Overview of Provisions in the Amendment in the Nature of a Substitute to H.R. 3962 Offered by Mr. Boehner of Ohio

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Summary

Health care reform is at the top of the domestic policy agenda for the 111th Congress, driven by concerns about the growing ranks of the uninsured and the unsustainable growth in spending on health care and health insurance. Improving access to care and controlling rising costs are seen to require changes to both the financing and delivery of health care. Experts point to a growing body of evidence of the health care system's failure to consistently provide high-quality care to all Americans.

Several comprehensive bills have been introduced on the topic of health reform in the 111th Congress, such as H.R. 3962 (the Affordable Health Care for America Act), S. 1679 (Affordable Health Choices Act), and S. 1796 (America's Healthy Future Act of 2009).

On November 3, 2009, an additional health reform proposal was made public: *Amendment in the Nature of a Substitute to H.R. 3962 Offered by Mr. Boehner of Ohio* ("the Amendment"). If adopted, the Amendment would replace the substantive text of H.R. 3962 with the text of the Common Sense Health Care Reform and Affordability Act. This report summarizes the contents of the proposed Amendment.

This report will be updated as appropriate.

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Introduction

Several comprehensive bills have been introduced on the topic of health reform in the 111th Congress, such as H.R. 3962 (the Affordable Health Care for America Act), S. 1679 (Affordable Health Choices Act), and S. 1796 (America's Healthy Future Act of 2009).[1]

On November 3, 2009, an additional health reform proposal was made public: *Amendment in the Nature of a Substitute to H.R. 3962 Offered by Mr. Boehner of Ohio* ("the Amendment"). If adopted, the Amendment would replace the substantive text of H.R. 3962 with the text of the Common Sense Health Care Reform and Affordability Act.[2] According to the Congressional Budget Office and the Joint Committee on Taxation, enacting the Amendment would result in a net reduction in federal deficits of $68 billion over the 2010-2019 period.[3] This report summarizes the contents of the proposed Amendment.

The Amendment consists of seven divisions. Division A provisions are intended to improve affordability of health insurance through the development of state reinsurance programs and high-risk pools, private insurance reforms, state innovation programs, and administrative simplification. Division B provisions are intended to improve access to health insurance for small businesses. These include the establishment of Association Health Plans. Division B would also establish requirements to improve interstate purchasing of health insurance coverage and expand tax preferences for health savings accounts and high-deductible health plans. Division C would establish national medical malpractice laws that would effectively preempt existing state medical malpractice laws, with certain exceptions. Division D is focused on the doctor-patient relationship and comparative effectiveness research. It would provide that the Act would not affect the doctor-patient relationship or the practice of medicine, and would repeal a federal council on comparative effectiveness. Division E focuses on employee wellness programs and would specify how a group health plan or a health insurer offering group health coverage could vary premiums and cost sharing based on participation in a standards-based wellness program. Division F focuses on fraud, waste, abuse, and abortion. Division G focuses on licensure of biosimilar products and would provide a pathway for such licensure.

This report discusses each of the broad topics addressed in the Amendment. Each discussion consists of an overview of the issue and current law followed by a summary of provisions of the Amendment.

[1] For a list CRS reports related to these bills, see CRS's Health Reform page, at http://www.crs.gov/Pages/subissue.aspx?cliid=3746&parentid=13.

[2] To access the full text of the Amendment, see http://docs.house.gov/rules/health/111_hr3962_boehner_sub.pdf.

[3] U.S. Congress, Joint Committee on Taxation, Preliminary Estimate of Direct Spending and Revenue Effects of the Amendment in the Nature of a Substitute to H.R. 3962 offered by Rep. Boehner, 111th Cong., 1st sess., November 4, 2009, p. 1, at http://www.cbo.gov/ftpdocs/107xx/doc10705/hr3962amendmentBoehner.pdf.

Division A. Making Health Care Coverage Affordable for Every American

Coverage Provisions for Individuals with Existing Health Conditions

Overview of Issue and Current Law

Regulation of the private health insurance market is primarily done at the state level. State regulatory authority is broad in scope and includes requirements related to the issuance and renewal of coverage, benefits, rating, consumer protections, and other issues. Federal regulation of the private market is more narrow in scope and applicable mostly to employer-sponsored health insurance (i.e., through the Employee Retirement Income Security Act of 1974 (ERISA)).[4]

States have taken the initiative to propose and enact health care reforms to address perceived problems related to health insurance coverage, health care costs, and other issues. Each state has implemented a unique set of reform strategies to address concerns about health insurance and the health care delivery system. However, most health reform discussions, at both the state and federal level, focus primarily on insurance. Under this broad policy area, coverage and cost concerns are paramount.

A couple of strategies that states have undertaken to address the twin concerns regarding cost and coverage are implementing reinsurance programs and high-risk pools. Typically, state reinsurance programs reimburse insurers that have experienced greater than average claims in a given year. states may finance reinsurance programs through assessments on all insurers in a particular market, as well as general revenue and the collection of premiums from participating insurers. To compensate insurers that may end up enrolling a sicker, more expensive population, the state may withhold a portion of premiums collected and distribute the withheld funds at a later time according to the actual risk enrolled by each participating insurer.

In an effort to expand the options for health coverage, 35 states have established high-risk health insurance pools. These programs target individuals who cannot obtain or afford health insurance in the private market, primarily because of pre-existing health conditions. Also, many states use their high-risk pools to comply with the portability and guaranteed issue provisions of the Health Insurance Portability and Accountability Act of 1996 (described below). In general, state high-risk pools tend to be small and enroll a small percentage of the uninsured.

The Health Insurance Portability and Accountability Act (HIPAA), which amended ERISA, requires that coverage sold to small groups (2-50 employees) must be sold on a guaranteed issue basis. That is, the issuer must accept every small employer that applies for coverage. (Guaranteed issue rules do not address premiums.) HIPAA also guarantees that each issuer in the individual

[4] Federal law mandates compliance if an employer chooses to offer health benefits, such as compliance with plan fiduciary standards, procedures for appealing denied benefit claims, rules for health care continuation coverage, limitations on exclusions from coverage based on preexisting conditions, and a few benefit requirements such as minimum hospital stay requirements for mothers following the birth of a child.

market make at least two policies available to all HIPAA eligible individuals ("guaranteed availability"). In addition, HIPAA guarantees renewal or continuation of group coverage at the option of the plan sponsor (e.g., employer) and individual coverage at the option of the individual, with some exceptions. Insurers may not renew coverage under specified circumstances, such as nonpayment of premiums or fraud. All states require issuers to offer policies to firms with 2-50 workers on a guaranteed issue basis, in compliance with HIPAA. As of January 2009 in the small group market, 13 states also require issuers to offer policies on a guaranteed issue basis to self-employed "groups of one." And as of December 2008 in the individual market, 15 states require issuers to offer some or all of their insurance products on a guaranteed issue basis to non-HIPAA eligible individuals.[5]

Summary of Provisions

State Reinsurance Programs and High-risk Pools

Each state would be required to establish and operate a qualified reinsurance program in the small group market or a qualifying high-risk pool to offer individual coverage. The Amendment would specify the features of such programs and pools. The HHS Secretary (hereinafter referred to as "the Secretary") would be permitted to waive the requirements of this provision as deemed appropriate. The Amendment would authorize an appropriation of $15 billion for seed and operational grants to states for FYs 2010-2019, and an additional $10 billion for FYs 2015-2019. Participation in qualifying high-risk pools and qualified reinsurance program would be limited to citizens and nationals of the United States. Citizenship would be verified in accordance with §1903(x) of the Social Security Act, which requires states to obtain satisfactory documentation of citizenship.[6] Legal permanent residents (LPRs), refugees, and other lawfully residing aliens would be not be eligible.

