

# Federal Legislation Quick Guide

April 23, 2008

## Pending Legislation—Health and Welfare Plans

**Note:** The following charts summarize federal legislation that is currently under active consideration by Congress or has recently been enacted into law. In most cases, other bills have also been introduced on the same issue, but are not being actively considered by Congress at this time. For more information on the summarized bills, or to find other bills on the same issue, go to the Library of Congress Web site at <http://thomas.loc.gov>.

### Health Savings Accounts

<b>Current Legislation</b>	■ Taxpayer Assistance and Simplification Act of 2008 (H.R. 5719).
<b>Status</b>	The House Ways and Means Committee approved H.R. 5719 on a party-line vote of 23-17 on April 9, 2008, and on April 15, 2008, the House approved the bill by a vote of 238 to 179. <a href="#">The bill now goes to the Senate, where it has been referred to the Committee on Finance.</a>
<b>Outlook</b>	The White House issued a Statement of Administration Policy (SAP) on April 14, 2008 threatening to veto the bill, in part, because the administration opposes the HSA provision. The HSA provision is estimated to raise \$308 million over 10 years (the Joint Committee on Taxation estimates it would raise \$485 million over 10 years). Prospects for the HSA provision are uncertain but are not favorable. The Senate majority has generally supported HSAs, and some view the substantiation provision as undermining HSAs. Even if the measure passed, it is likely there would be insufficient votes in the Senate to override a presidential veto.
<b>Details</b>	H.R. 5719 would require distributions from HSAs for qualified medical expenses to be substantiated or included in gross income plus a 10% penalty. The bill also would require trustees to report expenses not substantiated.
<b>Effective Date</b>	The HSA substantiation requirement would be effective for amounts paid or distributed from an HSA after December 31, 2008.

## Genetic Nondiscrimination

<b>Current Legislation</b>	<ul style="list-style-type: none"> <li>■ Genetic Information Nondiscrimination Act of 2007 (H.R. 493/S. 358).</li> </ul>
<b>Status</b>	<ul style="list-style-type: none"> <li>■ H.R. 493 as passed by the House in April 2007 was added to the House-passed mental health parity bill (H.R. 1424) upon passage on March 5, 2008.</li> <li>■ The Senate Health, Education, Labor and Pensions (HELP) Committee approved S. 358 by a vote of 19 to 2 on January 31, 2007.</li> </ul>
<b>Outlook</b>	<p>S. 358 may come to the Senate floor for a vote sometime this week via a unanimous consent vote or by a cloture vote which would eliminate further opportunity for debate. It is likely that S. 358 will pass the Senate by a wide margin due to strong bipartisan support for the bill. An agreement was reached to bring the bill to the Senate floor after Sen. Coburn (R-OK) released his “hold” on the bill and dropped his pursuit of the inclusion of a business necessity exemption. An earlier Bush administration Statement of Administration Policy (SAP) stated that while it generally supports GINA, it is concerned that the bill does not create an “adequate firewall” to keep plaintiffs from suing under employment law remedies for health care benefits.</p>
<b>Details</b>	<p>H.R. 493/S. 358 would bar group health plans or health insurers from requesting, requiring, or purchasing genetic information for underwriting purposes, to deny health coverage or to raise premiums. The bill would also establish federal privacy standards and protection for genetic information. A provision for injunctive relief would be created under ERISA for violations that would cause irreparable harm to the health of the participant or beneficiary. Equitable relief would include an administrative penalty of \$100 per day of noncompliance and the retroactive reinstatement of coverage. Administrative penalties would be limited to the lesser of 10% of the aggregate amount paid by an employer during the preceding taxable year for group health plans or \$500,000 for unintentional violations. Under the Public Health Service Act, the administrative penalties would be similar to that created under ERISA. The legislation would establish a commission to review the developing science of genetics and advise Congress on the advisability of providing for a disparate impact cause of action. H.R. 493 would also (1) impose an excise tax on employer sponsors for health plan noncompliance equal to \$100 per day for the noncompliance period; (2) extend the provisions to adopted children, seniors who purchase Medigap policies, and people participating in clinical trials; and (3) require the HIPAA privacy law to be amended to conform to the bill’s provisions. The bill would allow group health plans and insurers to request genetic testing or information, subject to a minimum necessary standard, for purposes of claims processing and benefit management.</p>
<b>Effective Date</b>	<p>H.R. 493/S. 358 would become effective 18 months after the date of enactment. The commission would be set up six years after enactment.</p>

