

**Side by Side of Selected Provisions in the
Senate Health Care Reform and the House Reconciliation Bill**

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
Medicare and Physician Program Reforms		
Independent Payment Advisory Board	Would establish an Independent Payment Advisory Board that would develop and submit proposals to Congress aimed at slowing Medicare cost growth, improving the quality of care delivered to Medicare beneficiaries, and slowing the growth in national health expenditures.	Same as Senate bill.
	The Board would have authority limited to Parts B (Physician), C, and D providers (C and D are limited to administrative expenses and performance bonuses for MA plans). Hospitals and hospices (Part A) are specifically excluded from consideration of cost reductions until 2019.	Same as Senate bill.
	Establishes a fast-track legislative process to expedite consideration by Congress. Congress could only vote down the recommendations if they pass legislation that reflects the same savings amount. If they take no action, the recommendations would be implanted by the Secretary of HHS.	Same as Senate bill.
	The Board would be comprised of 15 members, who would be appointed by the President and confirmed by the Senate. Qualifications would be similar to those for MedPAC but members of the Board would be required to be free of conflicts of interest and would be held to certain disclosure and accountability requirements.	Same as Senate bill. Same as Senate bill.
	The Board would be prohibited from presenting proposals that	Same as Senate bill.

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	<p>would ration care, increase revenues, or otherwise change Medicare beneficiary cost-sharing (including premiums), benefits, or eligibility standards.</p> <p>Congress could discontinue the Board by passing a joint resolution under certain procedures in the House and Senate in 2017.</p> <p>Would establish a Consumer Advisory Commission, which would be comprised of ten consumer representatives that would advise the Board on the impact of Medicare payment policies on consumers.</p> <p>Would require the GAO, by July 1, 2015, to conduct a study on the effect of the Board's proposals. Specifically, the study would assess the effect of the Board's proposal on Medicare beneficiaries' access to providers, affordability of premiums and cost-sharing, and quality of care provided. Subsequent studies would be required.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicare Physician Quality Reporting Initiative (PQRI) and the Physician Feedback Program	<p>Participation in PQRI would become mandatory for physicians accepting Medicare in 2015.</p> <p>Would extend the current PQRI incentive payments beyond 2010. Eligible professionals who successfully report in 2011 will receive a 1% payment bonus. Eligible professionals would receive a 0.5% bonus for successfully reporting in 2012, 2013, and 2014. Eligible professionals who fail to participate successfully in the program in 2015 would incur a 1.5% payment penalty. In 2016 and thereafter, the payment penalty would be 2%. The payment penalty would be based on the allowed charges for all covered services furnished by the eligible professional.</p> <p>Would provide an additional incentive payment of 0.5 percent from 2011 through 2014 for eligible professionals that meet certain criteria. In order to be eligible for the additional incentive payment, the eligible professional must: 1) satisfactorily submit data on</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>applicable quality measures for a year; and 2) have such data submitted on their behalf through a Maintenance of Certification program that meets certain criteria (such as the American Board of Medical Specialties Maintenance of Certification program). The eligible professional must also, more frequently than required to qualify for or maintain board certification status, participate in a Maintenance of Certification program for a year and successfully complete a qualified Maintenance of Certification Program practice assessment. In addition, the Maintenance of Certification program in which the eligible professional participated would need to submit certain information to the Secretary. For 2015 and thereafter, the Secretary would have the authority to incorporate participation in a Maintenance of Certification program and successful completion of a qualified Maintenance of Certification program practice assessment into the composite of measures of quality of care furnished pursuant to the Medicare physician fee schedule payment modifier.</p> <p>Would require CMS to develop a plan to integrate the PQRI program and electronic health record "meaningful use" measures related to the health information technology incentive program.</p> <p>Would require CMS to provide timely feedback to professionals on their performance and establish a PQRI appeals process.</p> <p>Would expand the Medicare physician feedback program beginning in 2012.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Value-Based Physician Payment Modifier	<p>Introduces a budget neutral, value-based modifier for the physician payment formula that would pay physicians and groups of physicians based on quality of care relative to cost.</p> <p>The modifier would be based on a composite quality score and a composite cost score determined by measures selected by the</p>	<p>Same as Senate bill.</p>

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	<p>Secretary and endorsed by a consensus organization.</p> <p>The Secretary would be required to publish the measures to be used in 2012 and to begin implementation through the rule-making process in 2013 for an initial test reporting period beginning in 2015. The modifier would be applied to all physician payments by 2017.</p>	
Primary Care/General Surgery Bonus Payments	Provides 10% bonus to primary care physicians and general surgeons.	Same as the Senate bill.
Misvalued Codes (Shadow RUC)	<p>Requires Secretary of HHS to periodically identify potentially misvalued physician services and make adjustments in the relative value units (RVUs), including consolidating individual services into bundled payments. Directs the Secretary to establish a process to validate RVUs.</p> <p>The Secretary would examine codes with the fastest growth, substantial changes in practice expenses, low relative values - particularly those often billed multiple times for a single treatment, codes for new technologies or services, multiple codes often billed in conjunction with one another, codes that have not been evaluated since the inception of the resource-based relative value scale (RBRVS) and other codes determined appropriate for review by the Secretary.</p>	Same as the Senate bill
Physician Compare	<p>Establishes a website that would make available to the public quality and value information about individual physician.</p> <p>Sources of data for Physician Compare: (A) Measures collected under the Physician Quality Reporting Initiative; (B) Assessment of patient health outcomes and the functional status of patients; -</p>	Same as the Senate bill.

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	(C) Assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use; (D) Assessment of efficiency; (E) Assessment of patient experience and patient, caregiver, and family engagement; (F) Assessment of the safety, effectiveness, and timeliness of care; and (G) Other information as determined appropriate by the Secretary.	
Medical Liability Reform	Expresses "Sense of the Senate," which has no legal standing, that health care reform presents an opportunity to address issues related to medical malpractice and states should be encouraged to develop and test ADR mechanisms.	Same as the Senate bill.
Graduate Medical Education	Redistributes unused residency slots to increase training, with a focus on primary care and general surgery.	Same as the Senate bill.
Disclosure and Transparency of Financial Relationships with Health Care Providers	Beginning March 31, 2013, drug, device, biologic, and medical supply manufacturers would be required to report any payments or transfers of value, with limited exceptions (less than \$10 but if annual aggregate equals \$100 or more then reporting requirements apply), made to a physician or teaching hospital. The \$10 and \$100 thresholds would be increased "for calendar years after 2012" based on the percentage increase in the CPI for urban consumers. The Secretary would be required to publish such information in a clear and searchable format. Procedures to be established by October 1, 2011. Beginning September 30, 2013 and on June 30 in subsequent years, the information would be made available on the internet. Would establish civil monetary penalties for failure to comply with the reporting requirements. Would preempt any state or local laws that require manufacturers to disclose the type of information required under this provision. However, the provision would not preempt any state or local laws that go beyond the scope	Same as Senate bill. Same as Senate bill.

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	<p>of this federal requirement.</p> <p>Manufacturers and related group purchasing organizations would be required to report annually to the Secretary information regarding any ownership or investment interest held by a physician in the manufacturer or GPO organization during the preceding year.</p> <p>Drug manufacturers and authorized drug distributors would be required to report to the Secretary information already collected pursuant to the Federal Food, Drug and Cosmetic Act, specifically, the type and amount of drug samples requested by and distributed to practitioners, along with the practitioners' names, addresses, professional designations and signatures. The reported information would not be publicly available.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Center for Quality Improvement	<p>Would require the existing AHRQ Center for Quality Improvement and Patient Safety to prioritize areas for the implementation of best practices in the delivery of health care services. The Director would provide grants to identify, develop, evaluate, and implement health care delivery system improvements.</p>	<p>Same as Senate bill.</p>
Quality Measure Development and Reporting	<p>Would require the Secretary to: 1) establish and update annually a national strategy to improve the delivery of health care services, patient health outcomes, and population health; 2) establish a federal health care quality internet website; 3) convene an interagency working group on health care quality. The legislation would also authorize federal funding to support the development, endorsement, and use of quality measures.</p> <p>Would require the Secretary to develop and periodically update provider-level outcomes measures for hospitals and physicians.</p> <p>Would require the Secretary to establish and implement an overall strategic framework to carry out the public reporting of certain quality measures. The Secretary would also be required to make</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>available to qualified entities certain Medicare data for the evaluation of provider and supplier performance.</p> <p>Would provide for the collection and dissemination of comparative information on physician quality.</p> <p>Within 9 months of the date of enactment, would require the Secretary to develop a plan to modernize computer and data systems at CMS in order to support improvements in care delivery.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Stakeholder Input Into Selection of Quality Measures	<p>Beginning no later than December 1, 2011 and annually thereafter, would require the Secretary to publicly release a list of measures being considered for use in Medicare payment systems.</p> <p>Would require a "consensus-based entity" to convene multi-stakeholder groups to provide recommendations on the selection of individual or composite quality and efficiency measures for reporting performance information to the public or for use in public health care programs. No later than February 1, 2012, and annually thereafter, the "consensus-based entity" would transmit the multi-stakeholder groups' recommendations to the Secretary.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicare Accountable Care Organizations	<p>Would allow groups of providers who voluntarily meet certain statutory criteria, including quality measurements, to be recognized as ACOs and be eligible to share in the cost-savings they achieve for the Medicare program. Beginning on Jan. 1, 2012, eligible ACOs would have the opportunity to qualify for an incentive bonus. ACO organizations must meet certain criteria and the Secretary will use certain measures to allow for participating organizations to qualify for incentive payments. ACOs with 3-year average Medicare expenditures that are determined by CMS to be below their benchmark would be eligible for shared savings at a rate determined by the Secretary. Physicians and practitioners could qualify as ACO professionals if they meet the specified criteria.</p>	<p>Same as Senate bill.</p>

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	<p>The Secretary would also be authorized to make payments to ACOs based on a partial capitation model or another payment model that the Secretary determines would improve the quality and efficiency of items and services furnished under Medicare.</p> <p>Would permit the Secretary to give preference to ACOs who are participating in similar arrangements with other payers.</p> <p>Would allow the Secretary to enter into agreements with an ACO under the Physician Group Practice Demonstration Program, subject to rebasing and other modifications deemed appropriate by the Secretary.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicare Bundled Payment	<p>The Secretary would be required to develop, test, and evaluate alternative payment methodologies through a national, voluntary five-year pilot program designed to provide incentives for providers to coordinate patient care across the continuum and to be jointly accountable for the entire episode of care starting no later than January 1, 2013. If evaluations find that the pilot program achieves the goals of improving patient outcomes, reducing costs, and improving efficiency, then the Secretary would be required to submit an implementation plan to Congress on making the pilot a permanent part of the Medicare program.</p> <p>Prior to the start of the program, the Secretary would be required to determine which patient assessment instrument should be used to evaluate a patient's clinical condition for the purposes of determining the most clinically-appropriate site for post-acute care (PAC). The Secretary would be required to work with AHRQ and the qualified consensus based entity to develop episode of care quality measures and quality measures that are applicable to all post-acute care settings. The Secretary would also be required to determine which Medicare statutory provisions and regulations</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>would be appropriate to waive in order to conduct the program.</p> <p>The Secretary would select ten conditions to be included in the program based on a number of enumerated factors. Additionally, the program may cover: acute care inpatient hospitalizations; physician services delivered inside and outside of the acute care hospital; outpatient hospital services, including emergency department visits; PAC services; and other services the Secretary deems appropriate.</p> <p>The episode of care established in the pilot would start three days prior to a qualifying admission to the hospital and span the length of the hospital stay and 30 days following the patient discharge, unless the Secretary determines another timeframe is more appropriate.</p> <p>The Secretary would be required to develop payment methods for the pilot program, including bundled payments and bids from entities for episodes of care. The payment amount for applicable beneficiaries for a year must not result in higher than would have otherwise applied. A payment methodology tested under the pilot program must include payment for the furnishing of applicable services and other appropriate services.</p> <p>The Secretary would be required to establish quality measures related to care provided by entities participating in the pilot program. The quality measures would include: 1) functional status improvement; 2) reducing rates of hospital readmissions; 3) rates of discharge to the community; 4) ER and hospital admission rates; 5) incidence of health care acquired infections; 6) efficiency measures; 7) measures of "patient-centeredness of care"; 8) measures of patient perception of care; and 9) other measures, including outcomes measures, determined appropriate by the</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>Secretary. Entities participating in the pilot program would be required to submit the required quality data to the Secretary.</p> <p>Would give the Secretary authority to expand the duration and scope of the pilot program if: 1) the Secretary determines that the expansion would reduce Medicare spending without reducing the quality of care; 2) the CMS Chief Actuary certifies that the expansion would reduce Medicare spending; and 3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits for Medicare beneficiaries.</p> <p>Would require the Secretary to separately pilot test the “continuing care hospital model.”</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Center for Medicare and Medicaid Payment Innovation	<p>Would establish, no later than January 1, 2011, a Center for Medicare and Medicaid Innovation within CMS that would have the authority to test new provider payment and delivery models for Medicare, Medicaid, and CHIP.</p> <p>The Secretary would be required to give preference to testing models for which there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary would also be required to focus on models expected to reduce program costs while preserving or enhancing the quality of care received by beneficiaries.</p> <p>The Secretary would be required to terminate or modify the design and implementation of a model unless, after testing has begun, the model is expected to: 1) improve the quality of patient care without increasing Medicare and Medicaid spending; and/or 2) reduce Medicare and Medicaid spending without reducing the quality of patient care.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>The Secretary would be required to consult with relevant federal agencies, clinical and analytical experts, and stakeholders through the use of open door forums and other mechanisms.</p> <p>The Secretary would have the authority to expand the duration and scope of a model being tested (including implementation on a nationwide basis) to the extent the Secretary determines that the model is expected to: 1) improve the quality of patient care without increasing Medicare and Medicaid spending; and/or 2) reduce Medicare and Medicaid spending without reducing the quality of patient care. The Secretary's decision to expand the duration and scope of the model would be contingent on a certification by the CMS Chief Actuary that the expansion would reduce (or not result in any increase in) net Medicaid and Medicare program spending. The Secretary would be required to ensure that the expansion would not deny or limit the coverage or provision of benefits under Medicare and Medicaid. The Secretary would also be required to select evaluation measures that reflect national priorities for quality improvement and patient-centered care.</p> <p>The Center would receive \$5B in funding for FY2010, \$10B in funding for FY2011-FY2019, and \$10B in funding for each for each subsequent ten-year period.</p> <p>Would require the Secretary to report to Congress every other year, beginning in 2012, on the Center's activities.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicare Part B Payment for Innovator Biologics, Biosimilars, and Interchangeable Biologics	<p>Would create a new payment methodology for biosimilar biological products. The payment amount for a biosimilar biologic would be equal to the weighted average ASP of the NDC codes assigned to the biosimilar biologic product plus six percent of the ASP of the reference biologic (i.e. the innovator product). The new payment methodology would become effective beginning on the first day of the second calendar quarter after enactment of legislation providing</p>	<p>Same as Senate bill.</p>

