosure</b>	<ul style="list-style-type: none"> <li>• A pending requirement that HHS disclose AMP on a Web site is amended to clarify that only weighted AMP should be disclosed, not individual manufacturers' AMP, effective October 1, 2010.</li> </ul>
<b>Section 340B Program</b>	<ul style="list-style-type: none"> <li>• Extends participation to certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers.</li> <li>• Prohibits certain hospitals from obtaining covered outpatient drugs from group purchasing organizations (GPOs).</li> <li>• Manufacturers are required to submit to HHS quarterly reports of 340B ceiling prices and the components used to calculate them.</li> </ul>
<b>Sunshine on Manufacturer Payments and Provider Ownership and Investment</b>	<ul style="list-style-type: none"> <li>• Requires manufacturers to report payments or other transfers of value made to physicians and teaching hospitals.</li> <li>• Excepts <i>de minimis</i> transfers (\$10 or less, unless aggregate transfers exceed \$100), samples for patients, short-term loans of some devices and discounts and rebates.</li> <li>• Penalties range from \$1,000 to \$10,000 per payment.</li> <li>• Preempts state laws, except certain requirements that go beyond the bill.</li> <li>• Manufacturers and GPOs also are required to report information regarding physician ownership and investment interest in their companies.</li> <li>• HHS is required to post searchable payment information on the internet, including the recipient's name, the amount, the form and nature of the payment, the name of products involved and other information.</li> <li>• All provisions effective 2013.</li> </ul>



<b>Pharmacy Benefit Manager (PBM) Reporting</b>	<ul style="list-style-type: none"> <li>Requires any PBM or health benefits plan that provides pharmacy benefit management services for a Part D or exchange plan to disclose information to HHS about the generic dispensing rate, rebates, discounts or price concessions negotiated by the PBM.</li> </ul>
<b>Drug Sample Reporting</b>	<ul style="list-style-type: none"> <li>Requires drug makers and distributors to report to HHS information about drug samples that is being internally collected.</li> </ul>
<b>Part D Formulary Regulations</b>	<ul style="list-style-type: none"> <li>Codifies the six classes of drugs — immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals and antineoplastics — for which Centers for Medicaid and Medicare Services (CMS) has said that substantially all of the drugs in the class must be covered by Part D formularies.</li> </ul>
<b>Biosimilars</b>	<ul style="list-style-type: none"> <li>Establishes a licensure pathway for biosimilars, effective immediately. Biologic must have no clinically meaningful difference in safety, purity or potency from the reference product and may not be licensed for 12 years after the licensing of the reference product.</li> </ul>
<b>Fraud, Abuse, and Compliance</b>	
<b>Medicare and Medicaid Anti-Fraud, Waste and Abuse Provisions</b>	<ul style="list-style-type: none"> <li>Increases funding to fight fraud by \$10 million a year for 10 years, plus an extra \$95 million in 2011, \$55 million in 2012, \$30 million in 2013 and 2014, and \$20 million in 2015 and 2016.</li> <li>Requires overpayments to a provider, supplier, Medicare Advantage plan or Part D plan be reported and returned within 60 days.</li> <li>Expands recovery audit contractor program to Medicaid and Medicare Parts C and D. These contractors identify underpayments and overpayments and recoup overpayments.</li> <li>Requires Medicare and Medicaid integrity program contractors to provide HHS with performance statistics on overpayments, fraud referrals and investment return.</li> </ul>
<b>Medicare/ Medicaid Anti-Kickback Act (AKA) Amendments</b>	<ul style="list-style-type: none"> <li>Amends AKA to provide that a claim that includes items or services resulting from an AKA violation constitutes a false claim for purposes of the False Claims Act (FCA), regardless of who submits it.</li> <li>Amends the AKA to provide that a person needs neither actual knowledge of the AKA nor specific intent to commit a violation.</li> <li>Creates a new exemption to the AKA for discounts offered to beneficiaries under the Part D coverage gap discount program.</li> </ul>
