



# Public Health, Workforce, Quality, and Related Provisions in H.R. 3590, as Passed by the Senate

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## Summary

Health care reform is at the top of the domestic policy agenda for the 111<sup>th</sup> 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 showing that the health care system fails to provide high-quality care to all Americans.

On December 24, 2009, by a vote of 60-39, the Senate passed a comprehensive health reform bill, the Patient Protection and Affordable Care Act (H.R. 3590, as amended). The legislation is an amalgam of separate measures reported by the Committee on Finance and the Committee on Health, Education, Labor, and Pensions (HELP). This report, one of a series of CRS products on Senate-passed H.R. 3590, discusses the bill's workforce, prevention, quality, and related provisions.

H.R. 3590, as passed by the Senate, includes numerous provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things. It would amend and expand on many of the existing health workforce programs authorized under Title VII (health professions) and Title VIII (nursing) of the Public Health Service Act (PHSA); create a Public Health Services Track to train health care professionals emphasizing team-based service, public health, epidemiology, and emergency preparedness and response; and make a number of changes to the Medicare graduate medical education (GME) payments to teaching hospitals, in part to encourage the training of more primary care physicians. The bill also would establish a national commission to study projected health workforce needs.

In addition, Senate-passed H.R. 3590 would create an interagency council to promote healthy policies and prepare a national prevention and health promotion strategy. It would establish a Prevention and Public Health Fund to boost funding for prevention and public health; increase access to clinical preventive services under Medicare and Medicaid; promote healthier communities; and fund research on optimizing the delivery of public health services. Funding would be provided for maternal and child health services, including abstinence education and a new home visitation program. The bill also would establish a national strategy for quality improvement; create an interagency working group to advance quality efforts at the national level; develop a comprehensive repertoire of quality measures; and formalize processes for quality measure selection, endorsement, data collection and public reporting of quality information. It would establish and fund a new private, nonprofit comparative effectiveness research institute.

Other key provisions in the H.R. 3590, as passed by the Senate, include programs to prevent elder abuse, neglect, and exploitation; a new regulatory pathway for licensing biological drugs shown to be biosimilar or interchangeable with a licensed biologic; new requirements for the collection and reporting of health data by race, ethnicity, and primary language to detect and monitor trends in health disparities; and electronic format and data standards to improve the efficiency of administrative and financial transactions between health care providers and health plans.

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## Introduction

Health care reform is at the top of the domestic policy agenda for the 111<sup>th</sup> 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.

Both the House and the Senate have passed comprehensive health care reform legislation. On November 7, 2009, by a vote of 220-215, the House approved the Affordable Health Care for America Act (H.R. 3962).<sup>1</sup> The legislation, introduced by Representative Dingell on October 29, 2009, is based on an earlier measure, the America's Affordable Health Choices Act of 2009 (H.R. 3200), which was jointly developed and reported by the House Committees on Ways and Means, Energy and Commerce, and Education and Labor.<sup>2</sup> The Senate passed an alternative health reform bill, the Patient Protection and Affordable Care Act (H.R. 3590, as amended), on December 24, 2009, by a vote of 60-39.<sup>3</sup> The Senate bill is an amalgam of separate measures reported by the Committee on Finance and the Committee on Health, Education, Labor, and Pensions (HELP).<sup>4</sup> To date, no further legislative action on health reform has occurred.

On February 25, 2010, President Obama hosted a health reform summit with congressional Democrats and Republicans in an effort to find common ground and revive stalled legislative activity on the issue. Ahead of the summit the President released his proposal for a health care overhaul. The President's proposal is based on the Senate-passed bill. It also incorporates several policies from the House-passed measure, as well as a number of the President's priorities and some provisions from Republican-sponsored legislation.<sup>5</sup>

This report summarizes the workforce, prevention, quality, and related provisions in H.R. 3590, as passed by the Senate. It begins with some background on health care delivery reform, followed by an overview of the report's content and organization.

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<sup>1</sup> The full text of the Affordable Health Care for America Act is at <http://www.congress.gov/cgi-lis/query/z?c111:H.R.3962/>.

<sup>2</sup> In July, each of the three committees considered an amendment in the nature of a substitute to H.R. 3200, offered by the chairman, and ordered the measure to be reported, as amended. The committees reported their respective versions of the legislation on October 14, 2009 (H.Rept. 111-299, Parts I, II, and III).

<sup>3</sup> The full text of the Patient Protection and Affordable Care Act is at <http://www.congress.gov/cgi-lis/query/z?c111:H.R.3590/>.

<sup>4</sup> The Senate Finance Committee approved the America's Healthy Future Act (S. 1796, S.Rept. 111-89) on October 13, 2009. The Senate HELP Committee approved the Affordable Health Choices Act (S. 1679) on July 15, 2009. The Patient Protection and Affordable Care Act was introduced and considered as an amendment (S.Amdt. 2786) in the nature of a substitute to H.R. 3590, a homeowner tax credit bill that passed the House unanimously on October 8, 2009, and was subsequently referred to the Senate.

<sup>5</sup> A summary of the key elements of the President's proposal and information about the President's policies to provide affordable health coverage and control health care costs is available on the White House website at <http://www.whitehouse.gov/health-care-meeting/proposal>.



## Health Care Delivery Reform

In a November 2008 report outlining its goals for health reform, the National Priorities Partnership, representing 32 key stakeholder groups in the health sector, identified four major challenges to the delivery of high-quality care.<sup>6</sup> According to the Partnership, the first is to improve patient safety by eliminating medical errors and other adverse events. These errors mostly result from faulty systems, processes, and conditions that lead to mistakes. The second challenge is to eradicate disparities in care. Racial and ethnic minorities and low-income groups face disproportionately higher rates of disease, disability, and mortality, largely because of variations in access to care, and quality of care. The third challenge is to reduce the burden of chronic disease, which affects almost half of all Americans and accounts for three-quarters of health care spending. The final challenge is to eliminate unnecessary and ineffective care that compromises quality, drives up costs, and neglects the needs of patients. According to the Institute of Medicine, an estimated 30%-40% of health care spending is wasted on unnecessary and even unsafe care.<sup>7</sup>

While primarily focused on health care financing issues, the health reform debate has encompassed a number of proposals to address these challenges and improve the delivery of health care services. They include initiatives to encourage individuals to adopt healthier lifestyles, and to change the way that physicians and other providers treat and manage disease. Delivery reform proposals focus on (1) expanding the primary care workforce, (2) encouraging the use of clinical preventive services, and (3) strengthening the role of chronic care management. The current system places a high value on specialty care, rather than primary care. Patients with multiple chronic conditions often receive care from several providers in different settings. Among other things, this can compromise patients' understanding of their conditions and ways to manage them. And the incomplete or inaccurate transfer of information among providers can lead to poor outcomes. Care coordination is seen as an important aspect of health care that helps avoid waste, and the over- and underuse of medications, diagnostic tests, and therapies.

Health workforce policy has emerged as an important component of the health reform debate. Transforming the nation's health care delivery system—from one that is focused on fragmented specialty care for acute illness to one that places a greater emphasis on primary care, disease prevention, and the coordination and management of care for chronic illness across settings—would require significant changes in health professions education and training. While some advisory groups have warned of a future physician shortage, based on the growing patient demand for services, others caution that simply adding more physicians to the current health care system will increase costs and not improve accessibility or quality. Currently, the number of physicians per capita varies significantly across the country. But that variation is largely driven by where physicians like to live and practice, rather than by patient need. Moreover, higher physician supply is not associated with better patient outcomes or satisfaction, or improved quality of care.<sup>8</sup> Instead of focusing on overall physician supply, many health policy analysts recommend a

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<sup>6</sup> National Priorities Partnership, *National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare*. Washington, DC: National Quality Forum, 2008. For more information on the work of the Partnership, go to <http://www.nationalprioritiespartnership.org/>.

<sup>7</sup> Institute of Medicine, National Academy of Engineering, *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Washington, DC: National Academies Press, 2005.

<sup>8</sup> David C. Goodman and Elliott S. Fisher, "Physician Workforce Crisis? Wrong Diagnosis, Wrong Prescription," *New England Journal of Medicine*, vol. 358, no. 16 (April 17, 2008), pp. 1658-1661.

workforce policy that couples the training of more primary care physicians (and other primary care providers) with the promotion and development of integrated systems of care.

Expanding the use of clinical preventive services is a key goal of delivery reform and often touted as having the potential to reduce health care costs. Such services include immunizations and other interventions that prevent the onset of disease (known as primary prevention), and screening tests that detect the presence of an incipient disease (known as secondary prevention). While there is clear evidence that clinical preventive services can improve health and may be cost-effective (i.e., providing good value for their cost), few of these interventions are cost-saving.<sup>9</sup>

Proponents of delivery reform have also embraced the concept of a medical home, intended to improve the quality of care through partnerships between patients and specially trained primary care physicians. In this model, the physician helps the patient manage his or her own care and coordinates services across settings (specialists' offices, hospitals, and laboratories) and types of care (acute, chronic, and preventive). Concern about the rising costs of treating chronic disease and the lack of coordination of care also has generated keen interest in disease management programs. These programs, typically focused on a specific disease such as diabetes, can help patients manage their own care. Program elements include patient education, symptom monitoring, and adherence to treatment plans. Disease management programs share similarities with the medical home concept. But whereas the medical home is built around a physician-patient partnership, disease management programs typically are run by health plans or specialized vendors.

## **Drivers of Reform**

Health care delivery reform relies on putting in place mechanisms to drive change in the systems of care. Key drivers include performance measurement and the public dissemination of performance information, comparative effectiveness research, adoption of health information technology, and, most important, alignment of payment incentives with high-quality care. Most health policy experts concede that improvements in the quality of health care will not be fully realized unless providers have financial incentives to change the way they deliver health care services. Under fee-for-service, the predominant method of payment, physicians are paid based on the volume of billable services, rather than the value or quality of care they provide. Increasingly, public and private payers are linking a portion of provider payments to their performance on a set of quality measures. Many policymakers are interested in expanding these pay-for-performance initiatives to incentivize other changes to the health care delivery system.

The use of performance measures to track the quality of care is growing in both the private and public health sectors, though concerns about the development and use of such data remain. The public reporting of quality information is seen as a necessary step in helping patients make informed choices about health care services and the organizations that provide them.

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<sup>9</sup> Joshua T. Cohen et al., "Does Preventive Care Save Money? Health Economics and the Presidential Candidates," *New England Journal of Medicine*, vol. 358, no. 7 (February 14, 2008), pp. 661-663.

## **American Recovery and Reinvestment Act**

Congress moved toward reforming the health care delivery system when it enacted the American Recovery and Reinvestment Act (ARRA; P.L. 111-5) in February 2009. ARRA incorporated the Health Information Technology for Economic and Clinical Health (HITECH) Act, which is intended to promote the widespread adoption of health information technology (HIT) for the electronic sharing of clinical data among hospitals, physicians, and other health care stakeholders. It also included \$2 billion to fund HIT grant programs authorized by the HITECH Act.<sup>10</sup>

HIT, which generally refers to the use of computer applications in medical practice, is widely viewed as a necessary and vital component of health care reform. It encompasses interoperable electronic health records (EHRs)—including computerized systems to order tests and medications, and support systems to aid clinical decision making—and the development of a national health information network to permit the secure exchange of electronic health information among providers. The promise of HIT comes not from automating existing practices, but rather its use as a tool to help overhaul the delivery of care. HIT has the potential to enable providers to render care more efficiently; for example, by eliminating the use of paper-based records and reducing the duplication of diagnostic tests. It can also improve the quality of care by identifying harmful drug interactions and helping physicians manage patients with multiple conditions. The widespread use of HIT could provide large amounts of clinical data for comparative effectiveness research, performance measurement, and other activities aimed at improving health care quality.

## **Overview of Report**

The Patient Protection and Affordable Care Act—referred to in this report as H.R. 3590, as passed by the Senate—originally comprised nine titles that cover the following general topics: Title I—health insurance; Title II—Medicaid, maternal and child health; Title III—Medicare, quality of care; Title IV—prevention and wellness; Title V—health workforce; Title VI—transparency, fraud and abuse, comparative effectiveness research, elder justice; Title VII—drugs and biologics; Title VIII—long-term care insurance; and Title IX—revenues. Title X was added as a manager’s amendment (S.Amdt. 3276) to the underlying Senate amendment to H.R. 3590. It amended numerous existing provisions in Titles I through IX and added several new provisions.

This report summarizes the workforce, prevention, quality, and related provisions in H.R. 3590, as passed by the Senate. The provisions are grouped and discussed under the following headings: (1) Community Health Center Fund; (2) Health Centers; (3) Health Workforce (including programs authorized under the Public Health Service Act, or PHS Act, and under other statutes); (4) Prevention and Wellness; (5) Maternal and Child Health; (6) Behavioral Health; (7) Quality; (8) Health Disparities; (9) Health Information Technology; (10) Emergency Care; (11) Pain Care and Management; (12) Elder Justice; (13) Food and Drug Administration (including provisions relating to medical devices, biological drugs, and food labeling); (14) 340B Drug Pricing; (15) Veterans Health Care; and (16) Miscellaneous. In most instances, each section of the report begins with some background on current law and practice so as to provide context for the

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<sup>10</sup> For more information, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by C. Stephen Redhead, and CRS Report R40161, *The Health Information Technology for Economic and Clinical Health (HITECH) Act*, by C. Stephen Redhead.

subsequent descriptions of the bill's provisions. Several of the provisions discussed in this report would affect federal direct spending and revenue, as scored by the Congressional Budget Office (CBO).<sup>11</sup> Unless otherwise stated, references to “the Secretary” refer to the Secretary of Health and Human Services (HHS). A list of all the acronyms used in the report is in the **Appendix**.