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Medicare Cost-Sharing for Preventative Care Services	<p>for a biosimilar approval pathway.</p> <p>Effective January 1, 2011, would eliminate beneficiary cost-sharing for preventive services covered by Medicare and recommended by the U.S. Preventive Services Task Force (USPSTF) with a grade of A or B.</p> <p>Effective January 1, 2011, would provide Medicare coverage, with no co-payment or deductible, for annual personalized prevention plan services unless the beneficiary has received an initial physical examination or personal prevention services within the preceding 12-month period.</p> <p>Effective January 1, 2010, the Secretary would have the authority to modify Medicare coverage of existing preventive services consistent with USPSTF recommendations.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Additional Medicare Reforms	<p>Would include the following Medicare reforms and related proposals: 1) direct the Secretary to implement payment reforms and/or reductions for certain providers; 2) direct the Secretary to submit a plan to Congress by October 1, 2011 outlining how to effectively move Medicare home health agencies and skilled nursing facilities into a value-based purchasing payment system, and effective in 2011, would require the Secretary to implement quality reporting programs for additional providers; 3) direct the Secretary to implement a value-based purchasing program for hospitals in FY2013; 4) direct the Secretary to develop plans for a value-based purchasing program for ambulatory surgical centers; 5) reduce payments to Medicare Advantage plans and implement new consumer protections for Medicare Advantage beneficiaries; 6) freeze current thresholds for income-related Part B premiums at 2009 levels through December 31, 2019; 7) reduce payments to certain hospitals with high rates of hospital acquired conditions and require public reporting of hospital acquired conditions data; 8) reduce payments to hospitals with readmission rates above a certain</p>	<p>Same as the Senate bill with the following modifications: 1) effective in 2011, would freeze Medicare Advantage payments; 2) effective beginning in 2012, would reduce Medicare Advantage payments; reductions would vary among high and low cost areas and would be phased-in; 3) effective beginning in 2012, would provide increased payments to high quality Medicare Advantage plans; 4) effective beginning in 2014, would require a minimum medical loss ratio of at least 85% for Medicare Advantage plans; 5) would repeal the Comparative Cost Adjustment program established by the Medicare Modernization Act; 6) would cut Medicare disproportionate share payments to hospitals effective in FY 2014 and, according to the Section-by Section analysis prepared by House Committee staff, would lower the ten-year reduction by \$3 billion; 7) would modify the hospital market basket reduction in FY 2014 through FY 2019 for inpatient hospitals, long-term care hospitals, inpatient rehabilitation facilities, psychiatric hospitals, and outpatient hospitals; 8) effective December 31, 2010, would prohibit physician ownership of hospitals to which they self refer</p>

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	<p>threshold for targeted conditions and fund eligible hospitals and community organizations providing transitional care services to Medicare beneficiaries at risk of preventable re-hospitalization 9) update outpatient payments for PPS-exempt cancer hospitals; 10) increase reimbursement for dual energy x-ray absorptiometry (DXA) services; 11) incorporate provisions to reduce waste, fraud and abuse in Medicare; 12) authorize a home-based chronic care management demonstration program; 13) provide funding to hospitals and community-based entities to furnish evidence-based transition services to Medicare beneficiaries at high risk for readmission; 14) would reduce Medicare payments to psychiatric hospitals that fail to report certain quality data; 15) would extend Medicare coverage to individuals exposed to certain environmental health hazard areas (Libby, Montana); 16) would extend the Rural Community Hospital Demonstration Program by five years and expand the number of states and hospitals eligible to participate in the Demonstration; 17) would eliminate the Medicare Advantage Regional Plan Stabilization Fund; 18) would permit the Secretary to award grants to eligible entities to support “community-based collaborative care networks” that meet certain requirements; and 19) additional reforms.</p> <p>Would require GAO to study the impact on access to care of including oral drugs for the treatment of end-stage renal disease (ESRD) in the case-mix adjusted bundled prospective payment system for Medicare outpatient ESRD dialysis facilities.</p> <p>Would require the Secretary, no later than January 11, 2016, to conduct budget-neutral Medicare value-based purchasing pilot programs for certain: 1) psychiatric hospitals and psychiatric units; 2) long-term care hospitals; 3) rehabilitation hospitals; 4) cancer hospitals exempt from Medicare prospective payment systems; and 5) hospice programs. The Secretary would have the authority to</p>	<p>with a limited exception for grandfathered physician owned hospitals that meet certain requirements; 9) would modify the assumed utilization rate for the practice expense portion of advanced diagnostic imaging services; 10) would adjust the physician practice expense geographic adjustment for 2010; 11) would additional payments to certain subsection (d) hospitals; 12) would impose new conditions of participation in Medicare on community mental health centers; 13) would repeal the Medicare prepayment medical review limitation; 14) would increase funding for the Health Care Fraud and Abuse Control Fund through Fiscal Year 2016; and 15) would require the Secretary to withhold payment for 90 days for initial claims of durable medical equipment furnished by suppliers where there is a significant risk of fraudulent activity.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	expand the duration and scope of the pilot programs, at any point after January 1, 2018, if: 1) the Secretary determines that the expansion would reduce Medicare spending without reducing the quality of care; 2) the CMS Chief Actuary certifies that the expansion would reduce Medicare spending; and 3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits for Medicare beneficiaries.	
Insurance and Health Coverage Reforms		
Individual Mandate	<p>Would require individuals to obtain qualifying health care coverage or be subject to financial penalties. The penalty for individuals who fail to obtain qualifying health insurance would be 1/12 of the following amounts for each month the taxpayer fails to obtain qualifying health care coverage:</p> <p><u>2014</u> The greater of \$95 or 0.5% of the taxpayer's household income</p> <p><u>2015</u> The greater of \$495 or 1% of the taxpayer's household income</p> <p><u>2016 and thereafter</u> The greater of \$750 (indexed to inflation after 2016) or 2% of the taxpayer's household income.</p> <p>The total applicable penalty amounts for a taxable year would be capped at no more than the national average premium for bronze</p>	<p>Would require individuals to obtain qualifying health care coverage or be subject to financial penalties. The penalty for individuals who fail to obtain qualifying health insurance would be 1/12 of the following amounts for each month the taxpayer fails to obtain qualifying health care coverage:</p> <p><u>2014</u> The greater of \$95 or 1% of the excess of the taxpayer's household income for the taxable year over the amount of the federal filing threshold.</p> <p><u>2015</u> The greater of \$325 or 2% of the excess of the taxpayer's household income for the taxable year over the amount of the federal filing threshold.</p> <p><u>2016 and thereafter</u> The greater of \$695 (indexed to inflation after 2016) or 2.5% of the excess of the taxpayer's household income for the taxable year over the amount of the federal filing threshold.</p> <p>Same as Senate bill.</p>

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	<p>level coverage under a qualified health plan offered through Exchanges for individual or family coverage. The applicable penalty amounts would be reduced for individuals under the age of 18.</p> <p>The following individuals would be exempted: 1) incarcerated individuals; 2) nonresident aliens; 3) those with religious objections; 4) individuals for whom the required contribution for coverage for the month exceeds 8% of the individual's household income; 5) taxpayers with income under 100 percent of poverty; 6) members of Indian tribes; 7) those who are not covered for a period of less than three months during the year; and 8) individuals that have obtained a hardship waiver.</p>	<p>Same as Senate bill.</p> <p>Would modify certain income definitions that are used for the purposes of determining premium subsidy eligibility and the individual mandate penalties.</p>
Employer Mandate	<p>Employers with more than 50 full-time employees that fail to offer their full-time employees (and their dependents) the opportunity to enroll in qualified coverage, and have at least one full-time employee enrolled in an Exchange plan and receiving a premium tax credit or cost-sharing reduction, would be required to pay an assessment of \$750 per full-time employee. In the case of employers that meet the criteria above, but have waiting periods for health care coverage, the assessment for each full-time employee would be \$600 for each full-time employee in a waiting period that exceeds 60 days.</p> <p>Employers with more than 50 full-time employees that offer health care coverage, but still have at least one full-time employee receiving a premium tax credit or cost-sharing reduction through the Exchange, would be required to pay an assessment equal to the lesser of \$3,000 for each of the employees receiving the premium</p>	<p>Employers with more than 50 full-time employees that fail to offer their full-time employees (and their dependents) the opportunity to enroll in qualified coverage, and have at least one full-time employee enrolled in an Exchange plan and receiving a premium tax credit or cost-sharing reduction, would be required to pay an assessment equal to \$2,000 multiplied by the number of full-time employees minus 30.</p> <p>Would eliminate the Senate provision imposing assessments on employees in waiting periods.</p> <p>Employers with more than 50 full-time employees that offer health care coverage, but still have at least one full-time employee receiving a premium tax credit or cost-sharing reduction through the Exchange, would be required to pay an assessment equal to the lesser of \$3,000 for each of the employees receiving the premium</p>