<b>Application of Fraud and Abuse Laws to Exchange Insurers</b>	<ul style="list-style-type: none"> <li>Applies the FCA to payments made by, through or in connection with the private exchange insurers if the payments include any federal funds.</li> <li>Penalties are between three and six times the amount of damages.</li> </ul>
<b>Public Disclosure Bar to FCA <i>Qui Tam</i> Actions</b>	<ul style="list-style-type: none"> <li>Eliminates the jurisdictional nature of the public disclosure bar and, under the circumstances, authorizes the court to try a <i>qui tam</i> action that was publicly disclosed and in which the relator is not an original source.</li> <li>Grants the government complete discretion regarding whether a defendant's public disclosure bar argument may be heard by the court.</li> <li>Limits public disclosures to federal criminal, civil or administrative hearings and federal reports, hearings audits or investigations and thereby eliminates parallel state actions from serving as a public disclosure.</li> <li>Expands the definition of "original source" to include (i) an individual who discloses to the government the information on which the claims are based prior to the public disclosure and (ii) an individual who has independent knowledge that adds materially to the publicly disclosed information.</li> </ul>

<b>Sentencing Guidelines</b>	<ul style="list-style-type: none"> <li>Amends the federal sentencing guidelines to provide a two-level increase for a federal health care offense involving a government health care program and a loss between \$1 million and \$7 million. The increase is three levels for such offenses involving a loss between \$7 million and \$20 million and four levels for such offenses with a loss exceeding \$20 million.</li> </ul>
<b>HHS Subpoena Authority in Exclusion Investigations</b>	<ul style="list-style-type: none"> <li>Extends HHS testimonial subpoena authority to program exclusion investigations and authorizes the delegation of this authority to the HHS Office of the Inspector General.</li> </ul>
<b>Compliance Programs</b>	<ul style="list-style-type: none"> <li>Requires Medicare and Medicaid providers and suppliers to establish compliance programs. HHS will determine the core elements for the compliance program for providers and suppliers within a given industry or category. HHS also will set the timeline for implementation.</li> </ul>
<b>Screening for Federal Health Program Providers</b>	<ul style="list-style-type: none"> <li>Requires HHS to establish screening procedures for new Medicare, Medicaid and Children's Health Insurance Program (CHIP) providers, which must include licensure checks and may include fingerprinting, criminal background checks, database inquiries and site visits.</li> <li>Requires HHS to determine the level of screening based on risk of each category of provider or supplier.</li> <li>Imposes an application fee of \$200 for individual practitioners and \$500 for institutional providers and suppliers, required at every renewal.</li> <li>Requires new providers and suppliers to disclose affiliations within the past 10 years with any provider or supplier with uncollected debt, suspended payments or exclusion or revoked billing privileges from a federal health care program. Would grant HHS discretion to deny enrollment if the affiliations pose undue risk.</li> <li>Authorizes CMS to match data with the Internal Revenue Service to identify providers with seriously delinquent tax debt as a means of detecting fraud.</li> <li>Provides for permissive exclusion of providers and suppliers who submit false information on an application to participate in a federal health program.</li> </ul>
<b>Medicaid Exclusion for Ownership or Control</b>	<ul style="list-style-type: none"> <li>Medicaid programs must exclude entities that own, control or manage an entity that has unpaid overpayments; are suspended, excluded or terminated from participation; or are affiliated with a suspended, excluded or terminated entity.</li> </ul>
<b>Penalties for Failure to Provide HHS With Information</b>	<ul style="list-style-type: none"> <li>Establishes a penalty of \$15,000 per day for delaying or refusing to grant HHS timely access to information for use in connection with audits, investigations, evaluations and other statutory functions.</li> </ul>
