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Summary Side-by-Side Comparison of House and Senate Health Care Reform Legislation

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Significant Provisions in Division A – Affordable Health Care Choices

House Tri-Committee bill (H.R. 3200)	Senate HELP Committee bill
Health Insurance Market Reforms	**Health Insurance Market Reforms**
• Provides that on or after 1/01/2013, a health benefits plan shall not be a 'qualified health benefits plan' (QHBP) unless it meets the requirements established by the bill relating to affordable coverage, essential benefits, and consumer protections. • Provides a grandfather for current employment-based health plans in existence as of 12/31/2012, with a 5-year grace period beginning on 1/01/2013 for such plans to meet the same requirements that apply to QHBPs. Only individual plans in existence as of 12/31/2012 are fully grandfathered; generally limits new enrollment in individual health plans on or after that date. • Requires all individual and employment-based plans to meet certain standards, including: (1) prohibition of pre-existing condition exclusions; (2) guaranteed issue and guaranteed renewal of coverage; and (3) limits age rating to a ratio of 2 to 1, and allows variation based only on geographic area and family enrollment. • Requires QHBPs to provide coverage that meets minimum benefit standards for an 'essential benefit package' that covers services recommended by the 'Health Benefits Advisory Committee' established by the bill and adopted by the Secretary of Health and Human Services (HHS Secretary). • Minimum standards include: (1) providing payment for the items and services in accordance with generally accepted standards of medical or other appropriate clinical or professional practice; (2) limiting cost-sharing for such covered health care items and services; (3) not imposing any annual or lifetime limit on the coverage of covered health care items and services; (4) complying with section 115(a) (relating to network adequacy); and (5) providing coverage that is equivalent, as certified by Office of the Actuary of the Centers for Medicare & Medicaid	• Amends the Public Health Service Act ("PHSA") to reform the individual and group markets for health insurance in all 50 states (adds new secs. 2701-2711 of the PHSA, as described below. • Provides that there is no requirement that an individual terminate coverage in a plan in which the individual was enrolled prior to date of enactment. With respect to both group and individual plans, family members can continue to enroll in health plans operating prior to enactment. The insurance market reforms in the bill will not apply to any individual or plan in which enrollment began prior to enactment. Collective bargaining agreements ratified prior to enactment and self-insured group health plans are also exempt. However, the reforms will apply if significant changes are made to the existing plan (under regulations to be established by HHS). • Provides that premium rates may vary based only on family composition, community rating area, the actuarial value of the benefits package, and age rating by a factor of not more than two to one, and may not vary by health-related factors, gender, class of business, or claims experience. • Requires guaranteed issue and guaranteed renewability of coverage at the option of the plan sponsor or individuals. • Requires health insurers to publically report the percentage of total premium revenue expended on clinical services, quality and all other non-claims costs as determined by the HHS Secretary. • Prohibits health status underwriting and the imposition of pre-existing condition exclusions. • Prohibits discrimination based on health status, medical conditions (including mental illness), claims experience, prior receipt of health care, medical history, genetic information, evidence of insurability, or disability. • Requires all insurance plans to implement a reimbursement structure that