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	<p>tax credit or cost sharing reduction, OR \$750 for each of their full-time employees. The dollar amounts listed above would be indexed to the growth in the premium adjustment percentage after 2014.</p> <p>Would require the Secretary of Labor to conduct a study to determine whether employees' wages are reduced as a result of the assessments.</p> <p>Would require large employers to report to the Secretary whether they offer full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan, the length of any applicable waiting period, the lowest cost option in each of the enrollment categories under the plan, and the employer's share of the total allowed costs of benefits provided under the plan. Would require the employer to also report the number and names of full-time employees receiving coverage and to furnish statements to employees about whom information is reported.</p> <p>Would require employers to provide notice to their employees at the time of hiring (or by March 1, 2013 for existing employees) informing them: 1) of the existence of an Exchange; 2) that if the employer plan's share of the total allowed costs of benefits is less than 60% of such costs, that the employee may be eligible for a premium assistance tax credit and cost sharing reduction; and 3) that, if the employee purchases a qualified health plan through the Exchange, the employee will lose the employer contribution (if any).</p>	<p>tax credit or cost sharing reduction, OR \$2,000 multiplied by the number of full-time employees. The dollar amounts listed above would be indexed to the growth in the premium adjustment percentage after 2014.</p> <p>Would specify that full-time equivalents would be treated as full-time employees for the purposes of determining which employers qualify as applicable large employers for a given month.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>Would amend the Internal Revenue Code related to cafeteria plans to provide that plans provided through the Exchange will not be an eligible benefit under an employer-sponsored cafeteria plan, except where certain employers offer a choice of plans to their employees through an Exchange.</p> <p>Would prohibit employers that provide health coverage from limiting eligibility for coverage based on the wages or salaries situated full-time employees.</p> <p>Would require employers with more than 200 employees to automatically enroll new full-time employees in coverage (subject to any waiting period authorized by law) and to continue the enrollment of current employees. Would require adequate notice and opportunity for opt out for an employee who is auto-enrolled.</p> <p>Would allow workers who qualify for an affordability exception to the individual mandate penalty, but do not qualify for tax credits, to use their employer contribution (in the form of a “free choice voucher”) to purchase coverage through an Exchange. The “free choice vouchers” would be excluded from the calculation of a worker’s gross income for federal tax purposes. The vouchers would also be tax deductible for employers.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Insurance Market Reforms	<p>“Immediate Reforms”: Effective for plan years beginning on or after the date that is 6 months after the date of enactment, would enact the following reforms: 1) bans lifetime coverage limits; 2) would permit plans to implement “restricted annual limits” on coverage prior to 2014—the term “restricted annual limits” would be defined by the Secretary; 3) a group health plan or health insurance coverage that is not required to provide essential benefits would be permitted to place annual or lifetime limits on “specific covered benefits” to the extent that such limits are otherwise</p>	<p>Same as Senate bill, with the following modifications: 1) would revise the Senate provision regarding dependent coverage to require plans offering dependent coverage to allow unmarried and married individuals under the age of 26 to remain on their parents’ health insurance; and 2) would extend certain reforms to grandfathered plans.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>permitted under federal and state law; 4) prohibits plans from rescinding coverage except in cases of fraud or misrepresentations; 5) requires plans to cover, without cost-sharing, certain preventative services and immunizations recommended by the U.S. Preventative Services Task Force and certain child preventative services recommended by the Health Resources and Services Administration (HRSA); 6) requires plans offering dependent coverage to allow unmarried individuals until age 26 to remain on their parents' health insurance; 7) requires the Secretary to develop standards for use by health insurers in compiling and providing an accurate summary of benefits and explanation of coverage; 8) would prohibit the plan sponsor of a group health plan (other than a self-insured plan) from limiting eligibility for coverage based on the wages and or salaries of full-time employees; and 9) require insurers to implement an effective process for appeals of coverage determinations and claims.</p> <p>Effective upon enactment, would prohibit pre-existing condition exclusions for children.</p> <p>Effective not later than 90 days after enactment, would establish a \$5 billion federally financed, temporary high-risk pool for certain individuals with pre-existing conditions.</p> <p>Would require plans to provide coverage for certain routine costs associated with participation in certain approved clinical trials conducted in relation to the prevention, detection, or treatment of cancer or other "life-threatening disease or condition."</p> <p>Effective for plan years beginning on or after the date that is 6 months after the date of enactment, would require insurers to provide a report to the Secretary containing the ratio of incurred loss (or incurred claims) plus the loss adjustment expense (or</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>change in contract reserves) to earned premiums. Plans would be required to include in the report the percentage of total premium revenues, after accounting for collections of receipts for risk adjustment and risk corridors and payments of reinsurance, that the plan expends on: 1) reimbursement for clinical services provided to enrollees; 2) activities that improve health care quality; and 3) all other non-claims costs, including an explanation of the nature of such costs, and excluding state taxes and licensing or regulatory fees. The reports would be made available to the public on the HHS website.</p> <p>Beginning no later than January 1, 2011, plans would be required to provide enrollees an annual rebate if they fail to spend a certain percentage of premium revenues on clinical services provided to enrollees and activities that improve health care quality. For health insurance issuers offering coverage in the group market, the threshold would be 85 percent, or a higher percentage as a state may determine by regulation. For health insurance issuers offering coverage in the individual market, the threshold would be 80 percent, or a higher percentage as a state may determine by regulation, except if the Secretary determines the threshold would destabilize the existing individual market in the state.</p> <p>Other Reforms: Effective when coverage becomes available through an Exchange (2014), the legislation would: 1) allow plans in the individual and small group markets to vary premiums based solely on family structure, geography, age (capped at a 3:1 ratio), and tobacco use (limited to a ratio of 1.5:1); 2) apply the premium variation limitations described above to the large group market if the state permits plans to offer large group coverage through the state Exchange; 3) require guaranteed availability and renewal in the individual and group market; 4) prohibit preexisting condition exclusions and other discriminations in the group and individual</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager’s Amendment to H.R. 4872)
	<p>markets based on health status, medical condition, claims experience, medical history, and other factors; 5) require plans in the small group and individual market to provide coverage that includes the essential benefits package determined by the Secretary; 6) require group health plans to ensure that any annual cost-sharing is at or below certain thresholds; 7) require certain plans to offer “child-only” plans; 8) prohibit waiting periods of more than 90 days for group or individual coverage; and 9) prohibit annual coverage limits.</p> <p>Would give existing plans “grandfathered” status. The grandfather clause does not appear to be time-limited.</p> <p>Beginning with plan year 2010, the Secretary, in conjunction with the states, would be required to establish a process for the annual review of “unreasonable” increases in health insurance premiums. The process would require health insurance issuers to justify an “unreasonable” increase in premiums by submitting information to the Secretary, the state, and by posting the information on their public website. The Secretary, in conjunction with the states, would begin monitoring premium increases inside and outside of an Exchange starting with plan years beginning in 2014. Would provide \$250M in grants to states to assist them in reviewing, and if appropriate under state law, approving health insurance premium increases, and in providing certain information and recommendations to the Secretary.</p> <p>Effective January 1, 2016, would allow two or more states to form Health Care Choice Compacts to facilitate the purchase of individual health insurance across state lines. Would require the Secretary to request that the National Association of Insurance Commissioners (NAIC) develop model guidelines for such compacts. Would ensure that such compacts require licensure in</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>each state and maintain authority of the state in which a covered individual resides to protect the individual. Would require the coverage offered by the compacts to meet certain requirements.</p> <p>Would permit insurers in the individual and small group markets to offer a qualified health benefit plan nationwide, which would be subject to only the state benefit mandates applicable in the state where the plan was issued. However, the plans would have to provide coverage for the essential benefits package as determined by the Secretary. States would be allowed to opt-out. Would require nationwide plans to meet certain other requirements.</p> <p>Effective no later than 2 years after enactment, the Secretary, in consultation with experts and stakeholders, would be required to develop reporting requirements for use by health plans, with respect to reimbursement structures that improve health outcomes through the use of care coordination, case management, medical homes, "medication and care compliance" initiatives, wellness programs, activities to prevent hospital readmissions, and activities to improve patient safety and reduce medical errors through adherence to best practices and evidence-based guidelines.</p> <p>Effective no later than July 1, 2010, the Secretary, in consultation with the states, would be required to establish an Internet website for the public to access information about coverage options.</p> <p>Would require the Secretary to accelerate the adoption of uniform standards and operating rules for electronic transactions that occur between providers and health plans that are governed by HIPAA.</p> <p>Would require that standards and requirements adopted by states be applied uniformly to all plans in each relevant market in a state.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>Would define the small group market as the market in which a plan is offered by a small employer that employs 1-100 employees. Would define the large group market as the market in which a plan is offered by an employer that employs more than 100 employees. Until January 1, 2016, would allow states to limit the small group market to employers with 50 employees or less.</p> <p>All individual market plans would be subject to a new temporary risk adjustment mechanism. Reinsurance entities would administer a transitional state-based reinsurance program for the individual market in each state from 2014-2016 that would be funded through contributions from health plans totaling \$25 billion. The Secretary would also be required to establish risk corridors over that same period for plans in the individual and small group markets.</p> <p>States would have the option to merge the pooling and rating requirements for the individual and small group markets.</p> <p>A health insurance issuer would be required to create a single individual market risk pool for all enrollees in an individual plan (except grandfathered plans), including individuals who purchase coverage outside of the Exchange, and a single group market risk pool for all enrollees in a small group health plan (except grandfathered plans), including groups who purchase coverage outside of the Exchange.</p> <p>Beginning in 2017, would allow states to apply for a waiver, applicable for up to 5 years, which would allow the states to waive otherwise applicable requirements relating to qualified health plans, Exchanges, cost-sharing reductions, tax credits, and the individual and employer mandates. Before approving any such waiver, the Secretary would be required to ensure that the state plan would provide coverage at least as comprehensive and affordable, and to</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>at least as many state residents, as the legislation would otherwise provide. In addition, the waiver could not increase the federal deficit. If the waiver is approved, the Secretary would provide to the state the aggregate amount of tax credits and cost-sharing reductions that would have been paid to residents of the state absent the waiver.</p> <p>Would prohibit the Secretary from promulgating any regulations that: 1) create “unreasonable barriers” to care; 2) impede timely access to care; 3) restrict providers’ ability to provide “full disclosure” of all relevant information and treatment option to patients making health care decisions; 4) violate the principles of informed consent and the ethical standards of health care professionals; and 6) limit the availability of health care treatment for the full duration of a patient’s medical needs.</p> <p>Would establish certain coverage requirements for emergency services, pediatric care, and OB/GYN care.</p> <p>Would establish medical reimbursement data centers to develop publicly available fee schedules and other tools that “fairly and accurately” reflect market rates for medical services and geographic differences.</p> <p>Would require the Secretary to prepare an aggregate annual report on self-insured group plans. Would require the Secretary to conduct a study of the large group market, including whether self-insured plans offer less costly coverage, as well as claims denial rates, potential conflicts of interest, and other matters.</p> <p>Would require the GAO to study and report, within one year of the date of enactment, on the rate of denial of coverage and enrollment by health insurance issuers and group health plans.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
Health Insurance Exchange	<p>Each state would be required to establish a health insurance Exchange to facilitate insurance enrollment for individuals and small businesses (through the SHOP Exchange) by January 1, 2014. Would require the Secretary to provide grants to states to assist them in establishing an Exchange.</p> <p>The Exchange would: 1) certify qualified plans; 2) develop a standardized enrollment application; 2) develop a standard format for describing insurance options and marketing; 3) provide call center support; 4) provide customer services; 5) rate of plans based on quality and price; 6) determine enrollment periods; and 7) certain other requirements. The exchanges must be self-sustaining after the first year.</p> <p>Would mandate prescription drug coverage as part of the “essential health benefits package” determined by the Secretary. Would limit out-of-pocket spending to the limits applicable to Health Savings Accounts (currently \$5,950 for individuals and \$11,900 for families). Would prohibit small group plans from adopting deductibles that are greater than \$2,000 for individuals and \$4,000 for families. Would index the limits and deductible amounts to the percentage increase in per capita premiums. Would create four tiers of coverage within an Exchange, with minimum actuarial values. Would also create a catastrophic plan available only to individuals who are under the age of 30.</p> <p>Would permit states to form regional or interstate Exchanges, subject to approval by the Secretary.</p> <p>Would allow states to merge their individual and small group</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>Exchanges.</p> <p>Certain individuals and small employers would be eligible to participate in the Exchange beginning in 2014. Beginning in 2017, states could make a determination as to whether large groups may participate in the Exchange.</p> <p>Would require Exchanges to award grants to “Navigators” to educate the public about qualified health plans, distribute information on enrollment and tax credits, facilitate enrollment, and provide referrals to questions and grievances.</p> <p>Would require that plans offered through the Exchange implement a “quality improvement strategy,” which would provide increased reimbursement or other incentives for certain activities that improve health outcomes and the quality of care.</p> <p>Would require Members of Congress and congressional employees to purchase coverage through a state-based exchange or a health plan created under legislation, rather than using the traditional Federal Employees Health Benefits Plan (FEHBP).</p> <p>If a state fails to establish and operate an Exchange by January 1, 2014, the Secretary would be required to implement and operate an Exchange in the state.</p> <p>Would allow qualified health plans to provide coverage through a qualified direct primary care medical home plan.</p> <p>Would require health plans seeking to participate in an Exchange to submit, and make public, information on claims payment policies, the number of claims denied, and other information.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	Would require the GAO to review and report on the cost and affordability of coverage through the Exchange for small business owners and employees.	Same as Senate bill.
Health Insurance Co-Operatives	Would provide \$6B in federal funding to support the creation of non-profit, member-run Consumer Operated and Oriented Plans (CO-OPs) that serve individuals in one or more states. CO-OPs would compete in the reformed non-group and small group insurance markets. Provides for federal loans for start-up costs and federal grants to meet state solvency requirements. In order to be eligible for federal funds, CO-OPs must be organized as nonprofit member corporations under state law, may not be sponsored by a government entity, and must not be an existing organization that provides insurance as of July 16, 2009. CO-OPs must meet additional requirements, including requirements to: incorporate ethics and conflict of interest standards to protect against insurance industry involvement and interference; ensure that substantially all of its activities consist of the issuance of qualified health benefit plans; provide that its governance must be subject to a majority vote of members; and operate with a strong consumer focus including timeliness, responsiveness and accountability to members. Any profits must be used to lower premiums, improve benefits or for other programs to improve the quality of health care delivered to members. Beginning no later than July 1, 2013, grants and loans would be awarded by the Secretary of HHS. CO-OPs would be required to re-pay the loans within five years and re-pay the grants within 15 years. The CO-OP plans would be required to meet the same insurance requirements that are imposed on other private insurance providers by the state in which CO-OP is located and the insurance requirements required by the federal government. The CO-OPs could not use federal funds to lobby Congress or for marketing.	Same as Senate bill.
State Option for a Basic Health	Would allow states to provide a basic health program option through negotiated contracts with one or more standard	Same as Senate bill.