<b>Penalties for Various Actions by Excluded Entities</b>	<ul style="list-style-type: none"> <li>Establishes a penalty of up to \$50,000 for excluded entities that prescribe an item, order a service, make false statements on applications or contracts to participate in a federal health care program or do not return a known overpayment.</li> </ul>
<b>Penalties for Misconduct By Medicare Advantage and Part D Plans</b>	<ul style="list-style-type: none"> <li>Establishes penalties for Medicare Advantage and Part D plans that misrepresent or falsify information of up to three times the amount claimed by a plan or plan sponsor in connection with the misrepresentation or falsified information.</li> <li>Authorizes sanctions and penalties for Medicare Advantage and Part D providers that enroll individuals in a plan without their consent or transfer an individual from one plan to another to generate commissions or fees.</li> </ul>
<b>Medicare In-Office Ancillary Exception</b>	<ul style="list-style-type: none"> <li>Adds an additional requirement to the Medicare in-office ancillary exception, requiring the referring physician to inform the patient, in writing, of the patient's right to obtain the proposed service from someone other than the referring physician or affiliate.</li> </ul>

<b>Controlling Multiple Employer Welfare Arrangements (MEWAs)</b>	<ul style="list-style-type: none"> <li>Subjects employees and agents of MEWAs to criminal penalties for false statements in marketing materials regarding a plan's financial solvency, benefits or regulatory status.</li> <li>Would prevent MEWAs from claiming federal preemption as a defense.</li> <li>Authorizes the Department of Labor (DOL) to issue "cease and desist" orders to temporarily shut down plans conducting fraudulent activities or posing a serious threat to the public until hearings can be conducted. Authorizes the seizure of plan assets.</li> <li>Requires MEWAs to register with the federal government before enrolling any participants.</li> </ul>
<b>Data Gathering and Sharing</b>	<ul style="list-style-type: none"> <li>Requires CMS to include claims and payment data in an integrated data repository from Medicare, Medicaid, CHIP and health programs administered by the Department of Veterans Affairs (VA), Department of Defense (DOD) and Indian Health Service (IHS). Grants the Department of Justice access to such data for law enforcement and oversight activities.</li> <li>Requires HHS to enter into data-sharing agreements with the Social Security Administration (SSA), DOD, VA and IHS to prevent fraud and abuse.</li> <li>Requires HHS to terminate the Healthcare Integrity and Protection Data Bank and maintain a national data collection program for reporting actions taken against health care providers and others.</li> </ul>
<b>Other Provisions</b>	
<b>Independent Payment Advisory Board</b>	<ul style="list-style-type: none"> <li>Creates an Independent Payment Advisory Board, effective 2015, to develop and submit proposals to Congress and the private sector to save costs when Medicare spending rises too fast. In years when Medicare costs are projected to be unsustainable, the board's proposals will take effect unless Congress passes an alternative measure that achieves the same level of savings. The board is prohibited from rationing care, raising taxes or Part B premiums or changing Medicare benefit, eligibility or cost-sharing standards. Hospitals and hospices are exempt from cost reductions through 2019.</li> </ul>
<b>CMS Innovation Center</b>	<ul style="list-style-type: none"> <li>Creates the CMS Innovation Center, as of 2011, to test payment reforms in Medicare, Medicaid and CHIP that reduce costs and preserve quality. CMS may expand successful reforms.</li> </ul>
<b>Medicaid Financing</b>	<ul style="list-style-type: none"> <li>The federal government will fully finance newly eligible Medicaid recipients from 2014 through 2016 and will finance at 95 percent in 2017, 94 percent in 2018, 93 percent in 2019 and 90 percent afterward. Also, the federal government will no longer fully finance Medicaid expansion in Nebraska.</li> </ul>