## Mental Health Parity

<p><b>Current Legislation</b></p>	<ul style="list-style-type: none"> <li>■ Mental Health Parity Act of 2007 (S. 558).</li> <li>■ Paul Wellstone Mental Health and Addiction Equity Act of 2007 (H.R. 1424).</li> <li>■ The Alternative Minimum Tax and Extenders Tax Relief Act of 2008 (S. 2886).</li> </ul>
<p><b>Status</b></p>	<ul style="list-style-type: none"> <li>■ The Senate approved S. 558 by unanimous consent on September 18, 2007.</li> <li>■ The House passed H.R. 1424 on March 5, 2008.</li> <li>■ H.R. 4848 was passed by the House (384-23) on February 7, 2007.</li> <li>■ S. 2886 was introduced by Sen. Baucus (D-MT) on April 17, 2008</li> </ul>
<p><b>Outlook</b></p>	<p>The Senate-passed S. 558 has the endorsement of business, mental health advocates, and health insurers, and President Bush has signaled his support of full mental health parity. The House bill contains a broader mandate and is much more restrictive of employer discretion in the design and administration of their group health plans and does not have the support of business. The White House issued a Statement of Administrative Policy indicating it strongly opposes the House bill, but stopped short of a veto threat. Reportedly, on March 18, Senators Kennedy (D-MA) and Domenici (R-NM) offered a compromise bill to the House that addressed some of the major differences between the House and Senate bills. According to reports, the compromise would not require employers to cover everything listed in the DSM-IV but would move closer to the House bill regarding out-of-network coverage. Other provisions are currently unknown. Rep. Patrick Kennedy (D-RI) stated that the compromise offered does not have business support. He also stated that they are negotiating alternative funding proposals than the ones passed in the House, and is optimistic that an agreement can be reached this year. It is also being reported that the House is preparing a counter-proposal to the Kennedy-Domenici compromise bill and may deliver it the Senate later this week. Given the complexity of the negotiations, a formal House-Senate conference committee is unlikely to be convened.</p> <p>H.R. 4848 has been referred to the Senate Finance Committee.</p> <p>S. 2886 is a large tax extender package that has the support of both Sens. Baucus and Grassley, chairman and ranking member respectively of the Finance Committee and is expected to be approved.</p>
<p><b>Details</b></p>	<p>S. 558 would provide mental health parity for employers with 50 or more employees. If group health plans provide mental health coverage, the bill would require parity in both financial requirements and treatment limits between mental health and medical/surgical benefits. Group health plans would be able to negotiate separate reimbursement arrangements for mental health benefits and would be able to manage the provision of mental health benefits. Further, group health plans would not be required to provide out-of-network coverage. Plans would be exempt from the parity requirement if it is projected that the plan experience increased actual total costs of coverage by exceeding 2% of the actual total plan costs during the first plan year or exceeding 1% of the actual total plan costs each subsequent year. "Mental health benefits" would be defined as mental health services (including substance abuse treatment) as defined under the terms of the plan or coverage. State law parity requirements would be preempted by ERISA in the case of self-insured plans only. Plans would not be prohibited from applying utilization review and medical management to mental health benefits but states may still regulate entities that provide these services to health plans.</p>

## Mental Health Parity (continued)

<p><b>Details (continued)</b></p>	<p>H.R. 1424 would amend ERISA, the Public Health Service Act and the Internal Revenue Code to expand and make mental health parity permanent. The bill would require group health plans that provide any mental health or substance abuse benefits to have them apply the same treatment and financial limits applicable to medical/surgical benefits within that same category of items or services, including for out-of-network coverage. The bill would require plans to disclose to current and potential plan participants or health care providers the criteria that a plan uses for making “medical necessity” determinations for mental and substance abuse benefits.</p> <p>The reasons for any denial of payment or coverage must be made available on request. Group health plans would have to provide coverage for any mental health or substance abuse disorder included in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM). A cost exemption would apply if there is an increase in the actual total costs of coverage for the plan year that exceeds 2% (1% in subsequent plan years). The bill permits states to have more expansive mental health parity mandates or consumer protections and remedies than in the federal parity law but only with respect to health insurance policies or group health insurance coverage. ERISA preemption with respect to self-insured group health plans would be preserved.</p> <p>H.R. 4848 would amend ERISA, the Internal Revenue Code, and the Public Health Service Act to extend the current mental health parity law through December 31, 2008. The provision expired at the end of 2007.</p> <p>S. 2886 would amend ERISA, the Internal Revenue Code, and the Public Health Service Act to extend the current mental health parity law through December 31, 2008. The provision expired at the end of 2007.</p>
<p><b>Effective Date</b></p>	<p>S. 558 would be effective in the first plan year that begins on or after January 1 of the first calendar year that begins more than one year after the date of enactment.</p> <p>H.R. 1424 would be effective for plan years beginning on or after January 1, 2009, with a delayed effective date for collectively bargained plans.</p> <p>H.R. 4848 would be effective on the date of enactment.</p> <p>S. 2886 would be effective on the date of enactment.</p>