Private Health Insurance Market Reforms

The Amendment would impose new federal requirements on the private health insurance market. Specifically, the proposal would:

- expand eligibility for guaranteed availability protections in the individual market for HIPAA eligible individuals;
- prohibit health insurance issuers from imposing an annual or lifetime benefit limit on any health insurance coverage;
- prohibit health insurance rescissions[7] in the application of guaranteed renewability protections in the individual market, except under certain conditions such as nonpayment of premiums, fraud, and other circumstances; and

[5] For additional information about health insurance generally, see CRS Report RL32237, *Health Insurance: A Primer*, by (name redacted).

[6] For further discussion, see CRS Report RS22629, *Medicaid Citizenship Documentation*, by (name redacted).

[7] A health insurance rescission is an insurance industry practice of revoking an individual health insurance policy after medical claims have been made. A rescission results in the former enrollee being responsible for payments associated with medical care received as if that person was never insured.

- require issuers to provide (1) notice of a proposed nonrenewal, discontinuation, or rescission of an individual health insurance policy to the enrollee before such proposed action would take effect, and (2) the opportunity to appeal such proposed action to an independent, external third party, as specified by the Secretary.

State Innovations and Improved Coordination

Overview of Issue and Current Law

With the lack of comprehensive health care reform at the federal level, states have been engaged in innovative approaches using private expansions, subsidies and tax credits, and regulatory reforms in order to both expand coverage and keep premiums down.[8] Often these approaches have been hampered by funding issues. For example, while the Dirigo Health Agency in Maine has been successful in enrolling an estimated 9,000 to 11,000 previously uninsured individuals,[9] the program has had some financial struggles and operated at a net loss in 2008.[10] Such financial struggles are common for new programs, but there is not a mechanism in current law to provide federal grants to assist states in their attempts to implement innovative health reforms.

For those that argue that health care quality and cost pressures would improve if the health insurance system acted more like a competitive market, the lack of symmetric information is a problem for consumers.[11] This phenomenon occurs when any actors in the marketplace have informational advantages over others.[12] Consumers often have limited comparable and accessible information about health insurance plans. Current law contains no provisions for a coordinated national effort, federally or at the state level, to provide a comparative health plan finder except in the Medicare Advantage and Part D programs.

Summary of Provisions

State Innovations Programs

The Amendment provides $50 billion in incentives to states that adopt reforms that reduce the cost of health insurance and expand coverage. The appropriations would be broken up into three components: (1) $25 billion for reductions in cost in the small group market; (2) $10 billion for

[8] For a more comprehensive review of state health reform see CRS Report R40513, *State Health Reform Strategies*, by (name redacted).

[9] "Leading the Way? Maine's Initial Experience in Expanding Coverage Through Dirigo Health Reforms" by Debra J. Lipson, James M. Verdier, and Lynn Quincy, available at http://www.mathematica-mpr.com/publications/PDFs/dirigooverview.pdf.

[10] See un-audited financial statement at http://www.dirigohealth.maine.gov/Documents/IncomeStmt_FY2009_1231_Preliminary.pdf.

[11] For example, see "Study Reveals Lack of Information, Not "Invincible" Mindset, Stands Between Young Adults and Health Insurance," available at http://www.uhc.com/news_room/2009_news_release_archive/young_adults_lack_health_insurance_information.htm, and M. Mulkey and J. Yegian, "Small Businesses, Information, And The Decision To Offer Health Insurance," Health Affairs, Vol. 20, No. 5, Sept./Oct. 2001.

[12] For a more detailed discussion of this issue and health care markets see CRS Report RL33759, *Health Care and Markets*, by (name redacted).

reductions in cost in the individual market; and (3) $15 billion for reductions in the number of uninsured. The term "small group market" means the market for health insurance coverage through a group health plan maintained by an employer who employed on average at least 2 but not more than 50 employees on business days during a calendar year. The term ''individual market'' generally means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

Under the Amendment, states would have to meet targets as specified by the Amendment, for reductions in health plan premiums and the number of uninsured in order to receive funds. For premium reductions, the Secretary would determine if the targets have been met relative to a premium baseline. The premium baseline would for year one be the average per capita premiums for health insurance coverage in the state. In subsequent years, the premium baseline would be increased by a percentage calculated by a formula to be determined by the Secretary in consultation with the Congressional Budget Office and the Bureau of the Census. In determining the formula the Secretary would take into account the inflation in health care services costs in the year, historic premium growth rates, and historic average changes in the demographics of the population covered that impact the rate of growth of per capita health care costs. Under the Amendment, states could not meet these targets by directly subsidizing health insurance.

Under the Amendment, if the Secretary determined that a state has reduced the percentage of uninsured nonelderly residents in year five, year seven, or year nine, below the year one baseline the Secretary would pay an amount equal to the product of the bonus uninsured percentage and the maximum uninsured payment amount for the year as defined by the Amendment. The Secretary would establish a methodology for computing the percentage of nonelderly residents who are uninsured. The calculations would *include* nonelderly lawful residents (LPRs and all other lawfully residing aliens) and would *exclude* unauthorized aliens.

Health Plan Finders

The Amendment also contains a provision that would allow for the creation of State Health Plan Finders so consumers can effectively comparison shop for health insurance. Conceptually, by increasing the information available to consumers they will be empowered to make the best decisions for their families when purchasing health insurance. Under the Amendment, no later than 12 months after enactment, each state would be able to contract with a private entity to develop and operate a plan finder website which would provide information on health insurance. Multi-state plan finders would be permissible. The plan finder would not be used to directly enroll members into a plan. Each Plan Finder would be required to meet the following conditions:

- The Plan Finder would present complete information on the costs and benefits of health insurance plans in a uniform and standardized manner.
- The Plan Finder would be available on the internet and accessible to all individuals in the state.
- The Plan Finder would allow consumers to search and sort data on health insurance plans using specific criteria.
- The Plan Finder would contain data on quality.
- The Plan Finder would meet all relevant state laws and regulations including those related to marketing.

- The Plan Finder organization would meet solvency, financial, and privacy requirements and its employees would be appropriately licensed.
- The Plan Finder would also assist individuals who are eligible for Medicaid or the Children's Health Insurance Program (CHIP) by including information on options, eligibility, and enrollment for those programs. [13]
- Plans participating in the Plan Finder would be required to be actuarially sound, may not have a history of abusive policy rescissions, and would meet solvency and financial requirements.
- The Plan Finder organization could not have a conflict of interest with a health insurance issuer.

According to the Congressional Budget Office (CBO), provisions in the Amendment directly related to health insurance would increase the federal deficit by $8 billion over the 2009-2019 period. CBO analysis also shows that the insurance provisions in the Amendment would reduce average annual premiums per enrollee in the United States relative to what they would be under current law. The average reductions in premiums would be larger in the small group and individual markets where most of the provisions are concentrated. Specifically, the Amendment would lower average insurance premiums in the small group market by an estimated 7% to 10% relative to current law in 2016. Premiums in the individual market are estimated to decline by 5% to 8% compared to current law during the same time period. In the large group market, premiums are estimated to decline from 0% to 3%. CBO emphasizes that these are very preliminary estimates and are subject to a high degree of uncertainty. [14]

CBO estimates that the Amendment would likely reduce the number of nonelderly uninsured by about 3 million in 2019 (relative to current law). This would leave 52 million non-elderly residents uninsured; roughly in line with the current share of legal, nonelderly uninsured. CBO also estimates that insurance reforms would lead to a reduction in Medicaid and CHIP enrollment and a subsequent increase in employer coverage. They estimate this would result in a $6 billion reduction in the federal deficit over the 10-year period. [15]

[13] In terms of noncitizens, most newly arriving legal permanent residents (LPRs) are barred from Medicaid and CHIP for the first five years after entry. After five years, LPRs are eligible for CHIP, but their subsequent coverage for Medicaid becomes the state's option. Those longtime LPRs with a substantial work history—generally 10 years (40 quarters) of work documented by Social Security or other employment records—or a military connection (active duty military personnel, veterans, and their families) are also eligible. http://www.congress.gov/cgi-lis/bdquery/R?d111:FLD002:@1(111+3)P.L. 111-3 gives states the option of providing Medicaid and CHIP to certain children and pregnant women who are LPRs during the first five years that they are living in the United States. For a complete analysis, see CRS Report R40144, *State Medicaid and CHIP Coverage of Noncitizens*, by (name redacted), and CRS Report R40889, *Noncitizen Eligibility and Verification Issues in the Health Care Reform Legislation*, by (name redacted).

