

AMCP Federal Legislative Tracking Chart  
112th Congress (2011 - 2012)

Issue	Bill Number	Title (Sponsor)	Summary	Status
Medicare	US HR 103	Health Care Choices for Seniors Act (Rep. Marsha Blackburn (R-TN))	Establishes the Medicare Alternative Voucher program, which would allow Medicare-eligible seniors to opt-out of Medicare Part A. Program participants would receive a voucher to be used towards a health savings account and a high-deductible insurance plan. Would also eliminate late-enrollment penalties for beneficiaries between 65-70 years old.	Referred to House Ways and Means and Energy and Commerce- 01/05/2011
Health Care Reform	US HR 105	Empowering Patients First Act (Rep. Dan Burton (R-IN))	Would repeal the Patient Protection and Affordable Care Act of 2010.	Referred to the House Committee on Energy and Commerce and Ways and Means - 01/05/2011
Importation	US HR 147	Prescription Drug Affordability Act (Rep. Ron Paul (R-TX))	Would allow FDA-approved applicants (including manufacturers) to import prescription drugs and would allow for internet sales of prescription drugs.	Referred to House Energy and Commerce - 01/05/2011
Health Care Reform	US HR 364	Common Sense Health Reform Americans Actually Want Act (Rep. Tom Latham (R-IA))	Would repeal the Patient Protection and Affordable Care Act of 2010.	Referred to the House Committee on Energy and Commerce and Ways and Means - 01/20/2011
Health Care Reform	US HR 397	Reform Americans Can Afford Act of 2011 (Rep. Wally Herger (R-CA))	Would repeal the Patient Protection and Affordable Care Act of 2010.	Referred to the House Committee on Energy and Commerce and Ways and Means - 01/24/2011
Health Care Reform	US HR 408	Spending Reduction Act of 2011 (Rep. Jim Jordan (R-OH))	Would repeal the Patient Protection and Affordable Care Act of 2010.	Referred to the House Committee on Energy and Commerce and Ways and Means - 01/24/2011
Comparative Effectiveness Research	US HR 556	Preserving Patients' Choices Act of 2011 (Rep. Thaddeus McCotter (R-MI))	Would repeal sections of the Patient Protection and Affordable Care Act of 2010 that establish the Patient-Centered Outcomes Research Institute.	Referred to House Budget Committee - 02/08/2011
Medicare -Fraud, Waste and Abuse	US HR 675	Strengthening Medicare Anti-Fraud Measures Act of 2011 (Rep. Wally Herger (R-CA))	Would authorize CMS to exclude all entities associated with any entity being investigated for fraud, as well as any officer or managing employee of an affiliated entity, from participating in Medicare.	Referred to House Committee on Energy and Commerce - 02/18/2011
Health Care Reform	US HR 676	Expanded and Improved Medicare for All Act of 2011 (Rep. John Conyers (D-MI))	Would repeal the Patient Protection and Affordable Care Act of 2010 and replace it with expanded Medicare coverage, which would be made available to all.	Referred to House Committee on Natural Resources - 02/11/2011
Controlled Substances	US HR 866	National All Schedules Prescription Electronic Reporting Reauthorization Act of 2011 (Rep. Ed Whitfield (R-KY))	Would revise and update the controlled substance monitoring program, to include 1) grants to be used to maintain and operate existing state controlled monitoring programs, 2) require HHS to redistribute any funds that are returned among the remaining grantees 3) require a state to provide HHS with aggregate data and other information for evaluation and reporting purposes.	Referred to House Committee on Energy and Commerce Subcommittee on Health - 03/08/2011