## Trade Adjustment Assistance Act (Health Care Tax Credit and COBRA)

<p><b>Current Legislation</b></p>	<ul style="list-style-type: none"> <li>■ Trade and Globalization Adjustment Assistance Act of 2007 (S. 1848).</li> <li>■ Trade and Globalization Assistance Act of 2007 (H.R. 3920).</li> </ul>
<p><b>Status</b></p>	<ul style="list-style-type: none"> <li>■ S. 1848 was introduced by Sens. Baucus (D-MT) and Snowe (R-ME) on July 23, 2007 and is awaiting action in the Senate Finance Committee.</li> <li>■ The House approved H.R. 3920 on October 31, 2007 by a vote of 264 to 157.</li> </ul>
<p><b>Outlook</b></p>	<p>Although the TAA program expired at the end of December, the Labor Department insists that the program is still operating. The Senate Finance Committee is expected to mark up S. 1848 sometime later this spring.</p>

## Trade Adjustment Assistance Act (Health Care Tax Credit and COBRA) (continued)

<p><b>Outlook (continued)</b></p>	<p>TAA legislation is a top trade priority for Senate Finance Committee Chairman Baucus, and he, along with other prominent Democrats, has stated that he will not consider approving trade agreements until the TAA program is reauthorized. The White House issued a Statement of Administration Policy stating that while the president generally supports a reauthorization of TAA, he would veto H.R. 3920 because it converts the trade-related program into a “universal income-support and training program” and because he opposes the increase in the HCTC premium subsidy. However, in his State of the Union address, the president urged Congress to renew the TAA and make changes to help workers affected by trade. Analysts indicate that there now appears to be room for compromise on TAA.</p>
<p><b>Details</b></p>	<p>S. 1848 would increase the refundable, advanceable health care tax credit (HCTC) from 65% to 85% of monthly health insurance premiums for eligible workers under the Trade Adjustment Assistance Act (TAA). The bill would allow TAA recipients who are not enrolled in training programs to be eligible for the HCTC, and would amend the creditable coverage calculation period to exclude the time between the loss of coverage and the time when the individual receives notice of eligibility for the HCTC. In addition, spouses and dependents would continue to be eligible for the HCTC if the worker becomes eligible for Medicare, in the case of divorce, or death of the worker. The bill would require COBRA coverage to continue during the time that the worker is TAA-eligible. In addition, VEBAs would be added to the list of qualifying coverage for the HCTC.</p> <p>H.R. 3920 would increase the refundable, advanceable HCTC for qualified insurance premiums from 65% to 85% and allow the end-of-year credit to be applied to premiums for qualified insurance that are paid prior to a TAA-eligibility determination (provided the person is ultimately determined eligible for assistance) or December 31, 2007, whichever is later. The bill would allow workers not enrolled in a training program and who are receiving unemployment insurance to be eligible for the HCTC, and would amend the creditable coverage calculation period to exclude the time between the loss of coverage and five days after the individual receives notice of eligibility for the HCTC. The bill would allow spouses and dependents to continue to receive the HCTC when the worker becomes eligible for Medicare, dies, or is divorced. The GAO would be required to conduct a study on the HCTC to help Congress develop an alternative health benefit for trade-displaced workers. The bill would provide extended COBRA eligibility for: (1) PBGC pension recipients until the recipient’s date of death, and for a surviving spouse or dependents for 36 months after the date of death; (2) TAA-eligible individuals until TAA-eligibility ends; and (3) TAA-eligible individuals who are age 55 or have ten years of service with the employer until they obtain other group health coverage or become eligible for Medicare.</p>
<p><b>Effective Date</b></p>	<p>S. 1848 would apply to taxable years after December 31, 2007.</p> <p>Under H.R. 3920, the COBRA amendments would apply to periods of coverage that would end on or after January 1, 2008. The HCTC increase would apply to months beginning after December 31, 2007 in taxable years ending after that date, and the HCTC would sunset after December 31, 2009.</p>

