

**American Pharmacists Association
Pharmacy-Related Provisions of Health Care Reform Proposals
As of December 1, 2009**

Because Congress is far from reaching a consensus, many of these provisions could be changed or not included in a final bill.

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| Access to Pharmacy Products and Services | <p>Section 215. Requires qualified health plans that use a provider network to meet standards as the Health Commissioner may establish to assure the adequacy of the networks in ensuring enrollee access and transparency in the cost-sharing differentials among providers participating in the network and policies for accessing out-of-network providers.</p> <p>Section 222. Makes prescription drugs a mandatory benefit for a plan in the proposed “exchange.”</p> <p>Section 238. Clarifies that this law may not supersede State laws designed to prohibit a qualified health benefits plans (QHBP) from discriminating (with respect to participation, reimbursement, covered services, indemnification, or related requirements) against a health care provider that is acting within the scope of that provider’s license or certification under applicable State law.</p> <p>Section 531. Limits medication reimbursements from Health Savings Accounts (HSAs) and other similar</p> | <p>Section 1102. Directs the Secretary to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees. Defines “health benefits” as medical, surgical, hospital, prescription drug, and other such benefits as determined by the Secretary.</p> <p>Section 2706. Prohibits a group health plan and a health insurance issuer offering group or individual health insurance coverage from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider’s license or certification under applicable State law.</p> <p>Does not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer.</p> <p>Does not prevent a group health plan, a health insurance</p> |

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| | <p>accounts to prescribed drugs or insulin.</p> <p>Section 552. Imposes a first taxable sale of any medical device equal to 2.5% of the price for which it is sold. Defines “first taxable sale” to mean the first sale, for a purpose other than for resale, after production, manufacture, or importation. Clarifies that such term does not include the sale of any medical device if: such sale is made at a retail establishment on terms which are available to the general public; and such medical device is a type (and purchased in a quantity) which is purchased by the general public. Clarifies that if a medical device is sold for use in connection with providing any health care service to an individual, such sale shall not be treated as being for the purpose of resale (even if such device is sold to such individual). Also addresses resales pursuant to certain contract arrangements, as well as credits and refunds.</p> <p>Section 1143. By July 1, 2011, the Medicare Payment Advisory Commission (MedPAC) must submit to Congress a report on: the scope of coverage for home infusion therapy in various public and private health plans; a cost/benefit analysis of the benefit; an assessment of cost data sources that might be used to construct payment mechanisms in the Medicare program; and any recommendations on the structure of a Medicare payment system.</p> <p>Section 1131. Incorporates a productivity adjustment</p> | <p>issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.</p> <p>Section 1302. Directs the Secretary to define essential health benefits, which must include at least several general categories (and the items and services covered within the categories), including: prescription drugs; and preventive and wellness services and chronic disease management.</p> <p>Section 1313. No later than 5 years after the first date on which Exchanges are required to be operational, the Comptroller General (GAO) must conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges. Such study must review, among other things, how many physicians, by area and specialty, are not taking or accepting new patients enrolled in Federal Government health care programs, and the adequacy of provider networks of Federal Government health care programs.</p> <p>Section 3127. The Medicare Payment Advisory Commission must study the adequacy of payments for items and services furnished by providers of services and suppliers in rural areas under the Medicare program. Such study must include an analysis of:</p> <ul style="list-style-type: none"> • Any adjustments in payments to providers of services and suppliers that furnish items and services in rural areas; |

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| | <p>beginning in 2010 for ambulance services, ambulatory surgical centers, and durable medical equipment not subject to competitive bidding. Replaces the existing update for laboratory services of CPI minus 0.5 with an update of CPI less productivity.</p> <p>Sec. 1232. Lifts the current 36-month limitation on Medicare coverage of immunosuppressive drugs for kidney transplant patients who would otherwise lose this coverage on or after January 1, 2012 and makes technical changes to the bundled payment system for dialysis services.</p> <p>Section 1738. Provides States the option to disregard certain income in providing continued Medicaid coverage for certain individuals with extremely high prescription costs.</p> | <ul style="list-style-type: none"> • Access by Medicare beneficiaries to items and services in rural areas; • The adequacy of payments to providers of services and suppliers that furnish items and services in rural areas; and • The quality of care furnished in rural areas. <p>Section 4107. Requires Medicaid coverage of counseling and pharmacotherapy (including prescription and non-prescription FDA-approved tobacco cessation agents) for cessation of tobacco use by pregnant women.</p> <p>The services are furnished:</p> <ul style="list-style-type: none"> • By or under the supervision of a physician; or • By any other health care professional who: <ul style="list-style-type: none"> ○ Is legally authorized to furnish such services under State law (or other State regulatory mechanism provided by State law) of the State in which the services are furnished; and ○ Is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose. <p>Removes cost-sharing for these services and products.</p> <p>Section 9003. Limits medication-related reimbursements from health savings accounts, Archer medical savings accounts, health flexible spending arrangements and health reimbursement arrangements to expenses incurred</p> |

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| | | for prescribed drugs or insulin. |
| Administrative Simplification | <p>Section 115. Directs the Secretary to adopt and regularly update standards for financial and administrative transactions. The standards must be consistent with several goals, including: enable the real-time (or near real-time) determination of an individual’s financial responsibility at the point of service, and to the extent possible, prior to the service, including whether the individual is eligible for a specific service with a specific physician at a specific facility, on a specific date or range of dates, include utilization of machine-readable health plan beneficiary identification card or similar mechanism; enable, where feasible, near real-time adjudication of claims; provide for timely acknowledgment, response and status reporting applicable to any electronic transaction deemed appropriate by the Secretary.</p> <p>Also directs the Secretary to adopt a single, binding, comprehensive companion guide that includes operating rules for each X12 Version 5010 transaction, to be effective until the new version of these transactions are adopted and implemented.</p> <p>Expands electronic transactions in Medicare.</p> | <p>Section 1104. Expands the purpose of Health Insurance Portability and Accountability Act of 1996 (HIPAA) to purpose to include reducing the clerical burden on patients, healthcare providers, and health plans.</p> <p>Amends HIPAA by adding a definition of “operating rules”: The term ‘operating rules’ means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.</p> <p>Amends HIPAA by adding “electronic funds transfers” to the list of transactions for which the Secretary must adopt standards.</p> <p>Directs the Secretary to promulgate rules to establish:</p> <ul style="list-style-type: none"> • A unique health plan identifier. • A standard for electronic funds transfers. • A transaction standard and a single set of associated operating rules for health claims attachments that is consistent with the X12 Version 5010 transaction standards. <p>The standards and operating rules adopted by the Secretary must:</p> <ul style="list-style-type: none"> • To the extent feasible, enable determination of an individual’s eligibility and financial responsibility |

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| | | <p>for specific services prior to or at the point of care;</p> <ul style="list-style-type: none"> • Be comprehensive, requiring minimal augmentation by paper or other communications; • Provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and • Describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse). <p>In adopting these rules, the Secretary must consider recommendations for operating rules developed by a qualified nonprofit entity that meets the following requirements; the entity:</p> <ul style="list-style-type: none"> • Focuses its mission on administrative simplification. • Demonstrates a multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standard development organizations; • Has a public set of guiding principles that ensure that operating rules and process are open and transparent, and supports nondiscrimination and |

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| | | <p>conflict of interest policies.</p> <ul style="list-style-type: none"> • Builds upon the HIPAA transaction standards. • Allows for public review and updates of the operating rules. <p>The National Committee on Vital and Health Statistics will assist the Secretary in the development of the rules.</p> <p>In developing recommendations, the review committee (a committee designated by the Secretary to carry out this subsection) must ensure coordination, as appropriate, with the standards that support the certified electronic health record technology approved by the Office of the National Coordinator for Health Information Technology.</p> <p>By January 1, 2014, no Medicare Parts A or B payments will be made other than by electronic funds transfer or an electronic remittance in a form as specified in ASC X 12 835 Health Care Payment and Remittance Advice or subsequent standard.</p> |
| Biosimilars | <p>Section 1149A. Establishes a payment rate of 106% of ASP.</p> <p>Section 2575. Establishes a process under which the Secretary is required to approve applications for biological products that have been shown to be biosimilar or interchangeable to an already licensed biological product. Requires notification to the Federal Trade Commission and the Assistant Attorney General of certain types of agreements regarding biosimilar or reference</p> | <p>Section. 3139. Establishes the payment for biosimilars at 106% of ASP.</p> <p>Section 7002. Amends the Public Health Service Act to establish an approval process for biosimilars or interchangeable biological products.</p> <p>Establishes user fees for the approval of biosimilars or interchangeable biological products.</p> |

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| | <p>products.</p> <p>Section 2576. Allows for the collection of user fees for the approval of biosimilar or interchangeable biological products.</p> <p>Section 2577. Establishes that a biological product applicant’s submission of a statement regarding patents identified by the patent holder constitutes an act of infringement of the patents that claim the biological product.</p> | <p>Directs the Secretary of the Treasury, in consultation with the Secretary of HHS, to determine for each fiscal year the amount of savings to the Federal Government as a result of the enactment of this subtitle.</p> <p>The savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.</p> |
| Community Health Centers | <p>Section 2101. Authorizes an additional \$12 billion over the next five years (FY 2011 – FY 2015) for community health centers to be appropriated from the Public Health Investment Fund (under Sec. 2002). (Such funds are over and above the level of appropriations provided for FY 2008.)</p> | |
| Comparative Effectiveness Research (CER) | <p>Section 1401. Establishes a new CER Center within the Agency for Healthcare Research and Quality (AHRQ).</p> | <p>Section 6301. Authorizes the establishment of a nonprofit corporation, to be known as the ‘Patient-Centered Outcomes Research Institute’ to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and</p> |

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| | | <p>certain items.</p> <p>The Institute shall have a Board of Governors, which shall consist of the following members:</p> <ul style="list-style-type: none"> • The Director of Agency for Healthcare Research and Quality. • The Director of the National Institutes of Health. • Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows: <ul style="list-style-type: none"> ○ 3 members representing patients and health care consumers. ○ 5 members representing physicians and providers, including at least 1 surgeon, nurse, State-licensed integrative health care practitioner, and representative of a hospital. ○ 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits. ○ 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers. ○ 1 member representing quality improvement or independent health service researchers. ○ 2 members representing the Federal |

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| | | <p>Government or the States, including at least 1 member representing a Federal health program or agency.</p> <p>The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B).</p> |
| Conscience Protections | <p>Sec. 258. Clarifies that nothing in this act pre-empts state laws with regard to abortion nor changes existing federal laws regarding conscience protections, willingness or refusal to provide abortion, and discrimination on the basis of such willingness or refusal.</p> <p>Section 259. Prohibits a Federal agency or program, or any State or local government that receives Federal financial assistance under this Act (or an amendment made by this Act) from:</p> <ul style="list-style-type: none"> ○ Subjecting any individual or institutional health care entity to discrimination; or ○ Requiring any health plan created or regulated under this Act (or an amendment made by this Act) to subject any individual or institutional health care entity to discrimination on the basis that the health care entity does not provide, pay for, provider coverage of, or refer for abortions. ○ Defines “health care entity” to include an individual | <p>Section 1303. Stipulates that no individual health care provider or health care facility may be discriminated against because of a willingness or unwillingness, if doing so is contrary to the religious or moral beliefs of the provider or facility, to provide, pay for, provide coverage of, or refer for abortions.</p> <p>Clarifies that nothing in this Act shall be construed to have any effect on Federal laws regarding:</p> <ul style="list-style-type: none"> ● Conscience protection; ● Willingness or refusal to provide abortion; and ● Discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. <p>Clarifies that nothing in this subsection shall alter the rights and obligations of employees and employers under title VII of the Civil Rights Act of 1964.</p> |

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| | <p>physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization or plan.</p> | <p>Clarifies that nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including EMTALA.</p> <p>Section 1553. The Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act or any health plan created under this Act, may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.</p> <p>In this section, the term “health care entity” includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.</p> <p>Nothing in subsection (a) shall be construed to apply to, or to affect, any limitation relating to:</p> <ul style="list-style-type: none"> • The withholding or withdrawing of medical treatment or medical care; • The withholding or withdrawing of nutrition or hydration; • Abortion; or |