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Medicare Part D -MTM	US HR 891	Medication Therapy Management Benefits Act of 2011 (Rep. Cathy McMorris Rodgers (R-WA))	Amends Medicare Part D benefit to expand the number of beneficiaries eligible for MTM services. Directs the Secretary of HHS to: (1) establish measures and standards for data collection by PDP sponsors to evaluate performance of pharmacies and other entities in furnishing MTM services; and (2) support the continued development and refinement of performance measures. Provides pharmacies and other entities that furnish MTM services with additional incentive payments based on their performance in meeting quality measures established under this Act. Requires a PDP sponsor to offer any willing pharmacy in its network and any other qualified health care provider the opportunity to provide MTM services. Requires the PDP sponsor to reimburse pharmacists and other qualified health care providers furnishing MTM services based on the resources used and the time required to provide such services. <b>**See similar Senate legislation S 274**</b>	Referred to House Committee on Energy and Commerce Subcommittee on Health - 03/08/2011
PBM Regulation	US HR 979	FEHBP Prescription Drug Integrity, Transparency, and Cost Savings Act of 2011 (Rep. Stephen Lynch (D-MA))	Would require PBMs that contract with health plans in the federal employees health benefits program (FEHBP) to meet certain requirements, including restrictions on manufacturer and pharmacy ownership, as well as restrictions on drug substitutions, drug pricing and reimbursement amounts and the sale of utilization data, as well as any willing provider requirements.	Referred to House Committee on Oversight and Government Reform - 03/09/2011
Medicare Part D -Public Option Plan	US HR 999 US S 560	Medicare Prescription Drug Savings and Choice Act of 2011 (Rep. Jan Schakowsky (D-IL))	Would establish a nationwide Part D plan operated by the federal government to compete alongside privately sponsored plans. The plan would have uniform premiums nationwide. CMS would be able to develop a formulary with input from AHRQ on clinical effectiveness. The plan would be able to use a tiered co-payment structure, reference pricing, prior authorization, step therapy, MTM and generic substitution when developing a formulary.	Referred to House Committee on Energy and Commerce and House Committee on Ways and Means - 03/10/2011
Medicare Part D -Off-Label Use	US HR 1055	Part D Off-Label Prescription Parity Act of 2011 (Rep. Mac Thornberry (R-TX))	Would permit a Part D plan sponsor to offer coverage of covered Part D drugs for uses that are determined to be for medically accepted indications based upon: (1) guidance provided by CMS and (2) supportive clinical evidence in peer reviewed medical literature.	Referred to Committee on Ways & Means - 03/11/2011
Controlled Substances	US HR 1266	Fraudulent Prescription Prevention Act of 2011 (Rep. Michael Grimm (R-NY))	Would require the Attorney General to establish a web portal through which prescribers and pharmacies to collect and enter certain patient-specific information before prescribing or dispensing a schedule II or III controlled substance. Would establish a national database for tracking information.	Referred to Committee on Energy & Commerce and Committee on Judiciary - 03/30/2011
Controlled Substances	US HR 1316	Stop Oxy Abuse Act of 2011 (Rep. Mary Bono Mack (R-CA))	Would require the FDA to modify approval of controlled release oxycodone hydrochloride to limit approval to use for the relief of severe-only instead of moderate-to-severe pain.	Referred to Committee on Energy & Commerce - 04/01/2011

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FDA	US HR 1483	Drug Safety Enhancement Act of 2011 (Rep. John Dingell (D-MI))	Various FDA reforms and re-authorizations.	Referred to House Committee on Energy & Commerce - 04/12/2011
Medicaid	US HR 1683 US S 868	State Flexibility Act (Rep. Phil Gingery (R-GA) and Sen. Orrin Hatch (R-UT))	Would repeal Medicaid and CHIP maintenance of effort requirements under both the American Recovery and Reinvestment Act and Affordable Care Act.	Referred to Committee on Energy & Commerce (House) - 05/03/2011 Referred to Committee on
PBM/Health Plan Regulation -Collective Bargaining	US HR 1839	Community Pharmacy Fairness Act of 2011 (Rep. Anthony Weiner (D-NY))	Would allow independent pharmacists to collectively bargain reimbursement rates with PBMs and health plans, including Medicare Advantage and Part D plan sponsors.	Referred to House Committee on the Judiciary - 05/11/2011
PBM.Health Plan Regulation -Collective Bargaining	US HR 1946	Preserving Our Hometown Independent Pharmacies Act of 2011 (Rep. Tom Marino (R-PA))	Would allow independent pharmacists to collectively bargain reimbursement rates with PBMs and health plans. Negotiations with Medicare Advantage and Part D plan sponsors would be exempt.	Referred to Committee on the Judiciary - 05/23/2011
PBM Regulation	US HR 1971 US S 1058	Pharmacy Competition and Consumer Choice Act of 2011 (Rep. Cathy McMorris Rodgers (R-WA))	Would require PBMs that contract with group health plans to make required annual disclosures to plan sponsors (including information such as number and total cost of prescriptions filled at mail and retail, estimate of the aggregate average payments per prescription made to mail and retail pharmacies, generic fill rates, and information on rebates, discounts, price concessions, etc., negotiated with pharmaceutical manufacturers). Would regulate frequency of updated pricing information and methodology used to determine maximum allowable cost. Would regulate contracting, including network participation requirements, use of pharmacies owned by PBM and co-payment parity between different pharmacies. Would establish audit requirements. Would regulate the use of claims data.	Referred to Committee on Education and Workforce - 05/24/2011.
Electronic Prescribing	US HR 2128	Stripping the E-Prescribe Arbitrary Mandates (STEAM) Act of 2011 (Rep. Renee Ellmers (R-NC))	Would prevent the application of Medicare payment adjustments to eligible professionals who are not successful electronic prescribers.	Referred to Committee on Ways and Means - 06/03/2011.
FDA -Drug Approval Process	US HR 2182 US S 1734	Generating Antibiotic Incentives Now Act of 2011 (Rep. Phil Gingrey (R-GA))	Would establish incentives, including priority review of applications and additional market exclusivity rights, for pharmaceutical manufacturers to develop new antibiotics.	Referred to Committee on Energy & Commerce - 06/15/2011
Medicare Part D Medicaid	US HR 2190 US S 1206	Medicare Drug Savings Act of 2011 (Rep. Henry Waxman (D-CA) and Sen. Jay Rockefeller (D-WV))	Would require pharmaceutical manufacturers to pay Medicaid "best price" rebates for drugs purchased by dual eligibles covered under Medicare Part D.	Referred to Committee on Ways and Means - 06/15/2011