[14] Congressional Budget Office, Letter to Honorable John A. Boehner from the Director, November 4, 2009.

[15] Ibid.

Administrative Simplification

Overview of Issue and Current Law

To promote the growth of electronic record keeping and claims processing in the nation's health care system, the Health Insurance Portability and Accountability Act's (HIPAA) Administrative Simplification provisions (SSA Secs. 1171-1179) instructed the Secretary to adopt electronic format and data standards for nine specified administrative and financial transactions between health care providers and health plans. Those transactions include patient eligibility inquiry and response, reimbursement claims, claims status inquiry and response, and payment and remittance advice. In addition, HIPAA directed the Secretary to adopt a standard for transferring standard data elements among health plans for the coordination of benefits and the sequential processing of claims. In 2000, the Centers for Medicare and Medicaid Services (CMS) issued an initial set of standards for seven of the nine transactions and for the coordination of benefits. As required under HIPAA, the Secretary published updated standards in early 2009 to replace the versions currently in use. The compliance deadline for the updated standards is January 1, 2012.

The health care payment and remittance advice transaction is a communication from a health plan to a provider that includes an explanation of the claim and payment for that claim. The HIPAA standard for this transaction can accommodate an electronic funds transfer (EFT), in which payment is electronically deposited into a designated bank account. EFT is common in the health care sector—health plan contracts often require it—but there is no EFT mandate in federal law for Medicare, Medicaid, or private health insurance.

HIPAA does not mandate that providers conduct the transactions electronically, though health plans increasingly require it. However, providers that elect to submit one or more of the HIPAA transactions electronically must comply with the standard for those transactions. In 2001, Congress enacted the Administrative Simplification Compliance Act, which mandated that Medicare claims be submitted electronically in the HIPAA standard format, with the exception of those from small providers and in other limited circumstances.

The HIPAA electronic transactions standards, which are the result of a consensus-based development process, include optional data/content fields that can accommodate plan-specific information. Providers often are faced with a multiplicity of companion guides and plan-specific requirements and must customize transactions on a plan-by-plan basis.

HIPAA instructed the Secretary to adopt unique identifiers for health care providers, health plans, employers, and individuals for use in standard transactions. Unique identifiers for providers and employers have been adopted, while the health plan identifier is still under review. Congress has blocked the development of a unique individual identifier through language added to the annual Labor-HHS appropriations bill.

Summary of Provisions

The Amendment would establish a timeline for the development, adoption and implementation of a single set of consensus-based operating rules for each HIPAA transaction for which there is an existing standard, with the goal of creating as much uniformity in the implementation and use of the transactions standards as possible. Operating rules would be defined as the necessary business rules and guidelines for the electronic exchange of information that are not defined by the

electronic standards themselves. In adopting the operating rules, the Secretary would rely on the recommendations of a qualified non-profit entity. Also, the section would add EFT for the payment of health claims as a HIPAA transaction and provide for the adoption and enforcement of an EFT standard.

Operating rules for eligibility and health claims status transactions would have to be adopted by July 1, 2011, and take effect by January 1, 2013. Operating rules for claims payment/remittance and EFT would have to be adopted by July 1, 2012, and take effect by January 1, 2014. The Secretary would have to adopt operating rules for the remaining HIPAA transactions, including health claims, plan enrollment and disenrollment, health plan premium payments, and prior authorization and referrals, by July 1, 2014, to take effect by January 1, 2016. The Secretary would also be required to establish a committee to biennially review and provide recommendations for updating and improving the HIPAA standards and operating rules.

By December 31, 2013, health plans would be required to file a certification statement with the Secretary that their data and information systems comply with the most current published standards, including the operating rules, for the following transactions: eligibility, health claims status, claims payment/remittance and EFT. By December 31, 2015, health plans would be required to certify to the Secretary that their data and information systems comply with the most current published standards and operating rules for the remaining completed HIPAA transactions. The Secretary would be permitted to designate an outside entity to verify that health plans have met the certification requirements and would have to conduct periodic audits of plans to ensure that they maintain compliance with the standards and operating rules. The section would require the Secretary, no later than April 1, 2014 and annually thereafter, to assess a penalty fee against health plans that fail to meet the certification requirements. The Secretary of the Treasury, acting through the Financial Management Service (FMS), would be responsible for the collection of penalty fees. Unpaid penalty fees would be increased by an interest payment determined in a manner similar to underpayment of income taxes and would be considered debts owed to federal agencies, which may offset and reduce the amount of tax refunds otherwise payable to a health plan.

In addition to the above provisions, the Amendment would require that as of January 1, 2014, no Medicare payment would be made for benefits delivered under Part A or Part B other than by EFT or an electronic remittance in a form specified in the HIPAA payment/remittance advice (i.e., ACS X12 835) standard. It would also require the Secretary, by July 1, 2013, to report to Congress on the extent to which the Medicare and Medicaid programs and the providers that serve beneficiaries under those programs transact electronically in accordance with the HIPAA standards.

Finally, the Amendment would require the Secretary to issue a rule to establish a unique health plan identifier. The Secretary would be permitted to issue an interim final rule, which would take effect no later than October 1, 2012.

According to CBO, these provisions would result in about $6 billion in savings in Medicaid over a 10-year period. In addition, those provisions would result in an increase in revenues of about $13 billion as indirect effect of reducing the costs of private health insurance plans. [16]

[16] Congressional Budget Office, Letter to Honorable John A. Boehner from the Director, November 4, 2009.

Division B. Improving Access to Health Care

Small Businesses Health Insurance

Overview of Issue and Current Law

Less than half of all small employers (less than 50 employees) offer health insurance coverage;[17] such employers cite cost as the primary reason for not offering health benefits. One of the main reasons is a small group's limited ability to spread risk across a small pool. Insurers generally consider small firms to be less stable than larger pools, as one or two employees moving in or out of the pool (or developing an illness) would have a greater impact on the risk pool than they would in large firms. Other factors that affect a small employer's ability to provide health insurance include certain disadvantages small firms have in comparison with their larger counterparts: small groups are more likely to be medically underwritten, have relatively little market power to negotiate benefits and rates with insurance carriers, and generally lack economies of scale.

Summary of Provisions

Association Health Plans

The Amendment would establish Association Health Plans (AHPs) to facilitate the offer and purchase of health insurance sponsored by bona fide business associations. Such associations would meet certain qualifications: organized and maintained in good faith for purposes other than that of obtaining or providing medical care; established as a permanent entity with the active support of members who are required to pay dues for eligibility; have been in existence for a minimum of three years; and other characteristics. Associations would be required to seek certification from the Secretary of Labor to sponsor AHPs. The Labor Secretary would establish procedures for the continued certification for fully insured and self-insured plans.

AHPs would be required to comply with the following:

- Would be allowed to offer a self-insured plan only if the plan existed before the date of enactment; membership is not restricted to one or more trades and instead represents a broad cross section of trades and businesses or industries; or the plan includes eligible participating employees in one or more high-risk trades (as listed in the Amendment).
- Would be required to have at least 1,000 participants and beneficiaries if offering a self-funded coverage option.