<b>Medicare Advantage Financing</b>	<ul style="list-style-type: none"> <li>Freezes Medicare Advantage payments in 2011. Restructures payments as a percentage of Medicare fee-for-service costs, to be phased in.</li> <li>Provides payment bonuses to plans with four or five stars, based on the existing five-star system, effective 2012.</li> <li>Requires Medicare Advantage plans to partially return money to HHS if they have an MLR below 85 percent. HHS must suspend enrollment for three years if the MLR remains below 85 percent for two consecutive years. It must terminate the contract if the MLR remains at this level for five consecutive years.</li> </ul>
<b>Public Plan</b>	<ul style="list-style-type: none"> <li>Does not include a public plan. Office of Personnel Management (OPM) will contract with private insurers to offer at least two multistate plans in each state's exchange, one of which must be nonprofit and one of which cannot cover elective abortions (functions are not exclusive). OPM's role will be limited to negotiating and certifying plans that meet its qualifications with respect to MLR, profit margins, premiums and other terms and conditions.</li> </ul>

<b>CHIP</b>	<ul style="list-style-type: none"> <li>Preserves CHIP. States will receive a 23 percent higher federal reimbursement rate, beginning 2015.</li> <li>Requires states to maintain current eligibility levels until 2019. Benefit and cost-sharing rules will continue.</li> <li>CHIP-eligible children unable to enroll due to enrollment caps are eligible for exchange credits.</li> </ul>
<b>Insurance for the Severely Disabled</b>	<ul style="list-style-type: none"> <li>Creates CLASS, a federal insurance program that provides community living assistance and supports (not less than \$50 per day) to people with severe disabilities, effective 2011.</li> <li>The program is funded by voluntary contributions; working adults must opt out to be excluded.</li> <li>Premiums would cover full cost of benefits, which would average at least \$50 per day.</li> </ul>
<b>Co-ops</b>	<ul style="list-style-type: none"> <li>Creates a program to facilitate, through loans and grants, creation of nonprofit, member-run insurers. Appropriates \$6 billion by 2013.</li> <li>Eligible organizations cannot be an existing insurer, must be oriented toward issuing qualified health benefit plans in states of licensure, must have majority-vote governance, must have a strong consumer focus and must use all profits to lower premiums, improve benefits or improve quality.</li> </ul>
<b>State Group Insurance</b>	<ul style="list-style-type: none"> <li>Permits states to create a basic health plan for people between 133-200 percent FPL who would otherwise be exchange-eligible. In such states, these people would not receive exchange subsidies. The program would be funded with 95 percent of the money the federal government would otherwise give as subsidies to individuals.</li> </ul>
<b>Community Health Centers</b>	<ul style="list-style-type: none"> <li>Provides \$11 billion over five years for community health centers, effective 2011.</li> </ul>
<b>Alternative State Innovations</b>	<ul style="list-style-type: none"> <li>Starting in 2017, a state can obtain a five-year waiver of some requirements if it can prove its alternative coverage model provides coverage to all residents that is at least as comprehensive as that offered under an exchange plan and does not increase the federal deficit.</li> </ul>
<b>Posting Nutrition Information</b>	<ul style="list-style-type: none"> <li>Mandates that chain restaurants with 20 or more locations will have to display nutritional and calorie information.</li> </ul>
<b>Costs and Financing</b>	
<b>Overall Price Tag</b>	<ul style="list-style-type: none"> <li>Estimated cost is \$938 billion over 10 years, with projected budget savings of \$143 billion over that period.</li> </ul>