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Medicare Part D	US HR 2195 US S 1203	Medicare Home Infusion Therapy Coverage Act of 2011 (Rep. Eliot Engel (D-NY) and Sen. Olympia Snowe (R-MN))	Would require Medicare Part D plans and MA-PD plans to cover drugs used in home infusion therapy. Would require plans to have an open formulary for such drugs.	Referred to Committee on Ways & Means - 06/15/2011
Medicare Part D -Drug Price Negotiation	US HR 2248 US S 44	Medicare Prescription Drug Price Negotiation Act of 2011 (Rep. Peter Welch (D-VT) and Sen. Amy Klobuchar (D-MN))	Would require the federal government to negotiate prescription drug prices for the Medicare Part D prescription drug benefit directly with manufacturers.	Referred to Committee on Ways & Means - 06/21/2011
Prescription Drug Distribution Channel -Drug Shortages	UR HR 2245	Preserving Access to Life-Saving Medicines Act of 2011 (Rep. Diana DeGette (D-CO))	Establishes regulations regarding the responsibility of a pharmaceutical manufacturer to notify the Secretary of Health and Human Services of a discontinuance, interruption or other adjustment of the manufacture of the drug that would likely result in a shortage of the drug. Would require public notifications of shortages.	Referred to Committee on Energy & Commers - 06/22/2011
Prescription Drug Assistance Programs	US HR 2296	America Rx Act of 2011 (Rep. Michael Michaud (D-ME))	Would establish a national prescription drug assistance program for individuals without access to a pharmacy benefit. The Secreary of HHS would negotiate rebate agreements directly with manufacturers which are no less than rebates paid under the Medicaid program. Manufacturers who choose to not participate would be unable to deduct advertising and marketing expenses for tax purposes. Rebates would be used to fund administration of the program, including pharmacy reimbursement. The Secretary would have the authority to terminate the program if he or she determines that health insurance exchanges provide adequate access opportunities.	Referred to Committee on Energy & Commerce - 06/22/2011
EHR/HIT	US HR 2577	SAFE Data Act of 2011 (Rep. Mary Bono Mack (R-CA))	Would establish national standards for protection of personal information related to commercial activity.	Referred to Committee on Energy & Commerce - 07/18/2011
Copayment Parity	US HR 2746	Cancer Drug Coverage Parity Act of 2011 (Rep. Brian Higgins (D-NY))	Would require group and individual health insurance policies covered under ERISA to cover oral chemotherapy drugs on terms no less favorable than coverage for intravenous chemotherapy drugs.	Referred to Committee on Energy & Commerce - 08/01/2011
Drug Disposal	US HR 2939	Pharmaceutical Stewardship Act of 2011 (Rep. Louise Slaughter (D-NY))	Would establish the private, non-governmental National Pharmaceutical Stewardship Organization, tasked with implementing a national certified drug stewardship program. The costs of the program would be borne by manufacturers contributing in proportion to the market shares of their products.	Referred to Committee on Ways & Means - 09/15/2011
Prescription Drug Safety	US HR 3026	Safeguarding America's Pharmaceuticals Act of 2011 (Rep. Jim Matheson (D-UT))	Would establish uniform national standards for a prescription drug tracking and identification system.	Referred to Committee on Energy & Commerce - 09/22/2011