Services, to the average prevailing employer-sponsored coverage. • Establishes a Health Benefits Advisory Committee (HBAC) that will make recommendations to the HHS Secretary for health benefits standards and periodic updates to such standards that take into account innovation in health care and how such standards could reduce health disparities. • Establishes the Health Choices Administration (HCA) as an independent executive branch agency, headed by the Health Choices Commissioner (HCC), who is appointed by the President. The HCC's duties include establishing qualified plan standards, operating the Health Insurance Exchange, administering of affordability credits, and additional functions set forth in the bill.	incorporates incentives for high quality health care (as defined by the HHS Secretary). • Covers preventive health services and prohibits other than minimal cost-sharing for certain preventive services endorsed by the U.S. Preventive Services Task Force, for immunizations recommended by the Centers for Disease Control, and child preventive services recommended by the Health Resources and Services Administration. • Permits coverage of dependents on parents' policies until age 26. • Prohibits lifetime and annual limits on the dollar value of benefits. • Prohibits limits on eligibility based on wages or salaries of employees.
National Health Insurance Exchange	**State Gateways**
• Establishes a National Health Insurance Exchange (Exchange) within the HCA under the direction of the HCC to give individuals and employers access to a variety of health insurance coverage options, including a public health insurance option. • The HCC will establish standards for, obtain bids from, and negotiate and enter into contracts with QHBP offering entities for the offering of health benefit plans through the Exchange.	• Each State will have an American Health Benefit Gateway (Gateway), established either by the State or by the HHS Secretary, administered through a governmental agency or non-profit entity established by the State. • The Gateways will facilitate voluntary purchase of health insurance coverage and related insurance products at an affordable price by qualified individuals and qualified employer groups.
National Public Insurance Option	**Community Health Insurance Option**
• Requires the HHS Secretary to develop a new national public health insurance option to be offered through the Exchange beginning 1/01/2013. The public option must operate on a level playing field with private plans (i.e., must offer basic, enhanced and premium plans and meet the same insurance market reforms, consumer protections, etc). • The HHS Secretary will establish geographically-adjusted provider payment rates for the public option. The underlying bill provides that for the first three years (2013-2015), rates are based on Medicare rates, with Medicare participating providers receiving an additional 5 percent. However, the en bloc Ross (D-AR) amendment adopted during the House Energy & Commerce Committee markup strikes the language relating to the use of Medicare rates and provides instead that the HHS Secretary will negotiate payment rates. The HHS Secretary is provided authority to develop conditions for provider participation in the public option. Providers must be licensed in the State in which they do business.	• Requires the HHS Secretary to establish a public health insurance option known as the community health insurance option (CHIO), offered through State Gateways, that must operate on a level playing field with private plans by complying with the bill's health plan requirements and covering certain minimum benefits. • The HHS Secretary will negotiate rates for provider reimbursement, which shall not be higher than the average of all Gateway reimbursement rates. There are no requirements that health care providers participate in the CHIO or that individuals join the plan. Each State will establish a State Advisory Council to provide recommendations to the Secretary on the policies and procedures of the CHIO.
Individual Mandate and Related Provisions	**Individual Mandate and Related Provisions**
• Requires all individuals to maintain 'acceptable health care coverage' (defined as coverage under a qualified health plan (e.g., grandfathered plans, Medicare, Medicaid, TRICARE, Veterans Administration coverage) and other coverage approved by the Treasury Secretary in coordination with the HCC).	• Requires all individuals to obtain health insurance coverage. Exemptions will be made for individuals for whom affordable health care coverage is not available or for those for whom purchasing coverage creates an exceptional financial hardship. Individuals deemed to lack availability to "affordable coverage", Indians, individuals living in states where