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
Plan	health plans (as defined) to provide at least an essential benefits package (as described above) to residents of a state whose household incomes are between 133 percent and 200 percent of FPL, and who are not eligible for employer coverage. Would permit states to negotiate a regional compact with other states to include coverage of eligible individuals in all such states in agreements with standard health plans. Would encourage the coordination of the program's administrative functions with the state's Medicaid program. Would permit the plan to encourage care coordination, managed care techniques, and the use of performance measures.	
Subsidies for Individuals and Families	Effective January 1, 2014, would provide sliding scale "premium assistance credits" for certain individuals and families between Medicaid eligibility levels and 400% of the federal poverty level (FPL). Would implement income-based cost-sharing levels and cap total out-of-pocket spending.	<p>Similar to Senate bill. However, the amount of the premium subsidies and the caps on total out-of-pocket spending are more generous than those in the Senate bill.</p> <p>In addition, beginning in 2015, the premium subsidies would be adjusted to reflect the excess of the rate of premium growth for the preceding calendar year over the rate of income growth for the preceding calendar year. Beginning in 2019, the premium subsidies would be adjusted as described above and to reflect the rate of premium growth for the preceding calendar year over the rate of growth in the consumer price index (CPI). However, the CPI adjustment would not apply if the aggregate amount of premium credits for the preceding calendar year exceeds 0.504% of the gross domestic product for the preceding calendar year.</p> <p>Would modify certain income definitions that are used for the purposes of determining premium subsidy eligibility and the individual mandate penalties.</p>
Tax Credits for Small Businesses	Effective January 1, 2010, small employers (those employing less than 25 full-time employees and having average annual wages of less than \$50,000, indexed per CPI after 2013) who purchase health insurance for their employees would be eligible to receive a sliding	Would make no changes to the Senate provision.

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>scale tax credit. Small employers with 10 or fewer full-time workers with an average wage of \$25,000 or less would receive a tax credit equal to 50% of the aggregate amount of non-elective contributions made by the employer on behalf of employees, or 50% of the contributions an employer would have made based on average premiums in 2014 and beyond.</p> <p>The tax credit would be gradually phased out for employers with more than 10 full-time employees or average annual wages above \$25,000. The maximum tax credit for tax-exempt small employers would be 35% rather than 50%.</p> <p>To qualify for a tax credit, an employer must contribute at least 50 percent of the total premium cost of a benchmark premium.</p>	
Administrative Simplifications	<p>No later than January 1, 2012, the Secretary would be required to seek input on: 1) whether application forms for enrollment of health care providers by health plans could be standardized; 2) whether certain standards and operating rules should apply to the health care transactions of automobile insurance, worker's compensation and other programs or persons; 3) whether standardized forms could apply to financial audits required by health plans, federal and state agencies, and other relevant entities; 4) whether there could be greater transparency and consistency of methodologies and processes used to establish claim edits used by health plans; and 5) whether health plans should be required to publish their timeliness of payment rules.</p> <p>No later than January 1, 2011, the Secretary would be required to task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input from stakeholders regarding the crosswalk of ICD-9 and ICD-10 posted on the CMS website, and to make recommendations about appropriate revisions to the crosswalk. The Secretary would be required to make appropriate</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	revisions to the crosswalk and post any revisions on the CMS website.	
Medicaid Prescription Drug Reforms		
Changes to the Average Manufacturer Price Definition and Retail Survey Prices¹	<p><i>Would amend the definition of AMP to state that AMP is the average price paid to the manufacturer for the drug in the United States by: 1) wholesalers for drugs distributed to retail community pharmacies; and 2) retail community pharmacies that purchase drugs directly from the manufacturer.</i></p> <p>Would amend the definition of AMP to <u>exclude</u> from the calculation 1) customary prompt pay discounts extended to wholesalers; 2) bona fide service fees paid by manufacturers to wholesalers <i>or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs); 3) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction; and 4) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business primarily as a wholesaler or a retail community pharmacy.</i></p>	<p>Same as Senate bill.</p> <p>Same as Senate bill. Would also exclude from the AMP calculation any discounts provided by manufacturers under the Medicare Part D coverage gap discount program.</p>

¹ Changes to the current AMP definition have been italicized.

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p><i>Would clarify that, notwithstanding the exclusions, any other discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies must be included in the AMP for a covered outpatient drug.</i></p> <p><i>Would define the term “retail community pharmacy” to mean a traditional independent pharmacy, traditional chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by a state and that dispenses medications to the general public at retail prices. The term would not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.</i></p> <p><i>Would define the term “wholesaler” to mean a drug wholesaler that is licensed as a wholesaler by a state and that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions.</i></p> <p><i>Would change the definition of a “multiple source drug” in the Medicaid statute to state that the term “multiple source drug” means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent, pharmaceutically equivalent, and</i></p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager’s Amendment to H.R. 4872)
	<p><i>bioequivalent, and is sold in the United States during the rebate period. Current law requires only that such drug be sold in the state.</i></p> <p><i>Would strike language from the current multiple source definition which states that “a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.”</i></p> <p><i>Would modify the survey of covered outpatient drug retail prices in current law to apply to “retail community pharmacy.”</i></p> <p><i>Would become effective on the first day of the first calendar quarter that begins 180 days after enactment, without regard to whether or not the Secretary has promulgated final regulations.</i></p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
New AMP Reporting Requirement	<p>Would require manufacturers to report to the Secretary, no later than 30 days after the last day of each month of a rebate period, the total number of units that are used by the manufacturer to calculate the monthly AMP for each covered outpatient drug. Would become effective on the first day of the first calendar quarter that begins 180 days after enactment, without regard to whether or not the Secretary has promulgated final regulations.</p>	<p>Same as Senate bill.</p>
Public Disclosure of AMPs	<p>Current law requires the Secretary “to disclose (through a website accessible to the public) average manufacturer prices” and update the information on at least a quarterly basis. In its July 17, 2007, interim final rule entitled “Medicaid Program; Prescription Drugs,” CMS interpreted this requirement as requiring the agency to report AMPs for brand and generic products. However, CMS is currently enjoined from posting AMP data on a public website under order from the U.S. District Court of the District of Columbia.</p>	<p>Same as Senate bill.</p>

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	<p>The Senate legislation would amend the current law requirement to require the Secretary to “to disclose (through a website accessible to the public) <i>the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug</i>” and update the information (<i>relating to the weighted average of the most recently reported monthly average manufacturer prices</i>) on at least a quarterly basis.</p> <p>It is unclear if the legislation would prevent CMS from releasing brand drug AMPs on a public website.</p> <p>Would become effective on the first day of the first calendar quarter that begins 180 days after enactment, without regard to whether or not the Secretary has promulgated final regulations.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Increase in the Medicaid Rebate for Single Source and Innovator Multiple Source Drugs	<p>Effective January 1, 2010, would increase the Medicaid base rebate for most single-source and innovator multiple source drugs to 23.1% of AMP. For certain clotting factors and drugs approved by the FDA exclusively for pediatric use, the base rebate would be increased to 17.1% of AMP.</p> <p>Would require the Secretary to recapture amounts received by the states that are attributable to the rebate increase, as estimated by the Secretary based on utilization and other data.</p> <p>Would limit the total Medicaid rebate liability for a single source or innovator multiple source drug to no more than 100% of the product's AMP.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Application of the Medicaid	<p>Effective for drugs that are paid for by a state after December 31, 2009, would require manufacturers to calculate the Medicaid rebate</p>	<p>Would require manufacturers to calculate the Medicaid rebate amount for a line extension of a single source drug or an innovator</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager’s Amendment to H.R. 4872)
Additional Rebate to New Formulations of Existing Drugs	<p>amount for a new formulation (such as an extended-release formulation) of an existing single source or innovator multiple source drug based on the greater of: 1) the rebate amount of the new formulation as calculated based solely on the new formulation; or 2) the product of the AMP for each dosage form or strength of the new formulation drug, the highest additional rebate for any strength of the original single source or innovator multiple source drug, and the total number of units of each dosage form and strength of the new formulation paid for under the state Medicaid plan in the rebate period (as reported by the state).</p> <p>The new rebate calculation for new formulations of existing drugs would not apply to new formulations of orphan drugs.</p> <p>Would limit the total Medicaid rebate liability for a single source or innovator multiple source drug to no more than 100% of the product’s AMP.</p>	<p>multiple source drug that is an oral solid dosage form based on the <u>greater of</u>: 1) the rebate amount of the new drug calculated based solely on the new drug; or 2) the product of the AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the highest additional rebate (calculated as a percentage of AMP) for any strength of the original single source or innovator multiple source drug, and the total number of units of each dosage form and strength of the line extension product paid for under the state Medicaid plan in the rebate period (as reported by the state).</p> <p>Would clarify that the term “line extension,” for the purposes of this provision, means a new formulation of the drug, such as an extended release formulation.</p>
Extension of Medicaid Rebates to Medicaid Managed Care Organizations	<p>Would require brand and generic manufacturers to pay rebates to state Medicaid programs for certain covered outpatient drugs dispensed to beneficiaries enrolled in Medicaid managed care organizations. The legislation does not specify an implementation date for the provision.</p> <p>Would exclude from the new rebate requirement covered outpatient drugs that are: 1) dispensed by health maintenance organizations; and 2) subject to 340B discounts.</p> <p>Would require Medicaid MCOs to report to the state, as specified by the Secretary, information on the total number of units of each</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>dosage form, strength, and package size by NDC of each covered outpatient drug dispensed to beneficiaries enrolled in the plan and for which the plan is responsible for coverage of such drug (except for drugs dispensed by a health maintenance organization), and any other data the Secretary determines to be necessary.</p> <p>Would require that capitation rates paid to Medicaid MCOs be based on actual cost experience related to rebates and subject to federal regulations requiring actuarially sound rates.</p>	Same as Senate bill.
Increase in the Medicaid Rebate for Generic Drugs	Effective January 1, 2010, would increase the Medicaid rebate for non-innovator multiple source drugs (i.e. generics) to 13% of AMP.	Same as Senate bill.
Medicaid Pharmacy Reimbursement	<p>Would require the Secretary to calculate a federal upper payment limit that is no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary would also be required to implement a smoothing process for AMPs to ensure that federal upper reimbursement limits do not vary significantly from month to month as a result of rebates, discounts, and other pricing practices. The Secretary would be required to ensure that the smoothing process is similar to the smoothing process used to calculate the Medicare Part B Average Sales Price.</p> <p>Would become effective on the first day of the first calendar quarter that begins 180 days after enactment, without regard to whether or not the Secretary has promulgated final regulations.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicaid Prescription	Effective January 1, 2014, states would be permitted (but not required) to provide coverage for barbiturates, benzodiazepines,	Same as Senate bill.