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Medicare Part D	US HR 3150	Medicare Safe Needle Disposal Coverage Act of 2011 (Rep. Ed Whitfield (R-KY))	Would require Part D plan sponsors to provide coverage of needle disposal services for plan members.	Referred to Committee on Energy & Commerce - 10/18/2011
EHR/HIT	US HR 3239	Safeguarding Access For Every Medicare Patient Act of 2011 (Rep. Tom Marino (R-PA))	Would establish legal safe harbors to Medicare and Medicaid providers participating in HER meaningful use program or otherwise demonstrate use of certified health information technology.	Referred to House Committee on Energy & Commerce - 10/21/2011
Medicaid Generic Drug Utilization	US HR 3342 US S 1356	Affordable Medicines Utilization Act of 2011 (Rep. Charles Bass (R-NH))	Would allow states to receive a bonus payment equal to 50 percent of savings associated with an increase in generic utilization among Medicaid recipients.	Referred to Committee on Energy & Commerce - 11/03/2011
Medicare Medicaid Fraud, Waste, Abuse	US HR 3399 US S 1251	Medicare and Medicaid FAST Act (Rep. Peter Roskam (R-IL))	Among other actions, would direct the Secretary of HHS to prohibit Part D plan sponsors from paying prescription drug claims that do not include a valid NPI. Directs the Secretary to establish automated prepayment review of all Medicare claims. Requires the Secretary of HHS, the HHS Inspector General and the Attorney General to increase coordination and data sharing.	Referred to Committee on Judiciary - 11/21/2011
Counterfeit Drugs	US HR 3468 US S 1886	Counterfeit Drug Penalty Enhancement Act of 2011 (Rep. Patrick Meehan (R-PA))	Would increase fines for selling counterfeit drugs to a maximum of \$4 million, plus a life term in prison for individuals or a maximum fine of \$10 million for person other than an individual. For multiple offenses, the maximum fine would increase to \$8 million for individuals and \$20 million for a person other than an individual.	Referred to Committee on the Judiciary - 11/17/2011
Medicare Medicaid Fraud, Waste, Abuse	US HR 3474	PRIME Act of 2011 (Rep. Cliff Stearns (R-FL))	Would increase civil and monetary penalties for Medicare or Medicaid fraud. Would require HHS to submit annual fraud reports to Congress on Medicare, Medicaid and CHIP fraud. Would require a National Provider Identifier to be present on all Medicare Part D and Medicaid pharmacy claims. Encourages the establishment of state prescription drug monitoring programs.	Referred to Committee on Energy & Commerce and Committee on Ways & Means - 11/18/2011
Diagnostics Testing Patent Extensions	US HR 3497	Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network (MODDERN) Cures Act of 2011 (Rep. Leonard Lance (R-NJ))	Would establish within HHS the Advanced Diagnostics Education Council to recommend terms and definitions for patients, physicians, health care providers, payers and policymakers. Would restructure fee schedule amounts for new tests under Medicare to create incentives for development of innovative diagnostic tests. Would allow for patent extensions for products for which the manufacturer develops diagnostic tests that would identify patient populations for which the drug will or will not work or the most appropriate patient population for the drug.	Referred to Committee on the Judiciary - 11/18/2011
Medicare Part D Patient Cost-Sharing	US HR 3613	Part D Beneficiary Appeals Fairness Act (Rep. Hank Johnson (D-GA))	Would require Medicare Part D plans to establish an exceptions process for patient cost-sharing amounts. Plans would be prohibited from excluding any formulary tiers from the exceptions process, including specialty tiers.	Referred to Committee on Energy & Commerce and Committee on Ways & Means - 12/08/2011