[17] Health insurance can be provided to groups of people that are drawn together by an employer or other organization, such as a trade union. Small groups typically refer to firms with between 2 and 50 workers, although some self-employed individuals are considered "groups of one" for health insurance purposes in some states. Consumers who are not associated with a group can obtain health coverage by purchasing it directly in the nongroup (or individual) market.

- Would be operated by a board of trustees with complete fiscal control and responsibility for all operations.
- Would be required to meet solvency standards relating to reserves, excess/stop loss insurance, surplus, and indemnification insurance as the Labor Secretary considers appropriate.

The Amendment would impose several non-discrimination requirements on AHPs:

- Association membership, dues, or plan coverage would not be determined on the basis of health factors.
- All employers who are members of the association must be eligible to qualify as participating employers, and all geographically available coverage options must be made available upon request to eligible employers.
- No participating employer would be allowed to provide coverage in the individual market to an employee for coverage that is similar to the AHP if exclusion of the employee from the group plan is based on health factors.
- Premiums for any particular small employer would be prohibited from being based on the health status of the plan participants, or on the type of business or industry in which the employer was engaged.

AHPs would have sole discretion to determine the specific items and services to be included as benefits, except in the case of state laws that prohibit the exclusion of a specific disease from coverage, or relate to newborn and maternal minimum hospital stays, mental health parity, and reconstructive surgeries following mastectomies. Moreover, AHPs would be permitted to set premiums based on claims experience and state rating rules.

The Amendment would authorize the Labor Secretary to promulgate regulations for the purpose of carrying out the provisions relating to AHPs. The Labor Secretary would take action in the case of a possible AHP failure, as specified in the Amendment. The Amendment would establish an "Association Health Plan Fund" from which the Labor Secretary would make payments to ensure continued benefits on behalf of AHPs in distress. The fund's activities would be financed by annual payments of $5,000 made by AHPs, supplemental payments as determined necessary by the Labor Secretary, penalties for non-payments to the fund, and investment income.

The penalty for willfully misrepresenting a plan, as a certified AHP meeting the requirements of this Amendment, would be, upon conviction, imprisonment for not more than five years, fines, or both. If the Secretary shows the operation, promotion or marketing of an AHP or similar arrangement, is not certified under the insurance laws of any state offering or providing benefits, a district court of the U.S. would require the plan or arrangement to cease activities.

The Secretary would consult with the "primary" state, with respect to an AHP, regarding the Secretary's authority to enforce requirements and to certify AHPs. The "primary" state would be the state in which filing and approval of policy type offered by the plan was obtained. The Secretary would take into account the places of residence of the participants and beneficiaries under the plan and the state in which the trust is maintained.

Title II of the Amendment, relating to AHPs would be effective one year after enactment. Prior to implementation, the Secretary of Labor would first be required to issue regulations relating to AHPs.

Certain existing plans would be deemed to be a group health plan for Title 1 of this Amendment, and certain ERISA requirements would be deemed to be met, for those arrangements: (1) in existence on the date of enactment which are maintained in a state for the purpose of medical care benefits for employees and beneficiaries of participating employers with at least 200 employees, (2) that have been in existence for at least 10 years, and (3) are licensed under the laws of one or more states.

Treatment of Multiple Businesses as Single Employers

The Amendment would clarify that two or more trades or businesses that establish and maintain a multiple employer welfare arrangement (MEWA, as defined in ERISA) for the purpose of providing medical care to the employees of two or more employers would be deemed a single employer, as long as such trades or businesses are under common control. Determination of whether a trade or business is under common control would be made under regulations by the Labor Secretary, as specified in the Amendment. In determining whether medical care is provided to employees of two or more employers, the MEWA would be treated as having only one participating employer if the number of current and former workers of one employer with health coverage through the MEWA represents 75% of all workers from all firms with coverage through the MEWA.

Targeted Efforts to Expand Access to Health Insurance Coverage

Overview of Issue and Current Law

Currently, employers are not required to offer health insurance to their employees and even if they do provide coverage, they can choose whether or not to extend that coverage to dependents. There are no federal statutes that specify an age for "aging out" of dependent coverage through employer-sponsored health insurance. Certain states require that young adults who are offered coverage under their parents' health insurance policy may remain on that policy until a certain age or under certain circumstances (e.g., unmarried dependent). Auto-enrollment in health insurance refers to a mechanism that allows the sponsor of health insurance coverage to automatically enroll eligible persons in a health plan. There are no federal statutes concerning auto-enrollment.

Summary of Provisions

The Amendment would require a group health plan or health insurance coverage offered in connection with a group health plan that chooses to cover dependents, to continue coverage until at least the end of the plan year in which the dependent turns 25. This would apply for plan years that begin more than three months after the date of enactment.

States could not establish laws preventing employers from instituting auto-enrollment in a group health plan or health insurance coverage offered in connection with such a plan, as long as individuals could decline the coverage. Employer using auto-enrollment would be required to provide annual notification, including an explanation of any required employee contribution and the right to decline coverage. Employees who failed to decline coverage within a reasonable period of time could be auto-enrolled into a plan.

Interstate Purchasing of Health Insurance

Overview of Issue and Current Law

States' insurance requirements number in the thousands and can be complicated. Even the laws of two states addressing the same matter can differ on many dimensions. In addition to the benefits that comprise health insurance products, state laws and regulations require patient protections, address how insurance carriers develop the rates charged for their products, and describe procedures for approval of those rates. State laws and regulations address how entities in the business of selling health insurance conduct their business in order to meet licensing requirements, and fund their enterprises and prepare against the risk of insolvency. They are subject to fair marketing practice laws, requirements related to the filing of grievances against the plans, and appealing plan decisions. Entities selling health insurance may also be subject to state taxes.

Summary of Provisions

The Amendment would allow a health insurance issuer, in compliance with the health insurance laws and regulations of one state ("primary state"), to offer individual health insurance in another state ("secondary state"). Individual health insurance offered in a secondary state would be exempt from the health insurance laws and regulations of such state to the extent that such laws (1) prohibit or regulate the operation of the issuer in the secondary state, (2) require such coverage to be countersigned by an insurance agent or broker, or (3) otherwise discriminate against the issuer offering such coverage in the primary or secondary state. A primary state has sole jurisdiction over the enforcement of the primary state's health insurance laws on health insurance coverage offered in the primary and any secondary states.

Secondary states would retain authority over certain regulatory activities with respect to health insurance issuers, including:

- Payment of premium and other taxation;
- Submission of financial information;
- Compliance with a lawful order issued in a delinquency proceeding due to the state finding financial impairment;
- Compliance with a court-issued injunction upon state petition alleging hazardous financial condition;
- Participation in a guaranty or similar association;
- Compliance with state fraud and abuse and claims settlement laws; and
- Compliance with independent review requirements, as specified in the Amendment.

For any health insurance coverage offered in a secondary state, an issuer would disclose that such coverage is not subject to all of the health insurance laws and regulations of that state in a format specified in the Amendment. At time of renewal of the individual health insurance policy, the issuer would be prohibited from reclassifying the enrollee based on health factors, or increasing the premium based on health factors or claims experience. Issuers would be permitted to (1)

terminate or discontinue coverage in cases of nonpayment of premiums, fraud, and other circumstances as allowed under federal law, (2) raise premiums based on claims experience for all policyholders within a class, (3) offer premium discounts for participation in wellness activities, (4) reinstate lapsed coverage, and (5) retroactively adjust rates if the initial rates were based on misrepresented information at the time of issue. The issuer would be required to submit to the state insurance commissioners in primary and secondary states information about the plan that would be offered, notice of any change in designation of the primary state, and notice of issuer's compliance with the laws of the primary state. Issuers would also submit to the insurance commissioners in secondary states quarterly financial statements, containing a statement on loss and loss adjustment expense reserves, certified by an independent public accountant.