A companion product, CRS Report R40892, *Public Health, Workforce, Quality, and Related Provisions in H.R. 3962*, summarizes the provisions in the House-passed health reform legislation that are comparable to the Senate provisions discussed in this report. Both reports are organized and formatted in the same way to ease comparison of the House and Senate bills. A crosswalk of the two sets of provisions is provided in **Table 1**.

## **Other CRS Products**

The following CRS reports discuss the private health insurance and Medicare provisions in the Senate health reform legislation:

- CRS Report R40942, *Private Health Insurance Provisions in Senate-Passed H.R. 3590, The Patient Protection and Affordable Care Act*, by Hinda Chaikind et al.
- CRS Report R40981, *A Comparative Analysis of Private Health Insurance Provisions of H.R. 3962 and Senate-Passed H.R. 3590*, coordinated by Chris L. Peterson.
- CRS Report R40970, *Medicare Program Changes in Senate-Passed H.R. 3590*, coordinated by Patricia A. Davis.
- CRS Report R40842, *Community Living Assistance Services and Supports (CLASS) Provisions in H.R. 3962 and Senate-Passed H.R. 3590*, by Janemarie Mulvey and Kirsten J. Colello.

In addition, the following general distribution memoranda, available from CRS, provide a comparison of the provisions in H.R. 3962 with similar provisions in Senate-passed H.R. 3590:

- *Side-by-Side Comparison of Provisions in Division C of H.R. 3962 (as passed by the House), Similar Provisions in H.R. 3590 (as passed by the Senate), and Current Law*, updated January 7, 2010.
- *Workforce Provisions in the House and Senate Health Reform Legislation: A Side-by-Side Comparison of H.R. 3962 (as passed by the House) and H.R. 3590 (as passed by the Senate)*, updated January 8, 2010.
- *Comparison of Prevention and Wellness Provisions in House and Senate Health Reform Legislation*, updated January 5, 2010.

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<sup>11</sup> CBO's budgetary analysis of the Patient Protection and Affordable Care Act is at [http://www.cbo.gov/ftpdocs/108xx/doc10868/12-19-Reid\\_Letter\\_Managers\\_Correction\\_Noted.pdf](http://www.cbo.gov/ftpdocs/108xx/doc10868/12-19-Reid_Letter_Managers_Correction_Noted.pdf).

## Community Health Center Fund

H.R. 3590, as passed by the Senate, would amend numerous PHSA programs. While authorizations of appropriations for many of these programs have expired, in most cases programs continue to receive an annual appropriation. The Senate-passed measure includes new authorizations of appropriations to fund most of these programs, typically through FY2014 or FY2015. It also would create a multi-billion dollar Community Health Center Fund to which would be appropriated a total of \$8.5 billion over the five-year period FY2011 through FY2015. As discussed below, those funds would be used to provide supplementary funding for the federal health center program and the National Health Service Corps. An additional \$1.5 billion would be appropriated for the construction and renovation of community health centers.

## Health Centers

### Background and Issues

PHSA Sec. 330 authorizes the federal health center program, administered by the Health Resources and Services Administration (HRSA), which provides grants to community health centers, migrant health centers, health centers for the homeless, and health centers for residents of public housing.<sup>12</sup> Health centers are a key component of the nation's health care safety net and provide primary care and preventive services to many uninsured and underinsured. These centers are required to accept all patients regardless of ability to pay and must offer sliding-scale fee arrangements for patients. Health centers are located in medically underserved areas and target populations with insufficient health care access. PHSA Sec. 224 provides health centers that receive Sec. 330 funding with liability protection from medical malpractice claims under the Federal Tort Claims Act (FTCA). FTCA coverage for health centers also applies to its employees, board members, and certain contactors. However, it does not extend to health care providers who volunteer their services at health centers. The Government Accountability Office (GAO) found that the lack of medical malpractice coverage is a barrier to such volunteerism, though not the only one. Other barriers to provider volunteerism include lack of time to volunteer, licensure costs, misperceptions about litigiousness, and the limited capacity of health centers to recruit, retain, and effectively use volunteers.<sup>13</sup>

The health center program, which enjoys broad bipartisan support, has been expanded in recent years. In 2002, there were approximately 3,500 health center sites; in 2009, there are an estimated 9,000 sites.<sup>14</sup> The program was reauthorized by the Health Care Safety Net Act of 2008 (P.L. 110-355). The Act also included the requirement that GAO study the economic costs and benefits of school-based health clinics (SBHCs) and their impact on student health. SBHCs are not explicitly authorized in the PHSA, but have been established pursuant to the general authority to establish community health centers. Studies show that health centers increase access to primary health care

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<sup>12</sup> For more information on the health center program, go to <http://bphc.hrsa.gov>.

<sup>13</sup> U.S. Government Accountability Office, *Federal Torts Claims Act: Information Related to Implications of Extending Coverage to Volunteers at HRSA-Funded Health Centers*, 09-693R, June 24, 2009.

<sup>14</sup> An individual health center may operate multiple sites.

services, which helps reduce disparities and reduce costs by averting more expensive emergency room visits.<sup>15</sup>

### **Sec. 5601. Authorization of Appropriations**

This section would amend **PHSA Sec. 330** by authorizing to be appropriated for the health center program the following amounts: \$2,988,821,592 for FY2010; \$3,862,107,440 for FY2011; \$4,990,553,440 for FY2012; \$6,448,713,307 for FY2013; \$7,332,924,155 for FY2014; and \$8,332,924,155 for FY2015. For FY2016 and subsequent fiscal years, the amount authorized to be appropriated for that year would be based on a specified formula that takes into account the preceding year's appropriation, the per patient costs, and increases in the number of patients served by the health centers program.

Nothing in this section would prevent a community health center (CHC) from contracting with specified entities for the delivery of primary health care services that are available at the specified entity to individuals who would otherwise be eligible for free or reduced-cost care if that individual were able to obtain that care at the CHC. Such services may be limited in scope to the primary health care services available at the facility. In order to receive funds under such a contract, the clinic/hospital could not discriminate on the basis of an individual's ability to pay and would have to establish a sliding fee scale for low-income patients.

### **Sec. 10503. Community Health Center Fund**

This section would transfer from the Community Health Center Fund the following amounts for the health center program: \$700 million for FY2011; \$800 million for FY2012; \$1 billion for FY2013; \$1.6 billion for FY2014; and \$2.9 billion for FY2015. It also would appropriate \$1.5 billion for construction and renovation of community health centers to be available for FY2011 through FY2015. Funds would remain available until expended.

### **Sec. 10608. Liability Protection for Health Center Volunteers**

This section would amend **PHSA Sec. 224(o)(1)** extending FTCA liability protection against medical malpractice to officers, governing board members, employees, and contractors of free clinics. (Note: Secs. 6801 and 10607 of the bill also address medical liability, as discussed later under "Miscellaneous.")

### **Sec. 4101. School-Based Health Centers**

Subsection 4101(a) would require the Secretary to create a grant program for the establishment of SBHCs. To receive a grant, an SBHC or a sponsoring facility of an SBHC would have to agree to use grant funds for certain specified purposes including facility construction, expansion, and equipment. SBHCs would be prohibited from using funds for personnel or to provide health services. The Secretary would be required to give preference to SBHCs that serve a large population of children eligible for the Medicaid and CHIP programs. The section would

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<sup>15</sup> J. Hadley and P. Cunningham, "Availability of Safety Net Providers and Access to Care of Uninsured Persons," *Health Services Research*, vol. 39, iss. 5 (August 2004), pp. 1527-46.

appropriate, out of Treasury funds not otherwise appropriated, \$50 million for each of FY2010 through FY2013, to remain available until expended.

Subsection 4101(b), as amended by Sec. 10402(a), would create a new **PHSA Sec. 399Z-1, *School-Based Health Centers***, requiring the Secretary to award grants for the operating costs of SBHCs. To receive a grant, an SBHC would have to meet certain specified criteria, unless granted a waiver for a specified time period, match 20% of the grant amount from non-federal sources unless granted a waiver by the Secretary, agree to use grant funds for certain specified purposes (including equipment, training, and personnel salaries), and agree to use grant funds to supplement and not supplant funds received from other sources. SBHCs would be required to provide only age-appropriate services and would be prohibited from providing abortion services and from providing services to minors without parental or guardian consent. Entities that are in violation of state reporting and parental notification laws, and entities receiving funding under PHSA Sec. 330 that would overlap with the SBHC grant period would be prohibited from receiving funds under this section. The Secretary would be authorized to give preference to applicants who demonstrate ability to serve communities with specified barriers to access. In addition, the Secretary would be authorized to consider whether an applicant received a grant under this section to establish an SBHC. The section would authorize to be appropriated such sums as may be necessary (SSAN) for each of FY2010 through FY2014.

### **Sec. 5208. Nurse-Managed Health Clinics**

This section would create a new **PHSA Sec. 330A-1, *Nurse-Managed Health Clinics***, requiring the Secretary to establish a grant program to fund the operation of Nurse-Managed Health Clinics (NMHCs) that provide comprehensive primary health care and wellness services to vulnerable or underserved populations. To be eligible to receive a grant, an NMHC would have to submit an application to the Secretary containing assurances that (1) nurses are a major provider of services at the NMHC, (2) the NMHC will provide care to all patients regardless of income or insurance status, and (3) the NMHC will establish a community advisory committee where the majority of members are individuals served by the NMHC. When determining grant amounts, the Secretary would be required to take into account the financial need of the NMHC, including other funding sources available to the NMHC, and other factors determined appropriate by the Secretary. The section would authorize to be appropriated \$50 million for FY2010, and SSAN for each of FY2011 through FY2014.

## **Health Workforce**

### **Background and Issues**

Existing health professions education and training programs authorized under PHSA Title VII provide funding to medical schools and other facilities to promote community-based and rural practice, primary care, and opportunities for minorities and disadvantaged students. In the early 1970s, annual funding for Title VII programs reached over \$2.5 billion (in 2009 dollars); in recent years, it has been about \$200 million. PHSA Title VIII authorizes a comparable set of programs to promote nursing education and training. Appropriations authority for most Title VII and VIII programs has expired, though many of them continue to receive funding. The National Health Service Corps (NHSC) program, authorized under PHSA Title III, provides scholarships and student loan repayments for medical students, nurse practitioners, physician assistants, and others

who agree to a period of service as a primary care provider in full-time clinical practice in a federally designated Health Professional Shortage Area (HPSA). NHSC clinicians may fulfill their service commitments in health centers, rural health clinics, public or nonprofit medical facilities, or within other community-based systems of care. However, there is far more demand for NHSC clinicians and there are many more clinicians interested in scholarships or loan repayment opportunities than can be met under the program's budget. Currently, HHS estimates that the NHSC is filling only 8% of the total need for primary care practitioners in HPSAs.<sup>16</sup>

Medicare pays the costs of graduate medical education (GME) by making two types of payments to teaching hospitals. First, direct graduate medical education (DGME) payments help cover the costs of the residency training program, including resident salaries and benefits, supervisory physician salaries, and administrative overhead expenses. DGME payments are calculated based on the product of three factors: a hospital-specific per resident amount, a weighted count of full-time equivalent (FTE) residents supported by the hospital, and the hospital's Medicare patient share. Second, indirect medical education (IME) payments, which vary with the intensity of a hospital's residency program, are intended to compensate hospitals for the higher costs of patient care in teaching hospitals. Those costs are the result of such factors as having sicker patients and the fact that inexperienced residents may order more tests. The IME adjustment is a percentage add-on to a hospital's Medicare payments for inpatient care and is based, in part, on the hospital's resident-to-bed ratio. Medicare includes the time that residents spend in both patient care and non-patient care activities, including didactic activities, when calculating DGME payments. When calculating IME payments, however, only the time spent in patient care activities is included. In 2008, Medicare DGME and IME payments totaling an estimated \$9 billion were paid to more than 1,100 teaching hospitals to educate and train about 90,000 residents, equivalent to approximately \$100,000 per resident. Health policy analysts view Medicare GME payments as a potentially important instrument for shaping future health workforce policy; for example, by linking the subsidies to delivery system reform and by structuring them to encourage the training of more generalists and to increase the amount of time residents spend in non-hospital settings such as community health centers and rural health clinics.<sup>17</sup>

## **National Health Service Corps**

### **Sec. 5207. Authorization of Appropriations**

This section would amend **PHSA Sec. 338H(a)**, authorizing the following amounts for NHSC scholarships and loan repayments: \$320,461,632 for FY2010; \$414,095,394 for FY2011; \$535,087,442 for FY2012; \$691,431,432 for FY2013; \$893,456,433 for FY2014; and \$1,154,510,336 for FY2015. For FY2016 and subsequent fiscal years, the amount authorized to be appropriated would be based on the amount appropriated for the preceding fiscal year, adjusted by the product of the change in the costs of health professions education and the change in the number of individuals residing in HPSAs.

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<sup>16</sup> For more information on the NHSC program, see CRS Report R40533, *Health Care Workforce: National Health Service Corps*, by Bernice Reyes-Akinbileje.

<sup>17</sup> For a recent review of medical education in the United States and an analysis of the GME program and its potential role in health care delivery reform, see the Medicare Payment Advisory Commission's June 2009 *Report to Congress: Improving Incentives in the Medicare Program*, Chapter 1, at [http://www.medpac.gov/chapters/Jun09\\_Ch01.pdf](http://www.medpac.gov/chapters/Jun09_Ch01.pdf).