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Medicare Part D Non-Interference Clause	US HR 3638	Act for the 99% (Rep. Raul Grijalva (D-AZ))	Sec. 3013 would allow the federal government to negotiate lower drug prices in Medicare Part D.	12/16/2011 - Referred to the House Energy and Commerce Subcommittee on Health
Fraud, Waste, and Abuse	US HR 3782	Online Protection and Enforcement of Digital Trade Act	Increases the penalties for selling or distributing prescription drugs without having a valid prescription through a website.	Referred to House Judiciary Committee - 01/18/2012
Comparative Effectiveness Research	US HR 3827	To repeal the Patient-Centered Outcomes Research program and comparative effectiveness research funding.	Would repeal PCORI and CER funding.	Referred to House Energy and Commerce - 01/25/2012
Biosimilars	US HR 3988	Generic Drug and Biosimilar User Fee Act of 2012 (Rep. Tim Murphy (R-PA))	Would create new fees for certain drug applications and drug facilities that would be allocated to expediting the process of reviewing biosimilar biological product applications. Also creates a biosimilar biological product development fee, reactivation fee, application fee, establishment fee, and product fee for the purpose of defraying the costs of the process for the review of biosimilar biological product applications.	Referred to the House Committee on Energy and Commerce - 02/08/12
Generic Drug Access	US HR 3995	Protecting Consumer Access to Generic Drugs Act of 2012 (Rep. Bobby Rush (D-IL))	Would make it unlawful to settle a patent infringement claim in which the ANDA filer receives anything of value and in which the ANDA filer agrees not to research, develop, manufacture, market or sell the drug that is subject to the patent infringement claim.	Referred to House Judiciary Committee - 02/09/12
Drug Labeling	US HR 4087	Prescription Drug Labeling Promotion Act of 2012 (Rep. Edward Markey (D-MA))	Would establish a working group to develop and promulgate guidance constituting best practices on access to prescription drug labeling for the visually impaired.	Referred to House Committee on Energy and Commerce - 02/24/12
Co-Payment/Co-Insurance Parity	US HR 4209	Patients' Access to Treatments Act of 2012 (Rep. David McKinley (R-WV))	Would require group and individual health insurance policies covered under ERISA which use a formulary for prescription drug coverage to charge the same co-payment/co-insurance rate for specialty drugs as the co-payment/co-insurance rate for non-preferred brand name drugs.	Referred to House Committee on Energy & Commerce - 03/19/2012
Medicare Part D Audits	US HR 4215	Medicare Pharmacy Transparency and Fair Auditing Act (Rep. Cathy McMorris-Rodgers (R-WA))	Would establish audit requirements and other transparency requirements for Medicare Part D plan sponsors.	Referred to House Committee on Energy & Commerce - 03/20/2012

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Medicare Advantage	US HR 4254	Medicare Advantage Program Integrity Act of 2012 (Rep. Pete Stark (D-CA))	Would revise coding intensity adjustment factor in the formula for the demographic adjustment used in calculating payments to Medicare+Choice organizations for 2015 and beyond. Sets the timing of pre-payments for Medicare+Choice organizations and to Medicare Advantage organizations for months beginning with January 2013.	Referred to House Committee on Ways & Means and Energy & Commerce - 03/22/2012
Prescription Drug Monitoring Programs	US HR 4292 US S 2254	Interstate Drug Monitoring Efficiency and Data Sharing Act (Rep. Hal Rogers (R-KY))	Would direct the US Department of Justice to establish uniform standards for the exchange of controlled substance and prescription information for the purpose of preventing diversion, fraud and abuse of controlled substances and other prescription drugs.	Referred to House Committee on Energy & Commerce - 03/28/2012
Drug Labeling	US HR 4382	Patient Safety and Drug Labeling Improvement Act (Rep. Chris Van Hollen (D-MD))	Would permit generic drug manufacturers to provide additional warnings with respect to such drugs in the same manner that the FDA allows manufacturers of innovator products to do so.	Referred to House Committee on Energy & Commerce - 04/18/2012
Drug Approval Process	US HR 5334	To expedite the development and review of breakthrough therapies (Rep. Brian Bilbray (R-CA))	Would expedite the development and review of drugs intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.	Referred to House Committee on Energy & Commerce - 05/07/2012
Generic Drug Access	US S 27	Preserve Access to Affordable Generics Act (Sen. Herb Kohl (D-WI))	Would prohibit settlement agreements between manufacturers of innovator products and generic manufacturers in which the generic manufacturer agrees to delay entry into the market in exchange for compensation. Grants the FTC exclusive authority to litigate matters relating to anticompetitive practices in connection with the sale of generic brand drugs. Establishes a three-year limitation period for bringing FTC enforcement actions (other than cease and desist requests) under this Act.	Passed by Committee on Judiciary - 07/21/2011
Medicare Part D -Drug Price Negotiation	US S 31	Prescription Drug and Health Improvement Act of 2011 (Sen. Al Franken (D-MN))	Would authorize the federal government to negotiation prescription drug prices for the Medicare Part D prescription drug benefit directly with manufacturers.	Referred to Committee on Finance - 01/25/2011
Medicare Part D -Drug Price Negotiation	US S 44 US HR 2248	Medicare Prescription Drug Price Negotiation Act of 2011 (Sen. Amy Klobuchar (D-MN) and Rep. Peter Welch (D-VT))	Would require the federal government to negotiate prescription drug prices for the Medicare Part D prescription drug benefit directly with manufacturers.	Referred to Committee on Finance - 01/25/2011