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| | | <ul style="list-style-type: none"> The use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason. |
| Drug Information | | <p>Section 3507. The Secretary, acting through the Commissioner of FDA, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers.</p> <p>If the Secretary determines that this would improve health care decision making by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the required report, shall promulgate proposed regulations as necessary to implement such format.</p> <p>Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.</p> |
| Fraud, Waste and Abuse | <p>Section 1601. Increases funding and flexibility to fight fraud and abuse.</p> <p>Section 1611. Enhances penalties for false statements on provider or supplier enrollment applications.</p> | <p>Section 6401. No later than 180 days after the date of enactment, the Secretary, in consultation with the Inspector General of the Department of HHS, shall establish procedures under which screening is conducted with respect to providers of medical or other items or</p> |

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| | <p>Section 1612. Enhances penalties for submission of false statements material to a false claim.</p> <p>Section 1613. Enhances penalties for delaying inspections.</p> <p>Section 1615. Enhances penalties for individuals excluded from program participation.</p> <p>Section 1618. Enhances penalties for obstruction of program audits.</p> <p>Section 1619. Excludes certain individuals and entities from participation in Medicare and state health care programs.</p> <p>Sec. 1620. Provides OIG authority to exclude from federal health care programs officers and owners of entities convicted of fraud.</p> <p>Section 1617. Enhances penalties for Medicare Advantage and Medicare Part D marketing violations.</p> <p>Section 1631. Allows the Secretary to designate program areas of “significant risk” in which enhanced oversight can be applied to prohibit fraud, waste, and abuse. Directs the Secretary to establish screening procedures for new</p> | <p>services and suppliers under Medicare, Medicaid, and the CHIP program.</p> <p>The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening:</p> <ul style="list-style-type: none"> • Shall include a licensure check, which may include such checks across States; and • May, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include: <ul style="list-style-type: none"> ○ A criminal background check; ○ Fingerprinting; ○ Unscheduled and unannounced site visits, including pre-enrollment site visits; ○ Database checks (including such checks across States); and ○ Such other screening as the Secretary determines appropriate. <p>The Secretary shall impose a \$200 fee (increases each year by CPI) on each individual provider of medical or other items or services or supplier (such as a physician, physician assistant, nurse practitioner, or clinical nurse specialist) with respect to which screening.</p> <p>The Secretary shall impose a \$500 (increases each year by CPI) fee on each institutional provider of medical or other</p> |

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| | <p>providers.</p> <p>Section 1632. Requires new suppliers or providers to disclose affiliations within the past 10 years with any provider or supplier that has uncollected debt or has been suspended from Medicare, Medicaid, or CHIP.</p> <p>Section 1633. Establishes a “payment modifier” when service results in ordering additional services, prescription drugs, or durable medical equipment, in order to assist efforts to identify fraud.</p> <p>Section 1635. Requires providers and suppliers to adopt programs to reduce fraud, waste, and abuse.</p> <p>Section 1636. Reduces the period for Medicare claims submissions from the current 36 months to one year after the date of service.</p> <p>Section 1638. Requires physicians or suppliers to maintain and provide upon request of the Secretary, documentation related to the ordering of DME, home health services, or other areas of high risk.</p> <p>Section 1639. Requires a face-to-face (or telemedicine) encounter with a patient before a physician may certify home health services or DME.</p> <p>Section 1641. Clarifies that when a provider, supplier, or Part D plan becomes aware of a Medicare or Medicaid</p> | <p>items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted.</p> <p>The Secretary may, on a case-by-case basis, exempt a provider or supplier from the application fee if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee for providers enrolled in a State Medicaid program for which the State demonstrates that imposition of the fee would impede beneficiary access to care.</p> <p>Requires providers of medical or other items or services or suppliers who submit an application for enrollment or revalidation of enrollment in one of these programs on or after the date that is 1 year after the date of enactment to disclose any current or previous affiliation (directly or indirectly) with a provider or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program, has been excluded from participation under Medicare, Medicaid, or the CHIP program, or has had its billing privileges denied or revoked. If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal.</p> <p>The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, in</p> |

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| | <p>overpayment, it must be reported and returned within 60 days.</p> <p>Section 1642. Expands application of hardship waivers for OIG exclusions to beneficiaries of any Federal health care program.</p> <p>Section 1646. Requires provider and supplier payments under Medicare to be made through direct deposit or electronic funds transfers.</p> <p>Section 1753. Requires Medicaid providers and suppliers to adopt programs to reduce waste, fraud and abuse.</p> <p>Section 1756. Allows for termination of provider participation under Medicaid and CHIP if the provider is terminated under Medicare or other state or child health plans.</p> <p>Section 1757. Authorizes the exclusion of any individual or entity from participation in the Medicaid program if they own, control, or manage an entity (or the reverse, they are owned by) that: has unpaid overpayments considered to be delinquent; is suspended or excluded from participation under or whose participation is terminated under this title; or is affiliated with an individual or entity that has been suspended or excluded from participation or whose participation is terminated.</p> | <p>Medicare, Medicaid, or under the CHIP program if the Secretary determines it is necessary to prevent or combat fraud, waste, or abuse.</p> <p>Requires a provider or supplier, as a condition of enrollment in Medicare, Medicaid or the CHIP program, to establish a compliance program that contains certain core elements with respect to that provider or supplier and industry or category. Such core elements will be established by the Secretary, in consultation with the Inspector General of the Department of HHS.</p> <p>Requires State Medicaid programs to comply with the above provisions.</p> <p>Section 6402. Authorizes the Secretary to require a provider of services or supplier to provide the Secretary on a continuing basis with a surety bond in an amount (not less than \$50,000) that the Secretary determines is commensurate with the volume of the billing of the provider or supplier. The Secretary may waive this requirement if the provider or supplier provides a comparable surety bond under State law.</p> <p>Authorizes the Secretary to suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud against the provider or supplier, unless the Secretary determines there is good cause not to suspend such payments.</p> |

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| | | <p>Section 6404. Maximum period for submission of Medicare claims reduced to not more than 12 months.</p> <p>Section 6405. Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals.</p> <p>Section 6406. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse.</p> <p>Section 6407. Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare.</p> <p>Section 6408. Enhances penalties for making false statements or delaying inspections. Enhances penalties for Medicare Part D plan marketing violations.</p> <p>Section 6410. Expands Round 2 of the DME competitive bidding program by including the next 21 largest metropolitan statistical areas by total population in the round. Requires the Secretary to either competitively bid areas or use competitive bid prices by 2016.</p> <p>Section 6501. Termination of provider participation under Medicaid if terminated under Medicare or other State plan.</p> <p>Section 6502. Directs Medicaid to exclude, with respect</p> |

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| | | <p>to a period, any individual or entity from participation in the program under the State plan if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that):</p> <ul style="list-style-type: none"> • Has delinquent unpaid Medicaid overpayments during such period; • Is suspended or excluded from participation or is terminated under Medicaid during such period; or • Is affiliated with an individual or entity that has been suspended or excluded from participation under Medicaid or whose participation is terminated under Medicaid during such period. |
| Generic Drugs | Section 2573. Prohibits any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which: 1) an Abbreviated New Drug Application (ANDA) filer from receiving anything of value, and 2) then agreeing to limit or forego research, development, manufacturing, marketing, or sales, for any period of time of the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim | |
| Health Disparities | Section 1221. Requires the Secretary of HHS to conduct a study that examines the extent to which Medicare providers utilize, offer or make available language services for beneficiaries who are limited English proficient and ways that Medicare should develop payment systems for language services. | |

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| | <p>Section 1222. Directs the Secretary to award no fewer than 24 3-year grants to eligible Medicare service providers to improve effective communication between such providers and Medicare beneficiaries who are living in communities where racial and ethnic minorities, including populations that face language barriers, are underserved with respect to such services. To be eligible, an entity shall be a Medicare Part A provider of services, a service provider under Medicare Part B, a part C organization offer a Part C plan, or a prescription drug sponsor under Part D.</p> | |
| HIT | <p>Section 263. Requires the Secretary of HHS to conduct a study of the potential methods to increase the use of qualified electronic health records by small providers including higher reimbursement rates, training, and education.</p> <p>Section 1124. Directs the Secretary to integrate the PQRI program and the “meaningful use” measures used by the health information technology incentive program.</p> <p>Section 1161. Establishes a quality-based payment adjustment for Medicare Advantage plans. Directs the Secretary to establish reporting requirements on quality measures, which may include measures of: rates of admission and readmission to a hospital; prevention quality, such as those established by AHRQ (that include hospital admission rates for specified conditions); patient mortality and morbidity following surgery; health functioning (such as limitations on activities of daily</p> | <p>Section 1561. No later than 180 days after the date of enactment of this title, requires the Secretary, in consultation with the HIT Policy Committee and the HIT Standards Committee, to develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs, as determined by the Secretary.</p> <p>Section 3002. No later than January 1, 2012, requires the Secretary to develop a plan to integrate reporting on quality measures under this subsection with reporting requirements relating to the meaningful use of electronic health records.</p> |

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| | <p>living) and survival for patients with chronic diseases; and patient safety.</p> <p>Section 2402. Establishes the position of Assistant Secretary for Health Information to provide health information on key health indicators; to facilitate better data sharing; and to develop standards for the collection of data to study and address health disparities.</p> <p>Section 3101. Amends the Indian Health Care Improvement Act with: Section. 522. Authorizes the Secretary to make grants to urban Indian organizations under Title V for the development, adoption, and implementation of health information technology, telemedicine services development, and related infrastructure.</p> | |
| Home Infusion Therapy | Section 1143. Directs the Secretary to make recommendations on the most appropriate way for Medicare to cover and pay for home infusion services. | |
| Hospital Readmissions | Section 1151. Creates financial incentives for hospitals to prevent readmissions. Transitional services include an assessment of an individual’s medication regimen and adherence. Other transitional care activities include providing a summary of medication orders upon discharge. | <p>Section 3025. The Secretary must reduce payments that would otherwise be made to hospitals to account for excess readmissions to the hospital. No later than two years after the date of enactment, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations.</p> <p>Section 3026. Requires the Secretary to establish a Community-Based Transitions Program under which the Secretary provides funding to eligible entities that furnish</p> |

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| | | <p>improved care transition services to high-risk Medicare beneficiaries.</p> <p>An application to participate must include a detailed proposal for at least 1 care transition intervention, which may include the following:</p> <ul style="list-style-type: none"> • Initiating care transition services for a high-risk Medicare beneficiary not later than 24 hours prior to the discharge of the beneficiary from the eligible entity. • Arranging timely post-discharge follow-up services to the high-risk Medicare beneficiary to provide the beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with information regarding responding to symptoms that may indicate additional health problems or a deteriorating condition. • Providing the high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with assistance to ensure productive and timely interactions between patients and post-acute and outpatient providers. • Assessing and actively engaging with a high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) through the provision of self-management support and relevant information that is specific to the beneficiary's condition. • Conducting comprehensive medication review and management (including, if appropriate, counseling |

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| | | and self-management support). <i>See Medicare Advantage Plans & MTM (Section 3201).</i> |
| Indian Health | <p>Section 3101. Amends the Indian Health Care Improvement Act with:</p> <p>Section 517. Authorizes the Secretary to make grants to urban Indian contractors or grantees for diabetes prevention, treatment, and control.</p> <p>Section 815. Declares that Congress encourages memoranda of agreement among state, local, and tribal law enforcement agencies to streamline law enforcement and maximize limited resources in order to improve law enforcement services in Indian tribal communities and address problems related to methamphetamine use in Indian Country.</p> <p><i>Also see Workforce section.</i></p> | |
| Integrated Care Models | <p>Section 1301. Establishes an Accountable Care Organization (ACO) Pilot Program to test different payment incentive models intended to promote accountability, encourage investment in processes that result in high quality and efficient care, and reward providers for high quality and efficient care.</p> <p>ACO's may involve services not currently compensated for by Medicare—such as pharmacist services.</p> | <p>Section 2703. Beginning January 1, 2011, through a State plan amendment, a State may provide for medical assistance under Medicaid to eligible individuals with chronic conditions who select a designated provider, a team of health care professionals operating with such a provider, or a health team as the individual's health home for purposes of providing the individual with home health services.</p> <p>Defines home health services as:</p> |

