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Summary of "The Patient Protection and Affordable Care Act"

As signed into law by President Obama, March 23, 2010

This summary identifies key provisions in the new health care law signed by President Obama. The new law impacts nearly every aspect of health care, especially the Medicare and Medicaid programs and the insurance industry. The following 15 key areas are described in this summary and emphasize senior care and pharmacist-related issues:

1. Medicaid Coverage
2. New Options for States to Provide Long-Term Services and Supports
3. Medicaid Prescription Drug Coverage
4. New Payment and Care Delivery Models
5. Medicare Part D
6. Independent Medicare Advisory Board
7. Medication Therapy Management
8. PBM Transparency
9. Nursing Home Transparency and Improvement
10. Patient-Centered Outcomes Research
11. Enrollment Disclosure Requirements
12. Medicare and Medicaid Program Integrity
13. Additional Medicaid Program Integrity Provisions
14. Biosimilar Biological Products
15. Long-Term Care Insurance

For in-depth information on the new law, including the full text of the 2,000+ page law, visit: http://dpc.senate.gov/dpcdoc-sen_health_care_bill.cfm

Medicaid Coverage

Creates a new State option to provide Medicaid coverage through a State plan amendment beginning on January 1, 2011. Eligible individuals include: all non-elderly, non-pregnant individuals who are not entitled to Medicare (e.g., childless adults and certain parents). Creates a new mandatory Medicaid eligibility category for all such "newly-eligible" individuals with income at or below 133 percent of the Federal Poverty Level (FPL) beginning January 1, 2014. Also, as of January 1, 2014, the mandatory Medicaid income eligibility level for children ages six to 19 changes from 100 percent FPL to 133 percent FPL. States have the option to provide Medicaid coverage to all non-elderly individuals above 133 percent of FPL through a State plan amendment.

New Options for States to Provide Long-Term Services and Supports

Community First Choice Option. Establishes an optional Medicaid benefit through which States could offer community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require the level of care offered in a hospital, nursing facility, or intermediate care facility for the mentally retarded.

- Removal of barriers to providing home and community-based services. Removes barriers to providing HCBS by giving States the option to provide more types of HCBS through a State plan amendment to individuals with higher levels of need, rather than through a waiver, and to extend full Medicaid benefits to individuals receiving HCBS under a State plan amendment.
- Money Follows the Person Rebalancing Demonstration. Extends the Money Follows the Person Rebalancing Demonstration through September 30, 2016 and changes the eligibility rules for individuals to participate in the demonstration project by requiring that individuals reside in an inpatient facility for not less than 90 consecutive days.

Medicaid Prescription Drug Coverage

- Prescription drug rebates. The flat rebate for single source and innovator multiple source outpatient prescription drugs would increase from 15.1 percent to 23.1 percent, except the rebate for clotting factors and outpatient drugs approved by the Food and Drug Administration exclusively for pediatric indications would increase to 17.1 percent. The basic rebate percentage for multi-source, non-innovator drugs would increase from 11 percent to 13 percent. Drug manufacturers would also be required to pay rebates for drugs dispensed to Medicaid beneficiaries who receive care from a Medicaid managed care organization (MCO). Total rebate liability would be limited to 100 percent of the average manufacturer price (AMP). Additional revenue generated by these increases will be remitted to the federal government.
- Elimination of exclusion of coverage of certain drugs. Beginning with drugs dispensed on January 1, 2014, smoking cessation drugs, barbiturates, and benzodiazepines would be removed from Medicaid's excludable drug list.
- Providing adequate pharmacy reimbursement. Requires the Secretary to calculate the Federal upper limit (FUL) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies.