<b>Funding the Legislation: Industry Fees</b>	<ul style="list-style-type: none"> <li>Imposes annual fees on pharmaceutical manufacturers based on market share of branded sales and according to a schedule governing the overall assessment. Starts at \$2.5 billion in 2011 and crests at \$4.1 billion in 2018 before settling at \$2.8 billion from 2019 forward. Manufacturers in different sales tiers will account for differing percentages of their branded sales in calculating their amount owed. Companies in the highest tier, with more than \$400 million in branded sales, will take into account all of their branded sales. Companies in the next-highest tier, with branded sales between \$225 and \$400 million, will take into account only 75 percent of their branded sales. Companies with branded sales of \$5 million or less are exempted from the fee. The fee is not tax-deductible.</li> <li>Imposes a 2.9 percent excise tax on the sale of any taxable medical device from 2013 forward. Exceptions: Class I devices, eyeglasses, contact lenses, hearing aids and any device that is generally purchased by the public at retail for individual use.</li> <li>Imposes annual fees on insurers, allocated by market share. Fees will be \$8 billion in 2014, \$11.3 billion in 2015 and 2016, \$13.9 billion in 2017 and \$14.3 billion in 2018. In subsequent years, the fees will be further increased by the rate of premium growth. For nonprofit insurers, only 50 percent of net premiums are taken into account in calculating the fee. Fees do not apply to insurers that have net premiums written of \$25 million or less or nonprofit providers for which more than 80 percent of revenues come from the SSA programs targeting low income, elderly, or disabled populations.</li> </ul>

<b>Funding the Legislation: New Taxes</b>	<ul style="list-style-type: none"> <li>• 40 percent tax on high-end employer plans worth \$10,200 for an individual plan or \$27,500 for a family plan. To be delayed until 2018.</li> <li>• An increase of 62 percent of Medicare Part A payroll tax rate for individuals making over \$200,000 a year or families making over \$250,000, and a 3.8 percent surtax on investment income from interest, dividends, royalties, rents, gross income from a trade or business and net gain from disposition of property for individuals in the same bracket, both effective 2013.</li> <li>• 10 percent tax on services by indoor tanning salons, effective July 1, 2010.</li> </ul>
<b>Funding the Legislation: Other Changes to Tax Code</b>	<ul style="list-style-type: none"> <li>• Eliminates deduction for employers who receive a subsidy for providing retiree prescription drug coverage, effective 2013.</li> <li>• Deductibility of employee compensation is capped at \$500,000 per individual for insurers that get at least 25 percent of gross premium income from minimal plans. Effective 2013 with respect to services performed after 2009.</li> <li>• Increases threshold for itemized deduction for unreimbursed medical expenses from 7.5 percent of adjusted gross income to 10 percent, effective 2013; temporarily waived for seniors.</li> </ul>
<b>Timeline for Implementation of Selected Provisions</b>	
<b>January 1, 2010</b>	<ul style="list-style-type: none"> <li>• Several Medicaid drug rebate changes go into effect retroactively.</li> </ul>
<b>Upon passage</b>	<ul style="list-style-type: none"> <li>• Licensure pathway for biosimilars is established.</li> <li>• Many fraud and abuse provisions go into effect.</li> </ul>
<b>90 days after passage</b>	<ul style="list-style-type: none"> <li>• Temporary insurance for uninsured individuals with pre-existing conditions becomes available.</li> <li>• Temporary reinsurance for employer health plans for Medicare-ineligible retirees begins.</li> </ul>
<b>July 1, 2010</b>	<ul style="list-style-type: none"> <li>• Indoor tanning salon services subject to a 10 percent tax.</li> </ul>
<b>August 1, 2010</b>	<ul style="list-style-type: none"> <li>• Physician-owned hospitals are excluded from Medicare unless they meet certain requirements.</li> </ul>
<b>Six months after passage</b>	<ul style="list-style-type: none"> <li>• Many changes to new and grandfathered insurance plans go into effect.</li> </ul>
<b>2010</b>	<ul style="list-style-type: none"> <li>• Temporary small business tax credit begins for small, low-wage firms.</li> <li>• Medicare beneficiaries who hit the Part D coverage gap will receive a \$250 rebate.</li> <li>• Resources are allocated to encourage education and training of public health, primary care and nursing professionals.</li> <li>• MLR reporting begins for all insurers and nonprofit Blue Cross Blue Shield plans become subject to their special MLR requirement.</li> <li>• Rate review begins.</li> </ul>