• Individuals who do not maintain acceptable heath care coverage for themselves and qualifying children are subject to an additional tax equal to the lesser of: (1) 2.5% of the excess of the taxpayer's modified AGI over the threshold amount of income required for filing a return for that taxpayer under section 6012(a)(1); or (2) the 'applicable national average premium,' (i.e., the average premium (as determined by the HHS Secretary, in coordination with the HCC) for self-only coverage under a basic plan offered in the Exchange for the calendar year in which the taxable year begins. This tax is in addition to both regular income tax and the alternative minimum tax. • Creates "affordability premium credits" and "affordability cost-sharing credits" for people with incomes above 133% and up to 400% of the federal poverty level ("FPL"). Affordability premium credits are applied against the cost of premiums for the Exchange plan in which the individual is enrolled, and affordability cost sharing credits reduce annual out-of-pocket spending for co-payments, deductibles, etc. The credits are phased out on a sliding scale designed to limit premium spending to 1.5 percent of income for people at 133% of FPL, increasing to 12% of income for individuals with incomes up to 400% of FPL. • In general, employees who are offered employer coverage are ineligible for affordability credits, but beginning in year 2014, employees whose coverage under the employer-provided plan meets an affordability test (i.e., premiums for employer coverage is more than 12% of their income) are eligible to obtain health coverage and income-based affordability credits through the National Health Insurance Exchange. (Note: The underlying bill provided for 11% of income, but the affordability test was increased to 12% of income by the en bloc amendment offered by Rep. Ross (D-AR) during the Energy and Commerce Committee markup.)	Gateways are not yet established, and individuals without coverage for fewer than 90 days operating are exempt from the mandate and penalty. • Coverage is determined to be unaffordable if the premium paid by the individual is greater than 12.5% of the individual's adjusted gross income. The Secretary shall establish an affordability standard and procedures for updating this standard linked to the Consumer Price Index for urban consumers. • "Qualifying coverage" coverage includes any coverage under which an individual is enrolled on the date of enactment and, after that date, coverage the meets the criteria for minimum qualifying coverage to satisfy personal responsibility standards, and coverage which meets grandfather standards. Qualifying coverage includes coverage under Medicare, Medicaid, CHIP, TRICARE, Veteran's Health, the Federal Employees Health Benefit Plan, the Indian Health Service medical program, State health benefit high risk pools, and others meeting the conditions for minimum qualifying coverage. • Enforces the individual mandate through a fine rather than a tax. Provides that the minimum penalty will be no more than $750 per year. • Low- and moderate-income Americans who enroll in plans through the Gateways will be eligible for premium credits on sliding scale. Gateways will administer the credits, which are provided on a sliding scale up to 400% of FPL ($88,080 for a family of 4), with those at lower end receiving more. To account for regional premium variations, credits will be based on a reference premium calculated on the average premiums of the three lowest cost qualified plans offered in each area. The subsidies would be tied to the average of the three lowest premium bids submitted by insurers in each area of the country for each tier of coverage (the "reference bid"). For people with income between 150 and 200% of the FPL, the subsidies would apply to that reference bid for the highest-tier plans; for people with income between 200 and 300% of the FPL, the subsidies would apply to that reference bid for the middle-tier plans; and for people with income between 300 and 400% of the FPL, the subsidies would apply to that reference bid for the lowest-tier plans.
Employer Requirement and Related Provisions	**Employer Requirement and Related Provisions**
• Creates a requirement for employers to offer health coverage for their employees and make minimum contributions of 72.5% of the premium of the lowest cost plan offered by the employer for individual coverage and 65% of the premium for family coverage. • Beginning 1/01/2014, if an employee who meets the affordability test described above declines the employer's offer of coverage and obtains coverage in an Exchange-participating health benefits plan, the employer must contribute to the Exchange with respect to each such employee. The contribution is generally 8% of the average wages paid by the employer during the period of enrollment. In the case of small employers (i.e., with annual payroll of $400,000 or less in the preceding	• Employers with more than 25 employees are required to make a payment with respect to each employee not offered qualifying coverage or if the employer is not paying 60% of monthly premiums. • Employers with 25 or fewer employees are excluded. • Employers are required to pay $750 for each full-time employee not offered coverage or for whom the employer pays less than 60% of monthly premium. A pro rata amount of $375 will apply for part-time employees. The amount of the contribution is subject to annual adjustment by the HHS Secretary beginning in 2013. • Beginning in 2010, employers with 50 or fewer full-time workers who pay 60% or more of their employees' health insurance premiums and had an