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
Drug Coverage	and certain smoking cessation agents.	
Medicaid Program Reforms		
Medicaid Eligibility Expansion	<p>From April 1, 2010 through December 31, 2013, states would be given the option to cover certain non-mandatory, non-elderly, non-pregnant individuals who are not eligible for Medicare and whose income does not exceed 133% of poverty.</p> <p>Effective January 1, 2014, would create a new mandatory Medicaid eligibility category for certain non-elderly, non-pregnant individuals that are not eligible for Medicare and whose income does not exceed 133% of poverty.</p> <p>Effective January 1, 2014 to December 31, 2016, would provide a 100% federal matching rate (FMAP) to cover the cost of extending coverage to newly eligible individuals. In 2017, states would receive an FMAP increase of either 34.3% or 30.3% for services provided to newly eligible individuals. In 2018, states would receive an FMAP increase of either 33.3% or 31.3% for services provided to newly eligible individuals. Beginning in 2019 and thereafter, all states would receive an FMAP increase of 32.3% for services provided to newly eligible individuals.</p> <p>Effective January 1, 2014 through September 30, 2019, would provide an FMAP increase of 2.2% to certain states for non-newly eligible individuals.</p> <p>Effective January 1, 2014 to December 31, 2016, would provide an additional FMAP increase of 0.5% to the state with the highest percentage of its population insured during 2008 (Massachusetts).</p> <p>Would provide a 100% federal matching rate to the state of</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Would provide the following FMAP rates to states (other than “expansion” states) to cover the costs of extending coverage to newly eligible individuals: 100% in 2014-2016, 95% in 2017, 94% in 2018, 93% in 2019, and 90% in 2020 and thereafter.</p> <p>Would reduce the state share of the costs of covering non-pregnant childless adults for certain “expansion” states that had previously expanded their Medicaid eligibility criteria.</p> <p>Would strike this provision from the Senate bill.</p> <p>Would strike this provision from the Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>Nebraska on or after January 1, 2017 for amounts expended for newly-eligible individuals.</p> <p>Newly-eligible, non-elderly, non-pregnant individuals would receive coverage that would be at least actuarially equivalent to the essential benefits required by the Secretary in an Exchange. The coverage provided to such individuals would also be specifically required to include prescription drug coverage and mental health services.</p> <p>States would be required to meet certain "maintenance of effort" requirements regarding eligibility levels.</p> <p>Beginning January 1, 2014, states would be required to use modified gross income to determine Medicaid eligibility, except for certain exempted groups (exempted groups would include individuals eligible for Medicaid through another program, the elderly or SSDI program beneficiaries, the medically needy, enrollees in a Medicare Savings Program, and the disabled).</p> <p>Effective January 1, 2014, states would be required to provide premium assistance to any Medicaid beneficiary who is offered employer-sponsored insurance, if it is cost-effective for the state to do so.</p> <p>Effective January 1, 2014, states would have the option to expand Medicaid eligibility to certain non-elderly individuals with income above 133% of poverty. The state would receive federal matching funds, but not the enhanced FMAP rate applicable to newly eligible individuals with incomes at or below 133% of poverty.</p> <p>Effective January 1, 2014, would extend Medicaid coverage to certain individuals below the age of 26 who were formerly in foster</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	care.	
Medicaid Coverage for Preventative Care Services	Would provide increased federal funding for states providing Medicaid coverage and eliminating associated cost sharing for certain recommended preventive services and immunizations. Would permit states to apply for grant funds to provide incentives to Medicaid beneficiaries who participate in certain programs to improve their health status.	Same as Senate bill.
Medicaid Medical Home	<p>Beginning January 1, 2011, states would have the option of enrolling Medicaid beneficiaries with certain chronic conditions into a "health home." The Secretary would be required to establish qualification standards for health home providers. Health home services would include: 1) comprehensive care management; 2) care coordination and health promotion; 3) comprehensive transitional care; 4) patient and family support; 5) referral to community and social support services; and 6) the use of health IT to link services, as feasible and appropriate.</p> <p>The federal government would provide "planning grants" to assist states in developing a health home state plan amendment. In addition, during the first eight fiscal quarters in which the health home state plan amendment is in effect, the federal matching rate for such services would be 90% rather than the standard matching rate.</p> <p>No later than January 1, 2014, the Secretary would be required to survey states with health home programs and report to Congress on the nature, extent, and use of the home health option.</p> <p>Would require the Secretary to contract with an independent entity to evaluate and assess state health home programs, and submit the evaluation and report to Congress by no later than January 1, 2017.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicaid Accountable	Effective January 1, 2012 to December 31, 2016, would permit states to apply to participate in a demonstration project that would	Same as Senate bill.

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Care Organizations	allow pediatric medical providers who meet certain criteria to be recognized as ACOs. Participating providers would be required to meet minimum annual savings targets and would share in any savings they achieve in excess of the target. The demonstration would also include quality of care guidelines.	
Medicaid Bundled Payment Demonstration Projects	<p>Would establish a Medicaid bundled payment demonstration project in up to 8 states, from January 1, 2012 to December 31, 2016, to test the provision of integrated care for a Medicaid beneficiary with respect to an episode of care that includes a hospitalization and for concurrent physician services provided during a hospitalization.</p> <p>Would establish a "Medicaid Global Payment System" demonstration project in up to five states from 2010 to 2012, in which participating states would be permitted to adjust payments for large, safety net hospital systems or networks from fee-for-service to a "global capitated payment model." The CMS Innovation Center would be required to evaluate the demonstration project.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Medicaid Non-Payment for Certain Health Care Acquired Conditions	Would require the Secretary to identify current state practices to prohibit payment for health care acquired conditions and develop Medicaid regulations that incorporate the practices deemed appropriate by the Secretary. Effective July 1, 2011, the regulations would prohibit federal Medicaid matching payments for services related to health care acquired conditions specified by the Secretary.	Same as Senate bill.
Other Medicaid Reforms	Effective no later than January 1, 2014, would permit individuals to apply for and enroll in Medicaid, CHIP, or an Exchange through a state-run website. Would require state Medicaid and CHIP programs and the Exchanges to coordinate enrollment procedures.	<p>Same as Senate bill.</p> <p>Would require state Medicaid programs to reimburse certain physicians at 100% of the Medicare payment rate for certain primary care services furnished in 2013 and 2014. Eligible</p>

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	<p>Effective January 1, 2014, would permit hospitals to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories.</p> <p>Would require the Secretary to identify and publish a “core set” of health care quality measures for Medicaid eligible adults in the same manner as the Secretary currently identifies and publishes a core set of child health quality measures.</p> <p>Would permit states the option of extending limited Medicaid coverage to certain individuals. The coverage would be limited to family planning services and supplies, and related medical diagnosis and treatment services.</p> <p>Would amend the Medicaid statute to clarify that the term “medical assistance” encompasses both payment for services provided and the services themselves.</p> <p>Includes provisions which are intended to reduce and prevent fraud, waste and abuse in the Medicaid program.</p> <p>Would clarify the topics to be reviewed by the Medicaid and CHIP Payment and Access Commission (MACPAC), including federal Medicaid and CHIP regulations, additional reports of state-specific data, and an assessment of adult services in Medicaid. Would authorize \$11 million to fund the MACPAC in FY2010.</p>	<p>physicians would include physicians with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine. Would provide 100% federal funding for the added costs incurred by states.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Includes the provisions in the Senate bill and additional provisions and funding to prevent fraud, waste and abuse.</p> <p>Same as Senate bill.</p>

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	<p>Would require states to provide Medicaid coverage for certain counseling and pharmacotherapy furnished to pregnant women for cessation of tobacco use. Would prohibit cost-sharing for these services.</p> <p>Would provide incentives to states to offer home and community-based services a long-term care alternative to nursing homes.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Increases federal Medicaid funding for the territories.</p>
Medicare Part D Reforms		
Reduction of the Medicare Part D Donut Hole in 2010	<p>Would increase the Medicare Part D annual initial coverage limit by \$500 effective January 1, 2010. Would require the Secretary to adjust payments to Part D plans in order to compensate them for the costs associated with the increased annual coverage limit. The Secretary would also be required to retroactively reimburse affected beneficiaries if the provision is not implemented before January 1, 2010. The increase would only apply with respect to the plan year beginning on January 1, 2010 and would not affect the initial coverage limit for plan years beginning on or after January 1, 2011.</p>	<p>Would repeal the Senate provision and replace it with a \$250 rebate to Part D enrollees that reach the donut hole in 2010.</p>
Elimination of the Medicare Part D Donut Hole	<p>No such provision.</p>	<p>Would close the Part D coverage gap for generic and brand drugs by 2020.</p>
Reductions in Medicare Part D Beneficiary Cost Sharing After 2010	<p>No such provision.</p>	<p>Would provide for coverage of and establish coinsurance requirements for generic drugs in the coverage gap. The coinsurance percentage would be set at 93% for 2011, would decrease by 7% for each year between 2012 and 2019, and would be set at 25% for 2020 and thereafter. Would provide for actuarially equivalent coinsurance amounts.</p> <p>Would provide for coverage of and establish coinsurance</p>

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		<p>requirements for the negotiated price of brand drugs in the coverage gap. The coinsurance would be equal to the difference between the applicable gap percentage and the discount percentage. Would provide for actuarially equivalent coinsurance amounts. The applicable gap percentage would be 97.5% for 2013 and 2014, 95% for 2015 and 2016, 90% for 2017, 85% for 2018, 80% for 2019, and 75% for 2020 and each subsequent year. These provisions coupled with the coverage gap discount program would result in beneficiary cost sharing of 25% for brand drugs in 2020 and thereafter.</p> <p>Would clarify that incurred costs (beneficiary true out-of-pocket costs) shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of this provision.</p>
Medicare Part D Out-of-Pocket Threshold	No such provision.	<p>Would makes changes to current law regarding annual increases in the Part D out-of-pocket threshold. Would reduce the otherwise applicable increase in the threshold by 0.25% in 2014 and 2015. For 2016 through 2019, the increase percentage would be based on the lesser of: 1) the annual percentage increase in the consumer price index for urban consumers (CPI-U) plus 2%; or 2) the annual percentage increase in average per capita Part D expenditures. For 2020, the increase would be calculated as though this provision had not been enacted.</p>
Discounts for Certain Medicare Part D Drugs in the Donut Hole	Effective July 1, 2010, in order to have their drugs covered under Medicare, manufacturers would be required to provide a 50% discount off the negotiated price for brand-name drugs covered on Part D plan formularies when beneficiaries enter the coverage gap. The negotiated price would not include any dispensing fee for the drug. Beneficiaries are eligible provided they do not qualify for low-income subsidies, do not have qualified retiree prescription	<p>Would make changes to the Senate provision, including the following: Effective January 1, 2011, in order to have their drugs covered under Medicare, manufacturers would be required to provide a 50% discount off the negotiated price for brand-name drugs covered on Part D plan formularies when beneficiaries enter the coverage gap. The negotiated price would not include any dispensing fee for the drug. Beneficiaries are eligible provided they</p>

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	<p>drug coverage, or do not pay higher Medicare premiums under Part B or Part D. Effective beginning with plan year 2010, for beneficiaries with supplemental benefits that provide some savings during the donut hole, the discount would be applied to the cost remaining after the supplemental benefits have been applied.</p> <p>An applicable drug would be a Part D covered drug approved under a new drug application under section 505(b) of the Federal Food, Drug and Cosmetic Act or a biologic product licensed under section 351 of the Public Health Service Act (other than a product licensed under section 351(k), as added by the legislation and related to the licensure of biological products as biosimilar or interchangeable). The drug must also be on the plan formulary (if the plan has a formulary), available for coverage (if the plan does not have a formulary), or be provided through an exception or appeal.</p> <p>Manufacturers would be required to calculate the discount amount based on the “negotiated price” for qualifying drugs. The term “negotiated price” would be defined as the price that: 1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider negotiate as the amount such network entity will receive, in total, for a particular drug, excluding dispensing fees; and 2) is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale. The language specifically states that the negotiated price would not include any dispensing fee for the applicable drug.</p> <p>The Secretary would be required to establish a model agreement by not later than April 1, 2010, in consultation with manufacturers and allow for comment on the model agreement.</p>	<p>do not qualify for low-income subsidies, do not have qualified retiree prescription drug coverage, Effective beginning with plan year 2011, for beneficiaries with supplemental benefits that provide some savings during the donut hole, the discount would be applied to the cost remaining after the supplemental benefits have been applied.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>The Secretary would be required to establish a model agreement by not later than 180 days after enactment, in consultation with manufacturers and allow for comment on the model agreement.</p>

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	<p>For 2010 and 2011, a manufacturer would be required to enter into a discount agreement with the Secretary by no later than May 1, 2010. The initial agreement would be effective for an initial period of not less than 18 months and would be automatically renewed for a period of not less than 1 year unless terminated by the Secretary or manufacturer. For 2012 and subsequent plan years, the manufacturer would be required to enter into an agreement not later than January 30 of the previous year.</p> <p>The Secretary would be authorized to terminate an agreement for a knowing and willful violation of the requirements of the agreement or for other good cause. The termination would be effective not earlier than 30 days after notice is provided to the manufacturer. The Secretary would be required to provide, upon request, a hearing concerning such a termination. The hearing would be required to take place prior to the effective date of the termination with sufficient time for the effective date to be repealed if the Secretary determines it would be appropriate to do so.</p> <p>Manufacturers would be allowed to terminate an agreement for any reason. If the manufacturer terminates the agreement before January 30 of the plan year, the termination would be effective as of the day after the end of the plan year. If the termination occurs on or after January 30 of the plan year, the termination would be effective as of the day after the end of the succeeding plan year.</p> <p>The manufacturer discount would count toward a beneficiary's annual out of pocket threshold effective on or after July 1, 2010.</p> <p>The discount would be provided to the beneficiary at the point of sale, or as soon as practicable after the point-of-sale, during the period between July 1, 2010 and ending on December 31, 2011.</p>	<p>For 2011, a manufacturer would be required to enter into a discount agreement with the Secretary by no later than 30 days after the establishment of a model agreement. The initial agreement would be effective for an initial period of not less than 18 months and would be automatically renewed for a period of not less than 1 year unless terminated by the Secretary or manufacturer. For 2012 and subsequent plan years, the manufacturer would be required to enter into an agreement not later than January 30 of the previous year.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>The discount would be provided to the beneficiary at the point of sale, or as soon as practicable after the point-of-sale, during the period between January 1, 2011 and ending on December 31, 2011.</p>