## Medicare Reforms

<p><b>Current Legislation</b></p>	<ul style="list-style-type: none"> <li>■ Medicare Funding Warning Response Act of 2008 (S. 2662/H.R. 5480).</li> <li>■ Medicare Prescription Drug Savings and Choice Act (S. 2219/H.R. 3932).</li> <li>■ Medicare Electronic Medication and Safety Protection (E-MEDS) Act of 2007 (S. 2408/H.R. 4296).</li> <li>■ Medicare Chronic Care Practice Research Network Act of 2007 (H.R. 4327).</li> <li>■ Ensuring Future Physician Workforce Act of 2008 (S. 2729/H.R. 5545).</li> <li>■ Save Medicare Act of 2008 (S. 2785).</li> <li>■ Medicare Rural Health Access Improvement Act of 2008 (S. 2786).</li> </ul>
<p><b>Status</b></p>	<ul style="list-style-type: none"> <li>■ Senate Finance Committee Chairman Baucus (D-MT) and Sen. Gregg (R-NH) introduced S. 2662 on February 26 and House Majority Leader Hoyer (D-MD) and Minority Leader Boehner (R-OH) introduced H.R. 5480 on February 25. Sen. Baucus and Rep. Hoyer stated that they introduced the legislation as required by law, not because they endorsed the contents of the bill, and stated that many changes to the bills are likely during committee consideration. S. 2662 will now be taken up by the Senate Finance Committee. H.R. 5480 was referred to the House Committees on Ways and Means, Energy and Commerce, and Judiciary.</li> <li>■ Sen. Durbin (D-IL) introduced S. 2219 and Rep. Berry (D-AR) introduced H.R. 3932 on October 23, 2007.</li> <li>■ Sen. Kerry (D-MA) introduced S. 2408 and Rep. Schwartz (D-PA) introduced H.R. 4296 on December 5, 2007.</li> <li>■ Rep. Tim Johnson (R-IL) introduced H.R. 4327 on December 6, 2007.</li> <li>■ Rep. Tom Price (R-GA) introduced H.R. 5445 on February 14, 2008.</li> <li>■ Sen. Cornyn (R-TX) introduced S. 2729 and Rep. Burgess (R-TX) introduced H.R. 5545 on March 6, 2008.</li> <li>■ Sen. Stabenow (D-MI) introduced S. 2785 on March 13, 2008.</li> <li>■ Sen. Grassley (R-IA) introduced S. 2786 on March 13, 2008.</li> </ul>
<p><b>Outlook</b></p>	<p>Under the MMA, the Bush Administration was required to propose legislation to address excess spending in Medicare prompted by a Medicare funding warning that was issued for two consecutive years. As enacted by the MMA, a Medicare funding warning is triggered whenever the Medicare Trustees determine, for two consecutive years, that more than 45% of total Medicare spending will be derived from general revenues within seven years. Congress must consider the S. 2662/H.R. 5480 under an “expedited” process. House committees with jurisdiction must consider it by June 30. If the House has not voted on final passage of a bill by July 30, then, after 30 more calendar days, any member can offer a discharge petition to bring the bill to the House floor. Such a petition would need only one-fifth of members to sign on versus the 218 required under regular rules. In the Senate, if the Finance Committee has not reported out a bill by June 30, then any senator may move to bring the bill up on the Senate floor, but a filibuster could be used to block the Senate from considering the bill.</p>

## Medicare Reforms (continued)

<p><b>Outlook (continued)</b></p>	<p>Democrats generally decried the proposal, and the funding warning in general, as a “scare tactic” to promote cuts to the Medicare program. However, Senate Finance Committee Chairman Baucus (D-MT) stated that the value-based purchasing and health IT provisions are important goals. Committees of jurisdiction may modify the bill in any way, and it is expected that the legislation will be substantially modified by both the House and Senate committees. In particular, Democrats may consider using this legislation as a vehicle to block the scheduled reduction in physician payments and/or to reduce Medicare Advantage payments. The immediate driving force behind the passage of Medicare-related legislation in this session is that physicians are slated to receive a 10.6% cut in Medicare payments starting July 1 and an additional cut of about 5% in 2009. Sen. Baucus and Sen. Grassley are negotiating with the Bush administration to try to come up with an agreement on a modest Medicare package. Once they reach an agreement, they are expected to introduce their own legislative package, sometime in May, that would bypass the Finance Committee and go directly to the Senate floor.</p>
<p><b>Details</b></p>	<p>S. 2662/H.R. 5480 would allow the Secretary of HHS to introduce principles of value-based health care in Medicare and to develop and implement proposals that reduce Medicare spending by increasing provider efficiency and encouraging beneficiaries to be wise health care consumers. More specifically, the proposal would improve health information technology, including the adoption of electronic medical records; provide transparency in price and quality information; and, create incentives for providers to deliver and beneficiaries to choose high quality, low-cost care. The bill would reform the medical liability system to prevent frivolous lawsuits. The proposal would impose a 3-year statute of limitations on filing a lawsuit (or 1 year after the claimant discovers or should have discovered the injury) and would limit noneconomic damages to \$250,000. Each party would be liable only for the portion of damages allocated to the party. Punitive damages of up to \$250,000 may be awarded only if there is clear and convincing evidence of malicious intent. Punitive damages against a drug manufacturer would be prohibited if the product alleged to have caused the harm was subject to pre-market approval, clearance or licensure and was approved by the FDA or if the product is generally characterized as safe by qualified experts. Punitive damages also could not be imposed unless the packaging or labeling of a drug product is found to be substantially in violation of regulations. Punitive damages may apply where a person knowingly misrepresented or withheld information from the FDA. Finally, the bill would implement an income-related Part D premium, similar to Part B.</p> <p>S. 2219/H.R. 3932 would establish a Medicare Part D prescription drug plan that would be operated by the federal Medicare program and compete with the privately sponsored plans currently offered under Part D. The bill also would require the Secretary of HHS to establish a formulary and negotiate Part D prescription drug prices directly with pharmaceutical manufacturers. In addition, the bill would direct the Agency for Health Research and Quality to assess the clinical benefit of prescription drugs covered by Part D and make recommendations for inclusion in the formulary of the Medicare-sponsored Part D plan.</p>

