



Health Care Reform



**Patient Protection and Affordable Care Act &
Health Care and Education Affordability
Reconciliation Act**

**NEW HHS AUTHORITIES &
NEW ENTITIES**

April 5, 2010

NEW AUTHORITIES FOR HHS & HHS AGENCIES



- **High Risk Pool.** Within 90 days, establish a high risk pool for un-insured individuals with preexisting conditions. Terminates in 2014 when state exchanges are operational. (PPACA § 1101).
- **Retiree Reinsurance.** Within 90 days, establish a temporary reinsurance program for early retirees (ages 55-64). Terminates in 2014 when state exchanges are operational. (PPACA §§ 1102, 10102).
- **Key Insurance Reforms.** Enforce insurance reforms. (PPACA § § 1001, 1201, 10101, 10103; Reconciliation § 2301). Key reforms include:
 - Eliminate lifetime limits for all plans, effective 6 months after enactment, and eliminate annual limits for all plans in 2014 (“restricted” annual limits permissible until 2014).
 - Effective 6 months after enactment, extend coverage to dependents until dependant is 26, unless the dependant is otherwise eligible for employer-sponsored insurance.
 - Prohibits insurers from excluding coverage of pre-existing conditions, effective 6 months after enactment for new plans for enrollees under 19, and in 2014 for all plans and all people.
 - Effective in 2014, requires guaranteed issue and renewability and, effective 6 months after enactment, prohibits rescission of coverage, except in the case of fraud.
 - Effective in 2014, prohibits discrimination based on health status for all new plans.

- **Premiums.** Effective in plan year 2010, work with state insurance commissioners to establish a process for annual review of insurance premiums to monitor premium increases and prevent “unreasonable” premium increases. (PPACA § 1003).
- **Essential Benefits.** Define essential health benefits to include: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorders; prescription drugs; rehabilitative services and devices; laboratory services; prevention and wellness services and chronic disease management; and pediatric services. (PPACA §§ 1301, 10104).
- **State Exchanges.** Provide grants to states to establish American Health Benefit Exchanges by 2014. (PPACA § 1311).
 - Grants begin one year after enactment and terminate in 2015.
 - Exchanges would also be required to establish a Small Business Health Options Program (SHOP) to help small employers find and purchase health insurance for their employees.
- **COOP.** By July 1, 2013, establish the Consumer Oriented and Operated Plan (COOP) to foster the establishment of nonprofit entities to offer qualified health insurance plans. (PPACA §§ 1322, 10104).
- **CLASS Act.** By Jan. 1, 2011 establish a national voluntary insurance program to enable individuals to purchase community living assistance services and support (CLASS). (PPACA §§ 8001-8002, 10801).

- **Improve Transparency.**

- By July 1, 2010, work with states to establish a website to enable individuals to identify affordable insurance options. (PPACA §§ 1103, 10102).
- Within one year, develop a standardized format for presentation of plan benefits, premiums, cost-sharing, and eligibility. (PPACA §§ 1103, 1001, 10104).
- Provide grants to states to assist consumers purchase, understand, and choose amongst available health insurance plans. (PPACA § 1002).

- **Other Insurance-Related Responsibilities.**

- Enforce individual and employer mandates. (PPACA §§ 1501, 1512, 10106; Reconciliation §§ 1002, 1003).
- Provide subsidies to low-income individuals for purchase of insurance plans. (PPACA § 1402; Reconciliation §§ 1001, 1004);
- Utilize HIT to facilitate enrollment in individual and employer plans. (PPACA § 1561).
- Implement a demonstration program to provide health care services to the low-income uninsured at reduced fees. (PPACA § 10504).

- **Prevention.** Oversee the Prevention, Health Promotion, and Public Health Council established by the President within HHS to provide coordination and leadership among all Federal agencies with respect to prevention, wellness, and health promotion practices. (PPACA § 4001).
- **Public Health.** Beginning in FY2010, administer the Prevention & Public Health Fund to expand and sustain national investment in prevention and public health programs. (PPACA § 4002).
- **Wellness Programs.**
 - Enforce employer wellness provisions applicable to the group market and work with the Secretaries of Labor and Treasury to implement a 10-state pilot program to apply wellness program provisions to the individual market. (PPACA § 1201).
 - Provide grants to small businesses to offer employer wellness programs. (PPACA § 4206).