### **Sec. 10503. Community Health Center Fund**

This section would transfer from the Community Health Center Fund the following amounts for the NHSC: \$290 million for FY2011; \$295 million for FY2012; \$300 million for FY2013; \$305 million for FY2014; and \$310 million for FY2015. Funds would remain available until expended.

### **Sec. 5508(b). Counting Teaching Time Towards Service Obligation**

This subsection would amend **PHSA Sec. 338C(a)** to allow up to 50% of the time spent teaching by an NHSC member to be counted towards his or her service obligation. The provision would not necessarily apply to individuals who are fulfilling their NHSC service requirement through work in private practice.

### **Sec. 10501(n). Part-Time Service, Loan Repayment, Teaching**

This section would amend **PHSA Sec. 331**, allowing the Secretary to waive the requirement that NHSC service be provided in full-time clinical practice so that the service obligation could be fulfilled on a half-time basis (i.e., a minimum of 20 hours per week in clinical practice). Individuals fulfilling their service obligation in this manner would have to agree to double the period of obligated service that would otherwise be required, or, if receiving loan repayment, accept a minimum of two years of obligated service and 50% of the amount that would otherwise be provided. The section also would amend **PHSA Sec. 337** by deleting language that prohibits the reappointment of members to the NHSC National Advisory Council. It would amend **PHSA Sec. 338B**, increasing the maximum annual NHSC loan repayment amount from \$35,000 to \$50,000, adjusted annually for inflation beginning in FY2012. Finally, the section would further amend **PHSA Sec. 338C(a)** by striking the requirement added by Sec. 5508(b) of the bill and instead permitting the Secretary to treat teaching as clinical practice for up to 20% of the period of obligated NHSC service. However, for NHSC clinicians participating in the teaching health centers GME program under new **PHSA Sec. 340H** (established by Sec. 5508(c) of the bill), up to 50% of time spent teaching may be counted towards the NHSC service obligation.

### **Sec. 5602. Designating Medically Underserved Populations and HPSAs**

This section would require the Secretary, through a negotiated rulemaking process, to establish a comprehensive methodology and criteria for designating medically underserved populations and HPSAs. The Secretary would be required to consider the availability, timeliness, and appropriateness of the data necessary to make the designation and the impact of the methodology and criteria on various populations, institutions, and stakeholders. The Secretary would be required to (1) appoint a rulemaking committee and receive timely reports from the committee; (2) publish an interim final rule, subject to public comment and subsequent revision, by July 1, 2010; and (3) publish a final rule by July 1, 2011.

### **Sec. 10908. Loan Repayment Tax Exclusion**

This section would amend the **Internal Revenue Code (IRC) Sec. 108(f)** to exclude from an individual's gross income for tax purposes any amount received under the NHSC loan repayment program or under state loan repayment or loan forgiveness programs that are intended to increase

the availability of health care services in HPSAs or underserved areas. The tax exclusion would apply to amounts received by individuals in taxable years beginning after December 31, 2009.

## Primary Care and Dentistry

PHSA Title VII, Part A, comprising Secs. 701-735, authorizes student loan programs for health professions students. Sec. 735 establishes general provisions for the administration of the student loan fund. Part C, comprising Secs. 747 and 748, authorizes grants for health professions schools to develop and operate training programs in family medicine, general internal medicine, general pediatrics, physician assistants, and general and pediatric dentistry. Funds may also be used to provide financial assistance to medical students, interns, residents, and faculty who are participants in such programs. Authority to fund those programs expired at the end of FY2002. H.R. 3590, as passed by the Senate, includes the following sections that would establish or amend existing programs to increase the supply of primary care providers.

### Sec. 5201. Federally Supported Student Loan Funds

This section would amend **PHSA Sec. 723(a)** requiring medical students who receive loan funds to practice in primary care for 10 years or until the loan is repaid, whichever comes first. For a medical student who fails to comply with such requirements, the loan would accrue interest at a rate of 2% per year higher than the initial rate. In addition, the Secretary would be prohibited from requiring parental financial information when determining a loan applicant's financial need. Rather, the determination of whether to seek this information would be made at the discretion of the school loan officer. The section also would add a sense of Congress that funds repaid under the loan program should not be transferred to the Treasury or used for any purpose other than to carry out this provision.

### Sec. 5203. Pediatric Specialist Loan Repayment Program

This section would amend PHSA Title VII, Part E by adding a new subpart 3, Recruitment and Retention Programs, and, within that new subpart, create a new **PHSA Sec. 775, *Investment in Tomorrow's Pediatric Health Care Workforce***. The new section would require the Secretary to establish and implement a pediatric specialty loan repayment program under which eligible individuals would agree to work full-time for not less than two years in a pediatric medical specialty, in pediatric surgery, or in child and adolescent mental and behavioral health care (which could include substance abuse prevention and treatment). Eligible individuals, including practicing or in training pediatric medical specialists, pediatric surgical specialists, and child and adolescent mental and behavioral professionals, would have to work for a provider serving in a HPSA or medically underserved area, or among a medically underserved population that has a shortage of the specified pediatric specialty and a sufficient pediatric population, as determined by the Secretary, to support the specified pediatric specialty. In addition, individuals must be U.S. citizens or permanent legal residents and, for those currently enrolled in a graduate program, the program must be accredited and students must have an acceptable level of academic standing. The program would pay up to \$35,000 for each year of service, for a maximum of three years. There would be authorized to be appropriated (1) \$30 million for each of FY2010 through FY2014 for loan repayments for pediatric medical specialists and pediatric surgical specialists; and (2) \$20 million for each of FY2010 through FY2013 for loan repayments for child and adolescent mental and behavioral health professionals.

### **Sec. 5301. Primary Care Training and Enhancement**

This section would strike and replace **PHSA Sec. 747** authorizing the Secretary to award grants or enter into contracts for a variety of activities to support training programs in primary care—defined as family medicine, general internal medicine, or general pediatrics—and for capacity building. Entities eligible for the training grants would include accredited public or nonprofit hospitals, schools of medicine or osteopathic medicine, academically affiliated physician assistant training programs, or public or private nonprofit entities. However, only schools of medicine or osteopathic medicine would be eligible for capacity building grants. In awarding grants or contracts, the Secretary would be required to give preference to qualified applicants proposing certain specified activities. Grants awarded under this section would be for five years. The section would authorize to be appropriated \$125 million for FY2010, and SSAN for each of FY2011 through FY2014, and require that 15% of the amount appropriated in each fiscal year be allocated to physician assistant training programs that prepare students for practice in primary care. For purposes of carrying out programs that integrate academic administrative units and programs, the section would authorize to be appropriated \$750,000, out of the total amount authorized, for each of FY2010 through FY2014.

### **Sec. 5302. Training Opportunities for Direct Care Workers**

This section would add a new **PHSA Sec. 747A** that would require the Secretary to establish a grant program to provide new training opportunities for direct care workers employed in specified long-term care settings. Entities eligible for grants include accredited institutions of higher education that have established a partnership with a long-term care setting as specified. Eligible entities would be required to use grant funds to provide tuition and fee assistance for eligible individuals, defined as individuals who are enrolled and making satisfactory progress in courses provided by an eligible entity. Individuals receiving assistance under this section would be required to work in the field of geriatrics, disability services, long term services and supports, or chronic care management for a minimum of two years. There would be authorized to be appropriated \$10 million for each of FY2011 through FY2013.

### **Sec. 5303. Training in General, Pediatric, and Public Health Dentistry**

This section would redesignate **PHSA Sec. 748**, as amended by Sec. 5103 of the bill, as **PHSA Sec. 749** and insert a new **PHSA Sec. 748** authorizing the Secretary to make grants or enter into contracts with specified entities to support training, provide financial assistance, and fund projects for dental students, dental residents, dental hygienists, practicing dentists, or dental faculty in the fields of general dentistry, pediatric dentistry, or public health dentistry. The section also would establish a faculty loan repayment program under which individuals agree to serve full-time as faculty members in one of the specified dental fields, and the program agrees to pay specified percentages of the principal and interest on their outstanding student loans based on the number of years served as a full-time faculty member. Entities eligible for the programs under this section would include dental and dental hygiene schools and approved residency or advanced educational programs in the specified fields. Eligible entities also may partner with schools of public health so that dental residents or dental hygiene students may receive master's-level training in public health. When making training awards, the Secretary would be required to give priority to certain qualified applicants. When making awards for both the training and faculty loan repayment programs, the Secretary would be required to give preference to applicants based on their record of providing care in underserved areas or to populations experiencing health disparities, entities

that have established a formal relationship with Federally Qualified Health Centers (FQHCs), rural health centers, or accredited teaching facilities, or to entities that in the two fiscal years prior to receiving the award had an increased rate of placing their graduates in settings that serve health disparity populations. The section would authorize to be appropriated \$30 million for FY2010, and SSAN for each of FY2011 through FY2015. Entities receiving funds would be permitted to carry over funds across fiscal years, for up to three years, without obtaining permission from the Secretary.

### **Sec. 5304. Alternative Dental Health Care Provider Demonstration**

This section would add a new **PHSA Sec. 340G-1** that would authorize the Secretary to establish a demonstration program to train or employ alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities. Alternative dental health care providers include community dental health coordinators, advance practice dental hygienists, independent dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professionals the Secretary determines appropriate. Entities eligible for this grant program include qualified institutions of higher education, public-private partnerships, FQHCs, health facilities operated by an Indian tribe, the Indian Health Service (IHS), a tribal organization or an urban Indian organization as specified, state or county public health clinic, public hospitals or health systems, or other entities as specified. The Secretary would be authorized to award 15 grants of not less than \$4 million over a five-year period. The section also specifies the funding disbursement formula for grants and states that demonstration projects would be required to begin within two years after enactment and to conclude not later than seven years after enactment. Additionally, this section would require the Secretary to contract with the IOM to conduct a study of the demonstration program regarding access to dental health care. Nothing in the section would prohibit an IHS-approved dental health aide training program from being eligible for a grant under this section. There would be authorized to be appropriated SSAN.

### **Sec. 5508(a) and (c). Teaching Health Centers**

Subsection 5508(a) would add at the end of PHSA Title VII, Part C a new **PHSA Sec. 749A**, *Teaching Health Centers Development Grants*, authorizing the Secretary to award grants to teaching health centers (THC) to establish newly accredited or expanded eligible primary care residency programs. The section would define a THC as a community-based, ambulatory patient care center that operates a primary care residency program, including the following entities: FQHCs, community mental health centers, Rural Health Clinics (RHCs), Indian health centers, and entities receiving funds under PHSA Title X (family planning program). It would require that grants be awarded for not more than three years with a maximum award of \$500,000. Grant funds would be required to be used for activities associated with establishing or expanding a primary care residency training program including curriculum development; faculty and trainee recruitment, training, and retention; accreditation; and other specified purposes. The Secretary would be required to give preference to applications that document an existing affiliation agreement with an AHEC. In addition, there would be authorized to be appropriated \$25 million for FY2010, \$50 million for FY2011 and for FY2012, and SSAN for each fiscal year thereafter. No more than \$5 million annually may be used for technical assistance program grants.

Subsection 5508(c) would amend PHSA Title III, Part D by adding a new Subpart XI, *Support of Graduate Medical Education in Qualified Teaching Health Centers*, and, within this subpart,

create a new **PHSA Sec. 340H**, *Program of Payment to Teaching Health Centers that Operate Graduate Medical Education Programs*. The new section would require the Secretary to make payments for direct and indirect costs to qualified THC's for expansion of existing or establishment of new approved graduate medical residency training programs. It would specify how direct and indirect graduate medical education payments to THC's and annual updates for payments would be calculated. It also would require the Secretary to limit the funding of full-time equivalent residents to ensure that these payments do not exceed the annual appropriation under this section. The section would specify that THC graduate medical education payments would be in addition to any indirect or direct payments made to teaching hospitals and would not count against the limit on the number of full-time equivalent residents paid for by Medicare or by Children's Hospital Graduate Medical Education Programs. The section also would require the Secretary to determine any changes to the resident reporting requirements to determine whether hospitals have received overpayments. It would specify annual reporting requirements and authorize the Secretary to audit THC's. The section would require the Secretary to reduce the amount of payments made to a THC by 25% if a THC fails to report certain information, and would specify the THC's opportunity to remediate the failure to report. The Secretary would be required to promulgate regulations to carry out this section. To carry out the section, there would be appropriated SSAN, not to exceed \$230 million, for the period FY2011 through FY2015.

## **Nursing Workforce**

PHSA Title VIII, comprising Secs. 801-855, authorizes several programs to support nursing workforce development. These programs include funding for grant and scholarship programs for graduate and undergraduate nursing education in specified areas of nursing, including cultural competency, workforce diversity, nurse faculty members, advanced education nurses, and geriatric nursing. H.R. 3590, as passed by the Senate, would modify and reauthorize several of these existing programs.

### **Sec. 5202. Nursing Student Loan Program**

This section would amend **PHSA Sec. 836** by increasing the annual maximum amount of loan funds a recipient can receive during FY2010 and FY2011 from \$2,500 to \$3,300; increasing the final two-year amounts from \$4,000 to \$5,200 per year; and increasing the total loan amount from \$13,000 to \$17,000. The section would provide, for loans made after FY2011, for a cost-of-attendance increase for the yearly and aggregate amounts. The section also would amend applicable dates to require that financial need be a criterion for receiving a loan after 2000. Additionally, it would provide for partial loan cancellation for loan recipients working as full-time nurses in public or nonprofit settings who received loan funds before September 29, 1995.