year), the contribution percentage for employees who decline employer coverage and enter the Exchange is as follows: Up to $250,000 0 percent $250,000 - $300,000 2 percent $300,000 - $350,000 4 percent $350,000 - $400,000 6 percent • Provides that employers who elect not to comply with the health coverage participation requirements will be subject to the payroll tax in the amount of 8% of the wages that an employer pays to its employees. • Employers who elect to provide health care coverage, but fail to meet the minimum requirements are subject to an excise tax of $100 per day for each employee to whom the failure applies (with 30 days provide to cure the noncompliance before the excise tax is imposed). • Small employers (with an annual payroll that does not exceed $250,000) are exempt from the tax. The 8% payroll tax is phased in for employers with annual payroll from $250,000-$400,000 as in the table above. • Provides for a tax credit for certain small employers (employers with no more than 25 qualified employees employed during the employer's taxable year, and whose average annual employee compensation does not exceed $400,000). The amount of the tax credit is 50% of the amount paid for employee health coverage. The full amount of the credit is available only to employers with no more than 10 qualified employees and whose average annual employee compensation does not exceed $20,000. The credit is phased out based on average compensation of employees and on employer size. It is not allowed to employees with aggregate compensation over $80,000.	average wage of less than $50,000 for full-time employees will be permitted to receive subsidies for providing health care coverage. • Subsidy amounts for small employers are based on the type of employee coverage, size of the employer, and the proportion of time the employer paid employee health insurance expenses. Credits are available for up to 3 consecutive years. Certain self-employed individuals who do not receive credits for purchasing coverage through the Gateway are eligible.

Additional Tax Provisions in House Tri-Committee Bill, H.R. 3200 (no provisions in Senate HELP bill)
• Imposes a surtax on high-income individuals. For joint returns, the surtax rate is 1% of the taxpayer's modified adjusted gross income from $350,000-$500,000; 1.5% of modified adjusted gross income above $500,000-$1 million; and 5.4% of modified adjusted gross income in excess of $1 million. Modified adjusted gross income is the taxpayer's adjusted gross income reduced by the deduction allowed for investment interest expense. For married individuals filing separate returns, the dollar amounts are 50% of the above amounts. For single individuals, heads of households and trusts and estates, the dollar amounts are 80% of the above amounts. The surtax applies to tax years beginning after 12/31/2010, and the dollar amounts are indexed for inflation for taxable years beginning after 12/31/2011. • Delays the effective date of worldwide interest allocation rules for nine years, until taxable years beginning after 12/31/2019. • Limits tax treaty benefits with respect to U.S. withholding tax imposed on deductible related-party payments. The amount of U.S. withholding tax imposed on deductible related-party payments may not be reduced under any U.S. income tax treaty unless such withholding tax would have been reduced under a U.S. income tax treaty if the payment were made directly to the foreign parent corporation of the payee. A payment is a deductible related-party payment if it is made directly or indirectly by any entity to any other entity, it is allowable as a deduction for U.S. tax purposes, and both entities are members of the same foreign controlled group of entities. • Codifies the economic substance doctrine and imposes a 20% penalty on understatements attributable to transactions lacking economic substance (penalty is increased to 40% for transactions in which the relevant facts affecting the tax treatment of the transaction are not adequately disclosed). • Provides that with respect to medicines, the definition of medical expense for purposes of HRAs, Health FSAs, HSAs, and Archer MSAs is conformed to the definition for purposes of the itemized deduction for medical expenses. Thus, the cost of over-the-counter medicines may not be reimbursed with excludible income through a Health FSA, HRA, or HSA. Effective for expenses incurred after 12/31/2009.

Significant Provisions in Division B – Medicare and Medicaid Reforms

(House Bill Only, Senate HELP Bill Does Not Include Medicare and Medicaid Provisions)

Reforms Affecting Medicare Part A (Hospitals)

- Freezes market basket updates for the 2nd, 3rd and 4th quarters for skilled nursing facilities (SNFs) and inpatient rehabilitation facilities.
- Incorporates productivity adjustments in the market basket updates for inpatient acute hospitals, SNFs, long-term care hospitals, inpatient rehabilitation facilities, psychiatric hospitals, and hospice care.
- Requires the HHS Secretary, not later than 1/01/2016, to submit a report to Congress on Medicare DSH taking into account the impact of the health care reforms under Division A in reducing the uninsured and making recommendations to reduce DSH payments based on the amount of decrease in the national rate of the uninsured, which would take effect on 1/01/2017.