New Payment and Care Delivery Models

- Providing Federal coverage and payment coordination for dual eligible beneficiaries. Requires the Secretary to establish a Federal Coordinated Health Care Office (CHCO) within CMS by March 1, 2010. The purpose of the CHCO would be to bring together officials of the Medicare and Medicaid programs to (1) more effectively integrate benefits under those programs, and (2) improve the coordination between the Federal and State governments for individuals eligible for benefits under both Medicare and Medicaid (dual eligibles) to ensure that dual eligibles have full access to the items and services to which they are entitled.
- Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs. Establishes a path toward value-based purchasing for long-term care hospitals, inpatient rehabilitation facilities, and hospice providers by requiring the Secretary to implement quality measure reporting programs for these providers in FY2014. Providers under this section who do not successfully participate in the program would be subject to a reduction in their annual market basket update.
- Plans for a value-based purchasing program for skilled nursing facilities and home health agencies. Directs the Secretary to submit a plan to Congress by FY2012 outlining how to effectively move these providers into a value-based purchasing payment system.
- National strategy. Requires the Secretary to establish and update annually a national strategy to improve the delivery of health care services, patient health outcomes, and population health. Establishes, not later than January 1, 2011, a Federal health care quality internet website.
- Establishment of Center for Medicare and Medicaid Innovation within CMS. Establishes within the Centers for Medicare and Medicaid Services (CMS) a Center for Medicare & Medicaid Innovation. The purpose of the Center will be to research, develop, test, and expand innovative payment and delivery arrangements to

improve the quality and reduce the cost of care provided to patients in each program. Dedicated funding is provided to allow for testing of models that require benefits not currently covered by Medicare. Successful models can be expanded nationally.

- Medicare shared savings program. Rewards Accountable Care Organizations (ACOs) that take responsibility for the costs and quality of care received by their patient panel over time. ACOs can include groups of health care providers (including physician groups, hospitals, nurse practitioners and physician assistants, and others). ACOs that meet quality-of-care targets and reduce the costs of their patients relative to a spending benchmark are rewarded with a share of the savings they achieve for the Medicare program.
- National pilot program on payment bundling. Direct the Secretary to develop a national, voluntary pilot program encouraging hospitals, doctors, and post-acute care providers to improve patient care and achieve savings for the Medicare program through bundled payment models. Requires the Secretary to establish this program by January 1, 2013 for a period of five years. Before January 1, 2016, the Secretary is also required to submit a plan to Congress to expand the pilot program if doing so will improve patient care and reduce spending.
- Independence at home demonstration program. Creates a new demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes physician and nurse practitioner directed home-based primary care teams aimed at reducing expenditures and improving health outcomes.
- Hospital readmissions reduction program. Beginning in FY2012, this provision would adjust payments for hospitals paid under the inpatient prospective payment system based on the dollar value of each hospital's percentage of potentially preventable Medicare readmissions for the three conditions with risk adjusted readmission measures that are currently endorsed by the National Quality Forum. Also, provides the Secretary authority to expand the policy to additional conditions in future years and directs the Secretary to calculate and make publicly available information on all patient hospital readmission rates for certain conditions.
- Community-based care transitions program. Provides funding to hospitals and community-based entities that furnish evidence-based care transition services to Medicare beneficiaries at high risk for readmission.
- Increase in the physician payment update. Replaces the scheduled 21 percent payment reduction to the Medicare physician fee schedule for 2010 with a 0.5 percent positive update.
- Hospice reform. This provision would require the Secretary to update Medicare hospice claims forms and cost reports by 2011. Based on this information, the Secretary would be required to implement changes to the hospice payment system to improve payment accuracy in FY2013. The Secretary would also impose certain requirements on hospice providers designed to increase accountability in the Medicare hospice program.

Medicare Part D

- Fills the Medicare prescription drug donut hole. In 2010, Medicare beneficiaries who go into the donut hole will receive a \$250 rebate. After that they will receive a pharmaceutical manufacturers' 50 percent discount on brand-name drugs in 2011 and 75 percent coverage for all brand name and generic drugs, phased in to fill the donut hole by 2020.
- Improved information for subsidy-eligible individuals reassigned to prescription drug plans and MA-PD plans. Requires HHS, beginning in 2011, to transmit formulary and coverage determination information to subsidy-eligible beneficiaries who have been automatically reassigned to a new Part D low-income subsidy plan.

- Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs. Codifies the current six classes of clinical concern, removes the criteria specified in section 176 of MIPPA that would have been used by HHS to identify protected classes of drugs and gives the Secretary authority to identify classes of clinical concern through rulemaking.
- Reducing part D premium subsidy for high-income beneficiaries. Reduces the Part D premium subsidy for beneficiaries with incomes above the Part B income thresholds.
- Elimination of cost sharing for certain dual-eligible individuals. Eliminates cost sharing for beneficiaries receiving care under a home and community-based waiver program who would otherwise require institutional care.
- Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA-PD plans. Requires Part D plans to develop drug dispensing techniques to reduce prescription drug waste in long-term care facilities.
- Uniform exceptions and appeals process for prescription drug plans and MA–PD plans. Requires Part D plans to use a single, uniform exceptions and appeals process.

Independent Medicare Advisory Board

- Creates an independent, 15-member Medicare Advisory Board tasked with presenting Congress with comprehensive proposals to reduce excess cost growth and improve quality of care for Medicare beneficiaries. In years when Medicare costs are projected to be unsustainable, the Board's proposals will take effect unless Congress passes an alternative measure that achieves the same level of savings. Congress would be allowed to consider an alternative provision on a fast-track basis. The Board would be prohibited from making proposals that ration care, raise taxes or Part B premiums, or change Medicare benefit, eligibility, or cost-sharing standards.

Medication Therapy Management

- Grants to implement medication management services in treatment of chronic disease. Creates a program to support medication management services by local health providers. Medication management services will help manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing acute care costs and reducing hospital readmissions.

PBM Transparency

- Requires a pharmacy benefit manager (PBM) or a health benefits plan that provides pharmacy benefits management services that contract with health plans under Medicare or the Exchange to report to the Secretary information regarding the generic dispensing rate: the rebates, discounts, or price concessions negotiated by the PBM and the payment difference between health plans and PBMs and the PBMs and pharmacies. All disclosed information would be confidential, except for certain specific purposes.

Nursing Home Transparency and Improvement

- Required disclosure of ownership and additional disclosable parties information. Requires that skilled nursing facilities (SNFs) under Medicare and nursing facilities (NFs) under Medicaid make available on request by the Secretary, the Inspector General of the Department of Health and Human Services, the States, and the State long-term care ombudsman, information on ownership, including a description of the governing body and organizational structure of the facility and information regarding additional disclosable parties.
- Accountability requirements for skilled nursing facilities and nursing facilities. Requires SNFs and NFs to implement a compliance and ethics program to be followed by the facility's employees and its agents within 36 months of enactment, and requires the Secretary to evaluate this program and report the results to Congress.