### **Sec. 5305(c). Geriatric Education and Training**

This subsection would amend **PHSA Sec. 855** to include new language establishing traineeships for individuals preparing for advanced degrees in geriatric nursing or other nursing areas that specialize in elder care. It would authorize to be appropriated SSAN for each of FY2010 through FY2014. Note: Subsections 5305(a) and (b) of this bill amend the geriatric education and training provisions in PHSA Sec. 753; see below.

### **Sec. 5308. Advanced Nursing Education Grants**

This section would amend **PHSA Sec. 811** to establish separate authorizations for the support of nurse practitioner and nurse midwifery programs. It also would insert new language establishing expanded grant eligibility criteria for nurse midwifery programs. The section would delete the prohibition on obligating more than 10% of the traineeships for individuals in doctoral programs.

### **Sec. 5309. Nurse Education, Practice, and Retention Grants**

This section would amend **PHSA Sec. 831** by renaming the grant program, *Nurse Education, Practice, and Quality Grants*. It also would delete the provision's support for internship and residency programs to encourage mentoring and the development of specialties within nursing. The section would restate certain specified grant priority activities, and would redefine nursing schools to have the same meaning as the term in Sec. 801(2). The section would authorize to be appropriated SSAN for each of FY2010 through FY2014.

Additionally, the section would add a new **PHSA Sec. 831A**, *Nurse Retention Grants*, authorizing the Secretary to provide funding to eligible entities for nurse retention and promotion ("career ladder") programs. The Secretary would be required to give preference to entities that have not received a grant under this subsection, to entities that have not received a grant under the earlier nursing "career ladder" grant program, and to entities that address other high-priority areas as determined by the Secretary. The section would authorize to be appropriated SSAN to carry out grant programs in this section for each of FY2010 through FY2012.

### **Sec. 5310. Student Loan Repayment and Scholarship Program**

This section would amend **PHSA Sec. 846** by expanding eligibility for the nursing student loan repayment and scholarship program to individuals who agree to serve as nurse faculty at an accredited school of nursing for two years or more. This section also contains several technical and conforming amendments for **PHSA Title VIII**, including redesignating Sec. 841 (Funding) as Sec. 871.

### **Sec. 5311. Nurse Faculty Loan Program**

This section would amend **PHSA Sec. 846A** by renaming the nurse faculty loan program *School of Nursing Student Loan Fund*. It would add the requirement that loan fund agreements must be made with accredited schools of nursing. Priority would be given to support for doctoral nursing students. The section also would increase the annual loan limit from \$30,000 to \$35,500 for FY2010 and FY2011. Thereafter, the annual loan limit would be adjusted to provide for a cost-of-attendance increase. The bill would authorize to be appropriated SSAN for each of FY2010 through FY2014.

Additionally, the section would create a new **PHSA Sec. 847** authorizing the Secretary, acting through HRSA, to enter into an agreement with eligible individuals for the repayment of qualified education loans for the purpose of increasing the number of qualified nursing faculty. Award recipients would be required to serve as a faculty member at an accredited school of nursing for at least four of the six years after (1) the individual receives a qualifying degree; or (2) the date the individual entered the agreement. Priority would be given to support for doctoral nursing students. The section also would set the annual loan limit at \$10,000 for individuals with a

master's or equivalent degree in nursing (\$20,000 for those with a doctorate or equivalent degree in nursing), and an aggregate loan limit of \$40,000 for individuals with a master's or equivalent degree in nursing (\$80,000 for those with a doctorate or equivalent degree in nursing) for FY2010 and FY2011. Thereafter, the annual loan limits would be adjusted to provide for a cost-of-attendance increase. There would be authorized to be appropriated SSAN for each of FY2010 through FY2014.

### **Sec. 5312. Authorization of Appropriations**

This section would amend **PHSA Sec. 871** (as redesignated by Sec. 5310 of this bill) by authorizing to be appropriated \$338 million in FY2010 for Title VIII Parts B, C, and D (i.e., Secs. 811, 821, and 831), and SSAN for each of FY2011 through FY2016.

### **Sec. 5509. Medicare Graduate Nurse Education Demonstration Program**

This section would require the Secretary to establish a graduate nurse education demonstration program in Medicare. Under the demonstration program, up to five eligible hospitals would receive Medicare reimbursement for clinical training costs attributed to providing advanced practice nurses with qualified training. An advanced practice nurse would include a clinical nurse specialist, a nurse practitioner, a certified registered nurse anesthetist, and a certified nurse midwife as defined by Medicare statute. Advance practice nurses would receive training in the clinical skills necessary to provide primary care, preventive care, transitional care, chronic care management, and other nursing services appropriate for the Medicare-eligible population. At least half of all clinical training would occur in non-hospital community-based care settings. However, the Secretary would be authorized to waive this requirement for eligible hospitals located in rural or medically underserved areas. For any year, Medicare's payment amount would not exceed the amount of training costs attributed to an increase in the number of advance practice nurses enrolled in a qualified program during the year compared to the average number who graduated from that program in each year from January 1, 2006 to December 31, 2010 (as determined by the Secretary). To carry out this section, there would be appropriated, out of any funds in the Treasury not otherwise appropriated, \$50 million for each of FY2012 through FY2015, with amounts remaining available until expended.

### **Sec. 10501(e). Family Nurse Practitioner Demonstration**

This section would require the Secretary to establish a demonstration program to provide recently qualified nurse practitioners with 12 months of training for careers as primary care providers in FQHCs and NMHCs (see Sec. 5208 of this bill). Eligible FQHCs and NMHCs would receive three-year grants to create a training model that may be replicated nationwide. Grant amounts could not exceed \$600,000 per year. To be eligible for acceptance into a training program, a nurse practitioner would have to demonstrate a commitment to a career as a primary care provider in an FQHC or NMHC. Preference would be given to bilingual candidates. The Secretary would be authorized to award grants to one or more FQHCs or NMHCs with expertise in establishing nurse practitioner residency training programs to provide technical assistance to other grantees. There would be authorized to be appropriated SSAN for each of FY2011 through FY2014 to carry out the demonstration program.

## **Public Health Workforce**

PHSA Title VII, Part E, Subpart 2, comprising Secs. 765-770, authorizes the Secretary to conduct programs for public health workforce development by providing grants or contracts to schools, state and local health agencies, and others to operate public health training and re-training programs. Programs include grants for Public Health Training Centers; tuition, fees, and stipends for traineeships in public health and in health administration; and residency programs in preventive medicine and dental public health. Appropriations authority for these programs has expired, though all except the health administration traineeships continue to receive funding.

### **Sec. 5204. Public Health Workforce Loan Repayment Program**

This section would create a new **PHSA Sec. 776** requiring the Secretary, depending on appropriations, to establish a Public Health Workforce Loan Repayment Program for public health or health professionals who agree to work in a federal, state, local, or tribal public health agency or applicable fellowship after graduation. Among other contractual obligations, recipients would be required to serve for at least three years, or as determined by the Secretary. Annual repayment would be capped at \$35,000 per individual, or one-third of total debt, whichever is less. The section would authorize the appropriation of \$195 million for FY2010, and SSAN for each of FY2011 through FY2015.

### **Sec. 5206. Grants for State and Local Programs**

This section would amend **PHSA Sec. 765** to add public health workforce loan repayment programs to the list of the allowable activities for public health workforce development grants.

The section also would create a new **PHSA Sec. 777** authorizing the Secretary to make awards to eligible educational entities to award scholarships for the training of mid-career professionals in public health and allied health. Eligible individuals would include federal, state, tribal, or local public health and allied health employees. There are no stated scholarship amounts or service obligations. The section would authorize the appropriation of \$60 million for FY2010, and SSAN for each of FY2011 through FY2015. Appropriated funds would have to be evenly divided between programs for public health professionals and those for allied health professionals.

### **Sec. 5209. Elimination of Cap on Commissioned Corps**

**Sec. 202 of P.L. 102-394**, appropriations for Labor/HHS/Education for FY1993, capped the number of commissioned officers in the U.S. Public Health Service Regular Corps (versus the Reserve Corps) at 2,800 and prohibited the use of appropriations from that Act, or any subsequent appropriations act, to fund additional positions.<sup>18</sup> This section would amend Sec. 202 of P.L. 102-394 by eliminating the cap.

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<sup>18</sup> The ceiling was raised to 4,000 in Sec. 222 of P.L. 111-8, the Omnibus Appropriations Act, 2009.



### **Sec. 5210. Establishing a Ready Reserve Corps**

This section would amend **PHSA Sec. 203** to replace all mentions of the U.S. Public Health Service Reserve Corps with “Ready Reserve Corps.” In addition, members of the Reserve Corps serving on active duty would be deemed to be members of the Regular Corps. The Ready Reserve Corps would address a number of specified needs for additional commissioned personnel to assist the Regular Corps on short notice, for both routine public health and emergency response missions. The section would authorize the appropriation, for each of FY2010 through FY2014, of \$5 million for recruitment and training, and \$12.5 million for the Ready Reserve Corps.

### **Sec. 5313. Grants to Promote the Community Health Workforce**

This section, as amended by Sec. 10501(c) of the bill, would create a new **PHSA Sec. 399V**, requiring the CDC Director to award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers (CHWs). Funds would be used, among other things, to educate, guide, and provide outreach, including regarding enrollment in federal and state health programs; to identify and refer underserved populations to community-based programs; and to provide home visitation services. The Secretary would be required to establish guidelines for training and supervision of CHWs, monitor programs that receive grants, and provide technical assistance. Eligible entities would be public or nonprofit private entities, including states or subdivisions of states, public health departments, free health clinics, hospitals, FQHCs, or consortia of the above. The bill would authorize to be appropriated SSAN for each of FY2010 through FY2014.

### **Sec. 5314. Fellowship Training in Public Health**

This section would add a new **PHSA Sec. 778** authorizing the Secretary to expand existing CDC public health training fellowships in epidemiology, laboratory science, and informatics; the Epidemic Intelligence Service (EIS); and other training programs that meet similar objectives. Participants could be placed in state and local health agencies, and states could receive federal assistance for loan repayment programs for such participants. The section would authorize, for each of FY2010 through FY2013, the appropriation of \$24.5 million for EIS fellowships, and \$5 million each for epidemiology, laboratory, and informatics fellowships.

### **Sec. 5315. United States Public Health Sciences Track**

This section would add a new **PHSA Title II, Part D, *United States Public Health Sciences Track***, consisting of four new PHSA sections, described below. The Secretary and the U.S. Surgeon General (SG) would be required to consult with the National Health Care Workforce Commission (as established in Sec. 5101 of the bill) in administering activities under this Part. New **PHSA Sec. 271** would establish a science track at academic sites selected by the Secretary, to award degrees that emphasize team-based service, public health, epidemiology, and emergency preparedness and response. The track would be organized so as to graduate, annually, specified minimum numbers of students of medicine, dentistry, nursing (including advanced nursing), public health, behavioral and mental health, physician assistance, and pharmacy.

New **PHSA Sec. 272** would delegate administration of the science track to the SG, whose duties would include designating faculty and establishing their salary and benefits. The SG would be authorized to negotiate agreements to use appropriate federal and private accredited institutions to

support the functions of the science track, and would be required to establish appropriate programs of continuing medical education. Also, the SG would, contingent upon available budget authority, be authorized to enter in contracts; award grants; accept gifts, grants, and voluntary services; and take such other specified actions as needed to administer the science track. Persons who provided voluntary services would be considered federal employees for the purposes of Chapter 81 of U.S.C. Title 5 (compensation for work-related injuries) and Chapter 171 of U.S.C. Title 28 (tort claims), but not considered as federal employees for any other purpose.

New **PHSA Sec. 273** would establish requirements for selection of students for the science track, and their service obligations. The SG would be required to develop selection procedures, giving priority to students from rural communities and underrepresented minorities. Subject to appropriations, the SG could provide students with funding (as established by the SG) for tuition and a stipend for up to four years, subject to specified contractual obligations, among them a requirement to serve in the Commissioned Corps of the Public Health Service for a period of two years for each year of supported student enrollment. The term of obligated service could be reduced for specified reasons, including service in a federal medical facility located in a HPSA. Students dropped from the science track for deficiencies of conduct or studies, or other reasons, would be liable to the U.S. government for tuition and stipend support provided. The SG would be required to emphasize community-based training and to prioritize institutions that jointly train different types of providers through a shared curriculum. In addition, the SG would be required to develop criteria for the appointment of promising science track faculty, students, and graduates to elite federal disaster preparedness teams to train and to respond to public health emergencies.

New **PHSA Sec. 274** would require the Secretary, beginning in FY2010, to transfer from the Public Health and Social Services Emergency Fund SSAN to carry out this new Part.<sup>19</sup>

### **Sec. 10501(m)(1). Preventive Medicine and Public Health Training Grants**

This subsection would replace the existing **PHSA Sec. 768** with new language, requiring the Secretary to award grants to contracts for preventive medicine residency training. Eligible entities would be accredited schools of medicine, osteopathic medicine, or public health; accredited public or private hospitals; state, local, or tribal health departments; or consortia of the above.

### **Sec. 10501(m)(2). Authorization of Appropriations**

This subsection would amend **PHSA Sec. 770(a)** by authorizing to be appropriated \$43 million for FY2011, and SSAN for each of FY2012 through FY2015 for PHSA Secs. 765-769.