Reforms Affecting Medicare Part B (Providers)

- Changes payment rates for physicians' services to replace the 21% reduction in rates scheduled for 1/01/2010 under the "sustainable growth rate" formula with an inflation-based update. Updates physician payment rates by the Medicare Economic Index in 2010. The new formula, effective 1/01/2011, will rebase the update adjustment factor based on actual expenditures for physician services in 2009.
- Encourages physicians to form Accountable Care Organizations by providing such organizations with targets and update factors on 1/01/2012.
- Incorporates a productivity adjustment to the market basket update for outpatient hospital services beginning 1/1/2010.
- Incorporates productivity adjustments in market basket updates for ambulance services and ambulatory surgical centers on 1/1/2010, and for durable medical equipment not subject to competitive bidding effect on 7/01/2012.

Reforms Affecting Medicare Parts A and B

- Beginning in FY 2012, adjusts payments for inpatient hospitals, critical access hospitals and certain cancer hospitals based on the dollar value of each hospital's percentage of potentially preventable Medicare readmissions for 3 conditions with risk adjusted readmission measures endorsed by the National Quality Forum. Directs the HHS Secretary to expand the policy to additional conditions in future years and authorizes the Secretary to modify the adjustment based on a hospital's readmission performance compared to a national ranking of hospitals.
- Creates an interim readmissions policy for post-acute providers beginning in FY 2012, and directs the Secretary to develop risk adjusted readmission rates for post-acute providers and implement a readmissions payment system for those providers similar to the hospital system on or after FY 2015.
- Directs the HHS Secretary to submit a plan to Congress within 3 years after enactment on how to implement post-acute bundled payments (services furnished by SNFs, inpatient rehabilitation facilities, long-term care hospitals, hospital-based outpatient rehabilitation facilities and home health agencies). Converts the existing Acute Care Episode demonstration project to a pilot program and expands it to include bundling of payments for hospitals and post-acute care providers, effective 1/1/2011; requires a study and demonstration for bundling of payments for outpatient services.
- Freezes the market basket update for home health agencies for 2010.
- Accelerates the regulatory adjustment for home health case mix changes scheduled for 2011 to 2010; directs the HHS Secretary to rebase the home health prospective payment system amount for 2011, taking specific factors into account.
- Incorporates productivity improvements into the market basket for home health care services beginning in 2010.
- Prohibits physician ownership in new hospitals as of 1/1/2009; grandfathers ownership structures of physician-owned hospitals existing prior to 1/1/2009, but generally prohibits them from expanding facilities (i.e., prohibits increases in operating rooms, procedure rooms and beds in existence as of 1/1/2009).

Medicare Advantage Reforms

- Phases in changes to Medicare Advantage (MA) payments by adjusting blended benchmarks to fee-for-service levels over 3 years, reaching 100% of fee-for-service payment rates in 2013.
- Creates an incentive system to increase payments to high quality MA plans and MA plans that demonstrate improvement, phased-in over 2011-2013.
- Extends CMS's authority to adjust risk scores in Medicare Advantage for observed differences in coding patterns relative to fee-for-service.
- Amends Special Needs MA Plans (SNPs) to limit enrollment into SNPs effective 1/01/2011 other than through the annual open enrollment period or the time of the diagnosis of the disease or condition that qualifies the individual for SNPs, and reauthorizes SNPs through 12/31/2013 (unless the SNP had a contract with the State to provide an integrated Medicare-Medicaid SNP, in which case the reauthorization is through 12/31/2016).

Changes to Medicare Part D (Prescription Drug Benefits)

- Eliminates the Part D coverage gap (i.e., "donut hole"), beginning with a $500 reduction in 2011. Beginning in 2011, provides for a phased increase of the initial coverage limit and a phased decrease in the annual out of pocket threshold, eliminating the donut hole by 2023.
- Requires prescription drug manufacturers to provide drug rebates for full-benefit dual eligibles, effective 1/01/2011.
- Requires prescription drug manufacturers to provide 50% discounts for brand-name drugs and biologics used by Part D enrollees in the Part D donut hole.