- Nursing home compare Medicare website. Requires the Secretary to publish the following information on the Nursing Home Compare Medicare website: standardized staffing data, links to State internet websites regarding State survey and certification programs, the model standardized complaint form, a summary of substantiated complaints, and the number of adjudicated instances of criminal violations by a facility or its employee.
- Reporting of expenditures. Requires the Secretary to modify cost reports for SNFs to require reporting of expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.
- Standardized complaint form. Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a State survey and certification agency and a State long-term care ombudsman program. States would also be required to establish complaint resolution processes.
- Ensuring staffing accountability. Requires the Secretary to develop a program for facilities to report staffing information in a uniform format based on payroll data, and to also take into account services provided by any agency or contract staff.
- GAO study and report on Five-Star Quality Rating System. Requires the Government Accountability Office to conduct a study on the Five-Star Quality Rating System which would include an analysis of the systems implementation and any potential improvements to the system.
- Civil money penalties. Provides the Secretary with authority to reduce civil monetary penalties (CMPs) from the level that they would otherwise be by 50 percent for certain facilities that self-report and promptly correct deficiencies within ten calendar days of imposition. For CMPs that are cited at the level of actual harm and immediate jeopardy, the Secretary would be provided with the authority to place CMPs in an escrow account following completion of the informal dispute resolution process, or the date that is 90 days after the date of the imposition of the CMP, whichever is earlier. If the facility's appeal is successful, the CMP, with interest, would be returned to the facility. If the appeal is unsuccessful, some portion of the proceeds may be used to fund activities that benefit facility residents.
- National independent monitor demonstration project. Directs the Secretary to establish a demonstration project within one year of enactment for developing, testing and implementing a national independent monitor program to conduct oversight of interstate and large intrastate chains. The HHS OIG would evaluate the demonstration project after two years.
- Notification of facility closure. Requires the administrator of a facility that is preparing to close to provide written notification to residents, legal representatives of residents or other responsible parties, the State, the Secretary and the long-term ombudsman program in advance of the closure by at least 60 days. Facilities would be required to prepare a plan for closing the facility by a specified date that is provided to the State, which must approve it and ensure the safe transfer of residents to another facility or alternative setting that the State finds appropriate in terms of quality, services and location, taking into consideration the needs and best interests of each resident.
- National demonstration projects on culture change and use of information technology in nursing homes. Requires the Secretary to conduct two facility-based demonstration projects that would develop best practice models in two areas. The first would be designed to identify best practices in facilities that are involved in the "culture change" movement, including the development of resources where facilities may be able to access information in order to implement culture change. The second demonstration would focus on development of best practices in information technology that facilities are using to improve resident care.
- Dementia and abuse prevention training. Requires facilities to include dementia management and abuse prevention training as part of pre-employment initial training for permanent and contract or agency staff, and if the Secretary determines appropriate, as part of ongoing in-service training.

- Nationwide program for National and State background checks on direct patient access employees of long-term care facilities and providers. Requires the Secretary to establish a nationwide program for national and State background checks on direct patient access employees of certain long-term supports and services facilities or providers. This program is based on the background check pilot program in the Medicare Modernization Act.

Patient-Centered Outcomes Research

- Outcomes Research Institute governed by a public-private sector board appointed by the Comptroller General to identify priorities for and provide for the conduct of comparative outcomes research.
- Requires the Institute to ensure that subpopulations are appropriately accounted for in research designs. Prohibits any findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards to protect against discriminatory coverage decisions by HHS based on age, disability, terminal illness, or an individual's quality of life preference. Provides funding for the Institute and authorizes and provides funding for the Agency for Health Research and Quality to disseminate research findings of the Institute, as well as other government-funded research, to train researchers in comparative research methods and to build data capacity for comparative effectiveness research.
- Federal coordinating council for comparative effectiveness research. Upon date of enactment, this provision would sunset the Federal Coordinating Council created in the American Recovery and Reinvestment Act of 2010 (P.L. 111-5).
- Provider Screening. Requires that the Secretary, in consultation with the HHS Office of Inspector General (HHS OIG), establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP. The Secretary would be required to determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier. At a minimum, all providers and suppliers would be subject to licensure checks. The Secretary would have the authority to impose additional screening measures based on risk, including fingerprinting, criminal background checks, multi-State data base inquiries, and random or unannounced site visits. An application fee of \$200 for individual practitioners and \$500 for institutional providers and suppliers would be imposed to cover the costs of screening each time they re-verify their enrollment (every five years).

Enrollment Disclosure Requirements

- Providers and suppliers enrolling or re-enrolling in Medicare, Medicaid, or CHIP would be subject to new disclosure requirements. Applicants would be required to disclose current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a Federal health care program, or has had their billing privileges revoked. The Secretary would be authorized to deny enrollment in these programs if these affiliations pose an undue risk to a program.