- Quality.
 - By Jan. 1, 2011, develop National Strategy on Health Care Quality to improve the delivery of health care services, patient health outcomes, and population health. (PPACA §§ 3011, 10302);
 - Develop and publicly report on patient outcome measures. (PPACA § 10303).
- Workforce.
 - Requires HHS to sit on the National Health Care Work Force Commission to coordinate efforts to improve the quality and quantity of the health care work force. (PPACA § 5101).
 - Establishes the Community Health Center Fund, administered through the Office of the Secretary, to provide for expanded and sustained national investment in community health centers under the National Health Services Corps. (PPACA § 10503).
- Physician Sunshine. Beginning March 31, 2013, requires drug, device, biological and medical supply manufacturers to report information to HHS related to any payment or gift of value to physicians greater than \$10 per transaction or \$100 in aggregate annually. Information will be made available in a publicly searchable database. (PPACA § 6002).
- Minority Health. Codifies the Office of Minority Health within the Office of the Secretary of HHS and creates new Offices of Minority Health within HHS agencies, such as CDC, SAMSHA, HRSA, AHRQ, CMS, NIH, and FDA. (PPACA § 10334).

- **Comparative Effectiveness.** Requires AHRQ to sit on the Board of Governors of the independent Patient Centered Outcomes Research Institute, which conducts clinical comparative effectiveness research; requires AHRQ, with NIH to disseminate such research and to train individuals to conduct to such research. (PPACA §§ 6301, 10602).
- **National Quality Measures.** Pursuant to the HHS-developed National Strategy for Quality Improvement, authorizes \$75 million over 5 years for the development of quality measures by AHRQ and CMS. (PPACA § 3013).
- **Quality Improvement.** Authorizes \$20 million for FY 2010-2014 to enable AHRQ to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services. (PPACA § 3501).
- **Primary Care.** Creates a Primary Care Extension Program and a grant program to states through AHRQ to educate and provide technical assistance to primary care providers about evidence based therapies, preventive medicine, health promotion, chronic disease management, and mental health. (PPACA § 5405).

- **Wellness Programs.** Requires the CDC to study and evaluate best practices for employer-based wellness programs and to provide technical assistance to employers establishing such programs. (PPACA § 4303).
- **Community Grants.** Effective FY2010-2014, authorizes a grant program for states and community health organizations, particularly focused on rural areas, to reduce chronic disease rates, prevent the development of secondary conditions, and address health disparities. (PPACA § 4201).
- **Prevention Programs.**
 - Beginning in FY2010, authorizes a 5-year pilot program to provide public health community interventions, screenings, and clinical referrals for individuals between 55 and 64. (PPACA § 4202);
 - Requires CDC to provide funding for research on evidence-based practices relating to prevention and to identify strategies for delivering public health services in community settings. (PPACA § 4301).
- **Immunizations.** Establishes a demonstration program to award grants to states to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations. (PPACA § 4204).

CDC – Diseases Specific Programs

- **Oral Health Prevention.** Within 2 years of enactment, establishes a 5-year public education campaign on oral health prevention and education. (PPACA § 4102).
- **Infectious Diseases.** Establishes a grant program for state health departments to assist in the surveillance of and response to infectious diseases. (PPACA § 4304).
- **EARLY Act (Breast Cancer).** Requires CDC to conduct a national, evidence-based campaign targeted at young women and their knowledge of breast health. (PPACA § 10413).
- **Diabetes Prevention.** Requires CDC to establish a national diabetes prevention program targeted at adults at high risk for developing diabetes to prevent onset of the disease. (PPACA § 10501).

- **Center for Medicare & Medicaid Innovation.** By Jan. 1, 2011, establishes the Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures in Medicare/Medicaid/CHIP while enhancing quality. (PPACA §§ 3021, 10306).
- **Medicaid Expansion.** Effective April 1, 2010 expands Medicaid eligibility to include non-pregnant, childless adults under 65 who are at or below 133% of FPL; beginning in 2014, provides for a temporary FMAP increase for certain states that have expanded Medicaid eligibility. (PPACA §§ 2001, 10201; Reconciliation § 1201).
- **Medicaid Rx Drugs.**
 - Increases innovator drug base rebate to 23.1% except for clotting factors and exclusively pediatric drugs (increased to 17.1%). (PPACA § 2501; Reconciliation § 1206)
 - Increases base rebate to 13% of AMP for generic drugs. (PPACA § 2501; Reconciliation § 1206)
 - Extends rebates to MCOs. (PPACA § 2501; Reconciliation § 1206)
 - Establishes new rules for reformulations and federal upper payment limit. (PPACA § 2501; Reconciliation § 1206).
 - Allows coverage of smoking cessation drugs, barbiturates, and benzodiazepines (PPACA § 2502; Reconciliation § 1206).
 - Amends definition of AMP. (PPACA § 2503; Reconciliation § 1206)
- **Community First Choice Option.** Establishes an optional Medicaid benefit for states to offer community-based attendant services and support to Medicaid beneficiaries with disabilities who would otherwise require the level of care offered in a hospital, nursing facility, or intermediate care facility for the mentally retarded. (PPACA §§ 2401, 10202; Reconciliation § 1205)