Improving Health Savings Accounts

Overview of Issue and Current Law

Health Savings Accounts (HSAs) are one way people can pay for unreimbursed medical expenses (deductibles, copayments, and services not covered by insurance) on a tax-advantaged basis. HSAs can be established and funded by eligible individuals when they have a qualifying high deductible health plan (HDHP) and no other health plan, with some exceptions.[18] But not all individuals enrolled in an HDHP have a HSA. Under current law contributions to HSAs are tax deductible and withdrawals are not taxed if used for medical expenses. However, premiums for HDHPs are not considered a qualified medical expense. Unused balances may accumulate without limit.

Summary of Provisions

The Amendment includes a number of provisions to expand the tax-deductibility of HSAs and allow premiums for certain high deductible health plans to be tax-deductible. In addition, the Amendment would make a number of other changes to improve the coordination between administrators of HDHPs and HSA accounts to encourage enrollees to enroll in both at the same time. The Amendment would also provide a 60-day grace period for medical expenses incurred prior to the establishment of an HSA. According to the Congressional Budget Office, the HSA provisions in the Amendment are estimated to cost $5 billion over a 10-year period.[19]

Specifically, the Amendment would allow those making HSA contributions to receive a non-refundable tax credit in addition to the tax deduction they already receive. This tax credit would be included as part of the current retirement savings credit provisions (often called the Saver's Credit).[20] The amount of the HSA tax credit available would decline as income increases and completely phase out for those with adjusted gross income of over $55,500 for joint filers, and $27,750 for single filers. These thresholds are 2009 levels and would be indexed for inflation in future years.

[18] See CRS Report RL33257, *Health Savings Accounts: Overview of Rules for 2009*, by (name redacted).

[19] Congressional Budget Office, Letter to Honorable John A. Boehner from the Director, November 4, 2009.

[20] The $1,000 limit includes contributions to retirement savings plans as well. See CRS Report RS21795, *The Retirement Savings Tax Credit: A Fact Sheet*, by (name redacted).

Generally, a tax credit is applied directly against a taxpayer's tax liability. Since the HSA tax credit is nonrefundable, if the tax liability is less than the credit amount of all refundable credits available, then the taxpayer would not benefit from the full credit. Thus, the maximum credit applied to the sum of both HSA and qualified retirement savings contributions is the lesser of $1,000 or the amount of the tax that would have been owed without the credit.

The Amendment would also expand the definition of qualified medical expense to allow premiums for a high-deductible plan purchased in the individual market to be excluded from taxable income.

Division C. Enacting Real Medical Liability Reform

National Medical Malpractice Laws

Overview of Issue and Current Law

Although medical malpractice liability reform has often been considered by Congress, it is the states that regulate or have implemented tort reform for medical malpractice lawsuits. Where states have enacted tort reform, provisions vary regarding statutes of limitation and caps on non-economic damages or punitive damages. Typical tort reform provisions also include modifying common law tort doctrines such as joint and several liability, contributory and comparative negligence, periodic payments, and the collateral source rule. Recently, other tort reform efforts include requiring the parties to undergo pre-trial alternative dispute resolution, requiring the plaintiff to obtain an affidavit of merit from an expert that is to be filed with the complaint, or requiring the parties to first go before a panel to evaluate whether their claims are meritorious before filing in court.[21]

Summary of Provisions

The Amendment would impose national medical malpractice laws, and thus would effectively preempt existing state medical malpractice laws, with certain exceptions. A "health care lawsuit" under this section would encompass not only suits between a physician and patient, but also any claim against a health care organization, manufacturer, distributor, supplier, marketer, promoter or seller of a medical product and any claims concerning health care goods and services or medical products affecting interstate commerce. According to CBO, these provisions are expected to reduce spending by $41 billion over a 10-year period.[22]

Statute of Limitations

The Amendment would require a health care lawsuit to be brought within either three years after the date of manifestation of the injury, or within one year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first. No lawsuit could be brought after three years, but such a limitation could be extended upon a showing of (1) proof of fraud; (2) intentional concealment; or (3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured party. The statute of limitations provision for actions commenced by minors would vary somewhat to this general provision.

[21] For more information on this issue, please see CRS Report R40862, *Medical Malpractice Insurance and Health Reform*, by (name redacted), (name redacted), and (name redacted).

[22] Congressional Budget Office, Letter to Honorable John A. Boehner from the Director, November 4, 2009.

Compensating Patient Injury: Recovering Damages

The Amendment would not limit the amount of economic damages a claimant recovers. Economic damages under the Amendment would be defined as monetary losses incurred, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

The Amendment would limit noneconomic damages, if awarded, to $250,000, regardless of the number of parties against whom the action is brought, or the number of separate claims or actions brought with respect to the same injury. However, under the Amendment, this cap would not preempt a state law—enacted before, on, or after the passage of this Amendment—that limits noneconomic damages regardless of whether such a monetary amount is greater or lesser than is provided for in the Amendment. Noneconomic damages would be defined as damages for physical and emotional pain, suffering, inconvenience, physical impairment, and loss of enjoyment of life.

A jury would not be informed about the maximum award for noneconomic damages, and if the amount of noneconomic damages awarded is in excess of $250,000, then such an award would be reduced either before or after the judgment is rendered. If separate awards are rendered for past and future noneconomic damages and the combined awards exceed the cap, the future noneconomic damages would be reduced first.

Where there are multiple defendants, the Amendment would make each party responsible for an amount of damages that is in direct proportion to his or her individual percentage of fault, and it would not make an individual liable for the share of any other person. The trier of fact would determine the responsibility of each party for the claimant's harm.

Punitive Damages

The Amendment would limit punitive damages to the greater of $250,000 or two times the amount of economic damages awarded, although a jury would not be informed of the limitation. However, the cap on punitive damages would not apply so long as a state has enacted or enacts a cap on punitive damages, irrespective of whether such amount is greater or lesser than the limit provided for in the Amendment. Punitive damages would not be awarded in a health care lawsuit where a judgment for compensatory (i.e., economic and noneconomic) damages is not rendered.

Under the Amendment, punitive damages would only be awarded if it is proven by clear and convincing evidence that the defendant acted with malicious intent or that the defendant deliberately failed to avoid unnecessary injury that he or she knew the claimant would suffer. Malicious injury would be defined as intentionally causing or attempting to cause physical injury other than providing health care goods or services. A claimant, however, would not be permitted to make a demand for punitive damages when initially filing the health care lawsuit. Upon a motion by the claimant, a court would be permitted to allow the claimant to amend his or her pleading only after a hearing and a finding by the court that the claimant has established by a substantial probability that he or she will prevail on the claim for punitive damages.

Alternatively, under the Amendment, either party would be allowed to request that the trier of fact consider, in a separate proceeding, (1) whether punitive damages are to be awarded and the amount of such award, and (2) the amount of punitive damages following a determination of punitive liability. If this latter option is chosen, then no evidence relevant to the claim for punitive

damages would be admissible in any proceeding to determine whether compensatory damages are to be awarded.

If a separate proceeding is held, the Amendment sets forth specific factors that the trier of fact would be required to consider: (1) the severity of the harm caused by the conduct of such party; (2) the duration of the conduct or any concealment of it by such party; (3) the profitability of the conduct to such party; (4) the number of products sold or medical procedures rendered for compensation, as the case may be, that caused the harm complained of by the claimant; (5) any criminal penalties imposed on such party as a result of the conduct complained of; and (6) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

Maximizing Patient Recovery: Attorney Fees

Under the Amendment, the court would be empowered to supervise the arrangements for the payment of damages to protect against conflicts of interest (e.g., a claimant's attorney having a financial stake in the outcome by virtue of a contingency fee). The court would have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect the damages to the claimant.