## **Workforce Diversity, Cultural Competency, Interdisciplinary and Community-Based Training**

PHSA Title VII, Part B, comprising Secs. 736-741, authorizes several programs intended to promote diversity in the health workforce. Sec. 736 requires that the Secretary award grants to establish Centers of Excellence (COEs) at health professions schools that recruit and train

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<sup>19</sup> The Public Health and Social Services Emergency Fund is an HHS account administered by the Secretary, which Congress has typically used to provide one-time funding for non-routine activities.

significant numbers of underrepresented minority students to help support and facilitate those activities. Funds are allocated to the various types of COEs according to a formula, which is based on whether the appropriation for a given fiscal year is (1) \$24 million or less, (2) more than \$24 million but less than \$30 million, or (3) \$30 million or more. Centers must maintain their prior level of non-federal expenditures, and must first expend other federal funds before expending grant funds. Appropriations authority expired at the end of FY2002. Secs. 737 and 739 authorize scholarships and other educational assistance for students from disadvantaged backgrounds. Sec. 738 requires the Secretary to establish a loan repayment program for individuals from disadvantaged backgrounds with a health professions degree or in the final year of study who agree to serve as a faculty member in a health professions school. Eligible individuals may receive up to \$20,000 of education loan repayment for each year they serve as faculty. Sec. 741 authorizes grants to carry out research and demonstration projects on training health professionals how to reduce disparities in health care outcomes and provide culturally competent health care. Title VIII, Sec. 821 authorizes grants to increase nursing education opportunities for individuals from disadvantaged backgrounds.

Title VII, Part D, comprising Secs. 750-758, authorizes several grant programs to support interdisciplinary, community-based health workforce training. Sec. 751 authorizes the AHEC program, which provides grants to medical and nursing schools to establish and maintain community-based, primary care training programs in off-campus rural and underserved areas. The AHEC program is intended to educate and train students to become culturally competent primary care health professionals who will provide care to underserved populations. Appropriations authority expired at the end of FY2002. Sec. 752 authorizes funding for health education and training centers. To receive funding, an entity must be otherwise eligible for an AHEC award and, among other things, address unmet health care needs along the border between the United States and Mexico, in Florida, and in other urban and rural areas with serious unmet health care needs. Sec. 753 authorizes funding for Geriatric Education Centers (GECs) to develop and provide training programs in geriatrics, and requires the Secretary to establish a faculty fellowship program in geriatrics.

H.R. 3590, as passed by the Senate, includes the following sections that would amend and expand existing workforce diversity and interdisciplinary, community-based training programs.

### **Sec. 5305(a) and (b). Geriatric Education and Training**

Subsection 5305(a) would amend **PHSA Sec. 753** by adding two new subsections. The first subsection would require the Secretary to award grants or contracts for geriatric workforce development fellowship and training programs to qualified entities that operate a Geriatric Education Center (GEC). The awards would be used to (1) offer short-term intensive courses on geriatrics, chronic care management, and long-term care; and (2) offer family caregiver and direct care provider training, or develop and incorporate into all training courses best practices material on mental disorders among the elderly, medication safety issues for the elderly, and managing dementia. Each award would be \$150,000 with no more than 24 GECs authorized to receive an award. There would be authorized to be appropriated \$10.8 million for the period FY2011 through FY2014.

The second new subsection would create incentive grants or contracts for certain qualified health professionals entering the field of geriatrics, long-term care, and chronic care management. Health professionals receiving this award would be required to teach or practice in one of the

above fields for a minimum of five years. There would be authorized to be appropriated \$10 million for this program for the period FY2011 through FY2013.

Subsection 5305(b) would further amend **PHSA Sec. 753** by expanding eligibility for geriatric academic career awards to qualified faculty at any accredited health professions school, as determined by the Secretary. Entities receiving an award must meet specified targets and use award funds to supplement and not supplant funds otherwise available to the GEC.

### **Sec. 5307. Cultural Competency, Prevention, and Public Health and Individuals with Disabilities Training**

This section would amend **PHSA Sec. 741** requiring the Secretary to support the development and evaluation of research, demonstration projects, and model curricula for use in health professions schools and continuing education programs for providing training in cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities. The Secretary would be required to collaborate with specified entities and other organizations as deemed appropriate, and to coordinate with curricula and research and demonstration projects developed under **PHSA Sec. 807**. The Secretary also would be required to evaluate the adoption and implementation of the curricula, to facilitate their inclusion into quality measurement systems as appropriate, and to make them available through the Internet. There would be authorized to be appropriated SSAN for each of FY2010 through FY2015.

In addition, the section would amend **PHSA Sec. 807**—a grant program for cultural and linguistic competence training for nurses—to create a program for the nursing workforce that is parallel to the one authorized under **Sec. 741** (as amended) and to require coordination with that program. To carry out **Sec. 807**, there would be authorized to be appropriated SSAN for each of FY2010 through FY2015.

### **Sec. 5401. Centers of Excellence**

This section would amend **PHSA Sec. 736** by modifying the Centers of Excellence (COE) funding formula to add an additional set of specifications for allocating funds among the various types of COEs when the appropriation is \$40 million or more. It would authorize to be appropriated for the COE program \$50 million for each of FY2010 through FY2015, and SSAN for each subsequent fiscal year.

### **Sec. 5402. Health Care Professionals Training for Diversity**

This section would amend **PHSA Sec. 738(a)** by increasing the annual limit on the loan repayment amount to \$30,000. In addition, the section, would amend **PHSA Sec. 740** by authorizing the following appropriations: (1) for **Sec. 737** scholarships, \$51 million for FY2010, and SSAN for each of FY2011 through FY2014; (2) for **Sec. 738** loan repayments and fellowships, \$5 million for each of FY2010 through FY2014; and (3) for **Sec. 739** educational assistance, \$60 million for FY2010, and SSAN for each of FY2011 through FY2014.

### **Sec. 5403. Interdisciplinary, Community-Based Linkages**

This section would amend **PHSA Sec. 751**, *Area Health Education Centers*, replacing the existing provisions with new language. The new section would expand the current AHEC program and require the Secretary to award (1) infrastructure development grants to medical and nursing schools to plan, develop, and operate AHEC programs; and (2) point-of-service maintenance and enhancement grants to maintain and improve the effectiveness of existing AHEC programs. As with the current AHEC program, the new section would require a non-federal match, set the minimum award at \$250,000, and place certain time limits on the award period. It would authorize to be appropriated \$125 million for each of FY2010 through FY2014. It would be the sense of Congress that every state has an AHEC program.

In addition, the section would replace the existing section with a new **PHSA Sec. 752**, *Continuing Education Support for Health Professionals Serving in Underserved Communities*, requiring the Secretary to award grants to health professions schools, academic health centers, and state or local governments, among others, to fund innovative activities to enhance education through distance learning, continuing education, collaborative conferences, and telehealth, with a focus on primary care. It would authorize to be appropriated \$5 million for each of FY2010 through FY2014, and SSAN for each subsequent fiscal year.

### **Sec. 5404. Workforce Diversity Grants**

This section would amend **PHSA Sec. 821** by expanding the allowable uses of diversity grants to include stipends for diploma or associated degree nurses to enter a bridge or degree completion program, student scholarships or stipends for accelerated nursing degree programs, and advanced education preparation. In lieu of the existing consultation requirements, it would require the Secretary to take into account the recommendations of the National Advisory Council on Nurse Education and Practice and consult with nursing associations including the National Coalition of Ethnic Minority Nurse Associations and other appropriate organizations.

### **Sec. 5405. Primary Care Extension Program**

This section, as amended by Sec. 10501(f) of the bill, would add a new **PHSA Sec. 399V-1**, *Primary Care Extension Program*, to fund the creation of local Primary Care Extension Agencies to support and educate primary care providers about preventive medicine, health promotion, chronic disease management, mental health services, and evidence-based therapies. Primary care providers would work with community-based health connectors, referred to as “Health Extension Agents.” These agents would be any local, community-based health worker who provides assistance by implementing quality improvement or system redesign that incorporates the principles of the patient-centered medical home, provides guidance to patients in culturally and linguistically appropriate ways, and links practices to diverse health system resources.

The Secretary would be required to award competitive grants to states to establish Primary Care Extension Program State Hubs, consisting of the state health department and other specified entities. Hubs would be required to contract with and provide grant funds to county or local entities to serve as Primary Care Extension Agencies and organize statewide or multistate networks of such agencies to share information. Primary Care Extension Agencies would be required to (1) assist primary care providers to implement a patient-centered medical home; (2) develop and support primary care learning communities; (3) participate in a national network of

hubs and proposed how best practices can be shared; and (4) develop a plan for financial sustainability after the initial six-year period of funding under this section is completed.

The section would authorize both six-year program grants for entities that submit a fully developed hub plan, and two-year planning grants for entities to develop such a plan. A state receiving a program grant would be evaluated at the end of the grant period. After the sixth year of a grant, a state may receive additional support if its program receives a satisfactory evaluation. There would be authorized to be appropriated \$120 million for each of FY2010 and FY2011, and SSAN for FY2013 and FY2014.

### **Sec. 10501(d). Physician Assistant Education**

This section would amend **PHSA Sec. 738(a)** by adding schools offering physician assistant education programs to the list of specified health professions schools.

### **Sec. 10501(l). Rural Physician Training Grants**

This section would add a new **PHSA Sec. 749B**, *Rural Physician Training Grants*, requiring the Secretary, acting through HRSA, to award grants to medical schools to recruit and provide focused training and experiences to students likely to practice medicine in underserved rural communities. Priority would be given to medical schools with a demonstrated record of training students to practice in such communities, that have established rural community institutional partnerships, or who submit a long-term plan for tracking program graduates. Entities receiving grants would be required to use funds to establish, improve or expand a rural-focused training program that meets certain specified requirements, including (1) enrolling at least 10 students annually; (2) developing admission criteria that prioritize students with rural origins (as defined) or with expressed commitment to practice in a rural area; (3) providing rural coursework and clinical experiences applicable to rural communities; and (4) assisting program graduates with rural residency placements. Grantees would have to use the funds to supplement and not supplant federal and non-federal funds received from other sources, and maintain expenditures of non-federal amounts at levels not less than those expended in the fiscal year prior to the entity's receipt of the grant. There would be authorized to be appropriated \$4 million for each of FY2010 through FY2013.

## **Health Workforce Evaluation and Assessment**

PHSA Title VII, Part E, Subpart 1, comprising Secs. 761-763, establishes various projects to support health professions workforce information and analysis, including grants to entities in order to develop analysis of and information on the health workforce, an Advisory Council on Graduate Medical Education, and an evaluation of the number of pediatric rheumatologists. Other advisory groups established under PHSA Title VII include the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Committee on Interdisciplinary, Community-based Linkages (established under Secs. 748 and 756, respectively). In addition, PHSA Title VIII, Part G (i.e., Sec. 845) establishes a National Advisory Council on Nurse Education and Practice. Federal leadership for health workforce analysis is provided by HRSA's National Center for Health Workforce Analysis (NCHWA), which is not explicitly authorized in the PHSA.

The bill includes two sections that would add new language establishing a National Health Care Workforce Commission and a state health care workforce development grants program. A third section would replace existing PHSA provisions with new language creating in statute an NCHWA, establishing State and Regional Centers for Health Workforce Analysis, and increasing grant amounts for longitudinal evaluations of specified individuals who have received assistance from certain PHSA Title VII programs. Finally, the bill would create a federal task force on Alaska health care delivery.

### **Sec. 5101. National Health Care Workforce Commission**

This section, as amended by Sec. 10501(a) of the bill, would establish a National Health Care Workforce Commission to serve as a national resource that focuses on evaluating and meeting the need for health care workers. The Commission would be composed of 15 members appointed by the U.S. Comptroller General. It would be required to recognize partnerships that develop and offer effective health care career pathways; disseminate information on promising practices; and communicate important policies and practices regarding recruitment, retention, and training of the health care workforce. The Commission would have to review health care workforce supply and demand and make recommendations on national priorities and policies as well as review and make recommendations on one or more additional specified high priority topics areas and submit annual reports on both activities to Congress and the Administration beginning in 2011. The report on national priorities and policies would be due by October 1 each year; the report on high priority topics would be due by April 1 each year. The Commission also would be required to (1) review implementation progress reports and report on the state health care workforce development grants program (established by Sec. 5102 of the bill); (2) study effective mechanisms for financing education and training for careers in health care; (3) make recommendations about improving health care workers' safety, health, and protections in the workplace; and (4) assess reports from the NCHWA (established under PHSA Sec. 761(b), as amended by Sec. 5103 of the bill). There would be authorized to be appropriated SSAN to carry out this section.

### **Sec. 5102. State Health Care Workforce Development Grants**

This section would establish a competitive health care workforce development grants program for the purpose of enabling state partnerships to plan and implement activities leading to coherent and comprehensive health care workforce development strategies at the state and local levels. HRSA would be responsible for administering the program, in consultation with the Commission (established by Sec. 5101 of the bill). HRSA would also provide technical assistance to grantees and report performance information to the Commission. For planning grants, it would authorize to be appropriated \$8 million for FY2010, and SSAN for each subsequent fiscal year. For implementation grants, it would authorize to be appropriated \$150 million for FY2010, and SSAN for each subsequent fiscal year.

### **Sec. 5103. Health Care Workforce Program Assessment**

This section would amend **PHSA Sec. 761** by requiring the Secretary to (1) establish a National Center for Health Workforce Analysis; (2) establish State and Regional Centers for Health Workforce Analysis; and (3) increase grant amounts for longitudinal evaluations of specified individuals who have received education, training, or financial assistance from programs under PHSA Title VII. The section also would authorize the following appropriations for each of

FY2010 through FY2014: (1) \$7.5 million for National Centers; (2) \$4.5 million for State and Regional Centers; and (3) SSAN for grants for longitudinal evaluations. Funds could be authorized to be carried over from one fiscal year to another without obtaining approval from the Secretary; however, funds would not be carried over for more than three years. The section would require that all responsibilities of HRSA's existing NCHWA be transferred to the new National Center no later than 180 days after enactment.