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| | <p>Section 1302. Establishes a medical home pilot program to assess the feasibility of reimbursing for qualified patient-centered medical homes. Proposes two models: 1) independent patient-centered; 2) community based.</p> <p>The Community-based medical home model must employ community health workers that assist primary care providers in chronic care management activities such as medication therapy management services.</p> <p>Section 1312. Creates a new demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes primary care teams. An independence at home medical practice is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and others with experience providing home-based primary care.</p> <p>Section 1722. Establishes a 5-year pilot program to test the medical home concept with Medicaid beneficiaries including fragile children and high-risk pregnant women.</p> <p>Section 1730A. Directs the Secretary to establish a program to allow State Medicaid programs to pilot one or more of the models used in the Medicare ACO pilot program established in Section 1301 of the bill.</p> <p>Section 1907. Establishes within CMS a Center for</p> | <ul style="list-style-type: none"> • Comprehensive care management; • Care coordination and health promotion; • Comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; • Patient and family support; • Referral to community and social support services; and • Use of HIT to link services, as feasible. <p>Defines designated provider as a physician, clinical practice or clinical group practice, rural clinic, community health center, community mental health center, home health agency, or any other entity or provider that is determined by the State and approved by the Secretary to be qualified.</p> <p>Defines team of health care professionals as a team that may:</p> <ul style="list-style-type: none"> • Include physicians and other professionals, such as a nurse care coordinator, nutritionist, social worker, behavioral health professional, or any professionals deemed appropriate by the State; and • Be free standing, virtual, or based at a hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity deemed appropriate by the Secretary. <p>The Secretary must survey States that have elected this</p> |

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| | <p>Medicare and Medicaid Innovation 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 Medicare and Medicaid.</p> <p>Section 2534. Establishes a new program to support community-based collaborative care networks, a consortium of health care providers offering coordinated and integrated health care services for low-income patient populations or medically-underserved communities.</p> | <p>option and report on the nature, extent, and use of such option particularly as it pertains to:</p> <ul style="list-style-type: none"> • Hospital admission rates; • Chronic disease management; • Coordination of care for individuals with chronic conditions; • Assessment of program implementation; • Processes and lessons learned; • Assessment of quality improvements and clinical outcomes; and • Estimates of cost savings. <p>Section 2704. The Secretary must establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary:</p> <ul style="list-style-type: none"> • With respect to an episode of care that includes a hospitalization; and • For concurrent physician services provided during a hospitalization. <p>The demonstration project will be conducted in up to 8 States and will focus on conditions where there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished to Medicaid beneficiaries while reducing total expenditures under the State Medicaid programs selected to participate.</p> <p>Hospitals participating in the demonstration project must have or establish robust discharge planning programs to</p> |

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| | | <p>ensure that Medicaid beneficiaries requiring post-acute care are appropriately placed in, or have ready access to, post-acute care settings.</p> <p>Section 2706. The Secretary must establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating State to allow pediatric medical providers that meet specified requirements to be recognized as an accountable care organization.</p> <p>Section 3021. Establishes within CMS a Center for Medicare and Medicaid Innovation the purpose of which is to test innovate payment and service delivery models to reduce program expenditures under Medicare and Medicaid while preserving or enhancing the quality of care furnished to individuals in those programs. In selecting such models, the Secretary must give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals.</p> <p>The Secretary must select models to be tested from models where the Secretary determines that 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. These models include:</p> <ul style="list-style-type: none"> • Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, |

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| | | <p>medical homes that address women’s unique health care needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.</p> <ul style="list-style-type: none"> • Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment. • Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following: <ul style="list-style-type: none"> ○ An inability to perform 2 or more activities of daily living. ○ Cognitive impairment, including dementia. • Promote[ing] care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment. • Supporting care coordination for chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home telehealth technology. • Varying payment to physicians who order advanced diagnostic imaging services according to the physician’s adherence to appropriateness |

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| | | <p>criteria for the ordering of such services.</p> <ul style="list-style-type: none"> • Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act. • Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities. • Assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools. • Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State. • Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals. • Aligning nationally recognized, evidence-based guidelines of cancer care with payment incentives under Medicare in the areas of treatment planning and follow-up care planning. • Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge. • Funding home health providers who offer chronic |

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| | | <p>care management services to applicable individuals in cooperation with interdisciplinary teams.</p> <ul style="list-style-type: none"> • Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for: <ul style="list-style-type: none"> ○ Developing, documenting, and disseminating best practices and proven care methods; ○ Implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and ○ Providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs. ○ Facilitate[ing] inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems. • Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to |

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| | | <p>refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.</p> <ul style="list-style-type: none"> Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals. <p>In selecting models for testing, the CMI may consider several additional factors including:</p> <ul style="list-style-type: none"> Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching. <p>The Secretary must terminate or modify the design and implementation of a model unless the Secretary determines after testing has begun, that the model is expected to:</p> <ul style="list-style-type: none"> Improve the quality of care without increasing spending under the applicable title; Reduce spending under the applicable title without |

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| | | <p>reducing the quality of care; or</p> <ul style="list-style-type: none"> • Improve the quality of care and reduce spending. <p>The Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested or a demonstration project under section 1866C (the current Health Care Quality Demonstration Program, 42USC 1395cc-3) , to the extent determined appropriate by the Secretary, if:</p> <ul style="list-style-type: none"> • The Secretary determines that such expansion is expected to: <ul style="list-style-type: none"> ○ Reduce spending under applicable title without reducing the quality of care; or ○ Improve the quality of care and reduce spending; and • The Chief Actuary of CMS certifies that such expansion would reduce program spending under applicable titles. <p>Section 3022. No later than January 1, 2012, the Secretary must establish a shared savings program that promotes accountability for a patient population and coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under this program, groups of providers of services and suppliers meeting certain criteria may work together to manager and coordinate care for Medicare fee-for-service beneficiaries through an accountable care</p> |

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| | | <p>organization (ACO). ACOs that meet quality performance standards are eligible to receive payments for shared savings.</p> <p>Eligible ACOs must have established a mechanism for shared governance.</p> <p>An ACO professional is defined as a physician and a practitioner (a physician assistant, nurse practitioner, or clinical nurse specialist).</p> <p>Section 3023. The Secretary must establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization to improve the coordination, quality, and efficiency of health care services under this title.</p> <p>Defines “applicable services” as</p> <ul style="list-style-type: none"> • Acute care inpatient services. • Physicians’ services delivered in and outside of an acute care hospital setting. • Outpatient hospital services, including emergency department services. • Post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital. • Other services that the Secretary determines appropriate. |

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| | | <p>Defines “provider of service” as a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program [or, for purposes of section 1814(g) and section 1835(e), a fund].</p> <p>Defines “supplier” as the same as such term in section 1861(d) (unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.)</p> <p>Section 3024. The Secretary must conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries.</p> <p>The program shall test whether a model results in</p> <ul style="list-style-type: none"> • Reducing preventable hospitalizations; • Preventing hospital readmissions; • Reducing emergency room visits; • Improving health outcomes commensurate with the beneficiaries’ stage of chronic illness; • Improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests; • Reducing the cost of health care services covered |

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| | | <p>under this title; and</p> <ul style="list-style-type: none"> Achieving beneficiary and family caregiver satisfaction. <p>Defines an “independence at home medical practice” as a legal entity that meets several requirements including:</p> <ul style="list-style-type: none"> Is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who have experience providing home-based primary care to applicable beneficiaries, make in-home visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary’s chronic conditions and designed to achieve the desired specified results; <p>Nothing in this subsection shall be construed as preventing an independence at home medical practice from including a provider of services or a participating practitioner described in section 1842(b)(18)(C) [physician assistant, nurse practitioner, or clinical nurse specialist; a certified registered nurse anesthetist; a certified nurse-midwife; a clinical social worker; a clinical psychologist; a registered dietitian or nutrition professional that is affiliated with the practice under an arrangement structured so that such provider of services or practitioner participates in the demonstration program and</p> |

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| | | <p>shares in any savings under the demonstration program.</p> <p><i>See Medicare Advantage Plans & MTM (Section 3201).</i></p> <p>Section 3502. The Secretary must establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (“health teams”) to support primary care practices within the hospital service areas served by the eligible entities.</p> <p>To be eligible to receive a grant or contract under subsection (a), an entity must meet several requirements including:</p> <ul style="list-style-type: none"> • Ensure that the health team established by the entity includes an interdisciplinary, interprofessional team of health care providers, as determined by the Secretary; such team may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers (including substance use disorder prevention and treatment providers), doctors of chiropractic, licensed complementary and alternative medicine practitioners, and physicians’ assistants; <p>A health team established pursuant to a grant or contract under subsection (a) must meet certain requirements, including:</p> <ul style="list-style-type: none"> • Establish contractual agreements with care |

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| | | <p>providers to provide support services;</p> <ul style="list-style-type: none"> • Collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary; • In collaboration with local health care providers, develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary; • Incorporate health care providers, patients, caregivers, and authorized representatives in program design and oversight; • Provide support necessary for local primary care providers to coordinate and/or provide access to services, including: <ul style="list-style-type: none"> ○ Provide access to pharmacist-delivered medication management services, including medication reconciliation; • Provide 24-hour care management and support during transitions in care settings including: <ul style="list-style-type: none"> ○ A transitional care program that provides onsite visits from the care coordinator, |

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| | | <p>assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals, nursing home, or other institution setting;</p> <ul style="list-style-type: none"> ○ Discharge planning and counseling support to providers, patients, caregivers, and authorized representatives; ○ Assuring that post-discharge care plans include medication management, as appropriate; ○ Referrals for mental and behavioral health services, which may include the use of info lines; and ○ Transitional health care needs from adolescence to adulthood. |
| Medicaid: General | Section 1712. Prohibits State Medicaid programs from excluding from coverage tobacco cessation products. | <p>Section 2001. Medicaid benchmark benefits must consist of at least minimum essential coverage, including coverage of prescription drugs.</p> <p>Section 2502. Removes smoking cessation agents (including FDA-approved, over-the-counter agents), barbiturates, and benzodiazepines from Medicaid’s drug exclusion list.</p> |
| Medicaid: Payment | Section 1728. Requires State Medicaid programs to submit annually to the Secretary payment rates to be used to reimburse providers for furnishing covered services and directs the Secretary to review such rates for sufficiency. | Section 2503. “Fixes” the average manufacturers price (AMP) formula used by the Medicaid program to calculate reimbursement for generic drug products. The Federal upper limit (FUL) is set at no less than 175% of the weighted average AMP. |

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| | <p>Section 1741. Redefines AMP to more accurately reflect retail acquisition costs. Excludes from the AMP calculation:</p> <ul style="list-style-type: none"> • Customary prompt pay discounts to wholesalers. • Bona fide service fees paid by manufacturers. • Reimbursements for recalled, damaged, expired or otherwise unsalable returned goods, including reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction. • Sales directly to, or rebates, discounts, or other price concessions provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, mail order pharmacies that are not open to all members of the public, or long term care providers, provided that these rebates, discounts, or price concessions are not passed through to retail pharmacies. • Sales directly to, or rebates, discounts, or other price concessions provided to, hospitals, clinics, and physicians, unless the drug is an inhalation, infusion, or injectable drug, or unless the Secretary determines, as allowed for in Agency administrative procedures, that it is necessary to include such sales, rebates, discounts, and price concessions in order to obtain an accurate AMP for the drug. • Rebates, discounts, or other price concessions required to be provided under Medicare Part D agreements for | <p>Directs the Secretary to implement a smoothing process for AMP.</p> <p>Excludes from the average manufacturer price for a covered outpatient drug:</p> <ul style="list-style-type: none"> • Customary prompt pay discounts extended to wholesalers; • Bona fide service fees paid by manufacturers to wholesalers 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); • 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 • 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 as a wholesaler or a retail |