The Amendment would impose a sliding scale for attorney fees. In any health care lawsuit, the total of all contingency fees for representing all claimants would not exceed: (1) 40% of the first $50,000 recovered by the claimant(s); (2) 33 1/3% of the next $50,000 recovered by the claimant(s); (3) 25% of the next $500,000 recovered by the claimant(s); and (4) 15% of any amount where the recovery is in excess of $600,000. The sliding scale would be applicable regardless of whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

Introduction of Collateral Source Benefits

The Amendment would permit any party in a health care lawsuit involving injury or wrongful death to introduce evidence of collateral source benefits that an opposing party may receive. However, once a party introduces this evidence, the opposing party would be permitted to introduce evidence of any amount it has paid or contributed, or likely to pay or contribute in the future, to secure the right to the collateral source benefit. In other words, if, for example, a party has evidence introduced against it of collateral source benefits it is receiving or will receive, then such party would be allowed to introduce evidence of amounts paid or to be paid to the collateral source provider that gives it the right to such benefits.

The Amendment would also appear to preclude a provider of collateral source benefits from recovering any amount against the claimant or placing a lien or credit against the claimant's recovery, or from being legally subrogated to the right of the claimant in the health care lawsuit.

Under the Amendment, this section would not apply to 42 U.S.C. § 1395y(b), which provides for Medicare as a secondary payer, or 42 U.S.C. § 1396a(a)(25), which provides for state plans for medical assistance.

Periodic Payment of Future Damages

Under the Amendment, if an award of future damages is made that equals or exceeds $50,000, without a reduction to a present value, any party would be able to request to the court that the future damages be paid by periodic payment. This would be permitted so long as the party against whom the judgment was made has sufficient insurance or other assets to fund a periodic payment of such judgment.

Effect on Other Laws

The Amendment would not apply to title XXI of the Public Health Service Act (PHSA) to the extent that it establishes a federal rule of law applicable to a civil action brought for vaccine-related injury or death. However, the Amendment's provisions would apply in vaccine-related injury or death claims to the extent that a federal rule of law under title XXI of the PHSA does not apply.

The Amendment states that it would preempt provisions of the Federal Tort Claims Act (FTCA), chapter 171 of title 28 of the U.S. Code, to the extent that the FTCA (1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages than provided for in this title; or (2) prohibits the introduction of evidence regarding collateral source benefits, or mandates or permits subrogation or a lien on collateral source benefits.

Preemption

Any issue that would not be governed by a provision of this Amendment, including state standards of negligence, would be governed by otherwise applicable state or federal law.

Furthermore, the Amendment would not preempt any state or federal law that provides greater procedural or substantive procedures for health care providers and organizations from liability, loss, or damages.

As mentioned in the discussion on Recovering Damages and Punitive Damages, the Amendment would provide states with some flexibility, given that it would not preempt any state law, whether enacted before, on, or after the enactment of the Amendment, that specifies a particular monetary amount of economic, noneconomic, or punitive damages, regardless of whether such monetary amount is greater or lesser than would be provided for under this title.

Furthermore, the Amendment would not preempt any defense available to a party in a health care lawsuit.

Effective Date

The provisions of this division of the Amendment would be applicable to any health care lawsuit that is initiated on or after the date of enactment of the Amendment, except that the Amendment's statute of limitations would not apply to any health care lawsuit arising from an injury occurring prior to the date of enactment.

Division D. Protecting the Doctor-Patient Relationship

Overview of Issue and Current Law

The American Recovery and Reinvestment Act of 2009 (ARRA), the economic stimulus legislation signed into law on February 17, 2009 (P.L. 111-5), included supplemental FY2009 discretionary appropriations for biomedical research, public health, and other health-related programs within the Department of Health and Human Services (HHS). As enacted, ARRA included $17.15 billion for community health centers, health care workforce training, biomedical research, comparative effectiveness research (CER), HIT, disease prevention, and Indian health facilities.

Sec. 804 of ARRA established the Federal Coordinating Council for Comparative Effectiveness Research (FCCCER), an entity whose purpose is fostering the coordination of comparative effectiveness and related health services research conducted or supported by relevant federal departments and agencies. FCCCER, composed of senior officials from federal agencies with health-related programs, was instructed to submit an initial report describing current federal CER activities and providing recommendations for future research. The Council was to prepare an annual report on its activities and include recommendations on infrastructure needs and coordination of federal CER. Sec. 804 specifically stipulates that the Council may not mandate coverage, reimbursement, or other policies for any public or private payer, and that none of the reports or recommendations developed by the Council may be construed as mandates or clinical guidelines for payment, coverage or treatment.[23] The Council published its initial report on June 30, 2009.[24]

Summary of Provisions

The provisions in Division D of the Amendment would clarify through a rule of construction that nothing in this Act would be construed to interfere with the doctor-patient relationship or the practice of medicine. In addition, they would repeal Sec. 804 of ARRA, the provision which established FCCCER.

[23] For more information about the American Recovery and Reinvestment Act, please see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by (name redacted).

[24] HHS, Federal Coordinating Council for Comparative Effectiveness Research, Report to the President and the Congress, June 30, 2009, http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.

Division E. Incentivizing Wellness and Quality Improvements

Overview of Issue and Current Law

As employers and insurers have struggled with rising health care costs, there has been significant interest in reducing these costs by incentivizing healthy behaviors through wellness programs. These programs take many forms, from providing a gym at the workplace to subsidizing the co-pays of certain medications and linking health care benefits or discounts to certain healthy lifestyles. Wellness programs offered by employers may be subject to a number of federal laws. One of these laws is the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which amended the Employee Retirement Income Security Act (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC) to improve portability and continuity of health coverage.

Title I of HIPAA created certain nondiscrimination requirements, which provide, among other things, that a group health plan and a health insurance issuer offering group health coverage may not require an individual to pay a higher premium or contribution than another "similarly situated" participant, based on certain health-related factors such as claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability.[25] However, HIPAA clarifies that this requirement "do[es] not prevent a group health plan and a health insurance issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention [i.e., wellness programs]."[26] The HIPAA wellness program regulations divide wellness programs into two categories.[27] First, if a wellness program provides a reward[28] based solely on participation in a wellness program, or if the wellness program does not provide a reward, the program complies with the HIPAA nondiscrimination requirements without having to satisfy any additional standards, as long as the program is made available to all similarly situated individuals. Second, if the conditions for obtaining a reward under a wellness program are based on an individual meeting a certain standard relating to a health factor, then the program must meet additional requirements. Under one of these additional requirements, a reward offered by this type of wellness program must not exceed 20% of the cost of employee coverage under the plan (i.e., the amount paid by the employer and the employee for that employee for coverage).[29]

[25] 29 U.S.C. § 1182(b)(1); 42 U.S.C. § 300gg-1(b)(1); 26 U.S.C. § 9802(b)(1).

[26] 29 U.S.C. § 1182(b)(2)(B); 42 USC 300gg-1(b)(2)(B); 26 U.S.C. § 9802(b)(2)(B).

[27] Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006).

[28] The regulations provide that a reward can take the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (e.g., deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan (e.g., a prize). 29 C.F.R. § 2590.702(f)(2)(i); 45 C.F.R. § 146.121(f)(2)(i); 26 C.F.R. § 54.9802-1(f)(2)(i).

[29] In addition to employees, if dependents (such as spouses or spouses and dependent children) participate in the wellness program, the reward must not exceed 20% of the cost of the coverage in which an employee and any dependents are enrolled. The cost of coverage is determined based on the total amount of contributions made by both the employer and the employee for the benefit package under which the employee and any dependents receive coverage. 29 C.F.R. § 2590.702(f)(2)(i); 45 C.F.R. § 146.121(f)(2)(i); 26 C.F.R. § 54.9802-1(f)(2)(i).

Summary of Provisions

Division E of the Amendment would modify HIPAA's nondiscrimination requirements under ERISA, the PHSA, and the IRC to provide that a group health plan or a health insurer offering group health coverage may vary premiums and cost sharing by up to 50% of the value of the benefits under the plan or coverage based on participation in a standards-based wellness program. The division would also apply to insurers in the individual market, as regulated by the PHSA. The Amendments made by the division would apply to plan years and insurance coverage offered or renewed at least one year after the date of enactment of the act.