The section would amend **PHSA Sec. 791** by adding new language requiring the Secretary to give preference in awarding grants or contracts under Secs. 747 and 750 to any qualified applicant that utilizes a longitudinal evaluation and reports data from such system to a national workforce database. It also would amend Secs. 748, 756, and 762 to include additional duties regarding performance measures and guidelines for longitudinal evaluations for the Advisory Committee on Training in Primary Care Medicine and Dentistry; the Advisory Committee on Interdisciplinary, Community-based Linkages; and the Advisory Council on Graduate Medical Education.

### **Sec. 10501(b). Task Force on Alaska Health Care**

This section would establish the Interagency Access to Health Care in Alaska Task Force to develop a strategy to improve delivery of care to beneficiaries of federal health care systems in Alaska. The Task Force would be composed of nine federal officials appointed by specified Secretaries. The Task Force would be required, within 180 days of enactment, to submit a report to Congress with recommendations, policies, and initiatives. It would be terminated upon submission of the report.

## **Medicare Graduate Medical Education Payments**

With certain exceptions, Medicare caps the number of residents used to calculate GME payments for individual teaching hospitals at the level reported at the end of 1996. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 permitted a one-time redistribution of up to 75% of a teaching hospital's unused resident position to hospitals seeking to increase their medical residency programs, according to specific priorities. Rural teaching hospitals with fewer than 250 beds were exempt from the redistribution of any of their unfilled positions. The redistributed resident positions have different DGME and IME payment formulas from those used to reimburse hospitals' other residents. Medicare does not set targets for the type or mix of resident physicians that a hospital trains, nor are Medicare GME payments linked to promoting or fostering specific goals in medical education.

Medicare allows teaching hospitals to receive DGME and IME payments for the time residents rotate in non-hospital settings provided (1) they are performing patient care, and (2) the hospital pays all or substantially all (i.e., 90%) of the costs of the training at the non-hospital site, which include the resident stipends and fringe benefits and the costs associated with supervising physicians. Time spent in non-patient care activities in the non-hospital setting is not counted when calculating either type of payment. A hospital that jointly operates a residency program with another hospital cannot include the time spent by residents working at a non-hospital site if it incurs all or substantially all of the costs for only a portion of the residents in that program at the non-hospital site. Additional regulatory requirements discourage rotations in non-hospital settings. Moreover, hospitals have a financial incentive to retain the often lower-cost clinical labor that residents provide. While experts see value in having residents gain experience in nonhospital settings such as community health centers and nursing facilities, residency programs



today are largely based in inpatient, acute-care teaching hospitals. H.R. 3590 includes the following four sections, which collectively would make a number of changes to Medicare to address these and related issues.

### **Sec. 5503. Distribution of Additional Residency Positions**

This section would establish criteria to be used to reduce the otherwise applicable resident limit for a hospital that has unused residency positions, as defined, and direct the Secretary to redistribute 65% of those unused positions and assign them to other qualifying hospitals. Rural hospitals with fewer than 250 beds and the replacement facility for the former Martin Luther King Jr. Hospital would be exempt from the redistribution of any of their unfilled positions. Certain other hospitals would be exempt if they have a specific plan in place for filling the unused positions by no later than two years after enactment. No more than 75 FTE additional residents would be made available to a qualifying hospital.

A hospital that qualifies for an increase in residency positions would have to maintain its base level of primary care residents and ensure that not less than 75% of the additional positions are in primary care or general surgery residency. When determining the increase in a hospital's resident limit, the Secretary would take into account such factors as the likely speed with which the hospital would fill the positions, and whether the hospital has an accredited rural training track. Residency positions would be allocated, according to a specified formula, among the following qualifying facilities: (1) hospitals located in states with low resident-to-population ratios; (2) hospitals located in states with a high percentage of the population living in a HPSA; and (3) rural hospitals. DGME and IME payments for the redistributed residency positions would be made on the same basis as the payments for existing residency positions.

### **Sec. 5504. Counting Resident Time in Other Settings**

This section would require that all time spent by a resident in patient care activities be counted towards the DGME payment, regardless of the setting, provided the hospital incurs the costs of the stipends and the fringe benefits of the resident during the time spent in that setting. If more than one hospital incurs those costs, then each hospital would count a proportional share of the time that the resident spends training in that setting. Further, all the time spent by a resident in patient care activities in a non-hospital setting would be counted towards the IME payment, provided the hospital continues to incur those same costs. Again, if more than one hospital incurs the costs, then each hospital would count a proportional share of the time that the resident spends training in that setting.

### **Sec. 5505. Rules for Counting Resident Time for Non-Patient Care Activities**

This section, as amended by 10501(j) of the bill, would require that resident time spent in certain non-patient care activities—including attending conferences and seminars, but not research unless it is associated with the treatment or diagnosis of a patient—in a non-hospital setting that is primarily engaged in furnishing patient care be counted towards the DGME payment. In addition, Medicare would count all the vacation, sick leave, and other approved leave spent by the resident as long as the leave time does not extend the training program's duration.

When calculating IME payments, Medicare would adopt the same rules for counting residents' leave time. Resident time spent in hospital settings (as defined) on certain non-patient care

activities—including attending conferences and seminars, but not research unless it is associated with the treatment or diagnosis of a patient—would count towards the IME payment.

### **Sec. 5506. Preservation of Resident Cap Positions from Closed Hospitals**

This section would direct the Secretary, by rulemaking, to establish a process to redistribute medical residency slots from a hospital with an approved residency program that closes on or after a date that is two years before enactment to increase the otherwise applicable residency limit for other hospitals. Such residency slots would be redistributed based on a specified priority order, with first priority given to hospitals located in the same or contiguous core-based statistical area as the hospital that closed.

## **Other Workforce Provisions**

### **Sec. 5205. Allied Health Workforce Recruitment and Retention Programs**

This section would amend **Sec. 428K of the Higher Education Act of 1965** to include, among those eligible for a loan forgiveness program, an individual who is employed full-time as an allied health professional in a federal, state, local and tribal public health agency. Additional qualified employment locations would include acute care and ambulatory care facilities, and settings located in HPSAs, medically underserved areas or among medical underserved populations, as recognized by the Secretary.

The section would define the term “allied health professional,” as described in PHSA Sec. 799B(5), as an individual who has graduated and received an allied health professions degree or certificate from an institution of higher education and is employed with a federal, state, local, or tribal public health agency, or other qualified employment location.

### **Sec. 5507. Health Workforce Demonstrations; Family-to-Family Centers**

This section would amend Title XX of the Social Security Act (SSA) by adding the following new **Sec. 2008, *Demonstration Projects to Address Health Professions Workforce Needs***, establishing two separate demonstration projects. The first would require the Secretary, in consultation with the Secretary of Labor, to award grants to conduct demonstration projects that would provide individuals receiving assistance under the State Temporary Assistance for Needy Families (TANF) program and other low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand. The second would require the Secretary to award grants to states to conduct demonstration projects for the purposes of developing core training competencies and certification programs for personal or home care aides. It would require \$85 million to be appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, to carry out both demonstration projects for each of FY2010 through FY2014. The Secretary would be required to use \$5 million of the amount appropriated for each of FY2010 through FY2012 to carry out the second demonstration project. After FY2012, no appropriated funds would be required to carry out this project.

The section also would amend **SSA Sec. 501(c)**, which authorizes \$5 million for the Secretary (through grants, contracts, or otherwise) to provide for special projects of regional and national

significance for the development and support of family-to-family health information centers. This new language would appropriate to the Secretary, out of any money in the Treasury not otherwise appropriated, \$5 million for each of FY2009 through FY2012 to provide for the development and support of these centers.

### **Sec. 5701. Reports**

This section would require the Secretary to submit to Congress an annual report on the activities carried out under the amendments made by Title V (Health Care Workforce) of this legislation, and the effectiveness of such activities. The Secretary would be authorized to require, as a condition of receiving funds under the amendments made by Title V, that recipients of the funds submit reports on the effectiveness of activities carried out with such funds.

### **Sec. 8002(c). Personal Care Attendants**

This section would establish a Personal Care Attendants Workforce Advisory Panel, no later than 90 days after enactment, for the purpose of examining and advising the Secretary and Congress on workforce issues related to such workers.

### **Sec. 10501(g). National Diabetes Prevention Program**

This section would create a new **PHSA Sec. 399V-3**, requiring the Secretary, through the CDC, to establish a national diabetes prevention program, targeted at high-risk adults, with specified program components, including a training and outreach program for lifestyle intervention instructors. Entities eligible for program grants would be state or local health departments, tribal organizations, national networks of community-based non-profits focused on health and wellbeing, academic institutions, or other entities, as the Secretary determines. There would be authorized to be appropriated SSAN for each of FY2010 through 2014.

### **Sec. 10501(k). State Grants to Providers**

This section would authorize states to award grants to health care providers who treat a high percentage of the medically underserved or other special populations. Funds allocated to the Medicare, Medicaid, and Tricare programs could not be used to award grants or administer the grant program.

### **Sec. 10502. Hospital Construction Grants**

This section would authorize to be appropriated and would appropriate \$100 million for FY2010, to remain available through FY2011, for debt service on, or construction or renovation of, a hospital affiliated with a state medical and dental school, as specified. Any amount appropriated would only be made available to the Secretary upon receipt of an application from a state governor that meets certain specified requirements.

### **Sec. 10504. Access to Affordable Care Demonstration**

This section would require the Secretary, within six months of enactment, to establish a three-year demonstration project in up to 10 states to provide access to comprehensive health care services

to the uninsured at reduced fees. Each state would receive up to \$2 million. There would be authorized to be appropriated SSAN to carry out the demonstration.

## Prevention and Wellness

### Background and Issues

#### Overview

Prevention interventions are of two key types: those provided to individuals in clinical settings (e.g., cancer screenings) and those provided to communities (e.g., ad campaigns about exercise). Employer-sponsored wellness programs often use both types of interventions. Evidence suggests that many clinical and community-based prevention interventions can improve the health of patients and populations. However, contrary to common belief, many clinical preventive services (including cancer screenings) do not yield savings for the payer, but rather yield a net cost.<sup>20</sup> Evidence is less clear, and there is more debate, about (1) whether clinical preventive services may yield savings in a broader context (considering, for example, the value of lost workdays prevented), and (2) what savings, if any, may accrue to the federal government or society as a result of possible expansions of community-based prevention activities.

The federal government supports the development of evidence-based recommendations for the use of clinical and community preventive services primarily through three advisory committees. First, the U.S. Preventive Services Task Force (USPSTF), administered by the Agency for Healthcare Research and Quality (AHRQ), is an independent panel of private-sector experts in primary care and prevention that conducts assessments of scientific evidence of the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications (excluding vaccines).<sup>21</sup> The Task Force on Community Preventive Services (TFCPS), administered by CDC, conducts evidence reviews of community (i.e., population-based) interventions, using a process similar to that of the USPSTF.<sup>22</sup> Finally, the Advisory Committee on Immunization Practices (ACIP), administered by CDC, develops science-based recommendations for the use of vaccines in the U.S. population.<sup>23</sup>

Current law addresses prevention in several ways, including through (1) coverage of certain clinical preventive services under Medicare and Medicaid; (2) community-based research, disease prevention, and health promotion programs, which may be funded through federal grants; (3) support of evidence review processes to determine whether specific clinical and community-based prevention interventions are effective; and (4) regulation of certain employer-provided

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<sup>20</sup> See, for example, Congressional Budget Office, *The Budgetary Effects of Expanding Governmental Support for Preventive Care and Wellness Services*, Letter to the Honorable Nathan Deal, August 7, 2009, <http://www.cbo.gov/ftpdocs/104xx/doc10492/08-07-Prevention.pdf>.

<sup>21</sup> See the U.S. Preventive Services Task Force, established in Section 915(a) of the PHSA, at <http://www.ahrq.gov/clinic/uspstfix.htm>.

<sup>22</sup> See the Task Force on Community Preventive Services, not explicitly authorized but conducted under general authorities in Title III of the PHSA, at <http://www.thecommunityguide.org/index.html>.

<sup>23</sup> See the Advisory Committee on Immunization Practices at <http://www.cdc.gov/vaccines/recs/acip/default.htm>.

wellness programs, in order to strike a balance between flexibility and compliance with current federal privacy, civil rights, and other laws.<sup>24</sup>

## **Coverage of Clinical Preventive Services**

While federal law does not mandate coverage of preventive services for state and local government and private health insurance plans, Medicare Part B covers a number of clinical preventive services, including a one-time initial preventive physical examination (IPPE), certain periodic cancer screenings, and other services.<sup>25</sup> Medicare Part B also covers vaccines against influenza, pneumococcus, and, for individuals at increased risk, hepatitis B. Medicare Part D covers any FDA-licensed vaccine, when prescribed by a recognized provider. Congress has waived cost-sharing for some, but not all, Medicare covered preventive services in Part B. Medicare Advantage (Part C) is an alternative way for Medicare beneficiaries to receive covered benefits through private health plans. Medicare Advantage plans must cover benefits covered under Part B, but have considerable flexibility in how they apply or waive cost-sharing.<sup>26</sup> Many of these plans waive cost-sharing for preventive services.