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	<p>The legislation would require the Secretary to establish procedures to ensure that pharmacies and mail order services are reimbursed, within 14 days for electronic claims and 30 days for other claims after the dispensing of the drug, for the difference between the negotiated price and the discounted price.</p> <p>The Secretary would be required to provide a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries and the third party contracted to administer the drug discount program.</p> <p>The Secretary would be required to contract with one or more third parties to administer the drug discount program. Under the contract, the third party would be required to: 1) receive and transmit information between the Secretary, manufacturers and other entities as determined by the Secretary; 2) receive, distribute or facilitate the distribution of manufacturer funds to individuals or entities as appropriate; 3) provide information to manufacturers necessary for them to fulfill their obligations under the program; and 4) permit manufacturers to audit data and information used by the third party to determine discounts. The Secretary would be required to establish performance requirements for the third party and safeguards to protect the independence and integrity of the activities carried out by the third party.</p> <p>The Secretary would be prohibited from receiving or distributing funds of a manufacturer under the program, except with respect to drugs dispensed between July 1, 2010 and December 31, 2010 if the Secretary determines the exception is necessary to begin implementation and provide timely access to discounted prices.</p> <p>Each manufacturer with an agreement in effect would be subject to</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill</p> <p>.</p> <p>The Secretary would be prohibited from receiving or distributing funds of a manufacturer under the program, except with respect to drugs dispensed between January 1, 2011 and December 31, 2011 if the Secretary determines the exception is necessary to begin implementation and provide timely access to discounted prices.</p> <p>Same as Senate bill.</p>

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	<p>periodic audit by the Secretary. Manufacturers would be required to collect and have available appropriate data as determined by the Secretary to ensure that they can demonstrate compliance with the discount program.</p> <p>Manufacturers that fail to provide discounts in accordance with an agreement would be subject to civil money penalties assessed by the Secretary. Applicable fines would equal the amount the manufacturer would have otherwise had to pay under the agreement plus an additional penalty of 25 percent of the discount amount. The Secretary would be authorized to prohibit a manufacturer's products from being covered under Part D in cases of repeated non-compliance.</p> <p>The Secretary would have the authority to permit a drug to be covered under Part D even if the manufacturer does not have a discount agreement in effect if: 1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries; or 2) the Secretary determines that from July 1, 2010 to December 31, 2010, there were "extenuating circumstances."</p> <p>Would permit manufacturers to provide Part D discounts for applicable drugs furnished to applicable beneficiaries under the Medicare prescription drug discount program by: 1) excluding the provision of such discounts from prosecution under the federal anti-kickback statute; and 2) amending the definition of best price under Medicaid to exclude any discounts provided by manufacturers under the Medicare coverage gap discount program.</p>	<p>Same as Senate bill.</p> <p>The Secretary would have the authority to permit a drug to be covered under Part D even if the manufacturer does not have a discount agreement in effect if: 1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries; or 2) the Secretary determines that from January 1, 2011 to December 31, 2011 there were "extenuating circumstances."</p> <p>Would permit manufacturers to provide Part D discounts for applicable drugs furnished to applicable beneficiaries under the Medicare prescription drug discount program by: 1) excluding the provision of such discounts from prosecution under the federal anti-kickback statute; and 2) amending the definition of best price and AMP under Medicaid to exclude any discounts provided by manufacturers under the Medicare coverage gap discount program.</p> <p>Would amend existing law to permit Part D plans to apply tiered copayments as long as the tiered copayments are consistent with provisions (added by the bill) regarding coverage for brand and</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
		<p>generic drugs in the coverage gap.</p> <p>Would amend the definition of a qualified retiree prescription drug plan to require the plan sponsor to attest that the actuarial value of the prescription drug coverage is at least equal to the actuarial value of standard prescription drug coverage not taking into account the value of any discount or coverage provided during the coverage gap.</p>
Part D Protected Classes	<p>Would remove the criteria in current law that would have been used by the Secretary to identify protected classes of drugs. Would give the Secretary authority to identify classes of clinical concern as defined by the Secretary. Part D plan sponsors would be required to include all drugs in these classes in their formularies. The Secretary would be permitted to establish certain exceptions. Would codify the current six classes of clinical concern as they are currently specified through sub-regulatory guidance until the Secretary issues a final rule regarding classes of clinical concern to be protected on plan formularies. The provision would be effective beginning with plan year 2011.</p>	<p>Same as Senate bill.</p>
Utilization Management for Long Term Care Part D Enrollees	<p>Effective January 1, 2012, would require Part D plans to utilize specific, uniform dispensing techniques, such as weekly, daily or automated dose dispensing, when dispensing covered part D drugs to beneficiaries who reside in long-term care facilities in order to "reduce waste associated with 30-day fills."</p>	<p>Same as Senate bill.</p>
Part D Low-Income Reforms	<p>Effective not earlier than January 1, 2012, Part D cost sharing for full benefit, dual eligibles receiving services under a home and community based services waiver or services provided through enrollment in a Medicaid managed care organization, would be equal to the cost sharing for those who otherwise receive institutional care.</p> <p>Effective January 1, 2011, the Secretary would be required to exclude Medicare Advantage rebates and bonus payments when</p>	<p>Same as Senate bill.</p> <p>Effective January 1, 2011, would require that the Medicare Part D low income benchmark premium be determined before application</p>

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	<p>calculating the MA-PD regional low income subsidy benchmark premium amount.</p> <p>Effective January 1, 2011, would permit Part D plans to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of the premium is <i>de minimus</i>. If the premium is waived, the Secretary would be prohibited from reassigning subsidy eligible individuals to other plans based on the fact that the monthly premium was greater than the low-income benchmark premium amount.</p> <p>Effective January 1, 2011, would authorize the Secretary to auto-enroll subsidy eligible individuals who fail to enroll in a Part D plan in a Part D plan that has waived the monthly beneficiary premium.</p> <p>Effective January 1, 2011, would require the Secretary to provide LIS beneficiaries reassigned to another Part D plan with information on the formulary differences between the former plan and the new plan with respect to the individual's drug regimen, as well as a description of the individual's rights with respect to coverage determinations, exceptions, reconsiderations, appeals and grievances.</p> <p>Effective January 1, 2011, would delay LIS redetermination for a period of one year for a surviving spouse when the other spouse dies during the effective period for a determination or redetermination.</p>	<p>of the monthly beneficiary rebate and, for qualifying plans, before application of the increase provided as a result of quality provisions. Would make additional modifications to beneficiary rebates.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Part D Medication	Effective for plan years beginning on or after the date that is two years after enactment, would require Medicare Part D plan sponsors	Same as Senate bill.

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
Therapy Management	<p>to offer to targeted beneficiaries at least the following medication therapy management services: 1) an annual comprehensive medication review furnished person-to-person (or using telehealth) by a licensed pharmacist or other qualified provider; and 2) follow up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment.</p> <p>The annual comprehensive medication review must include: 1) a review of the individual's medications which may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and 2) a written or printed summary of the result of the review based on a standardized format to be developed by the Secretary, in consultation with stakeholders.</p> <p>Part D plan sponsors would be required to have a process in place to assess, at least quarterly, the medication use of at-risk individuals. Part D plan sponsors would also be required to automatically enroll targeted beneficiaries into medication therapy management programs. However, beneficiaries would be permitted to opt out of the program.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Other Medicare Part D Reforms	<p>Effective January 1, 2011, would allow drugs provided to patients by AIDS Drug Assistance Programs (ADAPs) or the Indian Health Service to count toward the annual out-of-pocket threshold.</p> <p>Would require the Secretary to develop and maintain a complaint tracking system capable of tracking beneficiary complaints through resolution and producing reports.</p> <p>Effective January 1, 2012, would require the development of a uniform exceptions and appeals process for plans.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager's Amendment to H.R. 4872)
	<p>Would require the OIG to report annually on the inclusion of drugs commonly used by dual eligibles on plan formularies. The first report would be due July 1, 2011.</p> <p>Would require the OIG to conduct a study and report to Congress by October 1, 2011 on the drug prices paid by Part D plans compared to those negotiated by state Medicaid plans for the top 200 drugs determined by volume and expenditures. The prices would include all rebates and discounts Medicaid and Part D plans receive. The OIG would assess the financial impact of any price discrepancies on the federal government and beneficiaries. The OIG would be given the authority to collect all necessary pricing information. The report would not disclose information that is deemed proprietary or likely to negatively impact a Medicaid program or Part D plan's ability to negotiate drug prices.</p> <p>Effective in 2011, would reduce the Part D premium subsidy amount for beneficiaries whose income is at or above the Part B income-relating thresholds (\$85,000 for individuals and \$170,000 per couple).</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Comparative Effectiveness Research		
Comparative Effectiveness Research	<p>Would create a non-profit institute to set a research agenda and provide for the conduct of comparative effectiveness research. The Institute would not be an agency or establishment of the federal government.</p> <p>The institute would be governed by a multi-stakeholder Board of Governors. The Board would have 19 members, including the Director of AHRQ and the Director of NIH (or their respective designees). The other 17 members would be appointed by the Comptroller General within 6 months after enactment. The Board</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>would include 3 members representing each of the following groups: patients and health care consumers; private payers; and pharmaceutical, device, and diagnostic manufacturers. The Board would include 5 members representing physicians and providers. The Board would include 2 members representing the federal government or the states, and one member representing quality improvement or independent health service researchers.</p> <p>When identifying national priorities for comparative clinical effectiveness research and establishing a research project agenda, the Institute would consider the need for a systematic review of existing research before providing for the conduct of new research. In setting priorities, the Institute would consider: disease incidence and prevalence in the U.S.; evidence gaps, in terms of clinical outcomes; practice variations, and health disparities in terms of delivery and outcomes of care; the potential for new evidence to improve patient health and quality of care; expenditures associated with a health care treatment strategy or health condition; patient needs, outcomes, and preferences, including quality of life; and relevance to assisting patients and clinicians in making informed health decisions.</p> <p>The legislation would allow the Institute to request and obtain data from federal, state, and private entities, including data from clinical databases and registries, if the request is granted by the entity.</p> <p>Requires the Institute to establish a process for peer-review of primary research, to allow evidence to be reviewed to assess scientific integrity and adherence to the methodological standards adopted. The Institute would make public a list of names of individuals contributing to any peer-review process during the preceding year or years and include the list in the Institute's annual reports.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>The Institute would be permitted to appoint permanent or ad hoc expert advisory panels to assist in identifying research priorities and agendas. The Institute would be required to convene advisory panels for clinical trials and research on rare diseases.</p> <p>Would allow the Institute to enter into contracts with federal agencies and appropriate academic research, private sector research or study-conducting entities to manage and conduct research. However, preference would be given to AHRQ and NIH, but only if the research conducted or managed under the contract is authorized by the governing statutes of AHRQ or NIH.</p> <p>Would require the AHRQ Office of Communication and Knowledge Transfer, in consultation with the NIH, to broadly disseminate the research findings that are published by the Institute and other government-funded research relevant to comparative clinical effectiveness research.</p> <p>The bill also includes the following provisions impacting the use and content of the Institute's research: 1) the research should take into account the potential for differences in effectiveness as used with various subpopulations and differences in treatment modalities; 2) the Secretary would be allowed to use the evidence and findings from the Institute's research to make a Medicare coverage determination if such use is through an "iterative and transparent" process which includes public comment and considers the effect on subpopulations; 3) nothing in the provision could be construed as superseding or modifying the Medicare coverage of items and services that the Secretary determines are reasonable and necessary; 4) the Secretary would not be authorized to deny Medicare coverage of items or services based solely on comparative effectiveness research; 5) the Secretary would be</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>prohibited from using evidence and findings from the Institute's research in determining coverage, reimbursement, or incentive programs under Medicare in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill; 6) the Secretary would be permitted to use evidence and findings from the Institute's research in determining coverage, reimbursement, or incentive programs under Medicare based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual's life due to the individual's age, disability, or terminal illness; 7) the Secretary would be prohibited from using the evidence and findings from the Institute's research in determining coverage, reimbursement, or incentive programs under Medicare in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability; and 8) the Institute would be prohibited from developing or employing a dollars-per-quality adjusted life year as a threshold to establish what type of health care is cost effective or recommended—the Secretary would be prohibited from utilizing such an adjusted life year (or similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under Medicare.</p> <p>The Institute would be funded through multiple sources including mandatory appropriations, the Medicare trust funds, and a fee on health plans.</p>	<p>Same as Senate bill.</p>
340B Drug Discount Program		
340B Drug Discount	Effective January 1, 2010, would expand the 340B drug discount program to include certain: 1) children's hospitals excluded from	Effective January 1, 2010, would expand the 340B drug discount program to include certain: 1) children's hospitals excluded from

Issue	Senate Bill (Based on H.R. 3590 as Approved by the Senate)	Budget Reconciliation Bill (Based on the Senate Bill as Amended in the House by H.R. 4872 and the Manager’s Amendment to H.R. 4872)
Program— Expansion of Eligible Entities	the Medicare prospective payment system; 2) free-standing cancer hospitals excluded from the Medicare prospective payment system; 3) critical access hospitals; 4) rural referral centers; and 5) sole community hospitals.	the Medicare prospective payment system; 2) free-standing cancer hospitals excluded from the Medicare prospective payment system; 3) critical access hospitals; 4) rural referral centers; and 5) sole community hospitals. Would amend the definition of a 340B “covered outpatient drug” to exclude outpatient orphan drugs sold to the new 340B covered entities listed above.
340B Drug Discount Program— Expansion to Inpatient Drugs	Effective January 1, 2010, would expand the 340B program to include inpatient drugs sold to 340B hospitals.	Would strike this provision from the Senate bill.
340B Drug Discount Program— Medicaid Credit	Effective January 1, 2010, would require certain 340B hospitals to provide a credit to state Medicaid programs based on the estimated annual cost of inpatient 340B covered drugs provided to Medicaid beneficiaries.	Would strike this provision from the Senate bill.
340B Drug Discount Program— Group Purchasing Arrangements	Effective January 1, 2010, would: 1) specifically permit 340B hospitals to obtain 340B inpatient covered drugs through group purchasing organizations (GPO); 2) authorize the Secretary to create certain exceptions to current law, which generally prohibits 340B hospitals from obtaining 340B covered outpatient drugs through a GPO; and 3) require the Secretary to ensure that 340B hospitals have “multiple options” for purchasing covered drugs for inpatients.	Would strike this provision from the Senate bill.
340B Drug Discount Program— Program Integrity	Effective January 1, 2010, would require manufacturers to offer each 340B covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.	The program integrity provisions are the same as those in the Senate bill except all references to the term “covered drugs” would be changed to “covered outpatient drugs.”