Division F. Protecting Taxpayers

Protecting Against Fraud, Waste, and Abuse

Overview of Issue and Current Law

Health care fraud costs the nation billions of dollars annually. Although the actual amount of money lost to fraud is unknown, estimates range from 3% of all health care expenditures to as much as 10%.[30] Losses to health care fraud translate into higher costs for consumers, health plans, and public insurance programs. As health care expenditures continue to rise, developing new and innovative approaches to fight fraud become increasingly important.

As the agency responsible for administering Medicare and Medicaid, the Centers for Medicare and Medicaid Services (CMS) conducts a variety of activities designed to prevent, detect, and investigate health care fraud. These activities are often referred to as program integrity activities. Program integrity activities encompass a broad set of strategies and processes designed to meet numerous objectives, including preventing improper payments, identifying and detecting fraud, conducting investigations, and prosecuting offenders. CMS shares responsibility for combating health care fraud with three federal agencies: the Department of Health and Human Services Office of the Inspector General (HHS OIG), the Department of Justice (DOJ), and the Federal Bureau of Investigation (FBI). The OIG is an independent unit within HHS that has the primary responsibility for detecting health care fraud and abuse in federal health care programs. The FBI conducts complex fraud investigations related to both private and public health care programs, and the OIG, FBI, and CMS refer suspected cases of fraud to the DOJ for prosecution.

Activities to fight both public and private sector health care fraud are funded through the Health Care Fraud and Abuse Control (HCFAC) program. The HCFAC program, which was established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), consists of three separate funding streams: 1) the HCFAC account, which funds the HHS and DOJ, 2) the Medicare Integrity Program which supports CMS's anti-fraud activities, and 3) the FBI. HIPAA appropriated funds to HHS, the OIG, and the FBI for activities undertaken for fiscal years 1997 through 2003. In December 2006, Congress passed the Tax Relief and Health Care Act or TRHCA which extended the mandatory annual appropriation for the HCFAC account and the FBI to 2010. For fiscal years 2007 through 2010, the mandatory annual appropriation is the limit for the preceding year plus the percentage increase in the consumer price index (CPI). Total funding for health care fraud activities for FY2009 amounted to approximately $1.4 billion.

[30] The National Health Care Anti-Fraud Association (NHCAA) estimates that 3% of all health care spending—or $68 billion—is lost to health care fraud, "The Problem of Health Care Fraud," available on the NHCAA website at http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centr&wpscode=TheProblemOfHCFraud. The Federal Bureau of Investigation (FBI) estimates that as much as 10% of total health care expenditures could be lost to public and private sector health care fraud, "Financial Crimes Report to the Public for Fiscal Year 2007," available on the FBI website at http://www.fbi.gov/publications/financial/fcs_report2007/financial_crime_2007.htm#health.

Summary of Provisions

Medicare Provider Enrollment

Medicare statute requires the Secretary to establish a process for enrolling providers and suppliers in the Medicare program. As part of the enrollment process, CMS collects information necessary to uniquely identify the provider such as Social Security Number, Tax ID number, and documentation to verify state licensure. The Amendment would require the Secretary to screen any provider or supplier enrolling in the program with a criminal background check, fingerprinting, licensure checks, site visits, and/or database checks. Screening would be funded through a revenue-neutral application fee. The Amendment also provides for enhanced oversight measures such as prepayment claims review, penalties and exclusions for false statements on enrollment applications, additional disclosure requirements, and moratoriums on enrollment. The Amendment would not apply if funding was not appropriated to implement these requirements.

Medicare and Medicaid Secondary Payer

Under the Medicare Secondary Payer statute, Medicare is prohibited from paying for medical services if payment has been made, or can reasonably expected to be made, by a "primary plan" such as a group health plan, workmen's compensation plan, or automobile or liability insurance policy. The Amendment would require the Secretary and the OIG to improve the identification of instances where the Medicare program should, but is not, acting as the secondary payer to private health insurance. The Amendment includes a similar provision with respect to Medicaid. The Medicaid statute requires that the states take reasonable measures to ascertain whether or not a third party is liable for payment for Medicaid services. Specifically, the Amendment would require that states include in their state Medicaid plan a strategy for how they intend to comply with these requirements. States that demonstrate compliance to the Secretary would be eligible for bonuses. Those that do not would receive a reduction in their Federal Medical Assistance Percentage or FMAP of 1 percentage point.

Data

In an effort to ensure that excluded providers and suppliers cannot bill Medicare, the Amendment includes several provisions targeting CMS's data and information systems.

Currently, claims and payment data for Medicare and Medicaid are housed in multiple databases. CMS is in the process of consolidating information stored in these databases into an Integrated Data Repository (IDR). According to the agency's website, the eventual goal of the IDR is to support an integrated data warehouse which will contain data related to Medicare & Medicaid claims, beneficiaries, providers, and health plans. The Amendment would require that the Secretary complete the development of the IDR. The Amendment would also authorize the Secretary to perform data matching between Medicare, Medicaid, and the Social Security Administration (SSA).

The Social Security Act requires the Secretary to develop and maintain a national health care fraud and abuse data collection program, the Health Care Integrity and Protection Data Bank (HIPDB), for the reporting of adverse actions taken against health care providers or suppliers. The Health Care Quality Improvement Act of 1986 established the National Practitioner Data Bank (NPDB). The NPDB collects and releases data on the professional competence of

physicians, dentists, and certain healthcare practitioners. In order to ensure that excluded providers do not continue to bill Medicare or Medicaid, the Amendment would require that the Secretary consolidate these databases, the List of Excluded Individuals and Entities maintained by the OIG, and a national patient abuse/neglect registry into one centralized database.

The Secretary would also be required to establish two other databases: 1) a provider database, and 2) a sanctions database. The provider database would be required to include information on ownership and business relationships, adverse events, site visits, and the results of provider oversight activities. The Secretary would be required to query this database prior to issuing a provider or supplier number. The sanctions database would include information on sanctions imposed on providers and suppliers. The Secretary would be required to link the sanctions database to related databases maintained by state licensure boards and federal and state law enforcement agencies.

Penalties

The Amendment would authorize the Secretary to impose civil monetary penalties (CMP) of up to $50,000 on Medicare and Medicaid providers and suppliers that submit erroneous information to the Secretary. The Amendment would also authorize the Secretary to exclude a provider or supplier from participating in the Medicare program or impose a CMP for making false statements on enrollment applications.

Funding

Currently, funding for the HCFAC account is divided between HHS and DOJ. A portion of this appropriation is earmarked for the OIG. The enacted FY2009 funding level for HCFAC was $266 million. Of this $266 million, $177 million was earmarked for the OIG and the remaining $89 million went to DOJ and HHS. Beginning with FY2010, the Amendment would increase the annual appropriation to the HCFAC account (HHS and DOJ) to $300 million annually. The Amendment would also increase the annual appropriation for the OIG by an amount equal to the difference between the new HCFAC appropriation ($300 million) and the amount appropriated to HCFAC in the preceding year plus an additional $100 million for years 2010 through 2019.

Abortion and Conscience Provisions

Overview of Issue and Current Law

Restrictions on the use of federal funds to pay for abortions are included in several of the annual appropriations measures that provide funds to various federal agencies.[31] Restrictive provisions in the annual appropriations measure for the Department of Health and Human Services ("HHS") are arguably the most well-known of the restrictions. These provisions were first offered by Representative Henry J. Hyde in 1976 as an Amendment to the Departments of Labor and Health, Education, and Welfare, Appropriation Act, 1977.[32] Since 1976, the so-called "Hyde Amendment"

[31] For additional discussion of the various abortion funding restrictions, see CRS Report RL33467, *Abortion: Legislative Response*, by (name redacted).