State Medicaid plans must cover a package of preventive services under the Early and Periodic Screening, Diagnostic, and Treatment Services program (EPSDT), for beneficiaries under 21 years of age. Current law does not explicitly require that Medicaid state plans cover preventive services for adults, although coverage may be required if a service meets another applicable requirement, such as a physician's service. Under the optional Medicaid prescription drug benefit, states are permitted to exclude coverage of eleven drug classes, including barbiturates, benzodiazepines, and smoking cessation products. Medicaid programs are permitted, but not required, to cover tobacco cessation counseling services for enrollees, including pregnant women.

An adopted amendment could affect the implementation of several provisions in the Senate bill. On December 2, 2009, the Senate adopted S.Amdt. 2808, introduced by Senator Vitter, which would provide that “for the purposes of this Act, and for the purposes of any other provisions of law, the current recommendations of the [USPSTF] regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.”<sup>27</sup> In November 2009, the USPSTF updated its recommendation regarding the use of mammography for breast cancer screening. Previously, the panel had recommended routine screening for women beginning at age 40; it now recommends that routine screening begin at age 50. The Vitter amendment, which would appear to negate the November 2009 recommendations, could affect provisions in the health reform bills that link USPSTF recommendations to coverage as such coverage would apply to screening mammography for female beneficiaries between age 40 and 49.<sup>28</sup>

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<sup>24</sup> See CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones; and CRS Report R40791, *Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act*, by Amanda K. Sarata.

<sup>25</sup> For more information, see CRS Report R40978, *Medicare Coverage of Clinical Preventive Services*, by Sarah A. Lister and Kirsten J. Colello.

<sup>26</sup> Medicare Advantage plans must also cover all Part A services, except hospice care. CRS Report R40374, *Medicare Advantage*, by Paulette C. Morgan.

<sup>27</sup> This provision amends Sec. 1001 of the bill, which would, among other things, create a new PHSA Sec. 2713.

<sup>28</sup> The USPSTF and the relationship between its recommendations and coverage decisions is discussed further in CRS Report R40978, *Medicare Coverage of Clinical Preventive Services*, by Sarah A. Lister and Kirsten J. Colello.

Beneficiary cost-sharing has been shown to decrease utilization of certain preventive services, in some contexts. Based on an evidence review, the TFCPS recommends reducing beneficiary cost-sharing in order to increase utilization of screening mammography. However, the Task Force found insufficient evidence to make the same recommendation for cervical or colorectal cancer screening.<sup>29</sup>

## Employer-Provided Wellness Programs

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 copays 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 PHSA, and the IRC to improve portability and continuity of health coverage. HIPAA created certain nondiscrimination requirements, which prohibit a group health plan or a group health insurance issuer from basing coverage eligibility rules on health-related factors including health status (physical or mental), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability.<sup>30</sup> In addition, a group health plan or health insurance issuer may not require that an individual pay a higher premium or contribution than another “similarly situated” participant, based on these health-related factors. 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].”<sup>31</sup>

The HIPAA wellness program regulations divide wellness programs into two categories.<sup>32</sup> First, if a wellness program provides a reward<sup>33</sup> 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

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<sup>29</sup> Task Force on Community Preventive Services, “Recommendations for Client- and Provider-directed Interventions to Increase Breast, Cervical, and Colorectal Cancer Screening,” *American Journal of Preventive Medicine*, vol. 35, suppl. 1 (2008), pp. S21-25. See also CDC, <http://www.thecommunityguide.org/cancer/screening/client-oriented/ReducingOutOfPocketCosts.html>.

<sup>30</sup> 29 U.S.C. § 1182(a); 42 U.S.C. § 300gg-1(a); 26 U.S.C. § 9802(a). It should be noted that the Internal Revenue Code does not apply to health insurance issuers.

<sup>31</sup> 29 U.S.C. § 1182(b)(2)(B); 42 U.S.C. § 300gg-1(b)(2)(B); 26 U.S.C. § 9802(b)(2)(B).

<sup>32</sup> Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 *Fed. Reg.* 75014 (December 13, 2006).

<sup>33</sup> 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).

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.<sup>34</sup>

## Private Health Insurance Provisions<sup>35</sup>

### Sec. 1001. Regarding Coverage of Preventive Services<sup>36</sup>

Among other things, this section would create a new **PHSA Sec. 2713** requiring a group health plan or a health insurance issuer in the group or individual health insurance market to cover the following preventive services, without cost-sharing requirements: (1) items or services recommended (i.e., with a grade of A or B) by the USPSTF; (2) immunizations recommended by the ACIP; (3) for infants, children and adolescents, preventive care and screenings provided for in comprehensive guidelines supported by HRSA; and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA.

A plan or issuer would be permitted to cover or deny additional services not recommended by the USPSTF. For the purposes of this section, the current USPSTF recommendations regarding breast cancer screening, mammography, and prevention would be considered the most current other than those issued in or around November 2009.<sup>37</sup> The Secretary would be permitted to develop guidelines to allow a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs. Coverage requirements would be effective for plan years beginning on or after the date that is six months after enactment.

### Sec. 1302. Essential Health Benefits Requirements

This section would define the elements of an “essential health benefits package,” the types of benefits that must be provided by plans offered in the individual and small group markets, and by Qualified Health Plans (QHPS) that participate in insurance exchanges. Among these required benefits, plans would have to cover preventive and wellness services, and could not apply the deductible to any such services specified in PHSA Sec. 2713, as established in Sec. 1001 of the bill (above). The Secretary would be required to determine the specific elements of such coverage. Such coverage would be required for plan years beginning on or after January 1, 2014.

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<sup>34</sup> 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).

<sup>35</sup> For more information, see CRS Report R40981, *A Comparative Analysis of Private Health Insurance Provisions of H.R. 3962 and Senate-Passed H.R. 3590*, coordinated by Chris L. Peterson. See also provisions in the subsequent section of this report, “Wellness Programs Offered by Employers/Private Insurers.”

<sup>36</sup> Summary reflects S.Amdt. 2791 (Sen. Mikulski) regarding preventive services for women and S.Amdt. 2808 (Sen. Vitter) regarding screening mammography and USPSTF guidelines.

<sup>37</sup> See the note regarding the Vitter amendment (S.Amdt. 2808) in the previous section, “Coverage of Clinical Preventive Services.”

## Prevention Under Medicare and Medicaid<sup>38</sup>

### Sec. 4103. Medicare Annual Visit and Personalized Prevention Plan

This section, as amended by Sec. 10402(b), would amend **SSA Sec. 1861** to require that Medicare Part B cover, beginning in 2011, personalized prevention plan services, including a comprehensive health risk assessment. The personalized plan could include several specified elements, among them: review and update of medical and family history; a 5- to 10-year screening schedule and referral for services recommended by the USPSTF<sup>39</sup> and ACIP; a list of identified risk factors and conditions, and a strategy to address them; lists of all medications currently prescribed and all providers regularly involved in the patient's care; review or referral for testing and treatment of chronic conditions; and cognitive impairment assessment.

All enrolled beneficiaries would be eligible for personalized prevention plan services once every year, without any cost sharing. During the first year of Part B enrollment, beneficiaries could receive only the initial preventive physical examination (IPPE). Beneficiaries could receive personalized prevention plan services each year thereafter provided that they have not received either an IPPE or personalized prevention plan services within the preceding 12 months. The Secretary would be required to develop appropriate guidance, and conduct outreach and related activities, with respect to personalized prevention plan services and health risk assessments.

### Sec. 4104. Removal of Cost-Sharing for Medicare Preventive Services

This section, as amended by Sec. 10406, would, effective in 2011, amend **SSA Sec. 1861** to define preventive services covered by Medicare as a specified list of currently covered services, including colorectal cancer screening services even if diagnostic or treatment services were furnished in connection with the screening. The list also would include the IPPE, as well as the personalized prevention plan services that would be covered pursuant to Sec. 4103 of the bill. Coverage would remain subject to all criteria that apply to each preventive service covered under current law.

In addition, this section would amend **SSA Sec. 1833** to waive beneficiary coinsurance requirements for most preventive services, requiring Medicare to cover 100% of the costs. Services for which no coinsurance would be required are the IPPE, personalized prevention plan services, any additional preventive service covered under the Secretary's administrative authority, and any currently covered preventive service (including medical nutrition therapy, and excluding electrocardiograms) if it is recommended with a grade of A or B by the USPSTF.<sup>40</sup> The section would generally waive the application of the deductible for the same types of preventive services noted above for which coinsurance would be waived. It would not, however, waive the application of the deductible for any additional preventive service covered under the Secretary's administrative authority.

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<sup>38</sup> See also the subsequent section "Sec. 4202. Community Wellness Pilot; Medicare Wellness Evaluation."

<sup>39</sup> See the note regarding the Vitter amendment in the previous section, "Coverage of Clinical Preventive Services."

<sup>40</sup> Ibid.



### **Sec. 4105. Evidence-Based Coverage of Medicare Preventive Services<sup>41</sup>**

This section would, effective January 1, 2010, authorize the Secretary to modify the coverage of any currently covered preventive service (including services included in the IPPE, but not the IPPE itself), to the extent that the modification is consistent with USPSTF recommendations. This section also would allow the Secretary to withhold payment for any currently covered preventive service graded D (i.e., not recommended) by the USPSTF. The enhanced authority and the prohibition would not apply to services furnished for the purposes of diagnosis or treatment (rather than as preventive services furnished to asymptomatic patients).

### **Sec. 4106. Medicaid Preventive Services for Adults**

This section would, effective in 2013, amend **SSA Sec. 1905(a)(13)** to, among other things, expand the current Medicaid state option to provide other diagnostic, screening, preventive, and rehabilitation services to include (1) any clinical preventive services recommended (i.e., with a grade of A or B) by the USPSTF,<sup>42</sup> and (2) with respect to adults, immunizations recommended by the ACIP, and the cost of their administration. Provisions would take effect in 2013. States that elect to cover these additional services and vaccines and prohibit cost-sharing for them would receive the increased federal medical assistance percentage (FMAP) for medical assistance for newly eligible mandatory individuals (as under Sec. 2001(a)(3)(A) of this bill, excluding the 95% cap on such FMAP), for which an additional one percentage point increase in that FMAP would apply for these services, and for counseling and drug therapy for tobacco cessation use by pregnant women (as added by Sec. 4107 of the bill, described below).

### **Sec. 4107. Medicaid Tobacco Cessation Services for Pregnant Women**

This section would, effective in October 2010, require states to provide Medicaid coverage to pregnant women for counseling and drug therapy for tobacco cessation. Such services would include diagnostic, therapeutic, and counseling services and drug therapy (including prescription and non-prescription tobacco cessation products approved by the FDA), as recommended by the U.S. Surgeon General, and other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women. These services would exclude coverage for drugs or biologics that are not otherwise covered under Medicaid. States would continue to be allowed to exclude coverage of products used for smoking cessation except in the case of pregnant women. This section would prohibit cost-sharing, under either traditional Medicaid or the DRA option,<sup>43</sup> for counseling and drug therapy, as well as for covered outpatient prescription and non-prescription drugs, provided to or used by pregnant women for tobacco cessation.

### **Sec. 4108. Incentives for Chronic Disease Prevention Under Medicaid**

This section would require the Secretary to award grants to states to provide incentives for Medicaid beneficiaries to participate in programs to promote the adoption of healthy lifestyles. The stated purpose of the initiative is to test approaches that may encourage behavior

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<sup>41</sup> Ibid.

<sup>42</sup> Ibid.

<sup>43</sup> See CRS Report RS22578, *Medicaid Cost-Sharing Under the Deficit Reduction Act of 2005 (DRA)*, by Elicia J. Herz.

modification, and determine scalable solutions. Programs would have to be comprehensive and targeted to the needs of Medicaid beneficiaries; address criteria developed by the Secretary according to evidence-based guidelines from the USPSTF, TFCPS, and the National Registry of Evidence-based Programs and Practices;<sup>44</sup> and have demonstrated effectiveness for managing cholesterol and/or blood pressure, losing weight, quitting smoking, and/or preventing or managing diabetes. Programs could address co-morbidities, such as depression, associated with these conditions.

This section would appropriate \$100 million for the program for a five-year period beginning on January 1, 2011. The Secretary would be authorized to waive Medicaid requirements relating to statewideness, and would be required to ensure that a participating state makes the program widely available. A number of outreach, evaluation, and reporting requirements would apply. Any incentives received by a beneficiary could not be taken into account for the purpose of determining eligibility for, or the amount of, benefits under any federally funded program.

## **Wellness Programs Offered by Employers/Private Insurers**

### **Sec. 1001. Reporting Requirements for Group Health Plans / Gun Ownership**

Among its provisions, this section would create a new **PHSA Sec. 2717**. This new section would, among other things, require the Secretary to develop reporting requirements for group health plans and health insurance issuers with respect to plan or coverage benefits and health care provider reimbursement structures that, among other things, implement “wellness and health promotion activities.” Health plans and insurance issuers would be required to annually submit to the Secretary and enrollees a report on whether the benefits under the plan or coverage satisfy these and other elements. The new section would also require the Secretary to promulgate regulations providing criteria for determining whether a reimbursement structure meets these elements. Under this new section, wellness and health promotion activities could include personalized wellness and prevention services “that are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program’s participants....” These activities could include wellness and prevention efforts such as smoking cessation, weight management, nutrition, and healthy lifestyle support.