## Medicare Reforms (continued)

<p><b>Details (continued)</b></p>	<p>S. 2408/H.R. 4296 would provide a one-time, start-up cost bonus to Medicare physicians who use e-prescribing and would mandate e-prescribing by 2011. Providers that do not use e-prescribing after that time would be subject to a 10% reduction in reimbursement. Providers who continue to meet a certain volume or proportion of e-prescriptions (to be established by the HHS Secretary) would receive an ongoing bonus of 1% of the allowed charges for such services.</p> <p>H.R. 4327 would establish a standing network of chronic care experts who would partner with Medicare to implement and analyze care management and care coordination interventions focused on patients with multiple chronic conditions. The Network would develop and evaluate evidence-based chronic care management practices for Medicare beneficiaries who have two or more chronic illnesses, with a focus on such beneficiaries who are provided benefits under the Medicare fee-for-service program and whose care is most costly. The network would (1) research, design, implement, test, and validate specific interventions designed to improve care management for Medicare beneficiaries with multiple chronic conditions; and (2) provide a reproducible, reliable, and scalable framework to standardize and translate best practices for all Medicare beneficiaries. The network would provide financial support for collaboration, infrastructure, patient recruitment and care management, and evaluation of the program.</p> <p>H.R. 5445 would provide another short term physician payment fix from July 1, 2008 through December 31, 2008.</p> <p>S. 2729/H.R. 5545 would provide positive Medicare reimbursement updates for physicians and eliminate the expenditure cap; increase incentives for physician data reporting; facilitate adoption by physicians of health information technology; educate and empower physicians and beneficiaries in relation to Medicare spending and benefits usage and study ways to realign the way Medicare pays for health care.</p> <p>S. 2785 would continue a 0.5% physician pay update for the last six months of 2008 and would institute a 1.8% update for 2009. It would extend the Physician Quality Reporting Initiative through 2010.</p> <p>S. 2786 would make a wide range of payment adjustments to providers of services under Medicare Parts A and B in order to support access to Medicare services in rural areas.</p>
<p><b>Effective Date</b></p>	<p>S. 2662/H.R. 5480 would generally be effective on enactment.</p> <p>S. 2219/H.R. 3932 would be effective as if included in the MMA.</p> <p>S. 2408/H.R. 4296 would be effective on enactment.</p> <p>H.R. 4327 would become effective on enactment</p> <p>H.R. 5445 would be effective July 1, 2008.</p> <p>S. 2729/H.R. 5545 would be effective 120 days after enactment.</p> <p>S. 2785 would be effective July 1, 2008.</p> <p>S. 2786 would be effective for items and services furnished on or after January 1, 2009.</p>