Medicaid Quality & Payment Reforms. Authorizes various payment and quality improvement reforms in Medicaid, including:

- Developing adult health care quality measures by Jan. 1, 2012. (PPACA § 2701)
- Prohibiting payments to states for Medicaid care related to health-care acquired conditions, effective July 1, 2011. (PPACA § 2702)
- Beginning in 2011, allowing states the option to provide medical or health homes for enrollees with chronic conditions to better manage those conditions. (PPACA § 2703)
- Beginning Jan. 1, 2012, authorizing a 4 year, 8-state demonstration project to evaluate a bundled payment system to encourage integrated care around a hospitalization (PPACA § 2704); and a demonstration project to evaluate expanding the number of inpatient emergency psychiatric beds (PPACA § 2707).
- Establishing a Medicaid Global Payment System demonstration project from 2010-2012 run through the CMS Innovation Center to test Medicaid payment on a capitation rather than fee-for-service basis. (PPACA § 2705).
- Creating a demonstration project from 2012-2016 to allow pediatric providers to be recognized as accountable care organizations (ACO) under Medicaid to share in savings for services which are provided at a lower cost by the ACO. (PPACA § 2706).

Medicare Quality & Payment Reforms. Authorizes various payment and quality improvement reforms in Medicare, including:

- Requiring establishment of a hospital value-based purchasing program, with possible extension to physician payments, skilled nursing facilities, ACSs, and other sites of care. (PPACA §§ 3001, 3006, 3007, 10301, 10326, 10335).
- Beginning in 2012, rewarding accountable care organizations (ACO) with a share of the savings ACOs achieve by meeting quality of care targets and reducing costs per patient relative to spending benchmarks. (PPACA §§ 3022, 10307).
- Establishing the 5-year National Payment Bundling Pilot Program by 2013 to evaluate integrated care during an episode of care provided to beneficiaries in Parts A and B. (PPACA §§ 3023, 10308).
- By Jan 1, 2012, establishing the Independence at Home demonstration project to test payment incentives which encourage the use home-based primary care teams for chronically ill patients. (PPACA § 3024).
- Beginning in 2012, adjusting hospital payments for preventable readmissions. (PPACA §§ 3025, 10309).
- Extending the Medicare gainsharing demonstration through 2014 to improve the quality and efficiency of care. (PPACA § 3027).

- **Medicare Part C.** Starting in 2012, implements reforms to Medicare Advantage payment and requires simplification of beneficiary enrollment procedures. (PPACA §§ 3201-3210, 10318; Reconciliation § 1102).
- **Medicare Part D.** Various reforms to the Part D program, which include:
 - Closing the coverage gap by 2019 by instituting a discount on covered Part D drugs in the donut hole, beginning Jan 1, 2011, and a one time \$250 coverage gap rebate in 2010. (PPACA § 3301, 3315; Reconciliation § 1101).
 - Modifying low-income subsidies and eligibility for such subsidies. (PPACA § 3302-3306)
 - Effective plan year 2011, codifying the six protected classes and providing CMS with the authority to identify additional classes of clinical concern which must be included in Part D formularies. (PPACA § 3307)
 - Reducing the Part D premium subsidy for high income beneficiaries. (PPACA § 3308)
 - Expanding requirements of Medication Therapy Management programs. (PPACA § 10328).

- **Biosimilars.** Requires reimbursement equal to the ASP of the biosimilar product plus 6% of ASP of the reference product. (PPACA § 3139).
- **Preventive Services.** Authorizes Medicaid & Medicare coverage and waiver of cost-sharing for certain preventive services and immunizations recommended by the USPSTF. (PPACA §§ 4103-4107, 10402, 10406)
- **Dual Eligibles.** (PPACA §§ 2601-2602, 3309).
 - Clarifies that Medicaid demonstration authority for coordination of care for dual eligibles may be conducted for up to 5 years, and extended for 5 year increments;
 - No later than March 1, 2010, establishes the Federal Coordinated Health Care Office within CMS to more effectively integrate benefits for dual eligibles;
 - By Jan 1, 2012, eliminates cost sharing for dual eligibles receiving care under a home and community-based waiver program who would otherwise require institutional care.