Payment Incentives for Primary Care

- Increases the Medicare payment rate for primary care services of physicians specializing in primary care by 5% (10% in the case of practitioners predominately furnishing services in an area designed as a primary care health professional shortage area), effective 1/01/2011.

Comparative Effectiveness Research

- Establishes a Center for Comparative Effectiveness Research (CCER) within the Agency for Healthcare Research and Quality (AHRQ) to conduct, support and synthesize research with respect to the comparative effectiveness of health care items, services, and systems, including pharmaceuticals, medical devises, medical and surgical procedures and other medical interventions.
- Establishes an independent Comparative Effectiveness Research Commission to oversee and evaluate the activities of the CCER. The 17-member Commission will be appointed by the HHS Secretary with input from the Comptroller General and the Institute of Medicine and will include the director of AHRQ, the Chief Medical Officer of CMS and additional members representing stakeholders such as clinicians, patients, researchers, third-party payers and consumers. Effective on enactment.

Physician Payments Sunshine Provisions

- Requires manufacturers or distributors of covered drugs, devices, biologicals, or medical supplies under Medicare, Medicaid, or CHIP and physicians and other health care entities to electronically report to the HHS OIG any payments or transfers of value (other than drug samples) made to a 'covered recipient'.
- The term 'payment or other transfer of value' means a transfer of anything of value for or of any of the following: gifts, food, or entertainment; travel or trips; honoraria; research funding or grants; education or conference funding; consulting fees, ownership or investment interest and royalties or license fees.
- The term 'covered recipient' means: physicians; physician group practices; any other prescriber of a covered drug, device, biological, or medical supply; pharmacies or pharmacists; health insurance issuers, group health plans, or other entities offering health benefits plans, including any employee of such an issuer, plan, or entity; pharmacy benefit managers, including any employee of such a manager; hospitals; medical schools; sponsors of continuing medical education programs; patient advocacy or disease specific groups; organizations of health care professionals; biomedical researchers; and group purchasing organizations.
- Requires hospitals or entities that bill Medicare to report any ownership share by a physician.
- Effective March 31, 2011 and annually thereafter.

Medicaid Provisions

- Requires State Medicaid programs to cover non-disabled, childless adults under age 65 with income at or below 133% of FPL ($14,400 per year for an individual); parents and individuals with disabilities under age 65 with income at or below 133% of FPL ($29,300 per year for a family of 4); and newborns up to the first 60 days of life who do not otherwise have acceptable coverage upon birth.
- The underlying bill provides that the additional expenditures would be subject to a 100% Federal Medical Assistance Percentage ("FMAP") for the costs of Medicaid coverage for this population, but the FMAP was changed to 90% by the en bloc Ross (D-AR) amendment adopted in the House Energy and Commerce markup. Effective 1/1/2013.
- Requires the HHS Secretary to report to Congress by January 1, 2016 on the continuing role of Medicaid DSH as health reform is implemented. Directs the Secretary to reduce Medicaid DSH payments to States by a total of $10 billion ($1.5 billion in FY 2017, $2.5 billion in FY 2018, and $6.0 billion in FY 2019) using a methodology that focuses on the uninsurance rate in each State and the amount of uncompensated care provided by hospitals.
- Requires that State Medicaid programs reimburse for primary care services furnished by physicians and other practitioners at no less than 80% of Medicare rates in 2010, 90% in 2011, and 100% in 2012 and after. Maintains the Medicare payment differentials between physicians and other practitioners. The Federal government would pay 100% of the incremental costs attributable to this requirement.