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Medicare Part D -Medication Therapy Management	US S 274	Medication Therapy Management Empowerment Act of 2011 (Sen. Kay Hagan (D-NC))	Amends Medicare Part D benefit to expand the number of beneficiaries eligible for MTM services. Directs the Secretary of HHS to: (1) establish measures and standards for data collection by PDP sponsors to evaluate performance of pharmacies and other entities in furnishing MTM services; and (2) support the continued development and refinement of performance measures. Provides pharmacies and other entities that furnish MTM services with additional incentive payments based on their performance in meeting quality measures established under this Act. Requires a PDP sponsor to offer any willing pharmacy in its network and any other qualified health care provider the opportunity to provide MTM services. Requires the PDP sponsor to reimburse pharmacists and other qualified health care providers furnishing MTM services based on the resources used and the time required to provide such services.	Referred to Committee on Finance - 02/03/2011
Prescription Drug Distribution Channel	US S 296	Preserving Access to Life-Saving Medicines Act of 2011 (Sen. Amy Klobuchar (D-MN))	Establishes regulations regarding the responsibility of a pharmaceutical manufacturer to notify the Secretary of Health and Human Services of a discontinuance, interruption or other adjustment of the manufacture of the drug that would likely result in a shortage of the drug. Would require public notifications of shortages.	Referred to Committee on Health, Education, Labor and Pensions - 02/07/2011
Importation	US S 319	Pharmaceutical Market Access and Drug Safety Act of 2011 (Sen. Olympia Snowe (R-ME))	Would allow FDA-approved applicants (including manufacturers) to import prescription drugs and would allow for internet sales of prescription drugs.	Referred to Committee on Health, Education, Labor and Pensions - 02/10/2011
Generic Drug Access	US S 373	Fair Prescription Drug Competition Act of 2011 (Sen. Jay Rockefeller (D-WV))	Would prohibit the introduction of an authorized generic product during the 180-day exclusivity period awarded to the first-filer generic.	Referred to Committee on Health, Education, Labor and Pensions - 02/16/2011
Medicare -Fraud, Waste and Abuse	US S 454	Strengthening Program Integrity and Accountability in Health Care Act of 2011 (Sen. Charles Grassley (R-IA))	Would change from discretionary to mandatory the authority of CMS to suspend Medicare and Medicaid payments pending investigation of credible allegations of fraud and require CMS to extend up to 365 calendar days for particular categories of service providers or suppliers in which FWA is likely the number of days in which Medicare claims are required to be paid in order to ensure the claims are clean. Establishes an information sharing program regarding beneficiary medical ID theft. Authorizes CMS to exclude entities affiliated with sanctioned entities from participation in federal health care programs. Would establish a public database for Medicare claims.	Referred to Committee on Finance - 03/02/2011
Medicare Part D -Public Option Plan	US S 560 US HR 999	Medicare Prescription Drug Savings and Choice Act of 2011 (Sen. Richard Durbin (D-IL))	Would establish a nationwide Part D plan operated by the federal government to compete alongside privately sponsored plans. The plan would have uniform premiums nationwide. CMS would be able to develop a formulary with input from AHRQ on clinical effectiveness. The plan would be able to use a tiered co-payment structure, reference pricing, prior authorization, step therapy, MTM and generic substitution when developing a formulary.	Referred to Senate Committee on Finance - 03/10/2011