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	<p>Would require manufacturers to furnish the Secretary with quarterly reports of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug.</p> <p>Would require the Secretary to develop a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities. The "system" would include: 1) developing and publishing through an appropriate policy or regulatory issuance, "precisely defined" standards and methodology for the calculation of ceiling prices; 2) regularly comparing the ceiling prices calculated by the Secretary with the quarterly pricing data reported to the Secretary by manufacturers; 3) performing "spot checks" of sales transaction by covered entities; and 4) inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, corrective action "as is appropriate" in response to such price discrepancies.</p> <p>Would require the establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including: 1) providing the Secretary with an explanation of why and how the refunds will be calculated, and to whom the refunds will be issued; 2) oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs.</p> <p>Would provide covered entities with access to an Internet website that would provide applicable ceiling prices for covered drugs as calculated by the Secretary. Would require that access to such a</p>	

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	<p>site be limited to covered entities and adequately assure the security and protection of privileged pricing data from unauthorized “re-disclosure.”</p> <p>Would require the development of a mechanism by which: 1) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; 2) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.</p> <p>Would require selective auditing of manufacturers and wholesalers to ensure the integrity of the 340B drug discount program.</p> <p>Would impose civil monetary penalties of up to \$5,000 for each instance that a manufacturer knowingly and intentionally charges a covered entity a price that exceeds the maximum applicable price.</p> <p>Would require the Secretary to implement the following “improvements in compliance” for covered entities to prevent diversions and duplicate discounts: 1) the development of procedures to enable and require covered entities to update, at least annually, certain information on the 340B website; 2) the development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the 340B website; and 3) the development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to state Medicaid agencies in a manner that avoids duplicate discounts; and 4) the establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the</p>	

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	<p>ordering, purchasing, and delivery of 340B covered drugs, including the processing of chargebacks for 340B covered drugs.</p> <p>Would require the Secretary to impose the following sanctions: 1) where a covered entity knowingly and intentionally violates rules prohibiting diversion of 340B drugs, the covered entity would be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable, such interest would be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve Board for the time period for which the covered entity is liable; 2) where the Secretary determines the violation was systematic and egregious as well as knowing and intentional, the Secretary would be required to remove the covered entity from the 340B program and disqualify the entity from re-entering the program for a “reasonable period of time” as determined by the Secretary; and 3) referring matters to appropriate federal authorities within the FDA, the OIG, or other federal agencies for consideration of appropriate action under other federal statutes.</p> <p>Would require the Secretary to promulgate regulations within 180 days of enactment to implement an administrative dispute resolution process.</p> <p>Would authorize necessary appropriations for the Secretary to carry out the new requirements.</p>	
340B Drug Discount Program—GAO Report	<p>Within 18 months of enactment, the Comptroller General would be required to make recommendations to Congress on: 1) whether individuals served by 340B covered entities are receiving “optimal health care services”; 2) whether the 340B program should be expanded “since it is anticipated that the 47M individuals who are uninsured as of the date of enactment of this Act will have health</p>	Same as Senate bill.

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	care coverage once this Act is implemented”; 3) whether mandatory sales of certain products by the 340B program could hinder patients access to those therapies through any provider; and 4) whether income from the 340B program is being used by the covered entities under the program to further the program objectives.	
Follow-On Biologic Approval Pathway		
Follow-On Biologics— Approval Pathway	<p>Would create an approval pathway for follow-on biologics. Manufacturers seeking approval for follow-on biologics would be required to demonstrate that the biological product is biosimilar to a reference product based upon data derived from: 1) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; 2) animal studies (including assessment of toxicity) ; and 3) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used for which licensure is sought for the product.</p> <p>Manufacturers’ applications would be required to demonstrate that: 1) the biological product and reference product utilize the same mechanism of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product; 2) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product; 3) the route of administration, the dosage form, and the strength of the biological product are the same as</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	<p>those of the reference product; and 4) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent. The Secretary would have the discretion to determine that one of the elements described above is unnecessary for a submitted application. The follow-on biologic application would also have to include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent.</p> <p>The follow-on biological application may also include: 1) information demonstrating that the biological product is interchangeable; and 2) any additional information in support of the application. The Secretary would be required to license the follow-on biologic product if: 1) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product is biosimilar to the reference product or meets interchangeability standards; and 2) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application.</p> <p>A biological product, in an application submitted to the Secretary, could not be evaluated against more than one reference product. The Secretary would have the same authority to impose risk evaluation and mitigation strategies on follow-on biologics as the Secretary currently has to impose such strategies on innovator biologic products. The Secretary would not be permitted to license a follow-on biologic product that contains certain select agents and toxins unless the Secretary determines that there would be no increased risk to the security or health of the public.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Follow-On Biologics— Interchangeabil-	Would require the Secretary to determine that a follow-on biologic is interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a	Same as Senate bill.

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ity	supplement to the application) is sufficient to show that: 1) the product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and 2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product with such alternation or switch.	
Follow-On Biologics— Innovator Exclusivity	The legislation states that the Secretary's approval of a biosimilar biological product could not take effect until 12 years after the date on which the reference biological product was first licensed. The period of exclusivity would be extended an additional six months (subject to certain exceptions) if the manufacturer of the reference biological satisfactorily completes pediatric studies requested by the Secretary. In addition, manufacturers would not be permitted to submit an application for a biosimilar biological product until four years after the date on which the reference biological product was first licensed.	Same as Senate bill.
Follow-On Biologics— Biosimilar Exclusivity	Would provide the first interchangeable follow-on biologic version of a reference product approved by the FDA with a certain period of exclusivity. The Secretary would not be permitted to determine that a second or subsequent biologic product is interchangeable for any conditions of use until the earlier of: 1) one year after the first commercial marketing of the first interchangeable biological product to be approved as interchangeable for the reference product; 2) 18 months after a final court decision on all patents in suit in an action against the applicant that submitted the application for the first approved interchangeable biosimilar biological product or the dismissal with or without prejudice of an action against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; 3) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted the application has been sued and such	Same as Senate bill.

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	litigation is still ongoing within such 42-month period; or 4) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted the application is not sued.	
Follow-On Biologics— Guidance Documents	Would permit the Secretary to issue guidance documents with respect to the licensure of biosimilar products. The Secretary would be required to establish a process for public input.	Same as Senate bill.
Follow-On Biologics— Treatment of Biological Products Previously Approved as Drugs	Would allow manufacturers to submit an application under Section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) if: 1) the biological product is in a product class for which a biological product in the class is the subject of an application approved under Section 505 of the FFDCA no later than the date of enactment; and 2) the application has been submitted to the Secretary on a date no later than 10 years after the date of enactment. However, the manufacturer would be prohibited from submitting an application under section 505 of the FFDCA if there is a biological product approved under section 351 of the Public Health Service Act (PHSA) that could be a reference product with respect to the application. All biological products approved under Section 505 of the FFDCA would be deemed to be licensed biological products under Section 351 of the PHSA effective 10 years after the date of enactment.	Same as Senate bill.
Follow-On Biologics— Other Provisions	Would: 1) generally provide six additional months of exclusivity for pediatric studies on certain biological products; 2) subject biosimilar products to user fees; 3) encourage the resolution of patent disputes between reference biologic drug sponsors and follow-on biologic drug sponsors by requiring the parties to exchange certain information; 4) require the IOM to review and assess the extent of pediatric studies of certain biological products; and 4) establish the exclusivity period for reference biological	Same as Senate bill.

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	<p>orphan products.</p> <p>Would require that savings to the federal government generated by the approval pathway be used to reduce the federal deficit.</p>	<p>Same as Senate bill.</p>
Miscellaneous Drug-Related Provisions		
Program to Facilitate Shared Decision-Making	<p>Would require the Secretary to encourage the development and use of patient decision aids by patients and providers “as soon as practicable after the date of enactment.” The decision aids would be intended to help patients decide with their health care providers what treatments are best for them based on their beliefs and preferences, treatment options, scientific evidence, and other circumstances. The Secretary would be required to contract with a qualified consensus-based entity to develop and identify standards to evaluate and endorse patient assistance aids based on synthesized evidence and input from a broad range of experts and key stakeholders. The Secretary would also be required to award grants or contracts for development of decision aids concerning the “safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options.” Grants would also support the evaluation of materials to ensure they are “balanced and evidence-based” and to educate providers on the use of decision aids.</p>	<p>Same as Senate bill.</p>
Drug Facts Box	<p>Would require the Secretary to submit a report to Congress no later than one year after the date of enactment on whether the addition of “standardized, quantitative summaries of the benefits and risks of drugs” in a standardized format (such as a table or drug facts box) to the promotion labeling or print advertising of drugs would “improve health care decision making by clinicians and patients</p>	<p>Same as Senate bill.</p>

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	<p>and consumers.” The Secretary would be required to consult with manufacturers, clinicians, patients, and other stakeholders.</p> <p>If the Secretary determines that the addition of a drug facts box or other alternative format would improve health care decision making, the Secretary would be required to promulgate regulations to implement such a requirement no later than three years after date on which the report was submitted to Congress.</p>	Same as Senate bill.
Amendment to the Federal Food, Drug, and Cosmetic Act (FDCA) Regarding Labeling Changes	Would amend section 505(j) of the FDCA, related to labeling revisions and the approval of drugs pursuant to an abbreviated new drug application.	Same as Senate bill.
Medication Management Grant Program	Effective May 1, 2010, would provide grants to certain eligible entities to implement medication management services in the treatment of chronic disease. Medication management services would be targeted at individuals who take 4 or more medications, take any “high-risk” medicines, have 2 or more chronic conditions, or have undergone a transition of care, or other factors (as determined by the Secretary) that are likely to create a high risk of medication-related problems. The Secretary would be required to submit an evaluation of the program that assesses, in part, “the impact of patient cost sharing requirements on medication adherence and recommendations for modifications.”	Same as Senate bill.
Pharmaceutical Benefit Manager (PBM) Transparency Requirements	Would require PBMs to share certain information with the Secretary and with plans the PBMs contract with through Medicare Part D or the Exchanges. Plans would only be given access to information on their own PBM contracts. The information would be considered confidential and must be protected by the Secretary and the plans. The PBM would be required to confidentially disclose	Same as Senate bill.