Medicaid Financing Provisions

- Extends current rules for Medicaid payments to pharmacists for multiple source drugs through December 31, 2010. Thereafter, limits Medicaid payments for such drugs to 130% of the weighted average manufacturer price (AMP). Redefines AMP to exclude certain price concessions, including those provided to pharmacy benefit managers, not passed through to retail pharmacies.
- Increases the minimum manufacturer rebate for brand-name drugs purchased by State Medicaid programs from 15.1% of average manufacturer price to 22.1% of average manufacturer price, and applies the additional Medicaid rebate to new formulations of brand-name drugs.
- Requires manufacturers to pay rebates to State Medicaid programs for drugs dispensed to program beneficiaries enrolled in Medicaid managed care organizations. Effective 7/1/2010.

Significant Provisions in Division C

House Tri-Committee bill (H.R. 3200)	Senate HELP Committee bill
Expanded Participation in 340B Program	**Expanded Participation in 340B Program**
Amends Section 340B(a)(4) of the PHSA to include the following to the list of covered entities receiving discounted prescription drug prices, for inpatient as well as outpatient drugs: • Certain children's hospitals. • Critical access hospitals (as determined under section 1820(c)(2) of the Social Security Act). • Entities receiving funds under title V of the Social Security Act (relating to maternal and child health) for the provision of health services. • Entities receiving funds under subpart I of part B of title XIX of the Public Health Service Act (relating to comprehensive mental health services) for the provision of community mental health services. • Entities receiving funds under subpart II of such part B (relating to the prevention and treatment of substance abuse) for the provision of treatment services for substance abuse. • Medicare-dependent, small rural hospitals.	Amends Section 340B of the PHSA to expand the list of covered entities eligible to receive discounted prices under the 340B program to include: • certain children's hospitals excluded from the Medicare prospective payment system; • critical access hospitals; • rural referral centers; and • sole community hospitals with disproportionate share adjustment greater than 8 percent. Extends the discount to include inpatient and outpatient drugs. Prohibits group purchasing arrangements on outpatient drugs with certain exceptions for administrative burdens, generic substitution, and drug shortages. Requires the HHS Secretary to develop compliance improvements for manufacturers including a system and oversight to verify of accuracy of ceiling prices and the provision of refunds for overcharges. HHS will provide a secure website for covered entities with applicable ceiling prices for covered drugs.

• Sole community hospitals. • Rural referral centers. (The 340B Drug Pricing Program requires prescription drug manufacturers to provide outpatient drugs to certain covered entities at a reduced price. The 340B price is a 'ceiling price', meaning it is the highest price the covered entity would have to pay for select outpatient and over-the-counter drugs and minimum savings the manufacturer must provide. Effective for drugs dispensed on or after 7/01/2010.	The Secretary shall conduct selective auditing of manufacturers and wholesalers to ensure program integrity. Civil monetary penalties may be assessed not exceeding $5000 for each instance of knowingly overcharging a covered entity. The Secretary will develop a system for using a standard identifier for covered entities. Creates sanctions for covered entities for violations. Creates an alternative dispute resolution system for covered entities overcharged for drug purchases and manufacturers for claims resulting from audit results.
Extension of Discounts to Inpatient Drugs	**Extension of Discounts to Inpatient Drugs**
Requires participating hospitals to credit State Medicaid programs with estimated annual cost savings resulting from the expanded 340B discounts, and establishes mechanisms for the calculation of such credits, payments deadlines, and a waiver of the credit requirement if hospitals can demonstrate to the State that it will lose reimbursements under the State plan and that the loss will exceed the amount of the credit otherwise owed by the hospital. Effective 7/01/2010.	Requires participating hospitals to issue a credit to State Medicaid programs for inpatient drugs as determined by the HHS Secretary within 90 days of filing Medicare cost reports.
National Medical Device Registry	**National Medical Device Registry**
Amends sec. 519 of the Federal Food, Drug, and Cosmetic Act to establish a national medical device registry to facilitate analysis of postmarket safety and outcomes data one each device that: (1) is or has been used on a patient; and (2) is a class III device, or a class II device that is implantable, life-supporting, or life-sustaining. Not later than 36 months after the date of enactment, the HHS Secretary shall publish regulations for the establishment and operation of the registry requiring, among others things: • device manufacturers must submit information to the registry, including the type, model and serial number of the device; • procedures to permit linkage of information submitted to patient safety and outcomes data, and permit analyses of linked data; • requirements for regular and timely reports to the Secretary for inclusion in the registry concerning adverse event trends or patterns, incidence and prevalence of adverse events, and other information the Sectary determines appropriate; • procedures to permit public access to information in the registry.	No provision.
Employer-Based Wellness Programs	**Employer-Based Wellness Programs**
Ed & Labor Chairman's amendment in the nature of a substitute requires the Labor Secretary to award grants to employers that have enacted a certified wellness program that includes health awareness, employee engagement, behavioral change, and supportive employee components. The size of the grant can be no more than 50% of the costs incurred directly from instituting the wellness program.	Provides more flexibility under HIPAA and increases the amount that employers are permitted to reward employees for participating in wellness programs from 20% (current law) to 30% premium discount. Allows the Secretaries of HHS, Labor and Treasury to increase this reward to 50%. Amends Title III of the PHSA to add the following: Requires the Director of the Centers for Disease Control and Prevention (CDC Director), in coordination with relevant worksite health promotion organizations, State and local health departments, and academic institutions, to conduct targeted educational campaigns to: • make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs; • establish a culture of health by emphasizing health promotion and disease prevention;