<b>2011</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical manufacturer fees begin.</li> <li>• Manufacturers begin discounts for brand-name drugs in the Part D coverage gap and the federal government begins subsidies for generic drugs.</li> <li>• Medicare beneficiaries may receive a free annual wellness visit and face no cost-sharing for preventive services.</li> <li>• Medicare Advantage payments freeze as a precursor to gradual ramping-down of payments based on a benchmark system.</li> <li>• CMS Innovation Center established.</li> <li>• States begin receive funding for creating exchanges.</li> <li>• CLASS goes into effect.</li> <li>• Several changes restricting personal savings accounts begin.</li> <li>• Insurers must provide rebates if MLR exceeds statutory threshold.</li> <li>• New obligations for nonprofit hospitals begin.</li> </ul>

(continued)

<b>2011</b> (continued)	<ul style="list-style-type: none"> <li>• Community health centers begin receiving new funding.</li> <li>• HHS must submit a plan to Congress on how to move home health and nursing home providers into a value-based purchasing payment system.</li> <li>• Hospitals in areas with low Medicare spending and primary care physicians and general surgeons in areas with a shortage of health professionals begin receiving temporary additional funding.</li> <li>• Unused medical education training slots are to be redistributed for purposes of increasing primary care training at other sites.</li> <li>• Grants are available for states to research and develop tort alternatives.</li> </ul>
<b>2012</b>	<ul style="list-style-type: none"> <li>• Medicare hospital value-based purchasing program and home care demonstration program and Medicaid payment bundling demonstration program begin.</li> <li>• Medicare payments adjust to discourage preventable hospital readmissions.</li> <li>• Certain Medicare and Medicaid accountable care organizations will be able to share in savings they produce.</li> <li>• Medicare Advantage payment bonuses to high-rated plans begin.</li> </ul>
<b>2013</b>	<ul style="list-style-type: none"> <li>• Tax on medical devices begins.</li> <li>• Increase on Medicare Part A payroll tax rate and extension to investment income for high-income individuals begins.</li> <li>• Federal subsidies for brand-name drugs in the Part D coverage gap begin.</li> <li>• Co-op funding becomes available.</li> <li>• Health FSA contributions limited to \$2,500 per year.</li> <li>• Medicaid payment rates to primary care physicians for furnishing primary care services match Medicare payment rates this year (and 2014).</li> <li>• Drug manufacturer “sunshine provisions” go into effect.</li> <li>• Medicare payment-bundling pilot for acute services begins.</li> <li>• Several changes to tax deduction rules begin.</li> </ul>
<b>2014</b>	<ul style="list-style-type: none"> <li>• Majority of insurance regulations come into effect.</li> <li>• State exchanges are created.</li> <li>• Insurer annual fees begin.</li> <li>• Individual penalty begins.</li> <li>• Large employer penalties begin.</li> <li>• Premium and cost-sharing tax credits for individuals become available.</li> <li>• Expanded small business tax credits become available.</li> <li>• Medicaid eligibility increases to 133 percent FPL.</li> <li>• Employers begin distributing vouchers to employees to obtain exchange insurance.</li> <li>• OPM, contracting with private insurers, offers multistate insurance plans.</li> <li>• The federal government begins fully financing newly eligible Medicaid recipients through 2017 and at an elevated rate after that.</li> <li>• Smoking cessation drugs, barbiturates and benzodiazepines are no longer excludable from Medicaid reimbursement.</li> </ul>



<b>2015</b>	<ul style="list-style-type: none"><li>• Independent Payment Advisory Board is created.</li><li>• Value-based Medicare payment modifier comes into effect.</li><li>• CHIP federal reimbursement rate increases by 23 percent.</li></ul>
<b>2016</b>	<ul style="list-style-type: none"><li>• States are allowed to form interstate compacts to facilitate the multistate sale of insurance plans.</li></ul>
<b>2017</b>	<ul style="list-style-type: none"><li>• States may allow large employers to purchase exchange insurance.</li><li>• States may obtain waivers of some requirements if they create an alternative system that meets certain requirements.</li></ul>
<b>2018</b>	<ul style="list-style-type: none"><li>• Excise tax on high-end “Cadillac” insurance plans begins.</li></ul>