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	<p>information on: 1) the percent of all prescriptions that are provided through retail pharmacies compared to mail order pharmacies, and the generic dispensing and substitution rates in each location; 2) the aggregate amount and types of rebates, discounts and price concessions that the PBM negotiates on behalf of the plan and the aggregate amount of these that are passed through to the plan sponsor; 3) the average aggregate difference between the amount the plan pays the PBM and the amount that the PBM pays the retail and mail order pharmacy. Entities not in compliance with the requirements would be subject to civil monetary penalties. The legislation does not specify an implementation date.</p>	
Vaccine Provisions Not Directly Related to Medicare or Medicaid	<p>Would authorize states to purchase adult vaccines under CDC contracts.</p> <p>Would require the Secretary to establish 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.”</p> <p>Would reauthorize the CDC’s Immunization Grant Program.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Diabetes Related Public Health Service Programs	<p>Would require the CDC to establish a national diabetes prevention program targeted at adults.</p> <p>Would require HHS to prepare a biennial national (and to the extent possible state) diabetes report card regarding health outcomes and preventative practices with respect to diabetes.</p> <p>Would require an IOM study on the appropriate level of medical diabetes education for physicians and other health care providers.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Congenital Heart Disease Surveillance	<p>Would establish a National Congenital Heart Disease Surveillance System and authorize expanded research into congenital heart disease.</p>	<p>Same as Senate bill.</p>

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System		
Breast Cancer Research and Education Campaigns	Would require CDC to conduct public and health care provider education campaigns regarding breast cancer in young women, and would require CDC to conduct research on breast cancer in young women.	Same as Senate bill..
Cures Acceleration Network	<p>Would require NIH to develop a “Cures Acceleration Network” and to award competitive grants, contracts to eligible entities to accelerate the development of “high need cures” (defined as drugs, biologics or devices that are a priority for the diagnosis, prevention or treatment of diseases or conditions which the commercial market is unlikely to develop).</p> <p>Entities eligible for funding would be public or private entities, including private or public research institutions, institutions of higher education, medical centers, biotechnology or pharmaceutical companies, disease or patient advocacy organizations or academic research institutions.</p> <p>Would limit awards in the first fiscal year to \$15 million per project and would allow entities to apply for additional funds not to exceed \$15 million in a subsequent fiscal year. Would authorize \$500 million in funding for FY 2010, and such sums as may be necessary in subsequent fiscal years.</p>	<p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>
Hospital Pricing Transparency	Would require hospitals to publicly list standard charges for items and services provided by the hospital, including for diagnosis-related groups established under Medicare.	Same as Senate bill.
Health Care-Related Tax Provisions		
Pharmaceutical Manufacturing Company Fee	Effective in 2010, would impose an annual fee on manufacturers and importers of single source and innovator multiple source drugs (i.e. brand drugs). The aggregate annual fee for the industry would	Effective in 2011, would impose an annual fee on manufacturers and importers of single source and innovator multiple source drugs (i.e. brand drugs) which would be apportioned based on each

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	<p>be \$2.3 billion, which would be apportioned based on each entity's sales to certain public programs (excluding orphan drug sales).</p> <p>The fee would be due on a date determined by the Secretary, but no later than September 30th.</p> <p>The Secretary of the Treasury would establish individual assessments by determining the relative market share for each covered entity. A covered entity's relative market share would be the entity's total covered domestic sales from all specified government programs as a percentage of the total covered domestic sales from all specified government programs for all covered entities.</p> <p>In determining each covered entity's relative market share, covered domestic sales will be taken into account as follows: 0 percent of sales up to \$5 million; ten percent of sales over \$5 million and up to \$125 million; 40 percent of sales over \$125 million and up to \$225 million; 75 percent of sales over \$225 million and up to \$400 million; and 100 percent of sales over \$400 million. The fee assessed is determined by the covered entity's market share in the preceding calendar year.</p> <p>The pharmaceutical manufacturer fees assessed under the legislation would not be deductible for U.S. income tax purposes.</p> <p>Would require the Secretary of the VA to review and report to Congress on what effect the fees assessed on pharmaceutical manufacturers, device manufacturers, and health insurance providers have on the cost of medical care provided to veterans and</p>	<p>entity's sales to certain public programs.</p> <p>The annual aggregate fee would be \$2.5 billion in 2011, \$2.8 billion in 2012 and 2013, \$3 billion in 2014 through 2016, \$4 billion in 2017, \$4.1 billion in 2018, and \$2.8 billion in 2019 and thereafter.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p> <p>Same as Senate bill.</p>

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	veterans' access to medical devices and branded drugs.	If more than one person is liable for payment of the fee with respect to a single covered entity, all such persons would be jointly and severally liable for payment of the fee.
Tax Credit to Encourage Development of New Therapies	Would provide a temporary tax credit to encourage investments in new therapies to prevent, diagnose, and treat acute and chronic diseases. The tax credit would be limited to businesses with 250 or fewer employees. The amount of the credit would be equal to 50% of investments in "qualified therapeutic discovery projects" in 2009 and 2010. A total of \$1 billion would be allocated for the program over the two-year period.	Same as Senate bill.
Tax-Free Account Distributions for Drugs	Effective for expenses incurred after December 31, 2010, would limit excludable expense reimbursement for a medicine or drug from an HSA, MSA, or as FSA, to a prescribed drug or insulin.	Same as Senate bill.
Limitation on Flexible Savings Account Contributions	Would limit salary reduction contributions to health FSAs to \$2,500 per year beginning in 2011. In 2012 and thereafter, the limit would be indexed to a cost-of-living adjustment.	Would limit salary reduction contributions to health FSAs to \$2,500 per year beginning in 2013. In 2014 and thereafter, the limit would be indexed to a cost-of-living adjustment.
Elimination of the Employer Exclusion for Part D Subsidies	Effective in 2011, would eliminate the exclusion from gross income for the subsidy for employers who maintain prescription drug plans for their Medicare Part D eligible retirees.	Effective in 2013, would eliminate the exclusion from gross income for the subsidy for employers who maintain prescription drug plans for their Medicare Part D eligible retirees.
Penalty Increases for the Use of Health Savings Account Funds for Non-Qualified Health	<p>Would increase the additional tax for Health Savings Account (HSA) withdrawals prior to age 65 that are not used for qualified medical expenses from 10% to 20% beginning in 2011.</p> <p>Would increase the additional tax for Archer MSA withdrawals that are not used for qualified medical expenses from 15% to 20%</p>	Same as Senate bill.

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Expenses	beginning in 2011.	
Modification of the Itemized Deduction for Medical Expenses	Would increase the threshold for the deduction from 7.5% of adjusted gross income to 10% of adjusted gross income beginning in 2013. Individuals age 65 and older (and their spouses) would be exempt from the threshold increase until 2017.	Same as Senate bill.
Medical Device Manufacturer Fee	<p>Would impose an annual \$2 billion dollar aggregate fee, beginning in 2011, on covered entities engaged in the business of manufacturing or importing medical devices offered for sale in the U.S. The annual fee would increase to \$3 billion after 2017.</p> <p>The aggregate fee would be apportioned among the covered entities each year based on each entity's relative share of gross receipts from medical device sales taken into account for the prior calendar year. The fee would be due each calendar year on a date to be determined by the Secretary, but in no event later than September 30th.</p> <p>A "covered entity" is defined as any manufacturer or importer with gross receipts from medical device sales. For purposes of the provision, a covered entity would include all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRS Code of 1986 or subsection (m) or (o) of section 414 of such Code. The otherwise applicable exclusion of foreign corporations under those rules is disregarded for these purposes.</p> <p>Each covered entity would be required to file an annual report of its gross receipts from medical device sales for the preceding calendar year (for purposes of allowing the Treasury Department to determine each entity's market share). Requirements for filing a return and paying the fee are not set forth in the legislation and would be prescribed by the IRS.</p>	<p>Would repeal all of the device manufacturer fee provisions in the Senate bill.</p> <p>Effective for sales after December 31, 2012, would impose a 2.3% tax on the sale of any taxable medical device by the manufacturer, producer, or importer.</p> <p>The term "taxable device" would include devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans with certain exceptions.</p> <p>The term "taxable device" would not apply to: 1) eyeglasses; 2) contact lenses; 3) hearing aids; and 4) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.</p> <p>Would make certain conforming changes to the tax code.</p>

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	<p>Covered entities that fail to file the required annual report on gross receipts from medical device sales would be subject to penalties of \$10,000 plus the lesser of: 1) an amount equal to \$1,000 multiplied by the number of days during which such failure to report continues; or 2) the amount of the fee imposed by the legislation “for which such report was required.”</p> <p>A covered entity’s individual assessment for each calendar year is the total fee multiplied by the ratio of: 1) the covered entity’s gross receipts from medical device sales taken into account during the preceding calendar year to 2) the aggregate gross receipts from medical device sales of all covered entities taken into account during such preceding calendar year.</p> <p>Sales taken into account for this purpose include zero percent of a covered entity’s gross receipts from medical device sales for the preceding calendar year up to \$5 million; 50 percent of a covered entity’s gross receipts from medical device sales for the preceding calendar year over \$5 million and up to \$25 million; and 100 percent of a covered entity’s gross receipts from medical device sales for the preceding calendar year over \$25 million.</p> <p>The calculation would exclude from the calculation sales of: 1) Class I medical devices and 2) Class II medical devices primarily sold to consumers at retail for not more than \$100 per unit.</p> <p>For purposes of procedure and administration under the rules of subtitle F of the IRS Code, any fee assessed under this provision is treated as an excise tax with respect to which only civil actions for refund under subtitle F apply. The Secretary may readjust covered entities’ shares of the fee for any calendar year for which the statute of limitations remains open.</p>	

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	<p>The fees would be treated as nondeductible taxes under section 275 of the Code for U.S. income tax purposes.</p> <p>Would require the Secretary of the VA to review and report to Congress on what effect the fees assessed on pharmaceutical manufacturers, device manufacturers, and health insurance providers have on the cost of medical care provided to veterans and veterans' access to medical devices and branded drugs.</p>	
Health Insurance Provider Fee	<p>Effective in 2011, would impose an annual fee on the health insurance sector, allocated by market share based on a formula set forth in the legislation. The aggregate industry fee would be \$2 billion in 2011, \$4 billion in 2012, \$7 billion in 2013, \$9 billion in 2014, 2015, and 2016, and \$10 billion in 2017 and thereafter.</p> <p>Would exempt from the annual fee certain nonprofit entities which meet certain requirements, including requirements for medical loss ratios. Would exempt certain insurance, including insurance for long-term care or Medicare supplemental health insurance, from the annual fee.</p> <p>Would require the Secretary of the VA to review and report to Congress on what effect the fees assessed on pharmaceutical manufacturers, device manufacturers, and health insurance providers have on the cost of medical care provided to veterans and</p>	<p>Effective in 2014, would impose an annual fee on the health insurance sector, allocated by market share based on a formula set forth in the legislation. The aggregate industry fee would be \$8 billion in 2014, \$11.3 billion in 2015 and 2016, \$13.9 billion in 2017, and \$14.3 billion in 2018. The annual fee in 2019 and thereafter would be increased by the rate of premium growth for the preceding calendar year.</p> <p>In the case of tax-exempt insurance providers, would provide that only 50 percent of the net premiums that relate to their tax-exempt status are taken into account in calculating the applicable fee.</p> <p>Would provide exemptions for voluntary employee benefit associations (VEBAs) and nonprofit providers more than 80 percent of whose revenues are received from government programs that target low income, elderly, or disabled populations under Medicaid, Medicare, and CHIP.</p> <p>Would require covered entities to pay an "accuracy-related penalty" if they understate their net insurance premiums.</p> <p>Same as Senate bill.</p>

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Non-Profit Hospital Requirement	Effective for taxable years beginning after the date of enactment, would establish new requirements, including a periodic community needs assessment, applicable to nonprofit hospitals. Applicable hospitals that fail to complete the required community needs assessment would be subject to a \$50,000 tax.	Same as Senate bill.
"High-Cost" Insurance Excise Tax	<p>Would levy an excise tax of 40 percent on insurance companies and insurance administrators for applicable employer-sponsored coverage that is above \$8,500 in value for single coverage and \$23,000 in value for family coverage. These threshold amounts would take effect in 2013 and would be indexed to the increase in the CPI-U plus one percent in subsequent years.</p> <p>The applicable thresholds would be increased for retired individuals over 55 and for plans that cover employees engaged in certain high-risk professions.</p>	<p>Would levy an excise tax of 40 percent on insurance companies and insurance administrators for applicable employer-sponsored coverage that is above \$10,200 in value for single coverage and \$27,500 in value for family coverage (subject to adjustment for unexpected increases in medical costs prior to the effective date). These threshold amounts would take effect in 2018 and would be indexed to the increase in the CPI-U in subsequent years.</p> <p>The applicable thresholds would be increased for retired individuals over 55 and for plans that cover employees engaged in certain high-risk professions.</p> <p>Would exclude dental and vision plans from the tax.</p> <p>Would permit an employer to reduce the cost of the coverage when applying the tax if the employer's age and gender demographics are not representative of the age and gender characteristics of a national risk pool.</p>
Medicare Hospital Insurance Tax	Effective in 2013, would increase the Medicare hospital insurance tax rate (commonly referred to as the Medicare payroll tax) by 0.9 percentage points for individuals earning over \$200,000 per year (\$250,000 for married couples filing jointly).	<p>Same as Senate bill.</p> <p>Would also impose a 3.8% surtax on investment income for individuals with adjusted gross income of \$200,000 per year</p>

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Increasing Transparency in Employer Reporting of Health Benefits Value	Effective in 2011, would require employers to disclose the value of the benefit provided by the employer for each employee's health insurance coverage on the employee's annual Form W-2. If employees receive multiple plans (i.e. vision, dental), employers will report the aggregate amount.	(\$250,000 for married couples filing jointly). Same as Senate bill.
Tax on Insurance Executive Compensation	Would limit the deductibility of executive compensation under Section 162(m) of the IR Code for insurance providers if at least 25 percent of the insurance provider's gross premium income from health business is derived from health insurance plans that meet the minimum essential coverage requirements in the legislation. In such cases, the deduction would be limited to \$500,000 for the taxable year.	Same as Senate bill.
833 Deduction for Blue Cross Blue Shield Plans	Effective in 2010, would require that non-profit BCBS organizations have a medical loss ratio of 85 percent or higher in order to take advantage of the tax benefits provided to them under IR Code Section 833.	Same as Senate bill.
Tax on Indoor Tanning Services	Would impose a 10 percent tax on certain indoor tanning services performed on or after July 1, 2010. The tax would be paid by the individual receiving the service.	Same as Senate bill.