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| | <p>dual-eligibles.</p> <p>The weighted average of brand and generic AMP data will be used.</p> <p>Sets the generic reimbursement at 130% of the weighted average AMP.</p> <p>Authorizes the Secretary to utilize a smoothing process to reduce significant variations from month to month due to rebates, discounts, and other pricing practices.</p> <p>AMP data will not be posted on a public website.</p> <p>The new Medicaid FUL benchmark will not be implemented until January 2011—the current benchmark (150% of the lowest published price) will be used until that date.</p> <p>Section 1746. Requires State Medicaid programs to submit annually to CMS information on the determination of rates of payment to providers for covered services.</p> | <p>community pharmacy.</p> <ul style="list-style-type: none"> Notwithstanding the clause above, any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the AMP for a covered outpatient drug. <p>Amends the law so that a generic must be widely available in the United States, not just a single state.</p> <p>Defines “retail community pharmacy” as an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does 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.</p> <p>Defines “wholesaler” as a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug</p> |

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| | | <p>warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.’’</p> <p>Requires public posting of the weighted average of the most recently reported monthly AMP and the average retail survey price determined for each multiple source drug.</p> <p>Clarifies that these amendments will take effect the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of this Act, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.</p> |
| Medicare Advantage Plans & MTM | | <p>Section 3201. Establishes a care coordination and management performance bonus for Medicare Advantage plans. These programs include:</p> <ul style="list-style-type: none"> • Care management programs that: <ul style="list-style-type: none"> ○ Target individuals with 1 or more chronic conditions; ○ Identify gaps in care; and ○ Facilitate improved care by using additional resources like nurses, nurse practitioners, and physician assistants. • Programs that focus on patient education and self-management of health conditions, including interventions that: <ul style="list-style-type: none"> ○ Help manage chronic conditions; ○ Reduce declines in health status; and ○ Foster patient and provider collaboration. |

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| | | <ul style="list-style-type: none"> • Transitional care interventions that focus on care provided around a hospital inpatient episode, including programs that target post-discharge patient care in order to reduce unnecessary health complications and readmissions. • Patient safety programs, including provisions for hospital-based patient safety programs in contracts that the Medicare Advantage organization offering the MA plan has with hospitals. • Financial policies that promote systematic coordination of care by primary care physicians across the full spectrum of specialties and sites of care, such as medical homes, capitation arrangements, or pay-for-performance programs. • Programs that address, identify, and ameliorate health care disparities among principal at-risk subpopulations. • Medication therapy management programs that are more extensive than is required under section 1860D-4(c). • Health information technology programs, including clinical decision support and other tools to facilitate data collection and ensure patient-centered, appropriate care. • Such other care management and coordination programs as the Secretary determines appropriate. |
| Medicare: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) | Section 1141A. Following the rental period of 13 months, allows beneficiaries to return group 3 support surfaces to the original supplier or to elect to take ownership of such equipment. The goal is to assure that | Section 3109. Prohibits the Secretary from requiring a pharmacy to have submitted to the Secretary evidence of accreditation prior to January 1, 2011. |

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| Program | <p>beneficiaries continue to have access to such item in the event of a recurrent medical need.</p> <p>Sections 1147. Removes the current Medicare surety bond requirement when a pharmacy or supplier that exclusively furnishes eyeglasses or contact lenses if the pharmacy or supplier has been enrolled as a supplier of DMEPOS and has been issued a supplier number for at least five years, and if a final adverse action has never been imposed on them.</p> <p>Waives accreditation requirements for pharmacies that supply diabetic testing supplies, canes, and crutches. Also, clarifies that a supplier that has applied for accreditation by August 1, 2009 to meet the accreditation requirements shall retain their supplier's provider or supplier number until an independent accreditation organization determines if such supplier complies with the relevant requirements.</p> <p>Section 1149B. Instructs the Government Accountability Office to evaluate establishment of a competitive bidding program for manufacturers of durable medical equipment and supplies.</p> | <p>Beginning January 1, 2011, exempts from the current DMEPOS accreditation requirements certain pharmacies that meet each of the following criteria:</p> <ul style="list-style-type: none"> • The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary. • The pharmacy has been enrolled as a DMEPOS supplier, has been issued (which may include the renewal of) a provider number for at least 5 years for which a final adverse action has not been imposed in the past 5 years. • The pharmacy attests to the Secretary that the pharmacy meets the above criteria. • The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the above criteria. Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary. <p>The Secretary may implement these amendments by program instruction or otherwise.</p> |

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| | | <p>Nothing in the provisions of or amendments made by this section shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under the Medicare program.</p> <p>The Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.</p> |
| Medicare: General | <p>Section 1313. Establishes Medicare payment for certified diabetes educators (CDE) for the provision of outpatient self-management training services.</p> <p>Section 1905. Requires CMS to establish a dedicated office or program to improve coordination of benefits and other policies for beneficiaries dually eligible for Medicare and Medicaid.</p> <p>Section 1906. Directs the Secretary to consult with relevant research agencies and conduct an assessment of the diseases and conditions that are or could become most cost-intensive for the Medicare program. Directs the Secretary to assess whether current research priorities are appropriately addressing such conditions and make funding recommendations concerning research that should be funded to improve the prevention, treatment, or cure of such conditions.</p> | <p>Section 3131. Adjusts Medicare payments for home health services to reflect such factors as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. In conducting the analysis under the preceding sentence, the Secretary may consider differences between hospital-based and freestanding agencies, between for-profit and nonprofit agencies, and between the resource costs of urban and rural agencies.</p> <p>The Medicare Payment Advisory Commission must conduct a study on the implementation of these amendments. Such study must include an analysis of the impact of such amendments on:</p> <ul style="list-style-type: none"> • Access to care; • Quality outcomes; • The number of home health agencies; and |

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| | | <ul style="list-style-type: none"> • Rural agencies, urban agencies, for-profit agencies, and nonprofit agencies. <p>The Secretary must conduct a study to evaluate the costs and quality of care among efficient home health agencies relative to other such agencies in providing ongoing access to care and in treating Medicare beneficiaries with varying severity levels of illness.</p> |
| Medicare Part D Coverage Gap | <p>Section 1181. Eliminates the Part D coverage gap (donut hole), beginning with a \$500 reduction in 2010 and completing the phase-out by 2019. Funds to do so are raised by requiring prescription drug manufacturers to provide Medicaid rebates for drugs used by dual-eligibles.</p> <p>Section 1182. For brand-name drugs, reduces the charge to patients in the donut hole to 50% while counting 100% of the drug cost towards the patient’s true out-of-pocket costs (TrOOP).</p> | <p>Section 3301. The Secretary must establish a Medicare coverage gap discount program by July 1, 2010. Under the program, the Secretary shall enter into agreements with manufacturers that require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.</p> <p>Such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by the mail-order service at the point-of-sale of an applicable drug. From July 1, 2010 to December 31, 2011, if it is not practicable to provide the discounted prices at the point-of-sale, then procedures must be established to provide the discounted prices as soon as practicable after the point-of-sale.</p> <p>Procedures must be established to ensure that, no later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail-order service, the pharmacy or mail-order service is reimbursed for an amount equal to the difference between:</p> <ul style="list-style-type: none"> • The negotiated price of the applicable drug; and • The discounted price of the applicable drug. |

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| | | The Secretary shall enter in a contract with one or more third parties to administer the requirements established by the Secretary to carry out this section. |
| Medicare Part D Direct Negotiation | Section 1186. Requires the Secretary to negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to a Medicare Part D prescription drug plan for covered Part D drugs. | |
| Medicare Part D General Improvements | <p>Section 1184. Includes AIDS drug assistance programs and Indian health services in calculating out-of-pocket costs.</p> <p>Section 1185. Limits mid-year changes in enrollment that result in adverse formulary changes.</p> <p>Section 1188. Clarifies that Part D plans may offer generic drugs to enrollees with zero copayment to encourage use of lower-cost generic drugs.</p> <p>Section 1202. Eliminates cost-sharing for people receiving care under a home and community-based waiver who would otherwise receive institutional care.</p> <p>Section 1205. Authorizes intelligent assignment of auto-enrolled full-benefit dual-eligibles to maximize the access to necessary prescription drugs while minimizing the costs to the beneficiary.</p> <p>Section 1206. Gives CMS authority to enroll subsidy-</p> | <p>Section 3305. No later than January 1, 2011, the Secretary must, in the case of a subsidy eligible individual who is reassigned by the Secretary to a new drug plan, provide the individual within 30 days of such reassignment:</p> <ul style="list-style-type: none"> • Information on formulary differences between the individual’s former plan and the plan to which the individual is reassigned with respect to the individual’s drug regimens; and • A description of the individual’s right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance. <p>Section 3307. Amends Medicare Part D’s process for determining what categories or classes of drugs are considered protected (and therefore included in total in Part D plan formularies).</p> <ul style="list-style-type: none"> • The Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern. • Until such time as the Secretary establishes the |

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| | <p>eligible beneficiaries into plans using a process that accounts for the quality, cost and/or formulary of plans, while also giving beneficiaries the option of choosing another plan.</p> <p>Section 1222. Directs the Secretary to award no fewer than 24 3-year grants to eligible Medicare service providers to improve effective communication between such providers and Medicare beneficiaries who are living in communities where racial and ethnic minorities, including populations that face language barriers, are underserved with respect to such services.</p> | <p>criteria, the following categories and classes of drugs are protected:</p> <ul style="list-style-type: none"> ○ Anticonvulsants. ○ Antidepressants. ○ Antineoplastics. ○ Antipsychotics. ○ Antiretrovirals. ○ Immunosuppressants for the treatment of transplant rejection <p>Section 3309. Amends the Social Security Act to adjust the cost sharing for certain dual eligible individuals who would be an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver or services provided through enrollment in a Medicaid managed care organization.</p> <p>Section 3312. Requires each Medicare Part D PDP sponsor to:</p> <ul style="list-style-type: none"> ● Use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and ● Provide instant access to such process by enrollees through a toll-free telephone number and an Internet website. |

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| | | <p>Section 3313. The Inspector General of the Department of HHS must conduct a study of the extent to which Medicare Part D plan formularies include drugs commonly used by full-benefit dual eligible individuals.</p> <ul style="list-style-type: none"> • No later than July 17 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate. <p>The Inspector General of the Department of HHS must conduct a study on prices for covered Part D drugs under the Medicare and Medicaid. Such study shall include the following:</p> <ul style="list-style-type: none"> • A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title, of: <ul style="list-style-type: none"> ○ (I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA- PD plans; and ○ (II) The prices paid for covered outpatient drugs by a State plan under Medicaid. • An assessment of: <ul style="list-style-type: none"> ○ The financial impact of any discrepancies in such prices on the Federal Government; and ○ The financial impact of any such |

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| | | <p>discrepancies on enrollees under part D or individuals eligible for Medicaid.</p> <p>Section 3314. Includes costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D.</p> <p>Section 3315. Reduces the Medicare Part D coverage gap by, beginning with January 1, 2010, increasing the initial coverage limit by \$500.</p> <ul style="list-style-type: none"> • The Secretary must establish procedures, which may include a reconciliation process, to fully reimburse PDP and MA-PD plans for the reduction in beneficiary cost sharing associated with the application of this change. ▪ The Secretary must establish a procedure for retroactive reimbursement of Part D eligible individuals who are covered under such a plan for costs which are incurred before the date of initial implementation. |
| Medicare Part D Long-Term Care Pharmacy | <p>Section 1183. Repeals current law (scheduled to begin 1/1/2010) requiring pharmacies located in or contracting with long-term care facilities to submit claims to a Part D sponsor no less than 30 days and no more than 90 days.</p> <p>Section 1187. Requires Part D plans to develop utilization management techniques to reduce prescription drug waste in long-term care facilities.</p> | <p>Section 3310. The Secretary must require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA-PD plans, and any other stakeholders the</p> |