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Comparative Effectiveness Research	US S 660	PATIENTS Act of 2011 (Sen. Jon Kyl (R-AZ))	Would prohibit the use of comparative effectiveness research to deny or delay coverage of items or services under federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.	Referred to Committee on Health, Education, Labor and Pensions - 03/29/2011.
Medicare Part D	US S 725	Medicare Safe Needle Disposal Coverage Act of 2011 (Sen. Johnny Isakson (R-GA))	Would require coverage of supplies associated with injection of insulin, of containment, removal, decontamination and disposal of home-generated needles, syringes, and other sharps through a sharps container or sharps-by-mail program under Medicare Part D.	Referred to Committee on Finance - 04/05/2011
Medicare -Fraud, Waste and Abuse	US S 756	Medicare Data Access for Transparency and Accountability Act of 2011 (Sen. Charles Grassley (R-IA) Sen. Ron Wyden (D-OR))	Would require CMS to issue regulations to make available a searchable Medicare payment database that the public can access at no cost. Clarifies that data on Medicare payments to physicians and suppliers do not fall under a Freedom and Information Act exemption.	Referred to Committee on Finance - 04/07/2011.
Medicare -Quality	US S 848	Consumer Information Enhancement Act of 2011 (Sen. John Cornyn (R-TX))	Would provide for the development of reports based on Medicare data in order to improve the quality and efficiency of health care, enhance the education and awareness of consumers for evaluating health care services and provide the public with reports on national, regional, and provider-and supplier-specific performance. Protects information deemed proprietary, such as negotiated rebates, concessions, etc., by MA-PD or Part D plans.	Referred to Committee on Finance - 04/14/2011.
Medicaid	US S 868 US HR 1683	State Flexibility Act (Sen. Orrin Hatch (R-UT) and Rep. Phil Gingery (R-GA))	Would repeal Medicaid and CHIP maintenance of effort requirements under both the American Recovery and Reinvestment Act and Affordable Care Act.	Referred to Committee on Finance (Senate) - 05/03/2011 Referred to Committee on Energy & Commerce (House) - 05/03/2011
Medicare -Fraud, Waste and Abuse	US S 882	Stop Trafficking of Pills (STOP) Act (Sen. Sherrod Brown (D-OH))	Would identify Medicaid and Medicare beneficiaries at high risk of misuse or overutilization of certain prescription drugs and would restrict access to those drugs.	Referred to Committee on Finance - 05/04/2011.
PBM Regulation	US S 1058 US HR 1971	Pharmacy Competition and Consumer Choice Act of 2011 (Sen. Mark Pryor (D-AR))	Would require PBMs that contract with group health plans to make required annual disclosures to plan sponsors (including information such as number and total cost of prescriptions filled at mail and retail, estimate of the aggregate average payments per prescription made to mail and retail pharmacies, generic fill rates, and information on rebates, discounts, price concessions, etc., negotiated with pharmaceutical manufacturers). Would regulate frequency of updated pricing information and methodology used to determine maximum allowable cost. Would regulate contracting, including network participation requirements, use of pharmacies owned by PBM and co-payment parity between different pharmacies. Would establish audit requirements. Would regulate the use of claims data.	Referred to Committee on Health, Education, Labor and Pensions - 05/24/2011.

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Medicare Part D Medicaid	US S 1206 US HR 2190	Medicare Drug Savings Act of 2011 (Rep. Henry Waxman (D-CA) and Sen. Jay Rockefeller (D-WV))	Would require pharmaceutical manufacturers to pay Medicaid "best price" rebates for drugs purchased by dual eligibles covered under Medicare Part D.	Referred to Committee on Finance - 06/15/2011
Medicare Medicaid Fraud, Waste, Abuse	US S 1251	Medicare and Medicaid FAST Act (Sen. Thomas Carper (D-DE))	Among other actions, would direct the Secretary of HHS to prohibit Part D plan sponsors from paying prescription drug claims that do not include a valid NPI. Directs the Secretary to establish automated prepayment review of all Medicare claims. Requires the Secretary of HHS, the HHS Inspector General and the Attorney General to increase coordination and data sharing.	Referred to Committee on Finance - 06/22/2011
Medicaid Generic Drug Utilization	US S 1356 US HR 3342	Affordable Medicines Utilization Act of 2011 (Sen. Scott Brown (R-MA))	Would allow states to receive a bonus payment equal to 50 percent of savings associated with an increase in generic utilization among Medicaid recipients.	Referred to Committee on Finance - 07/13/2011
Medicare Advantage and Medicare Part D Enrollment	US S 1479	Medicare Beneficiary Preservation of Choice Act of 2011 (Sen. Robert Casey (D-PA))	Would establish a continuous open enrollment period for Medicare Advantage plans during the first three months of a calendar year. Would limit beneficiary changes to once per period. Would apply to changes in a Part D plan for an individual who was previously enrolled in a Medicare Advantage plan offering prescription coverage.	Referred to Committee on Finance - 08/02/2011
Prescription Drug Safety	US S 1584	Drug Safety and Accountability Act of 2011 (Sen. Michael Bennet (D-CO))	Would require documentation standards for pharmaceutical supply chains. Would grant the Secretary of HHS authority to impose a mandatory recall in instances where they believe there is a public safety issue.	Referred to Committee on Health, Education, Labor and Pensions - 09/20/2011
Medicare Part B PBM Regulation Off-Label Use	US S 1699	Prescription Drug Cost Reduction Act of 2011 (Sen. Herb Kohl (D-WI))	Would mandate Medicaid rebates for the 20 most-expensive drugs covered under Medicare Part B. Would authorize HHS to negotiate Part B drug prices directly with manufacturers. Would empower Medicare to apply a "least costly alternative" approach to coverage decisions. Would reduce Part B reimbursement formula to below the current ASP+6% for drugs administered by physicians. Would require increased transparency for PBMs operating with MA-PD and Part D plans, the VA administration, TRICARE and FEHBP. Would require written certification for physicians when prescribing atypical antipsychotics to patients in nursing homes. Would expand the 340B drug discount purchasing program for community health centers to the Program of All-Inclusive Care for the Elderly.	Referred to the Committee on Finance - 10/12/2011
FDA -Drug Approval Process	US S 1734 US HR 2182	Generating Antibiotic Incentives Now Act of 2011 (Sen. Richard Blumenthal (D-CT))	Would establish incentives, including priority review of applications and additional market exclusivity rights, for pharmaceutical manufacturers to develop new antibiotics.	Referred to Committee on Health, Education, Labor and Pensions - 10/19/2011
Controlled Substances	US S 1760	Pill Mill Crackdown Act of 2011 (Sen. Joe Manchin (D-WV))	Would establish penalties for operating a pill mill.	Referred to Committee on the Judiciary - 10/20/2011