## Health Information Technology (IT)

<b>Current Legislation</b>	<ul style="list-style-type: none"> <li>■ Wired for Health Care Quality Act of 2007 (S. 1693)/Promotion of Health Information Technology (HIT) Act (H.R. 3800).</li> <li>■ Healthcare Information Technology Enterprise Integration Act (H.R. 2406).</li> <li>■ Independent Health Record Trust Act of 2007 (H.R. 2991).</li> <li>■ Technologies for Restoring Users' Security and Trust (TRUST) in Health Information Act (H.R. 5442).</li> </ul>
<b>Status</b>	<ul style="list-style-type: none"> <li>■ The Senate Health, Education, Labor, and Pensions (HELP) Committee approved S. 1693 by a voice vote on June 27, 2007. H.R. 3800 was introduced by Reps. Eshoo (D-CA) and Rogers (R-MI) on October 10, 2007 as a companion to S. 1693.</li> <li>■ H.R. 2406 was approved by the House Committee on Science and Technology on October 24, 2007 by voice vote. The bill now heads to the House floor for a vote but the timing is uncertain.</li> <li>■ H.R. 2991 was introduced by Reps. Moore (D-KS) and Ryan (R-WI) on July 11, 2007.</li> <li>■ H.R. 5442 was introduced by Reps. Markey (D-MA) and Emanuel (D-IL) on February 14, 2008.</li> </ul>
<b>Outlook</b>	<p>Senator Kennedy (D-MA) would like to bring S. 1693 to the floor but the bill is being blocked by Senator Leahy (D-VT) who does not believe the bill adequately addresses privacy concerns.</p>
<b>Details</b>	<p>S. 1693/H.R. 3800 would streamline the process for adoption of HIT interoperability standards; codify (and extend until 9/30/2014) the position of National Coordinator for HIT in the Department of HHS to facilitate interoperable HIT exchanges and coordinate the federal government's HIT activities and procurements; authorize funding to promote nationwide health care IT adoption, create a Partnership for Health Care Improvement (a public-private advisory body to recommend or endorse HIT interoperability standards and adoption time frames); authorize federal grants to assist states and local governments to adopt and promote HIT in their states; provide incentives for using broadband to deliver HIT to underserved areas; and provide patient privacy protections by establishing a system to certify electronic health record (EHR) products and granting patients rights to obtain, inspect, and correct inaccurate or fraudulent information in their EHRs.</p> <p>H.R. 2406 would require the National Institutes of Standards and Technology (NIST) (part of the U.S. Department of Commerce) to develop or adopt interoperable standards for health care information technology for federal agencies within one year of enactment. It would also require NIST to establish a program on health care information enterprise integration to build upon existing efforts at NIST, other federal agencies, and the private sector. Technical activities to be included in the NIST program may include: standards and interoperability analysis, software conformance and certification, security and privacy technical issues, information management, and medical device communication.</p>

## Health Information Technology (IT) (continued)

<p><b>Details (continued)</b></p>	<p>H.R. 2991 would establish an independent health record trust (IHRT) to maintain EHRs. IHRTs would be a voluntary system that is operated by member-owned institutions. Under an IHRT, participants would own their medical data and have access to their EHRs. Participants could also directly enter personal health information into their EHR and restrict the information that could be assessed and by whom. The bill would require IHRT providers to enter into a privacy protection agreement with participants. Such agreements would protect the confidentiality and integrity of identifiable health information and comply with HIPAA. The legislation would generally preempt state medical privacy protection laws except state physician-patient privilege laws.</p> <p>H.R. 5442 would expand upon and supersede the health information privacy and security requirements of HIPAA by granting individuals specific personal health information (PHI) privacy and security rights. These rights would include enabling patients to keep their medical records out of health IT systems unless they first give their consent, allowing patients to inspect and copy their PHI, correct, supplement or remove erroneous PHI, giving patients the right to receive an accounting of disclosures of one's PHI upon request, and the right to be notified if systems containing their health information are breached and their records are exposed. The bill would mandate the use of data security safeguards such as encryption and other technologies that render information unreadable to individuals who are not authorized to access it. Specific exceptions would be provided for functions such as law enforcement, health care research, and public safety. The bill would establish an Office of Health Information Privacy within HHS to oversee implementation and enforcement of the privacy and security standards. H.R. 5442 also contains provisions to promote the adoption of health IT. The bill would reauthorize the HHS Office of the National Coordinator for Health IT (ONCHIT) through September 2014, establish a public-private Partnership for Health Care Improvement to make recommendations concerning health IT standards, criteria for the electronic exchange of personal health information and related purposes to encourage the creation of a nationwide interoperable health information technology infrastructure. The bill would authorize competitive federal grants, including grants for state loan programs, to facilitate the adoption of interoperable health IT. The bill also contains provisions to promote the adoption and reporting of health care quality measures.</p>
<p><b>Effective Date</b></p>	<p>S. 1693/H.R. 3800 would become effective on date of enactment.</p> <p>H.R. 2406 would become effective on date of enactment.</p> <p>Under H.R. 2991, the FTC would establish regulations governing establishment, certification, operation, and interoperability of IHRTs within one year after the date of enactment.</p> <p>Most of the health care privacy and security provisions of H.R. 5442 would take effect 12 months after regulations are issued or 30 months after enactment, whichever is earlier. The provisions reauthorizing the activities of the ONCHIT expire at the end of September, 2014. Provisions relating to funding to facilitate health IT would expire in September 2012.</p>