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| | | <p>Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.</p> <p>This requirement shall apply to plan years beginning on or after January 1, 2012.</p> |
| <p>Medication Therapy Management (MTM) Grant/Pilot Programs</p> | <p>Section 2528. Directs the Secretary, acting through the Director of AHRQ, to establish a program to provide grants to eligible entities to implement medication management services (MTMS) provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases.</p> <p>Services are based upon the Core Elements of an MTM Service Model 2.0 and include assessing a patient’s medication therapy, developing an action plan, working with the rest of the care team to implement the action plan, monitoring the patient, and providing education and training to enhance the understanding and appropriate use of the medications by the patient.</p> <p>The services are provided to targeted individuals who: take 4 or more prescribed medications; take any ‘high risk’ medications; have 2 or more chronic diseases; or have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a</p> | <p>Section 3503. The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the ‘Center’) (see section 3501) , shall establish a program to provide grants or contracts to eligible entities to implement medication management (‘MTM’) services provided by licensed pharmacists, as a collaborative, multidisciplinary, interprofessional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.</p> <p>To be eligible to receive a grant or contract under subsection (a), an entity shall:</p> <ul style="list-style-type: none"> • Provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e); • Submit to the Secretary a plan for achieving long-term financial sustainability; • Where applicable, submit a plan for coordinating MTM services through local community health |

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| | <p>high risk of medication-related problems.</p> <p>Directs the Secretary of Health and Human Services to consult with experts in medication therapy management, to develop interdisciplinary care management programs through.</p> <p>Section 2593. Directs the Secretary of HHS to conduct a study to determine if any new grant programs are duplicative of one or more of other grant HHS grant programs. Authorizes the Secretary to attempt to integrate duplicative programs or if that’s not possible, to eliminate the duplicative grant program.</p> <p>Section 2594. Directs the Secretary of HHS, in collaboration with CDC, to review update and utilization of diabetes screening benefits to identify problems; and to establish an outreach program to increase awareness of diabetes screening benefits.</p> | <p>teams established in section 3502 of the Patient Protection and Affordable Care Act or in collaboration with primary care extension programs established in section 399W;</p> <ul style="list-style-type: none"> • Submit a plan for meeting the requirements under subsection (c); and • Submit to the Secretary such other information as the Secretary may require. • The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include: <ul style="list-style-type: none"> ○ Performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services; ○ Formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient; ○ Selecting, initiating, modifying, recommending changes to, or administering medication therapy; ○ Monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness; |

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| | | <ul style="list-style-type: none"> ○ Performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional follow up interventions on a schedule developed collaboratively with the prescriber; ○ Documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion; ○ Providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative; ○ Providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens; ○ Coordinating and integrating MTM services within the broader health care management services provided to the patient; and ○ Such other patient care services allowed under pharmacist scopes of practice in use |

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| | | <p>in other Federal programs that have implemented MTM services.</p> <p>MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who:</p> <ul style="list-style-type: none"> • Take 4 or more prescribed medications (including over-the-counter medications and dietary supplements); • Take any ‘high risk’ medications; • Have 2 or more chronic diseases, as identified by the Secretary; 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. <p>In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.</p> |

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| | | <p>An entity that receives a grant or contract under this subsection shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out, including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.</p> <p>The Secretary shall submit to the relevant committees of Congress a report which shall:</p> <ul style="list-style-type: none"> • Assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program; • Assess changes in overall health care resource use by targeted individuals; • Assess patient and prescriber satisfaction with MTM services; • Assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications; • Identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; |

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| | | <p>and</p> <ul style="list-style-type: none"> • Evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed. <p>The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.</p> |
| Pain Care | <p>Section 2561. Requires the Secretary to seek to enter into an agreement with the National Institute of Medicine to convene a conference on pain.</p> <p>Section 2562. Encourages the National Institutes of Health Director to continue to expand, through the Pain Consortium, a program of basic and clinical research on pain including research on the treatment of pain.</p> <p>Section 2563. Requires the Secretary to establish and implement a national education outreach and awareness campaign on pain management.</p> | <p>Section 4305. The Secretary shall enter into an agreement with the IOM to convene a Conference on Pain to:</p> <ul style="list-style-type: none"> ▪ Increase the recognition of pain as a significant public health problem in the United States; ▪ Evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the general population, and in demographic groups that may be disproportionately affected by inadequacies in the assessment, diagnosis, treatment, and management of pain; ▪ Identify barriers to appropriate pain care; ▪ Establish an agenda for action in both the public and private sectors that will reduce such barriers and significantly improve the state of pain care research, education, and clinical care in the United States. |

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| | | <p>Encourages the Director of NIH to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.</p> <p>Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, must develop and submit to the Director of NIH recommendations on appropriate pain research initiatives.</p> <p>The Secretary must establish and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee, to coordinate all efforts within the Department of HHS and other Federal agencies that relate to pain research. The Committee must be composed of the voting and non-voting members:</p> <ul style="list-style-type: none"> ▪ Voting members appointed by the Secretary include: <ul style="list-style-type: none"> ○ 6 non-Federal members from among scientists, physicians, and other health professionals. ○ 6 members from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. <p>The Committee must:</p> |

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| | | <ul style="list-style-type: none"> • Develop a summary of advances in pain care research supported or conducted by the Federal agencies; • Identify critical gaps in basic and clinical research on the symptoms and causes of pain; • Make recommendations to ensure that the activities of the NIH and other Federal agencies are free of unnecessary duplication of effort; • Make recommendations on how best to disseminate information on pain care; and • Make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, crosscutting research. <p>The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.</p> |
| Prevention and Wellness | <p>Section 112. Establishes a grant program for small employers to assist with the creation of employee wellness programs that promote healthy behaviors.</p> <p>Section 1305. Eliminates cost-sharing for Medicare preventive services, including: diabetes outpatient self-management training services; diabetes screening tests; and certain vaccinations.</p> | <p>Section 4001. The President shall establish, within HHS, a council to be known as the “National Prevention, Health Promotion and Public Health Council.” The Council shall:</p> <ul style="list-style-type: none"> • Provide coordination and leadership at the Federal level, and among all Federal departments and agencies, with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United |

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| | <p>Section 1311. Expands Medicare-covered preventive services at Federally Qualified Health Centers (FQHCs).</p> <p>Section 2301. Establishes a Prevention and Wellness Trust within the Public Health Service Act. Directs the Secretary to submit to Congress a national strategy that is designed to improve the Nation’s health through evidence-based clinical and community prevention and wellness activities including core public health infrastructure improvement activities. Directs the Secretary to establish a permanent task force to be known as the Task Force on Clinical Preventive Services.</p> <p>Directs the Secretary to establish a permanent task for to be known as the Task Force on Community Preventive Services.</p> <p>Requires the Secretary to develop and periodically update a national strategy designed to improve the nation’s health through evidence-based clinical and community-based prevention and wellness activities.</p> <p>Converts the existing U.S. Preventive Services Task Force into the Task Force on Clinical Preventive Services. The charge to the Task Force is to conduct evidence-based systemic reviews of data and literature to determine which clinical preventive services are scientifically proven to be effective.</p> <p>Establishes a grant program to support the delivery of</p> | <p>States;</p> <ul style="list-style-type: none"> • After obtaining input from relevant stakeholders, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States; • Provide recommendations to the President and Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition; • Consider and propose evidence-based models, policies, and innovative approaches for the promotion of transformative models of prevention, integrative health, and public health on individual and community levels across the United States; <p>Section 4003. The AHRQ Director must convene an independent Preventive Services Task Force to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical</p> |

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| | <p>evidence-based, community-based prevention and wellness services across the country. Eligible entities include state and local governments, nonprofits, and consortia such as community partnerships representing Health Empowerment Zones.</p> <p>Section 3101. Amends the Indian health Care Act, adding the following sections: Section 202. Directs the Secretary to provide health promotion and disease prevention services to Indians and to submit to the President an evaluation statement of the resources required to undertake these activities; and Section 203. Provides for the monitoring and treatment of diabetes, as well as data collection and dissemination.</p> <p>Section 3121. Requires the Secretary to develop and periodically update a national strategy designed to improve the nation’s health through evidence-based clinical and community-based prevention and wellness activities.</p> <p>Section 3131. Converts the existing U.S. Preventive Services Task Force into the Task Force on Clinical Preventive Services. The charge to the Task Force is to conduct evidence-based systematic reviews of data and literature to determine which clinical preventive services (i.e. preventive services delivered by traditional health care providers in clinical settings) are scientifically proven to be effective.</p> | <p>Preventive Services. Such recommendations shall consider clinical preventive best practice recommendations from the AHRQ, the NIH, the CDC, the IOM, specialty medical associations, patient groups, and scientific societies.</p> <p>The Director of the CDC shall convene an independent Community Preventive Services Task Force to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services, for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, non-profit organizations, Congress and other policy-makers, etc. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.</p> <p>Section 4103. Provides Medicare coverage of an annual personal prevention plan that includes a health assessment of the individual. Such assessment may include a screening schedule for the next 5 to 10 years as appropriate based on recommendations of the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual’s health status, screening history, and age-</p> |

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| | <p>Section 3132. Codifies the existing Task Force on Community Preventive Services. The charge to the Task Force is to conduct evidenced-based systematic reviews of data and literature to determine which community preventive services (i.e. preventive services that are delivered outside traditional clinic settings and frequently implemented across targeted groups) are scientifically proven to be effective.</p> <p>Section 3151. Establishes a grant program to support the delivery of evidence-based, community-based prevention and wellness services across the country. Eligible entities include state and local governments, nonprofits, and consortia such as community partnerships representing Health Empowerment zones.</p> <p>Section 1711. Requires State Medicaid programs to cover, without cost-sharing, preventive services that are recommended by the U.S. Preventive Services Task Force and appropriate for Medicaid beneficiaries.</p> | <p>appropriate preventive services covered under Medicare.</p> <p>Section 4104. Waives copays and deductibles for certain preventive services.</p> <p>Section 4108. Directs the Secretary to award grants to States to carry out initiatives to provide incentives to Medicaid beneficiaries who:</p> <ul style="list-style-type: none"> • Successfully participate in a program described below; and • Upon completion of such program demonstrate changes in health risk and outcomes, including the adoption and maintenance of healthy behaviors by meeting specific targets. <p>The programs are designed to address the needs of Medicaid beneficiaries and have demonstrated success in helping individuals achieve one or more of the following:</p> <ul style="list-style-type: none"> • Ceasing use of tobacco products. • Controlling or reducing their weight. • Lowering their cholesterol. • Lowering their blood pressure. • Avoiding the onset of diabetes or, in the case of a diabetic, improving the management of that condition. <p>Section 4201. The Secretary, acting through the Director of the CDC, must award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and</p> |

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| | | <p>dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming.</p> <p>Activities within a plan may focus on (but not be limited to):</p> <ul style="list-style-type: none"> • Creating healthier school environments; • Creating the infrastructure to support active living and access to nutritious foods in a safe environment; • Developing and promoting programs targeting a variety of age levels to increase access to nutrition, physical activity and smoking cessation, improve social and emotional wellness, enhance safety in a community, or address any other chronic disease priority area identified by the grantee; • Assessing and implementing worksite wellness programming and incentives; • Working to highlight healthy options at restaurants and other food venues; • Prioritizing strategies to reduce racial and ethnic disparities, including social, economic, and geographic determinants of health; and • Addressing special populations needs, including all age groups and individuals with disabilities, and individuals in both urban and rural areas. <p>Section 4202. The Secretary, acting through the CDC</p> |