*For AMCP use only. Bills highlighted in yellow represent legislation that has been identified as an AMCP priority.*

*More information may be found at <http://thomas.loc.gov>.*

AMCP Federal Legislative Tracking Chart  
112th Congress (2011 - 2012)

Issue	Bill Number	Title (Sponsor)	Summary	Status
Counterfeit Drugs	US S 1886 US HR 3468	Counterfeit Drug Penalty Enhancement Act of 2011 (Sen. Pat Leahy (D-VT))	Would increase fines for selling counterfeit drugs to a maximum of \$4 million, plus a life term in prison for individuals or a maximum fine of \$10 million for person other than an individual. For multiple offenses, the maximum fine would increase to \$8 million for individuals and \$20 million for a person other than an individual.	Passed by Senate - 03/06/2012
Health Information Technology	US S 2002	Online Pharmacy Safety Act (Sen. Dianne Feinstein (D-CA))	Would create a registry of legitimate online pharmacy websites in order to protect consumers from prescription drugs manufactured outside of FDA jurisdiction and protection from pharmacists unlicensed in the U.S.	Referred to the Committee on Health, Education, Labor and Pensions - (12/15/11)
FDA - Administrative Improvements	US S 2113	Transforming the Regulatory Environment to Accelerate Access to Treatments (Sen. Kay Hagan (D-NC))	Would expedite the drug approval process by allowing the Secretary to fast track drugs for serious or life threatening diseases and conditions. The bill also supports the work of the FDA by adding staff and adjusting staff responsibilities.	Referred to the Committee on Health, Education, Labor and Pensions - (02/15/12)
Prescription Drug Monitoring Programs	US S 2254 US HR 4292	Interstate Drug Monitoring Efficiency and Data Sharing Act (Sen. Rob Portman (R-OH))	Would direct the US Department of Justice to establish uniform standards for the exchange of controlled substance and prescription information for the purpose of preventing diversion, fraud and abuse of controlled substances and other prescription drugs.	Referred to Senate Committee on Health, Education, Labor and Pensions - 03/29/2012
FDA Reform	US S 2292	PATIENTS' FDA Act (Sen. Richard Burr (R-NC))	Would introduce multiple reforms of the FDA with the aim of promoting accountability, transparency, innovation, efficiency, and timeliness at FDA.	Referred to Senate Committee on Health, Education, Labor and Pensions - 04/17/2012
PDUFA Reauthorization	US S 2516	To revise and extend the user-fee programs for prescription drugs and medical devices (Sen. Tom Harkin (D-IA))	Would reauthorize the prescription drug user fee program (PDUFA), extend the program to generic small-molecule drug applicants and biosimilar applicants, among other things.	Passed Senate Health, Education, Labor and Pensions Committee, Placed on Senate Legislative Calendar - 05/07/2012

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