## Generic Drugs and Follow-On Biologics

<b>Current Legislation</b>	<ul style="list-style-type: none"> <li>■ Preserve Access to Affordable Generics Act (S. 316/H.R. 1432).</li> <li>■ Fair Prescription Drug Competition Act (S. 438).</li> <li>■ Biologics Price Competition and Innovation Act of 2007 (S. 1695).</li> <li>■ Patient Protection and Innovative Biologic Medicines Act of 2007 (H.R. 1956).</li> <li>■ Pathway for Biosimilars Act (H.R. 5629).</li> </ul>
<b>Status</b>	<ul style="list-style-type: none"> <li>■ The Senate Judiciary Committee approved S. 316 by voice vote on February 15, 2007. The House has not taken any action on H.R. 1432.</li> <li>■ S. 438 was introduced by Sen. Rockefeller (D-WV) on January 30, 2007.</li> <li>■ The Senate Health, Education, Labor, and Pensions (HELP) Committee approved S. 1695 by voice vote on June 27, 2007.</li> <li>■ H.R. 1956 was introduced by Reps. Inslee (D-WA), Green (D-TX), and Baldwin (D-WI) on April 19, 2007.</li> <li>■ H.R. 5629 was introduced by Reps. Eshoo (D-CA) and Barton (R-TX) on March 13, 2008.</li> </ul>
<b>Outlook</b>	<p>S. 316/H.R. 1432 could be considered in 2008 but its prospects are uncertain in a short legislative year and in the face of strong opposition from both the brand name and generic drug industries.</p> <p>Senator Rockefeller would like to move his bill this year, but it is unclear what action will be taken. Employers, labor, and the generic drug industry support S. 438, but it is strongly opposed by the brand name pharmaceutical industry. H.R. 5629 may be positioned for action in the House this year. While H.R. 5629 has some bipartisan support and support from the biotech industry, the generics industry is especially critical of the exclusivity periods, which it regards as too generous.</p> <p>The Bush Administration's HHS FY2009 budget proposal includes a request to Congress to allow the FDA authority to approve follow-on biologics. During a Senate Finance Committee hearing on the HHS budget proposal, Senator Schumer (D-NY) stated that he and FDA Commissioner Andrew von Eschenbach would be working together to draft legislation for follow-on biologics. HHS Secretary Michael Leavitt stated that the agency would support that effort.</p>
<b>Details</b>	<p>S. 316/H.R. 1432 would prohibit agreements between brand name drug manufacturers and generic drug manufacturers to settle patent infringement claims. The bill would require the Federal Trade Commission (FTC) to conduct a study to prevent unfair methods of competition, including examining the frequency of agreements in patent infringement suits during the last five years; the impact of such agreements on competition in the pharmaceutical market; and a comparison of frequency of other agreements among competitors in the pharmaceutical market.</p> <p>S. 438 would prohibit brand name drug manufacturers from manufacturing, marketing, selling, or distributing an authorized generic drug during the 180-day period of market exclusivity awarded to the first generic drug manufacturer to enter the market.</p>

## Generic Drugs and Follow-On Biologics (continued)

<p><b>Details (continued)</b></p>	<p>S. 1695 would amend the Public Health Service Act to allow the FDA to approve follow-on biologics. The bill would establish an approval process for safe biosimilar and interchangeable biological products. During the approval process, an applicant would be required to demonstrate that there are no clinically meaningful differences in safety, purity, and potency between the follow-on biologic product and the brand product. The legislation also would allow but not require the FDA to issue guidance on standards and criteria the agency will use in approving biosimilar and interchangeable products. The bill would allow for 12 years of data exclusivity for the brand product during which a biosimilar product may not be approved and one year of data exclusivity for the first interchangeable biological product. The legislation also would establish a multi-step patent resolution process for biosimilar products.</p> <p>H.R. 1956 would allow the FDA to approve follow-on biologics. Drug manufacturers would receive 14 years of data exclusivity for new follow-on biologics, which the Department of Health and Human Services (HHS) could extend for an additional year if a significant clinical benefit is demonstrated during the 12 years following its authorization. HHS would issue guidance on the data required for follow-on biologics in a specific product class. Under the bill, HHS would establish an advisory committee to provide expert scientific advice and recommendations on the development and approval of follow-on biologics. During the approval process, interested parties would be given a reasonable opportunity to comment. Within two years after the date of enactment, HHS would provide reports to Congress on the feasibility of the follow-on biologics approval process and therapeutic equivalence determinations.</p> <p>H.R. 5629 would allow the FDA to approve follow-on biologic drugs if the follow-on drug meets certain study requirements. The FDA could also determine if a follow-on drug is interchangeable with the innovator product. The first product determined to be interchangeable would receive 24 months of market exclusivity. The bill would provide innovator products with 12 years of exclusivity. An additional two years of exclusivity may be granted for a medically significant new indication, and another six months of pediatric exclusivity may also be granted. The bill would also create a process to resolve patent disputes prior to a patent's expiration.</p>
<p><b>Effective Date</b></p>	<p>S. 316/H.R. 1432 would become effective upon enactment.</p> <p>S. 438 would become effective on enactment.</p> <p>S. 1695 would become effective on enactment.</p> <p>H.R. 1956 contains various effective dates as noted in the details section above.</p> <p>H. R. 5629 would be effective on enactment.</p>