Medicare and Medicaid Program Integrity

- Integrated Data Repository. Requires CMS to include in the integrated data repository (IDR) claims and payment data from the following programs: Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs (VA) and Defense (DOD), the Social Security Administration, and the Indian Health Service (IHS).
- Access to Data. The Secretary would be required to enter into data-sharing agreements with the Commissioner of Social Security, the Secretaries of the VA and DOD, and the Director of the IHS to help identify fraud, waste, and abuse. The Committee Bill would grant the HHS OIG and the Department of Justice (DOJ) access to the IDR for the purposes of conducting law enforcement and oversight activities consistent with applicable privacy, security, and disclosure laws.
- Overpayments. Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

- National Provider Identifier. Requires the Secretary to issue a regulation mandating that all Medicare, Medicaid, and CHIP providers include their NPI on enrollment applications.
- Medicaid Management Information System. Authorizes the Secretary to withhold the Federal matching payment to States for medical assistance expenditures when the State does not report enrollee encounter data in a timely manner to the State's Medicaid Management Information System (MMIS).
- Permissive Exclusions. Subjects providers and suppliers to exclusion for providing false information on any application to enroll or participate in a Federal health care program.
- Civil Monetary Penalties. Expands the use of Civil Monetary Penalties (CMPs) to excluded individuals who order or prescribe an item or service, make false statements on applications or contracts to participate in a Federal health care program, or who know of an overpayment and do not return the overpayment. Each violation would be subject to CMPs of up to \$50,000.
- Testimonial Subpoena Authority. The Secretary would be able to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question by the Secretary.
- Surety Bonds. Requires that the Secretary take into account the volume of billing for a DME supplier or home health agency when determining the size of the surety bond. The Secretary would have the authority to impose this requirement on other providers and suppliers considered to be at risk by the Secretary.
- Payment Suspensions. Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.
- Health Care Fraud and Abuse Control Account. Increases Health Care Fraud and Abuse Control (HCFAC) funding would by \$10 million each year for fiscal years 2011 through 2020. The provision would also permanently apply the CPI-U adjustment to HCFAC and Medicare Integrity Program (MIP) funding.
- Medicare and Medicaid Integrity Programs. Requires Medicare and Medicaid Integrity Program contractors to provide the Secretary and the HHS OIG with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities.
- Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank. Requires the Secretary to maintain a national health care fraud and abuse data collection program for reporting certain adverse actions taken against health care providers, suppliers, and practitioners, and submit information on the actions to the National Practitioner Data Bank (NPDB). The Secretary would also be required to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in the HIPDB is transferred to the NPDB.
- Maximum period for submission of Medicare claims reduced to not more than 12 months. Beginning January 2010, the maximum period for submission of Medicare claims would be reduced to not more than 12 months.
- Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals. Requires durable medical equipment (DME) or home health services to be ordered by a Medicare eligible professional or physician enrolled in the Medicare program. The Secretary would have the authority to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.
- Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse. Beginning January 1, 2010, the Secretary would have the authority to disenroll, for no more than one

year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services. The provision would also extend the HHS OIG's permissive exclusion authority to include individuals or entities that order, refer, or certify the need for health care services that fail to provide adequate documentation to verify payment.