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| | | <p>Director, must award grants to State or local health departments and Indian tribes to carry out 5-year pilot programs to provide public health community interventions, screenings, and where necessary, clinical referrals for individuals who are between 55 and 64 years of age.</p> <p>A State or local health department must use the funds to conduct:</p> <ul style="list-style-type: none"> • Public health interventions such as efforts to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population. <ul style="list-style-type: none"> ○ A State or local health department shall enter into contracts with community health centers or rural health clinics and mental health and substance use disorder service providers to assist in the referral/treatment of at risk patients to community resources for clinical follow-up and help determine eligibility for other public programs. • Community preventive screenings to identify risk factors for cardiovascular disease, cancer, stroke, and diabetes. <p>The Secretary must conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries.</p> |

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| | | <p>Section 4303. Directs the Secretary to provide employers with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness program including:</p> <ul style="list-style-type: none"> ▪ Measuring the participation and methods to increase participation of employees in such programs; ▪ Developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and ▪ Evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees. |
| Privacy | <p>Section 239. Directs the Secretary of HHS to conduct a study on the use of physician prescriber information in sales and marketing practices of pharmaceutical manufacturers; to report to Congress on actions needed to protect providers from biased marketing and sales practices.</p> | |
| Public Health | <p>Section 1310. Transfers coverage from Medicare Part D to Medicare Part B for all Medicare-covered vaccines. Vaccines, except influenza, will be paid for using an ASP-based formula.</p> <p>Section 1725. Allows children who do not have insurance</p> | <p>Section 2713. A group health plan and a health insurance issuer offering group or individual health insurance coverage must provide for coverage for and shall not impose any cost sharing requirements for immunizations that have a recommendation from the Advisory Committee on Immunization Practices of the CDC with</p> |

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| | <p>coverage for immunizations to receive vaccines through the Vaccines for Children program at a public health clinic.</p> <p>Section 2524. Establishes a new program of demonstration projects to study the feasibility of using elementary and secondary schools as influenza vaccination centers.</p> | <p>respect to the individual involved.</p> <p>Section 4204. Authorizes the Secretary to negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided under subsection (e).</p> <p>Authorizes a State to obtain additional quantities of such adult vaccines through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.</p> <p>The Secretary, acting through the CDC Director, must 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>Funds received under a grant under this subsection must be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary) or other evidence-based interventions, including:</p> <ul style="list-style-type: none"> ▪ Providing immunization reminders or recalls for target populations of clients, patients, and consumers; ▪ Educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions; |

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| | | <ul style="list-style-type: none"> ▪ Reducing out-of-pocket costs for families for vaccines and their administration; ▪ Carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization; ▪ Providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services; ▪ Providing reminders or recalls for immunization providers; ▪ Conducting assessments of, and providing feedback to, immunization providers; ▪ Any combination of one or more interventions described in this paragraph; or ▪ Immunization information systems to allow all States to have electronic databases for immunization records. <p>Requires states to report on their progress and the Secretary to report to Congress on the effectiveness of the demonstration program with recommendations on whether to continue and expand such program.</p> <p>Authorized funds to be appropriated to carry out this subsection as may be necessary for each of fiscal years 2010 through 2014.</p> |

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| | | <p>Amends the Public Health Service Act to reauthorize an immunization program.</p> <p>Clarifies that nothing in this section or any other provision of this Act shall be construed to decrease children's access to immunizations.</p> <p>Requires the Comptroller General of the United States to conduct a study and report on the ability of Medicare beneficiaries who were 65 years of age or older to access routinely recommended vaccines covered under the prescription drug program under Medicare Part D over the period since the establishment of such program. Such study shall include the following:</p> <ul style="list-style-type: none"> ▪ An analysis and determination of: <ul style="list-style-type: none"> ○ The number of Medicare beneficiaries who were 65 years of age or older and were eligible for a routinely recommended vaccination that was covered under part D; ○ The number of such beneficiaries who actually received a routinely recommended vaccination that was covered under part D; and ○ Any barriers to access by such beneficiaries to routinely recommended vaccinations that were covered under part D. ▪ A summary of the findings and recommendations by government agencies, departments, and |

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| | | <p>advisory bodies (as well as relevant professional organizations) on the impact of coverage under part D of routinely recommended adult immunizations for access to such immunizations by Medicare beneficiaries.</p> <p>Appropriates \$1,000,000 for fiscal year 2010 to carry out this subsection.</p> |
| Public Plan | <p>Section 323. The Secretary negotiates payment for health care providers, and items and service, including prescription drugs. Medicare providers are presumed to be participating unless they opt out.</p> <p>Section 324. Authorizes the Secretary to utilize innovative payment mechanisms and policies to determine payments for items and services under the public health insurance option. Innovative payments must promote care that is integrated, patient-centered, quality and efficient; and the payments must be designed to: improve health outcomes; reduce health disparities; provide efficient and affordable care; address geographic variation in the provision of health services; or prevent or manage chronic illness.</p> <p>Section 325. Provides the Secretary of HHS the authority to develop conditions for provider participation. Providers must be excluded from participating in the public option if they are excluded from other federal health care programs.</p> | <p>Section 1323. Directs the Secretary to establish a community health insurance option to offer, through the Exchanges, health care coverage throughout the United States.</p> <p>Does not require a health care provider or an individual to participate in a community health insurance option or to impose any penalty for non-participation.</p> <p>A State may elect to prohibit Exchanges in such State from offering a community health insurance option if such State enacts a law to provide for such prohibition. A State may also repeal such a law to provide for the offering of such an option through an Exchange.</p> <p>Except as provided below, a community health insurance option offered under this section shall provide coverage only for the essential benefits (described in the “Access” section above).</p> <p>Does not preclude a State from requiring benefits in addition to the essential benefits package be provided to</p> |

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| | | <p>enrollees of a community health insurance option offered in such State.</p> <ul style="list-style-type: none"> • A State must make payments to or on behalf of an eligible individual to defray the cost of any such additional benefits. • Nothing prohibits an individual enrolled in a community health insurance option from paying out-of-pocket the full cost of any item or service not included as an essential health benefit or otherwise covered as a benefit by the health plan. Nothing in this subparagraph prohibits any type of medical provider from accepting an out-of-pocket payment from an individual enrolled in a community health insurance option for a service otherwise not included as an essential health benefit. <p>The Secretary must negotiate rates for the reimbursement of health care providers for benefits covered under a community health insurance option.</p> <ul style="list-style-type: none"> • A State Advisory Council may develop or encourage the use of innovative payment policies that promote quality, efficiency, and savings to consumers. <p>A State that establishes a State Advisory Council must include as its members representatives of the public and shall include health care consumers and providers.</p> <p>The Secretary may increase the plan fees based on the</p> |

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| | | <p>extent to which it meets certain performance requirements including the promotion of high quality clinical care.</p> <p>Section 1324. Stipulates that private health insurance coverage is not subject to any of the following Federal or State laws if a qualified health plan offered under the CO-OP, a community health insurance option, or a nationwide qualified health plan is not subject to such law: guaranteed renewal; rating; pre-existing conditions; non-discrimination; quality improvement and reporting; fraud and abuse; solvency and financial requirements; market conduct; prompt payment; appeals and grievances; privacy and confidentiality; licensure; and benefit plan bacterial or information.</p> <p>Section. 1331. The Secretary must establish a basic health program under which a State may enter into contracts to offer one or more standard health plans providing at least the essential health benefits (described in the “Access” section above).</p> <p>A State basic health program must establish a competitive process for entering into contracts with standard health plans. As part of this competitive process, there are State requirements including:</p> <ul style="list-style-type: none"> • Negotiation with standard health plans for the inclusion of innovative features in the plan including <ul style="list-style-type: none"> ○ Care coordination and care management for enrollees, especially for those with |

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| | | <p>chronic health conditions;</p> <ul style="list-style-type: none"> ○ Incentives for use of preventive services; and ○ The establishment of relationships between providers and patients that maximize patient involvement in health care decision-making, including providing incentives for appropriate utilization under the plan. |
| Quality | <p>Section 1441. Directs the Secretary to establish and periodically update national priorities for performance improvement.</p> <p>Section 1442. Directs the Secretary to give priority to the development of quality measures that allow the assessment of: health outcomes, presence of impairment, and functional status of patients; the continuity and coordination of care and care transitions for patients across providers and health care settings, including end of life care; patient experience and patient engagement; the safety, effectiveness, and timeliness of care; health disparities including those associated with individual race, ethnicity, age, gender, place of residence or language; and the efficiency and resource use in the provision of care.</p> <p>Section 1443. Provides for multi-stakeholder input into selecting quality measures. Defines a multi-stakeholder group as a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as: hospitals and other</p> | <p>Section 2717. Directs the Secretary, in consultation with experts in health care quality and stakeholders, to develop reporting requirements for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that:</p> <ul style="list-style-type: none"> • Improve health outcomes through the implementation of care activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance activities, including through the use of medical homes as defined later in the act; • Implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; |

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| | <p>institutional providers; physicians; health care quality alliances; nurses and other health care practitioners; health plans; patient advocates and consumer groups; employers; public and private purchasers of health care items and services; labor organizations; relevant departments or agencies of the United States; biopharmaceutical companies and manufacturers of medical devices; and licensing, credentialing, and accrediting bodies.</p> <p>Section 1446. Authorizes the Secretary to withhold payment for 90 days if the Secretary determines that there is significant risk of fraudulent activity among DME suppliers of a certain category of DME or within a certain geographic area, if it is a new supplier and their first DME claim.</p> <p>Section 2401. Creates a Center for Quality Improvement to identify, develop, evaluate and help implement best practices.</p> | <ul style="list-style-type: none"> • Implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and • Implement wellness and health promotion activities. <p>Section 1311. Regarding health plans in the Exchange, the Secretary, in consultation with experts in health care quality and stakeholders, must develop guidelines concerning the development of a payment structure that provides increased reimbursement or other incentives for:</p> <ul style="list-style-type: none"> • Improving health outcomes through the implementation of activities that shall include quality reporting, effective case management, care coordination, chronic disease management, medication and care compliance initiatives, including through the use of the medical home model, for treatment or services under the plan or coverage; • The implementation of activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; • The implementation of activities to improve patient safety and reduce medical errors through |

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| | | <p>the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and</p> <ul style="list-style-type: none"> • The implementation of wellness and health promotion activities. <p>Beginning January 1, 2015, a qualified health plan may contract with:</p> <ul style="list-style-type: none"> • A hospital with greater than 50 beds only if such hospital meets certain requirements including, implement: <ul style="list-style-type: none"> ○ A mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or • A health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require. <p>Section 3011. The Secretary must establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health. The Secretary shall ensure that priorities identified will:</p> <ul style="list-style-type: none"> • Have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations; |

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| | | <ul style="list-style-type: none"> • Identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care; • Address gaps in quality, efficiency, comparative effectiveness information, and health outcomes measures and data aggregation techniques; • Improve Federal payment policy to emphasize quality and efficiency; • Enhance the use of health care data to improve quality, efficiency, transparency, and outcomes; • Address the health care provided to patients with high-cost chronic diseases; • Improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections; • Reduce health disparities across health disparity populations and geographic areas; and • Address other areas as determined appropriate by the Secretary. <p>Section 3012. Directs the President to convene an Interagency Working Group on Health Care Quality.</p> <p>Section 3013. Directs the Secretary, in consultation with the Director AHRQ and the CMS Administrator, to identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that</p> |

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| | | <p>need improvement, updating, or expansion, consistent with the national strategy, for use in Federal health programs.</p> <p>In awarding grants, contracts, or agreements under this subsection, the Secretary must give priority to the development of quality measures that allow the assessment of:</p> <ul style="list-style-type: none"> • Health outcomes and functional status of patients; • The management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans; • The experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decision making about treatment options, including the use of shared decision making tools and preference sensitive care; • The meaningful use of health information technology; • The safety, effectiveness, patient centeredness, appropriateness, and timeliness of care; • The efficiency of care; • The equity of health services and health disparities across health disparity populations and geographic areas; • Patient experience and satisfaction; • The use of innovative strategies and methodologies; and |