## Long-Term Care

<b>Current Legislation</b>	<ul style="list-style-type: none"> <li>■ Long-Term Care Trust Account Act of 2007 (S. 504).</li> <li>■ Long-Term Care Affordability and Security Act of 2007 (H.R. 3363/S. 2337).</li> </ul>
<b>Status</b>	<ul style="list-style-type: none"> <li>■ S. 504 was introduced by Sens. Smith (R-OR) and Lincoln (D-AR) on February 6, 2007.</li> <li>■ H.R. 3363 was introduced by Reps. Pomeroy (D-ND) and Ramstad (R-MN) on August 3, 2007. S. 2337 was introduced by Sen. Grassley (R-IA) on November 13, 2007.</li> </ul>
<b>Outlook</b>	Legislation expanding or promoting the purchase of long-term care insurance plans could be considered in 2008, but enactment is uncertain.
<b>Details</b>	<p>S. 504 would create a new type of savings account to cover long-term care costs. Individuals who establish a long-term care trust account would be able to contribute up to \$5,000 annually, adjusted to inflation, to their account and receive a refundable 10% tax credit on that contribution. Contributions would have to be in cash. Interest accrued on these accounts would be tax-free, and funds could be withdrawn for the purchase of long-term care insurance or to pay for long-term care services. While an individual could contribute to another person's account, such contributions would be treated as a gift for income tax purposes.</p> <p>H.R. 3363/S. 2337 would allow employees to pay for long-term care insurance premiums on a pretax basis under cafeteria plans and flexible spending arrangements.</p>
<b>Effective Date</b>	<p>S. 504 would apply to taxable years beginning after December 31, 2006.</p> <p>H.R. 3363/S. 2337 would apply to taxable years beginning after December 31, 2006.</p>

## Lifetime Aggregate Limits

<b>Current Legislation</b>	Health Insurance Coverage Protection Act (S. 2706).
<b>Status</b>	S. 2706 was introduced by Sen. Dorgan (D-ND) on March 5, 2008.
<b>Outlook</b>	Prospects for S. 2706 are uncertain but the language of the bill could possibly be attached to another legislative vehicle aimed at modifying ERISA.
<b>Details</b>	S. 2706 would amend ERISA and the Public Health Service Act to require a minimum aggregate dollar lifetime benefit limit of \$5,000,000 in the first two plan years following enactment, and a minimum limit of \$10,000,000 for the third and fourth plan years after enactment. Thereafter, the amount would be indexed for inflation by the percentage increase in the consumer price index.
<b>Effective Date</b>	S. 2706 would take effect with the first plan year beginning on or after the date that is one year after date of enactment.

## Prosthetic Parity

<b>Current Legislation</b>	Group Health Plan Prosthetic Parity Act (H.R. 5615).
<b>Status</b>	H.R. 5615 was introduced by Reps. Andrews (D-NJ) and Miller (D-CA) on March 13, 2008.
<b>Outlook</b>	Prospects for H.R. 5615 are uncertain but the language of the bill could possibly be attached to another legislative vehicle, including any other bills aimed at modifying ERISA. Several states have recently enacted similar prosthetic parity bills.
<b>Details</b>	H.R. 5615 would amend ERISA to require self-insured group health plans and group health insurance offered to such plans, to provide parity between benefits for prosthetic devices and components and the medical and surgical benefits offered under those plans, including any out-of-network benefits. Separate annual or lifetime dollar limits for prosthetic benefits would be prohibited, and financial requirements (deductibles, cost-sharing such as copayments or co-insurance) and treatment limitations for prosthetic benefits could be no more restrictive than those required for “substantially all” other medical and surgical benefits under the plan. Medical necessity determinations and prior authorization would be permitted.
<b>Effective Date</b>	H.R. 5615 would take effect with the first plan year beginning on or after the date that is one year after date of enactment.