- Face-to-face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare. Requires physicians to have a face-to-face encounter with the individual prior to issuing a certification for home health services or DME. The Secretary would be authorized to apply the face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse.
- Enhanced penalties. Subjects persons who fail to grant HHS OIG timely access to documents, for the purpose of audits, investigations, evaluations, or other statutory functions, to CMPs of \$15,000 for each day of failure. Also, persons who knowingly make, use, or cause to be made or used any false statement to a Federal health care program would be subject to a CMP of \$50,000 for each violation. The violations that could be subject to the imposition of sanctions and CMPs by the Secretary would include Medicare Advantage (MA) or Part D plans that: (1) enroll individuals in a MA or Part D plan without their consent, (2) transfer an individual from one plan to another for the purpose of earning a commission, (3) fail to comply with marketing requirements and CMS guidance, or (4) employ or contract with an individual or entity that commits a violation. Penalties for MA and Part D plans that misrepresent or falsify information would be increased to up to three times the amount claimed by a plan or plan sponsor based on the misrepresentation or falsified information.
- Medicare self-referral disclosure protocol. Within six months of enactment, the Secretary, in cooperation with the HHS OIG, would be required to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.
- Adjustments to the Medicare durable medical equipment, prosthetics, orthotics, and supplies competitive acquisition program. Requires the Secretary to expand the number of areas to be included in round two of the competitive bidding program from 79 of the largest metropolitan statistical areas (MSAs) to 100 of the largest MSAs, and to use competitively bid prices in all areas by 2016.
- Expansion of the Recovery Audit Contractor (RAC) program. Requires States to establish contracts with one or more Recovery Audit Contractors (RACs). These State RAC contracts would be established to identify underpayments and overpayments and to recoup overpayments made for services provided under State Medicaid plans as well as State plan waivers. The Secretary would also be required to expand the RAC program to Medicare Parts C and D.

Additional Medicaid Program Integrity Provisions

- Termination of provider participation under Medicaid if terminated under Medicare or other State plan. Requires States to terminate individuals or entities from their Medicaid programs if the individuals or entities were terminated from Medicare or another State's Medicaid program.
- Medicaid exclusion from participation relating to certain ownership, control, and management affiliations. Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during the period as determined by the Secretary; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.
- Billing agents, clearinghouses, or other alternate payees required to register under Medicaid. Requires any agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the State and the Secretary in a form and manner specified by the Secretary.

- Requirement to report expanded set of data elements under MMIS to detect fraud and abuse. Requires States and Medicaid managed care entities to submit data elements from MMIS as determined necessary by the Secretary for program integrity, program oversight, and administration.
- Prohibition on payments to institutions or entities located outside of the United States. Prohibits States from making any payments for items or services provided under a Medicaid State plan or waiver to any financial institution or entity located outside of the United States.
- Overpayments. Extends the period for States to repay overpayments to one year when a final determination of the amount of the overpayment has not been determined due to an ongoing judicial or administrative process. When overpayments due to fraud are pending, State repayments of the Federal portion would not be due until 30 days after the date of the final judgment.
- Mandatory State use of national correct coding initiative. Requires States to make their MMIS methodologies compatible with Medicare's national correct coding initiative (NCCI) that promotes correct coding and controls improper coding.
- General effective date. Requires States to implement fraud, waste, and abuse programs before January 1, 2011.

Biosimilar Biological Products

- Establishes a process under which the Secretary is required to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product.
- Prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved. If FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until 1 year after the first commercial marketing of the first interchangeable product.
- Authorizes HHS to issue guidance with respect to the licensure of biological products under this new pathway, and it includes provisions governing patent infringement concerns such as the exchange of information, good faith negotiations, and initiation infringement actions. Applies certain provisions of the Food, Drug, and Cosmetic Act to this subtitle with respect to pediatric studies of biological products. Requires HHS to develop recommendations for Congress with respect to the goals for the process for the review of biosimilar biological product applications for the first five fiscal years after FY 2012.

Long-Term Care Insurance

- Establishment of national voluntary insurance program for purchasing community living assistance services and support (CLASS program). Establishes a new, voluntary, self-funded public long-term care insurance program, to be known as the CLASS Independence Benefit Plan, for the purchase of community living assistance services and supports by individuals with functional limitations. Requires the Secretary to develop an actuarially sound benefit plan that ensures solvency for 75 years; allows for a five-year vesting period for eligibility of benefits; creates benefit triggers that allow for the determination of functional limitation; and provides cash benefit that is not less than an average of \$50 per day. No taxpayer funds will be used to pay benefits under this provision.

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