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| | | <ul style="list-style-type: none"> • Other areas determined appropriate by the Secretary. <p>Section 3014. The Secretary must establish a pre-rulemaking process under which several steps occur with respect to the selection of quality measures including convening a multi-stakeholder group to provide input on the selection of quality measures.</p> <p>Section 3015. The Secretary must collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance measures and may award grants or contracts for this purpose.</p> <p>To be eligible for a grant or contact, an entity must be:</p> <ul style="list-style-type: none"> • A multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information; • An entity capable of submitting summary data for a particular population and providers; or • A Federal Indian Health Service program or health program operated by an Indian tribe. <p>The Secretary must make available to the public, through standardized Internet Web sites, performance information summarizing data on quality measures. Such data shall be tailored to respond to the differing needs of hospitals and</p> |

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| | | <p>other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders as the Secretary may specify.</p> <p>Section 3501. Amends the Public Health Service Act by adding a section on health care delivery system research to enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care, quality, safety and value.</p> <p>The Center for Quality Improvement and Patient Safety of AHRQ or any other relevant agency or department designated by the Director, must meet certain requirements including:</p> <ul style="list-style-type: none"> • Carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics; • Conduct or support activities consistent with the purposes described in subsection (a), and for: <ul style="list-style-type: none"> ○ Best practices for quality improvement practices in the delivery of health care services; and ○ That include changes in processes of care |

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| | | <p>and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;</p> <ul style="list-style-type: none"> • Identify health care providers, including health care systems, single institutions, and individual providers, that: <ul style="list-style-type: none"> ○ Deliver consistently high-quality, efficient health care services; and ○ Employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings; • Provide for the development of best practices in the delivery of health care services that: <ul style="list-style-type: none"> ○ Have a high likelihood of success, based on structured review of empirical evidence; ○ Are specified with sufficient detail of the individual processes, steps, training, skills, and knowledge required for implementation and incorporation into workflow of health care practitioners in a variety of settings; ○ Are designed to be readily adapted by health care providers in a variety of settings; and |

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| | | <ul style="list-style-type: none"> ○ Where applicable, assist health care providers in working with other health care providers across the continuum of care and in engaging patients and their families in improving the care and patient health outcomes; ● Provide for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services, including children’s health care, by involving multiple disciplines, managers of health care entities, broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and ● Build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out these activities. <p>The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve</p> |

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| | | <p>quality and efficiency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks. This research shall:</p> <ul style="list-style-type: none"> • Address the priorities identified by the Secretary in the national strategic plan established under section 399HH; • Identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by the entity with a contract under section 1890(a) of the Social Security Act in the report required under section 399JJ; • Address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (d); • Reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research; • Support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research; • Allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include: <ul style="list-style-type: none"> ○ The implementation of a national application of Intensive Care Unit |

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| | | <p>improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;</p> <ul style="list-style-type: none"> ○ Practical methods for addressing health care associated infections, including Methicillin-Resistant Staphylococcus Aureus and Vancomycin-Resistant Enterococcus infections and other emerging infections; and ○ Practical methods for reducing preventable hospital admissions and readmissions; <ul style="list-style-type: none"> ● Expand demonstration projects for improving the quality of children’s health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1139A of the Social Security Act for assessing and improving quality, where applicable; ● Identify and mitigate hazards by: <ul style="list-style-type: none"> ○ Analyzing events reported to patient safety reporting systems and patient safety organizations; and ○ Using the results of such analyses to develop scientific methods of response to such events; ● Include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery, as well as new research on improving such practices; and ● Include the examination of how to measure and |

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| | | <p>evaluate the progress of quality and patient safety activities.</p> <p>Section 3508. The Secretary may award grants to eligible entities or consortia under this section to carry out demonstration projects to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.</p> <p>To be eligible to receive a grant under subsection (a), an entity or consortium shall be or include:</p> <ul style="list-style-type: none"> • A health professions school; • A school of public health; • A school of social work; • A school of nursing; • A school of pharmacy; • An institution with a graduate medical education program; or • A school of health care administration. |
| Tele-health | <p>Section 1191. In Medicare, expands tele-health services that allow for access to care in underserved communities.</p> <p>Section 2523. Reauthorizes programs to support tele-health networks and tele-health resource centers and to provide incentives to coordinate telemedicine licensure activities among states.</p> | |
| Transparency | Section 233. When a QHBP offering entities contract with a pharmacy benefit manager (PBM) to manage | Section 6004. Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized |

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| | <p>prescription drug coverage or otherwise control prescription drug costs, the PBM must provide at least annually to the Commissioner and to the QHBP offering entity the following information:</p> <ul style="list-style-type: none"> • Information on the number and total cost of prescriptions under the contract that are filled via mail order and at retail pharmacies. • An estimate of aggregate average payments under the contract, per prescription (weighted by prescription volume), made to mail order and retail pharmacies, and the average amount, per prescription, that the PBM was paid by the plan for prescriptions filled at mail order and retail pharmacists. • An estimate of the aggregate average payment per prescription (weighted by prescription volume) under the contract received from pharmaceutical manufacturers, including all rebates, discounts, prices concessions, or administrative, and other payments from pharmaceutical manufacturers, and a description of the types of payments, and the amount of these payments that were shared with the plan, and a description of the percentage of prescriptions for which the PBM received such payments. • Information on the overall percentage of generic drugs dispensed under the contract at retail and mail order pharmacies, and the percentage of cases in which a generic drug is dispensed when available. | <p>distributor of record of an applicable drug shall submit to the Secretary the following information with respect to the preceding year:</p> <ul style="list-style-type: none"> • In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by: <ul style="list-style-type: none"> ○ The name, address, professional designation, and signature of the practitioner making the request, or of any individual who makes or signs for the request on behalf of the practitioner; and ○ Any other category of information determined appropriate by the Secretary. • In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by: <ul style="list-style-type: none"> ○ The name, address, professional designation, and signature of the practitioner making the request of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and ○ Any other category of information |

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| | <ul style="list-style-type: none"> • Information on the percentage and number of cases under the contract in which individuals were switched because of PBM policies or at the direct or indirect control of the PBM from a prescribed drug that had a lower cost for the QHBP offering entity to a drug that had a higher cost for the QHBP offering entity, the rationale for these switches, and a description of the PBM policies governing such switches. <p>Such disclosed information is confidential and shall not be disclosed by the Commissioner or the QHBP offering entity in a form which discloses the identity of a specific PBM or prices charged by such PBM or a specific retailer, manufacturer, or wholesaler, except only by the Commissioner:</p> <ul style="list-style-type: none"> • To permit State or Federal law enforcement authorities to use the information provided for program compliance purposes and for the purpose of combating waste, fraud, and abuse; • To permit the Comptroller General, the Medicare Payment Advisory Commission, or the Secretary of Health and Human Services to review the information provided; and • To permit the Director of the Congressional Budget Office to review the information provided. <p>Annually, the Commissioner must prepare a public report providing industry-wide aggregate or average information to be used in assessing the overall impact of PBMs on</p> | <p>determined appropriate by the Secretary.</p> <p>Section 6005. A health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan that manages prescription drug coverage under a contract with:</p> <ul style="list-style-type: none"> • A PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under Medicare Part D of title XVIII; or • A qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act, shall provide the information described above to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify. <p>The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:</p> <ul style="list-style-type: none"> • The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that |

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| | <p>prescription drug prices and spending.</p> <p>Noncompliant PBMs face penalties.</p> <p>Section 1451. Measures physician (and other health care providers (including pharmacists and pharmacies) financial relationships with manufacturers and distributors of drugs, devices, or supplies covered by Medicare, Medicaid and Children’s Health Insurance Program. Requires manufacturers and distributors to report “gifts” that they have given to health care providers.</p> <p>Defines manufacturers as an entity engaged in various activities, including compounding. Exempts retail pharmacies for the purposes of this section.</p> <p>Preempts similar state laws. Does not preempt certain additional requirements.</p> | <p>dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.</p> <ul style="list-style-type: none"> • The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are 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))that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed. • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed. <p>Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:</p> |

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| | | <ul style="list-style-type: none"> • As the Secretary determines to be necessary to carry out this section or Medicare Part D. • To permit the Comptroller General to review the information provided. • To permit the Director of the Congressional Budget Office to review the information provided. • To States to carry out section 1311 of this Act. <p>Penalties apply to a health benefits plan or PBM that fails to provide required information on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.</p> |
| Workforce Strategies | <p>Section 1505. Sets goals for approved medical residency training programs by setting broad goals that include: (1) training to work in non-acute traditional settings; (2) coordination of care within and across settings; (3) understanding cost and value of diagnostic and treatment options; (4) working in multi-disciplinary teams; (5) participating in quality improvement projects; and, (6) demonstrating meaningful use of electronic health records in improving quality of patient care. Directs the GAO to evaluate the extent to which residency training programs are meeting the goals cited.</p> <p>Section 1744. Clarifies that State Medicaid programs may receive federal matching payments for the costs of graduate medical education. Directs the Secretary to specify program goals for the use of such funds based on workforce needs.</p> | <p>Section 5101. Establishes the National Health Care Workforce Commission whose purpose includes:</p> <ul style="list-style-type: none"> ▪ Developing and commissioning evaluations of education and training activities to determine whether the demand for health care workers is being met; and ▪ Identifying barriers to improved coordination at the Federal, State and local levels and recommending ways to address such barriers. <p>Members of the Commission include providers of health care services.</p> <p>Specific topics to be reviewed include:</p> <ul style="list-style-type: none"> ▪ Current health care workforce supply and distribution; ▪ Health care workforce education and training |

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| | <p>Section 2211. Establishes a new loan repayment program, similar to the National Health Service Corps (which does not include pharmacists) for frontline health care providers, including pharmacists, who agree to serve at least 2 years in a scarcity area.</p> <p>Section 2214. Establishes a program to provide support for the development and operation of training programs for medical residents in community-based settings such as community health centers.</p> <p>Section 2231. Establishes a Public Health Workforce Corps to address public health workforce shortages. Modeled on the National Health Service Corps, the program provides scholarship and loan repayment support for public health professionals serving in areas of need.</p> <p>Section 2241. Provides scholarships and loan repayment support for individuals from disadvantaged backgrounds serving in the health professions. Provides funding for the Health Careers Opportunities Program that supports health professions schools that recruit and train individuals from disadvantaged backgrounds.</p> <p>Section 2251. Establishes a new program to promote cultural and linguistic competence among health care professionals.</p> <p>Section 2252. Establishes a new program to support the</p> | <p>capacity; the education and training infrastructure; and the education and training demands;</p> <ul style="list-style-type: none"> ▪ The education loan and grant programs; ▪ The implications of new and existing federal policies which affect the health care workforce; ▪ The health care workforce needs of special populations; and ▪ Recommendations creating or revising national loan repayment programs and scholarship programs to require low-income, minority medical students to serve in their home communities, if designated a medical underserved community. <p>Defines health care workforce as “all health care providers with direct patient care and support responsibilities, such as physicians, nurses...pharmacists...”</p> <p>Defines health professionals as including:</p> <ul style="list-style-type: none"> ▪ “Dentists, nurses...clinical pharmacists...” ▪ National representatives of health professionals; ▪ Representatives of “schools of medicine...nursing...pharmacy...pharmacists” ▪ Representatives of public and private teaching hospitals, and ambulatory health facilities, including Federal medical facilities; and ▪ Any other health professional the Comptroller General determines appropriate. <p>Section 5103. The Secretary must establish the National Center for Health Workforce Analysis. The Center must</p> |