- **Drug Facts Box.** Requires, within one year, a report to HHS on whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to promotional labeling and advertising of prescription drugs will improve health care decision making; authority to promulgate regulations within 3 years to implement a drug facts box if the report finds it would improve health care decision making. (PPACA § 3507).
- **Medical Equipment for Individuals with Disabilities.** Requires FDA to promulgate regulations setting for standards for the minimum technical criteria for medical diagnostic equipment (e.g., exam tables and chairs) to ensure that such equipment is accessible to individuals with disabilities. (PPACA § 4203).
- **Biosimilars.** Requires creation of a pathway for approval of biosimilar products. (PPACA §§ 7001-7003).
- **Nutrition Labeling.** Amends the FFDCA to require chain restaurants and retail food establishments to disclose the nutrient content of standard menu items. (PPACA § 4205).
- **Generic Drug Labeling.** Amends the FFDCA with respect to approval of the labeling of generic drugs in certain circumstances. (PPACA § 10609).

- **Preventive Services.** Develop guidelines on additional women's preventive services that are required to be covered, and for which cost-sharing must be waived, by qualified health plans. (PPACA § 1001).
- **Workforce Grant Programs.** Requires establishment at HRSA of the Rural Physician Training Grants program (PPACA § 10501), the Preventive Medicine and Public Health Training Grant Program (PPACA § 10501), and a grant program to support nurse-managed health clinics (PPACA § 5208).
- **Access to Affordable Care.** Requires HRSA to establish a 3-year demonstration program in 10 states to provide access to comprehensive health care services to the uninsured at reduced fees. (PPACA § 10504).
- **Federally Qualified Health Centers.** Authorizes appropriation of additional funding for FQHCs beginning in 2010 (PPACA § 5601); directs the Secretary (through HRSA and CMS) to develop and implement a prospective payment system for Medicare-covered services furnished by FQHCs (PPACA §§ 5502, 10501; Reconciliation § 2303).
- **340B.** Expands 340B pricing to new covered entities, improves 340B program integrity, and authorizes a GAO report on recommendation to improve the 340B program. (PPACA §§ 7101-7103; Reconciliation § 2302).

- **Comparative Effectiveness.** Requires NIH to sit on the Board of Governors of the independent Patient Centered Outcomes Research Institute, which conducts clinical comparative effectiveness research; requires NIH, with AHRQ to disseminate such research and to train individuals to conduct to such research. (PPACA §§ 6301, 10602).
- **Congenital Heart Disease.** Expands, intensifies, and coordinates research at the NIH on congenital heart disease. (PPACA § 10411).
- **Cures Acceleration Network.** (PPACA § 10409).
 - Creates the CAN within the Office of the Director of the NIH to follow recommendations of the new CAN Review Board and to award grants to accelerate the development and approval of “high need cures”.
 - The Review Board is tasked with identifying translational barriers to product development and coordinating and facilitating FDA review of high need cures.

NEW QUASI-GOVERNMENTAL ENTITIES



- **American Health Benefits Exchange.** Requires HHS to award grants to states to establish exchanges to enable state residents to purchase affordable insurance. Grants must be awarded within one year of enactment and terminate in 2015; state exchanges must be operational by 2014. (PPACA § 1311).
- **Medicaid and CHIP Payment Access Commission (MACPAC).** Reauthorizes MACPAC and clarifies MACPAC's authorities. (PPACA § 2801).
- **Independent Payment Advisory Board (IPAB).** Creates a 15-member Independent Payment Advisory Board tasked with presenting Congress with comprehensive proposals to reduce excess cost growth and improve quality of care for Medicare beneficiaries. The Secretary of HHS and representatives from CMS and HRSA are members of the Board. (PPACA §§ 3403, 10320).
- **National Health Care Workforce Commission.** Establishes a 15-member, national commission tasked with reviewing health care workforce and projected workforce needs. (PPACA §§ 5101, 10501).
- **Patient Centered Outcomes Research Institute.** Establishes a non-profit entity to identify, fund, and conduct clinical comparative effectiveness research. Representatives from AHRQ, NIH and other governmental entities, as well as private citizens from various professional practices must sit on the Board of Governors of the Institute. (PPACA §§ 6301, 10602).