	• emphasize an integrated and coordinated approach to workplace wellness; and • ensure informed decisions through high quality information to organizational leaders. The CDC Director is also directed to: • provide employers with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including: (1) measuring the participation and methods to increase participation in such programs; (2) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health; and (3) evaluating such programs as they relate to changes in employees' health status, absenteeism, productivity, rate of workplace injuries, and medical costs; and • build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs. Not later than 2 years after enactment and at regular intervals thereafter (to be determined by the Director), the Director shall conduct a national worksite health policies/programs survey to assess employer-based health policies and programs. Upon completion, the Director must submit a report to Congress that includes recommendations for the implementation of effective employer-based health policies and programs. The Director, in collaboration with academic institutions and employers, must also institute workplace demonstration projects designed to determine how best to transform the work environment to improve health, safety, and wellness, how to create integrated workplace health promotion and wellness programs, and how to create innovative and sustainable policy and environmental strategies to improve employee health and wellness. Upon completion, the Director must submit a report to Congress with recommendations for the implementation of effective employer-based health policies and programs.
Licensure Pathway for Biosimilar Biological Products	**Licensure Pathway for Biosimilar Biological Products**
Amendment adopted during the House Energy & Commerce Committee markup by Rep. Eshoo (D-CA) and others, similar to the Senate bill, would provide a licensure pathway for biosimilar biological products. In general, the amendment authorizes the Food and Drug Administration to approve generic versions of biologic drugs. The amendment also grants biologics manufacturers 12 years of exclusive use of their drug before generic manufacturers could begin developing competitors.	The HELP Committee adopted a compromise biologics amendment to provide a licensure pathway for biosimilar biological products. In general, the amendment authorizes the Food and Drug Administration to approve generic versions of biologic drugs. The amendment also grants biologics manufacturers 12 years of exclusive use of their drug before generic manufacturers could begin developing competitors.

Protecting Consumer Access to Generic Drugs	Protecting Consumer Access to Generic Drugs
E&C amendment offered by Rep. Rush (D-IL) to amend the Food, Drug, and Cosmetic Act to prohibit brand-name drug companies from settling patent litigation with generic competitors by paying them to delay marketing their products. Requires a GAO Study on litigation in U.S. courts during the period beginning [*] years prior to the date of enactment of this Act relating to patent infringement claims involving generic drugs. Requires a report to Congress of the findings of such a study and an analysis of the effect of the amendment on such litigation, whether such amendments have had an effect on the number and frequency of claims settled, and whether such amendments resulted in earlier or delayed entry of generic drugs to market, including whether any harm or benefits to consumers has resulted. (*not included in the language of the amendment as posted on the E&C Committee's website)	No provision.