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| | <p>development and operation of interdisciplinary training programs for health professions to improve coordination within and across health care settings, including medical home models and models that integrate physical, mental or oral health services.</p> <p>Section 2586. Extends medical malpractice liability protection currently available for employees or licensed or certified health professionals under contract with a community health centers to volunteer practitioners providing uncompensated services at such centers.</p> <p>Section 2591. Establishes a new program for the Secretary of Labor to support online training of health care workers. Authorizes \$50 million for each of FY 2011 through FY 2020 to carry out this program.</p> <p>Section 2261. Creates an Advisory Committee on Health Workforce Evaluation and Assessment to assess the adequacy and appropriateness of the nation’s health workforce; and to make recommendations to the Secretary on federal workplace policies to ensure that such workforce is meeting the nation’s needs.</p> <p>Section 2262. Requires the Secretary to collect data on the supply, diversity, and geographic distribution of the nation’s health workforce, including individuals participating in various Federal workforce programs.</p> <p>Section 2271. Requires the Secretary to collect data on the</p> | <p>collaborate with Federal agencies and relevant professional and education organizations or societies to link data regarding grants awarded under this title.</p> <p>Section 5204. Establishes the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in Federal, State, local and tribal public health agencies. To be eligible to participate, an individual must, among other things :</p> <ul style="list-style-type: none"> ▪ Be accepted for enrollment or be enrolled as a student in an accredited academic educational institution in the final year of a course of study or program leading to a public health or health professions degree or certificate; and have accepted employment with a Federal, State, local, or tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation; and ▪ Have graduated, during the preceding 10-year period, from an accredited educational institution in a State or territory and received a public health or health professions degree or certificate; and be employed by, or have accepted employment with, a Federal, State, local, or tribal public health agency or a related training fellowship, as recognized by the Secretary; <p>Section 5205. Authorizes an Allied Health Loan Forgiveness Program. The term ‘allied health</p> |

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| | <p>supply, diversity, and geographic distribution of the Nation’s health workforce, including individuals participating in various federal workforce programs.</p> <p>Section 3101. Amends the Indian Health Care Improvement Act, adding the following sections:</p> <p>Section 102. Authorizes grants to tribes, tribal organizations, urban Indian organizations, and public and nonprofit entities for recruitment of Indians into health professions.</p> <p>Section 103. Authorizes scholarships to Indians for compensatory pre-professional education as well as pre-graduate education leading to a B.A.in a preparatory field for a health profession.</p> <p>Section 104. Authorizes scholarships to Indians enrolled full- or part-time in accredited schools pursuing courses of study in the health professions.</p> <p>Section 106. Directs the Secretary to make grants to tribes and tribal organizations for scholarships to educate Indians to serve as health professionals in Indian communities.</p> <p>Section 107. Authorizes an extern program for enrollees in health professions recruitment programs, including high school programs.</p> | <p>professional’ means an allied health professional as defined in section 799B(5) of the Public Health Service Act (42 U.S.C. 295p(5)) (which excludes pharmacy):</p> <p>Section 5206. The Secretary may make grants to, or enter into contracts with, any eligible entity to award scholarships to eligible individuals to enroll in degree or professional training programs for the purpose of enabling mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.</p> <ul style="list-style-type: none"> ▪ The term ‘eligible entity’ indicates an accredited educational institution that offers a course of study, certificate program, or professional training program in public or allied health or a related discipline, as determined by the Secretary ▪ The term ‘eligible individuals’ includes those individuals employed in public and allied health positions at the Federal, State, tribal, or local level who are interested in retaining or upgrading their education. <p>Section 5301. The Secretary may make grants to or enter into contracts with accredited schools of medicine or osteopathic medicine to establish, maintain, or improve:</p> <ul style="list-style-type: none"> ▪ Academic units or programs that improve clinical teaching and research in certain fields; or ▪ Programs that integrate academic administrative units in certain fields to enhance interdisciplinary recruitment, training, and faculty development. |

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| | <p>Section 108. Authorizes the Secretary to provide programs or allowances for individuals to transition into Indian Health Programs. Also authorizes programs and allowances for IHS and tribal health professionals to take leave of their duty for professional consultation and for refresher training, professional management, and leadership training courses.</p> <p>Section 110. Directs the Secretary to establish a loan repayment program for health professionals who contract to work for a specified time for, or are already employed by, Indian Health Programs or urban Indian health programs.</p> <p>Section 111. Establishes a fund to finance scholarships, recruitment efforts and to employ health professionals.</p> <p>Section 112. Authorizes the Secretary to reimburse certain travel expenses to health professionals seeking either employment with Indian Health Programs or urban Indian health programs, or loan repayment contracts.</p> <p>Section 113. Requires the Secretary to fund, on a competitive basis, demonstration projects to enable Indian Health Programs and urban Indian organizations to recruit, place, and retain health professionals to meet their staffing needs.</p> <p>Section 114. Directs the Secretary to establish a program to enable health professionals who have worked for an</p> | <p>In awarding the above grants, the Secretary shall give priority to qualified applicants that meet certain criteria including:</p> <ul style="list-style-type: none"> • Proposes a collaborative project between academic administrative units of primary care; • Proposes innovative approaches to clinical teaching using models of primary care, such as the patient centered medical home, team management of chronic disease, and interprofessional integrated models of health care that incorporate transitions in health care settings and integration physical and mental health provision; • Establish formal relationships and submit joint applications with federally qualified health centers, rural health clinics, area health education centers, or clinics located in underserved areas or that serve underserved populations; • Teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; • Provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology, or other competencies as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act; or |

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| | <p>IHS, tribal, or urban Indian health program for a substantial period of time to pursue advanced training or research in areas of study where the Secretary determines a need exists.</p> <p>Section 118. Requires the Secretary to award grants to accredited and accessible community colleges to assist in establishing health profession education programs leading to a degree or diploma for individuals desiring to practice on or near an Indian reservation or in an Indian Health Program.</p> <p>Section 119. Authorizes the Secretary to pay retention bonuses to any health professional employed by an IHS or tribal or urban Indian health program who agrees to continue their current employment for not less than one year.</p> <p>Section 123. Authorizes the Secretary to fund demonstration programs for Tribal Health Programs to address chronic shortages in health professionals.</p> <p>Section 201. Authorizes the use of funds, designated the “Indian Health Care Improvement Fund”, to eliminate tribes’ health status and resource deficiencies.</p> | <p>Section 5305. A geriatric education center that receives an award under this subsection must use such funds to offer short-term intensive courses that focus on geriatrics, chronic care management, and long-term care that provide supplemental training for faculty members in medical schools and other health professions schools with programs in psychology, pharmacy, nursing, social work, dentistry, public health, allied health, or other health disciplines, as approved by the Secretary.</p> <p>The Secretary shall award grants or contracts under this section to individuals to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management.</p> <p>To be eligible to receive an award, an individual shall:</p> <ul style="list-style-type: none"> ▪ Be an advanced practice nurse, a clinical social worker, a pharmacist, or student of psychology who is pursuing a doctorate or other advanced degree in geriatrics or related fields in an accredited health professions school; and <p>Expands eligibility for geriatric academic career awards. To receive an Award, an individual shall:</p> <ul style="list-style-type: none"> ▪ Be board certified or board eligible in internal medicine, family practice, psychiatry, or licensed dentistry, or have completed any required training in a discipline and employed in an accredited health professions school that is approved by the |

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| | | <p>Secretary;</p> <ul style="list-style-type: none"> ▪ Have completed an approved fellowship program in geriatrics or have completed specialty training in geriatrics as required by the discipline and any addition geriatrics training as required by the Secretary; and ▪ Have a junior (non-tenured) faculty appointment at an accredited (as determined by the Secretary) school of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, pharmacy, or other allied health disciplines in an accredited health professions school that is approved by the Secretary. <p>Section 5315. Authorizes the establishment of a United States Public Health Sciences Track to grant appropriate advanced degrees in a manner that uniquely emphasizes team based service, public health, epidemiology, and emergency preparedness and response. It will graduate not less than:</p> <ul style="list-style-type: none"> ▪ 150 medical students annually, 10 of whom shall be awarded studentships to the Uniformed Services University of Health Sciences; ▪ 100 dental students annually; ▪ 250 nursing students annually; ▪ 100 public health students annually; ▪ 100 behavioral and mental health professional students annually; ▪ 100 physician assistant or nurse practitioner students annually; and |

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| | | <ul style="list-style-type: none"> ▪ 50 pharmacy students annually. <p>Medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students at the Track shall be selected under procedures prescribed by the Surgeon General. In so prescribing, the Surgeon General shall consider the recommendations of the National Health Care Workforce Commission. In developing such admissions procedures, the Surgeon General shall ensure that such procedures give priority to applicants from rural communities and underrepresented minorities.</p> <p>Upon being admitted to the Track, a student shall enter into a written contract with the Surgeon General that shall address tuition, stipends, academic requirements, residencies/internships, service with the Commission and Corps of the Public Health Service, etc.</p> <p>The period of obligated service shall be reduced:</p> <ul style="list-style-type: none"> ▪ In the case of a student who elects to participate in a high-needs specialty residency by 3 months for each year of such participation (not to exceed a total of 12 months); and ▪ In the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility that is located in a health professional shortage area, by 3 months for year of full-time practice in such a facility (not to exceed a total of 12 months). |

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| | | <p>During the third and fourth years in which a student is enrolled in the Track, training should be designed to prioritize clinical rotations in Federal medical facilities in health professional shortage areas, and emphasize a balance of hospital and community-based experiences, and training within interdisciplinary teams.</p> <p>The Surgeon General must give priority to health professions training institutions that train students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.</p> <p>The Surgeon General, in consultation with the Secretary, the CDC Director, and other appropriate military and Federal government agencies, must develop criteria for the appointment of highly qualified Track faculty, students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.</p> <p>Section 5403. The Secretary shall make 2 types of Area Health Education Centers (AHEC) awards:</p> <ul style="list-style-type: none"> ▪ Infrastructure Development Award: To enable entities to initiate health care workforce educational programs or to continue to carry out comparable programs that are operating at the time the award is made by planning, developing, operating, and evaluating an area health education |

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| | | <p>center program.</p> <ul style="list-style-type: none"> ▪ Point of Service Maintenance Enhancement Award: To maintain and improve the effectiveness and capabilities of an existing area health education center program, and make other modifications to the program that are appropriate due to changes in demographics, needs of the populations served, or other similar issues affecting the area health education center program. <p>An eligible entity shall use amounts awarded under a grant to carry out various activities, including: conduct and participate in interdisciplinary training that involves pharmacists...</p> <p>The Secretary must make grants to, and enter into contracts with, eligible entities to improve health care, increase retention, increase representation of minority faculty members, enhance the practice environment, and provide information dissemination and educational support to reduce professional isolation through the timely dissemination of research findings using relevant resources.</p> <p>For purposes of this section, the term ‘eligible entity’ means an entity described in section 799(b).</p> |
| 340B - Expansion of Eligible Entity List | <p>Adds to current list of ‘covered entities’:</p> <ul style="list-style-type: none"> • Children’s Hospitals that are excluded from Medicare PPS and meet all 340B(a)(4)(L) requirements for DSH including $\geq 11.75\%$ DSH percentage | |

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| | <ul style="list-style-type: none"> • Critical Access Hospital* • Programs receiving federal funds for: <ul style="list-style-type: none"> •• Maternal & Child Health services •• Community Mental Health services •• Substance Abuse services • Small Rural Hospital (Medicare dependent)* • Sole Community Hospital* • Rural Referral Center* <p>*as defined by pertinent provisions of the Social Security Act.</p> | |
| 340B - Extend Discount to Inpatient | Not included in House Bill | |
| 340B - GPO Prohibition | Extends prohibition to new hospital covered entities | |
| 340B - Medicaid Credits on Inpatient Drugs | <p>Nothing in House on Inpatient.</p> <p>“Freeze provision” also deleted in SSA (a(5)(D)) in conforming amendments. Also deletes freeze provisions in 340B statute.</p> | |
| 340B - AMP Adjustment for 340B ‘covered drugs’ | | |
| 340B - Manufacturer Pharmaceutical Pricing Agreement Changes | <p>Fixes mfg. freeze provision in 340B. No longer deemed compliance if comply with old law.</p> <p>Adds new requirements:</p> <p>Manufacturer must report ceiling prices of each drug</p> | |

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| | <p>quarterly to Secretary.</p> <p>Manufacturers must offer any covered entity any drug for purchase at or below the ceiling price if that drug has been made available to any other purchaser at any price.</p> | |