[32] P.L. 94-439, § 209, 90 Stat. 1418, 1434 (1976) ("None of the funds contained in this Act shall be used to perform (continued...)

has been added generally to the annual appropriations measure for the Departments of Labor, HHS, and Education.

The Omnibus Appropriations Act, 2009, provides appropriations for HHS and includes the Hyde Amendment. Section 507(a) of the omnibus measure states: "None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion."[33] An exception to the general prohibition on using appropriated funds for abortions is provided in section 508(a) of the measure:

> The limitations established in the preceding section shall not apply to an abortion –
>
> (1) if the pregnancy is the result of an act of rape or incest; or
>
> (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.[34]

In addition to limiting the use of federal funds to pay for abortions, federal law prohibits recipients of certain federal funds from discriminating against medical personnel and health care entities for engaging in or refusing to engage in specified activities related to abortion.[35] For example, under section 245 of the Public Health Service Act, federal, state, and local governments are prohibited from discriminating against health care entities that refuse to undergo abortion training, provide such training, perform abortions, or provide referrals for the relevant training or for abortions.[36] Under the so-called Weldon Amendment, which has been included in the annual appropriations measure for the Departments of Labor, HHS, and Education since 2004, appropriated funds may not be made available to a federal agency or program, or to a state or local government, that subjects any institutional or individual health care entity to discrimination on the basis that the entity does not provide, pay for, provide coverage of, or refer for abortions.[37]

Summary of Provisions

In general, the Amendment would codify the Hyde and Weldon Amendments, and thus eliminate the need to add such amendments to the Department of Labor, HHS, and Education appropriations measure each year. The codification of the amendments in title 1 of the U.S. Code would also seem to eliminate the need to add similarly restrictive provisions to other appropriations measures. For example, provisions that are generally included each year in the financial services and general government appropriations measure to prohibit the coverage of elective abortions in the Federal Employees Health Benefits Program would not be needed.[38]

(...continued)

abortions except where the life of the mother would be endangered if the fetus were carried to term.").

[33] P.L. 111-8, § 507(a), 123 Stat. 524, 802 (2009).

[34] P.L. 111-8, § 508(a), 123 Stat. 524, 803 (2009).

[35] For additional information on federal conscience protection laws, see CRS Report RL34703, *The History and Effect of Abortion Conscience Clause Laws*, by (name redacted).

[36] 42 U.S.C. § 238n.

[37] P.L. 111-8, § 508(d), 123 Stat. 524, 803 (2009).

[38] P.L. 111-8, §§ 613, 614, 123 Stat. 524, 676-77 (2009).

In addition, the Amendment indicates that it would not prohibit any individual, entity, state, or locality from purchasing a separate supplemental abortion plan or coverage that includes abortion so long as the plan or coverage was not paid for with funds authorized or appropriated by federal law, and the plan or coverage was not purchased with matching funds required for a federally subsidized program. The Amendment would also not restrict the ability of a managed care provider or other organization from offering abortion coverage, or restrict the ability of a state to contract separately with a managed care provider or other organization for abortion coverage using funds other than those authorized or appropriated by federal law, or derived from matching funds required for a federally subsidized program.

Division G. Pathway for Biosimilar Biological Products

Overview of Issue and Current Law

A biosimilar, often called a "follow-on" biologic, is *similar* to a brand-name biologic while a generic drug is the *same* as a brand-name chemical drug. Chemical drugs are small molecules for which the equivalence of chemical structure between the brand-name drug and a generic version is relatively easy to determine. In contrast, comparing the structure of a biosimilar and the brand-name biologic is far more scientifically challenging. A biologic is a preparation, such as a drug or a vaccine, that is made from living organisms. Most biologics are complex proteins that require special handling (such as refrigeration) and are usually administered to patients via injection or infused directly into the bloodstream. In many cases, current technology will not allow complete characterization of biological products. Additional clinical trials may be necessary before the FDA would approve a biosimilar.[39]

Congress is interested in creating an expedited pathway for the approval of biosimilars for the same reasons it was interested in allowing access to generic chemical drugs in 1984: cost savings. The pathway for biosimilars would be analogous to the FDA's authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417). Often referred to as the Hatch-Waxman Act, this law allows the generic company to establish that its drug product is chemically the same as the already approved innovator drug, and thereby relies on the FDA's previous finding of safety and effectiveness for the approved drug.

The generic drug industry achieves cost savings by avoiding the expense of clinical trials, as well as the initial drug research and development costs that were incurred by the brand-name manufacturer. The cost of brand-name biologics is often prohibitively high. For example, the rheumatoid arthritis and psoriasis treatment Enbrel reportedly costs $16,000 per year. It is thought that a pathway enabling the FDA approval of biosimilars will allow for market competition and reduction in prices, though perhaps not to the same extent as occurred with generic chemical drugs under Hatch-Waxman Act.

Summary of Provisions

The Amendment contains the exact same language as the biosimilars provision in H.R. 3962.

The Amendment would open a pathway for the approval of biosimilars. A biosimilar is defined as a biological product that is highly similar to the reference (brand-name) product such that there is no clinically meaningful difference between the biological product and the reference product. A biological product is defined as a protein (except any chemically synthesized polypeptide).

[39] For additional information, see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by (name reda cted).

The Amendment would allow the Secretary to determine that elements (such as clinical studies) in the application for the licensure of a biological product as biosimilar or interchangeable may be unnecessary. The Secretary would determine that the reference product and a biological product are interchangeable according to specified criteria. Interchangeable means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. Special requirements would apply to certain biosimilars that might present a greater risk (e.g., toxins or controlled substances).

The Amendment would allow for a period of exclusive marketing for the biological product that is the first to be established as interchangeable with the reference product. The provision also would provide a 12-year data exclusivity period (from the date on which the reference product was first approved) for the reference product and would provide an additional six months of exclusivity if pediatric studies show health benefits in that population.[40]

The Secretary may publish proposed guidance as specified for public comment prior to publication of final guidance on the licensure of a biological product. If guidance is to be developed, a process must be established to allow for public input regarding priorities for issuing guidance. The issuance or non-issuance of guidance would not preclude the review of, or action on, an application. The provision also would require the Secretary to ensure that the labeling and packaging of each biological product bears a unique name that distinguishes it from the reference product and any other biological products that are evaluated against the reference product.

The Amendment would set forth a process governing patent infringement claims against an applicant or prospective applicant for a biological product license. It also would establish new processes for identifying patents that might be disputed between the reference product company and the company submitting a biosimilar application.

The Amendment would require reference product and biosimilar product sponsors to file with the Assistant Attorney General and Federal Trade Commission copies of the text of any agreement they reach regarding the manufacture, marketing, or sale of either product. Agreements that solely concern purchase orders for raw materials, equipment and facility contracts, employment or consulting contracts, or packaging and labeling contracts are excluded. Failure to comply with this filing requirement may result in civil fines and other relief as the courts deem appropriate. With the concurrence of the Assistant Attorney General, the Federal Trade Commission may engage in rulemaking regarding the filing requirement.

The Amendment would allow for the collection of user fees for the review of applications for approval of biosimilars.

The Amendment would also stipulate that the filing of a statement by a biosimilar applicant regarding patents identified by the reference product sponsor and other interested parties may be considered an act of patent infringement. It would require reference product sponsors, and allow other interested parties, to identify patents that relate to the proposed biosimilar product. The biosimilar applicant would then be afforded the opportunity to state its position regarding those patents. If the biosimilar applicant responds by asserting that one or more of these patents are invalid, unenforceable, or would not be infringed by the proposed biosimilar product, the

[40] For more information on exclusivity and patents, see CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by (name redacted) and (name redacted).

biosimilar applicant would be deemed to have committed an act of patent infringement that would be immediately actionable in the courts.

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