Also, the new PHSA Sec. 2717, as established by Sec. 1001 and amended by Sec. 10101(e) of the bill, contains provisions relating to gun rights. Among them, a wellness or health promotion activity (as referenced above) could not require disclosure or collection of any information relating to the presence or storage of a lawfully possessed firearm or ammunition in the residence or on the property of an individual; or the lawful use, possession, or storage of a firearm or ammunition by an individual.

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<sup>44</sup> The National Registry of Evidence-based Programs and Practices is a database of interventions for the prevention and treatment of mental and substance use disorders, administered by SAMHSA. See <http://www.nrepp.samhsa.gov/>.

### **Sec. 1201. Regarding Prohibiting Discrimination Based on Health Status**

This section would include the creation of a new **PHSA Sec. 2705** that amends HIPAA's nondiscrimination requirements. Among other things, this new section would largely codify an amended version of the HIPAA wellness program regulations. Wellness programs that do not require an individual to satisfy a standard related to a health factor as a condition for obtaining a reward (or do not offer a reward) would not violate HIPAA, so long as participation in the programs is made available to all similarly situated individuals. Wellness programs with conditions for obtaining a reward that are based on an individual meeting a certain standard relating to a health factor, would have to meet additional requirements. Among these requirements, the reward must be capped at 30% of the cost of the employee-only coverage under the plan (instead of 20% under the current regulations), but the Secretaries of HHS, Labor, and the Treasury would have the discretion to increase the reward up to 50%. The HHS Secretary, in consultation with the Secretaries of the Treasury and Labor, would establish a 10-state pilot program in which participating states would be required to apply the wellness program provisions to health insurers in the individual market.

Also, while Sec. 1201 would only modify the PHSA, Sec. 1562, as amended by Sec. 10107, would make these provisions applicable to group health plans and health insurance issuers under ERISA and the IRC.

### **Sec. 4303. CDC Grants for Employer-Based Wellness Programs**

This section, as amended by Sec. 10404, would add a new Part U in PHSA Title III, *Employer-Based Wellness Program*, including several new sections. A new **PHSA Sec. 399MM** would require the CDC Director to provide employers with technical assistance and other resources to evaluate workplace wellness programs, including measuring employee participation; developing standardized measures of factors that have a positive effect on health behaviors, outcomes, and expenditures; and evaluating the effect of programs on health outcomes, absenteeism, productivity, workplace injury rates, and medical costs. The Director also would be required to build evaluation capacity among workplace staff and provide resources, technical assistance, and consultation. A new **PHSA Sec. 399MM-1** would require the CDC Director to conduct a national survey of employer-based health policies and programs, and to report to Congress on findings and recommendations for the implementation of effective policies and programs. In addition, a new **PHSA Sec. 399MM-2** would require the Secretary to evaluate all programs funded through the CDC before conducting such an evaluation of privately funded programs, unless an entity with a privately funded wellness program requests such an evaluation. Finally, a new **PHSA Sec. 399MM-3** would, notwithstanding any other provision of this Part, prohibit the use of any recommendations, data, or assessments carried out under this Part to mandate requirements for workplace wellness programs.

### **Sec. 4402. Effectiveness of Federal Health and Wellness Initiatives**

This section would require the Secretary, in order to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals, to conduct an evaluation and report to Congress regarding changes in the health status of the American public, and specifically the federal workforce, including absenteeism, productivity, the rate of workplace injury, and the medical costs incurred by employees; and health conditions, including workplace fitness, healthy food and beverages, and incentives in the Federal Employees Health Benefits Program.

## **Sec. 10408. Workplace Wellness Program Grants**

This section would require the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs. The program would be conducted for a five-year period. Eligible employers would be defined as those that employ fewer than 100 employees who work 25 or more hours per week, and that do not provide a wellness program as of the date of enactment. To receive a grant, such employers would be required to submit an appropriate application to the Secretary. The Secretary would be required to develop program criteria consistent with evidence-based research and best practices, considering the Guide to Community Preventive Services<sup>45</sup> and the National Registry for Effective Programs.<sup>46</sup> Wellness programs would have to be made available to all employees and include several specified components, including education, efforts to encourage participation, initiatives to change unhealthy behaviors, and supportive work environments. There would be authorized to be appropriated \$200 million in total, to be available until expended, for FY2011 through FY2015.

## **Public Health Systems**

### **Sec. 4001. National Prevention, Health Promotion and Public Health Council**

This section, as amended by Sec. 10401, would require the President to establish a National Prevention, Health Promotion and Public Health Council, composed of secretaries, chairmen, and directors of federal departments, boards and agencies (as specified), and appoint a chairperson. The Council would be required to provide federal coordination and leadership with respect to prevention, wellness, and health promotion practices; develop a national prevention, health promotion, and public health strategy; report to the President and Congress on activities under the strategy and progress toward identified goals; and other activities as specified.

### **Sec. 4002. Prevention and Public Health Fund**

The stated purpose of this section is to establish a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. The proposal would authorize the appropriation of, and appropriate to the Fund from the Treasury, the following amounts: \$500 million for FY2010; \$750 million for FY2011; \$1.00 billion for FY2012; \$1.25 billion for FY2013; \$1.50 billion for FY2014; and \$2.00 billion for each fiscal year thereafter. The Secretary would be required to transfer amounts from the Fund to HHS accounts to increase funding, over the FY2008 level, for programs authorized by the PHSA for prevention, wellness, and public health activities, including prevention research and health screenings. The House and Senate Committees on Appropriations would have the authority to transfer monies in the Fund to eligible activities under this section.

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<sup>45</sup> This Guide is published by the Task Force on Community Preventive Services.

<sup>46</sup> This presumably refers to the National Registry of Evidence-based Programs and Practices, a database of interventions for the prevention and treatment of mental and substance use disorders, administered by SAMHSA. See <http://www.nrepp.samhsa.gov/>.

### **Sec. 4003. Clinical and Community Preventive Services Task Forces**

Subsection 4003(a) would strike and replace **PHSA Sec. 915(a)**, the current authority for the USPSTF, with language requiring the AHRQ Director to convene a Preventive Services Task Force, composed of individuals with appropriate expertise. This Task Force would be required to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the *Guide to Clinical Preventive Services*. The Task Force would have specified duties, including development of topic areas for review, review and revision of existing recommendations at least once every five years, and improved integration with federal government health objectives and related targets for health improvement, among others. AHRQ would be required to provide administrative, research, and technical support for Task Force operations. All members of the Task Force convened under this subsection, and any recommendations made by such members, would be independent and, to the extent practicable, not subject to political pressure. There would be authorized to be appropriated SSAN for each fiscal year to carry out Task Force activities.

Subsection 4003(b) would create a new **PHSA Sec. 399U** requiring the CDC Director to convene a Community Preventive Services Task Force (“Community Task Force”), composed of individuals with appropriate expertise, to review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the *Guide to Community Preventive Services*. The Community Task Force would have specified duties similar to those of the Preventive Services Task Force above, except applied to policies, programs, processes, or activities designed to affect or otherwise affecting health at the population level. CDC would be required to provide administrative, research, and technical support for Community Task Force operations. There would be authorized to be appropriated SSAN for each fiscal year to carry out the activities of the Community Task Force.

Each Task Force would be required to coordinate its activities with the other and with the ACIP. In addition, neither Task Force would be subject to requirements of the Federal Advisory Committee Act (FACA).<sup>47</sup>

### **Sec. 4004. Education and Outreach Campaign Regarding Preventive Benefits**

This section would require the Secretary to carry out seven communications activities regarding health promotion and disease prevention, generally oriented toward the most common and serious chronic health problems, including poor nutrition, tobacco use, and obesity. The required activities would be as follows. First, the Secretary, in consultation with the Institute of Medicine (IOM), must plan and implement a national public-private partnership for a prevention and health promotion outreach and education campaign. Second, through the CDC Director, the Secretary must develop and implement a science-based media campaign, according to several specified conditions. Third, in consultation with private-sector experts, the Secretary must develop a website containing information for health providers and consumers regarding specified chronic diseases and conditions. Fourth, through the CDC Director, the Secretary must develop a program to disseminate information about health promotion to health care providers who participate in

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<sup>47</sup> For information about the Federal Advisory Committee Act, see CRS Report R40520, *Federal Advisory Committees: An Overview*, by Wendy R. Ginsberg.

federal health care programs. Fifth, through the CDC Director, the Secretary must develop a Web-based tool that individuals can use to develop personalized prevention plans. Sixth, the Secretary must establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities. Finally, the Secretary must provide guidance and relevant information to states and health care providers regarding preventive and obesity-related services that are available to Medicaid enrollees, including obesity screening and counseling for children and adults. In addition, each state would be required to design a public awareness campaign to educate Medicaid enrollees regarding the availability and coverage of such services.

The section states that funding for these activities would take priority over funding provided through CDC grants for similar purposes, and that no more than \$500 million could be spent on the activities required under this section. There would be authorized to be appropriated SSAN for each fiscal year to carry out these activities.

## **Community Prevention Grants and Related Activities**

### **Sec. 4102. Oral Health Activities**

This section would create a new **PHSA Title III, Part T, *Oral Healthcare Prevention Activities***, comprising a new **Sec. 399LL** that requires the Secretary, through the CDC Director, to establish a five-year national public education campaign on oral health, including prevention of oral diseases such as dental caries, periodontal disease, and oral cancer. The Secretary would be required to ensure that activities targeted toward specific populations were provided in a culturally and linguistically appropriate manner, and that science-based strategies were used to convey messages including, but not limited to, community water fluoridation and dental sealants. The section also would create a new **PHSA Sec. 399LL-1** requiring the Secretary, through the CDC Director, to award grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities. Eligible entities would be community-based providers of dental services (as defined by the Secretary), such as FQHCs, clinics of a state-owned hospital, state or local departments of health, private providers of dental services, certain educational institutions, dental programs of the Indian Health Service or tribes, or national organizations involved in improving children's oral health. The Secretary would be required to utilize information generated from grantees in planning and implementing the public education campaign under Sec. 399LL. The section also would create a new **PHSA Sec. 399LL-2** authorizing the appropriation of SSAN to carry out new PHSA Title III, Part T.

Additionally, the section would amend **PHSA Sec. 317M** to mandate a school-based dental sealant program that is currently discretionary, and to require the Secretary to award program grants to each of the 50 states and territories, and to Indians, Indian tribes, tribal organizations, and urban Indian organizations (as defined in Sec. 4 of the Indian Health Care Improvement Act).

The section also would add a new subsection 317M(d) (and redesignate existing subsections), requiring the Secretary, through the CDC Director, to enter into cooperative agreements with states and territories, and with tribal entities (as defined), to establish oral health leadership and program guidance for data collection and interpretation, delivery systems, and implementation of programs (including dental sealants and community water fluoridation) to improve oral health. There would be authorized to be appropriated SSAN for FY2010 through FY2014.

Finally, the section would require the Secretary to update, improve and implement oral health components in the following national health surveys and surveillance systems: (1) the Pregnancy Risk Assessment Monitoring System (PRAMS), administered by CDC; (2) the National Health and Nutrition Examination Survey (NHANES), administered by CDC; (3) the Medical Expenditures Panel Survey (MEPS), administered by AHRQ; and (4) the National Oral Health Surveillance System (NOHSS), administered by CDC. For NOHSS, there would be authorized to be appropriated SSAN for each of FY2010 through FY2014 to increase participation from the current 16 states to all 50 states, the territories, and the District of Columbia. Also, the Secretary would be required to ensure that NOHSS includes the measurement of early childhood caries.

### **Sec. 4201. Community Transformation Grants**

This section, as amended by Sec. 10403, would require the Secretary, through the CDC Director, to award competitive grants for the implementation, evaluation, and dissemination of evidence-based community preventive health activities, in order to reduce chronic disease rates, address health disparities, and develop a stronger evidence base of effective prevention programming. Eligible entities would be a state or local government agency, a national network of community-based organizations, a state or local non-profit organization, or an Indian tribe. Not less than 20% of such grants would have to be awarded to rural and frontier areas. Grantees would be required to: develop community transformation plans that include the policy, environmental, programmatic, and infrastructure changes needed to promote healthy living and reduce health disparities; and to conduct health promotion activities and evaluations and disseminate findings. The CDC Director would be required to provide appropriate training and technical assistance. Grant funds could not be used to create video games or to carry out any other activities that may lead to higher rates of obesity or inactivity. There would be authorized to be appropriated SSAN for FY2010 through FY2014 to carry out this program.

### **Sec. 4202. Community Wellness Pilot; Medicare Wellness Evaluation**

Subsection 4202(a) would require the Secretary, through the CDC Director, to award grants to state or local health departments or Indian tribes for five-year pilot programs to provide community prevention interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age. Grantees would be required to collaborate with CDC, the Administration on Aging, and relevant local agencies and organizations, and use funds to deliver interventions to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population. Grantees also would be required to conduct health screenings to identify risk factors for cardiovascular disease, stroke, and diabetes, and to ensure that individuals found to have these risk factors receive clinical referral/treatment for follow-up services to reduce such risk.

Grantees would be required to determine whether individuals found to have chronic health conditions have a source of health insurance coverage. Covered individuals would be referred to participating providers. For uninsured individuals, the grantee's community-based clinical partner would be required to assist the individual in determining eligibility for available public coverage options and identify other appropriate community health care resources and assistance programs. Grantees would be required to use funds provided under this program to measure changes in the prevalence of chronic disease risk factors among participants. The Secretary would be required to conduct an annual evaluation of program effectiveness by examining changes in the prevalence of uncontrolled chronic disease risk factors among new Medicare enrollees (or individuals nearing

enrollment) who reside in states or localities receiving grants under this section as compared with national and historical data. There would be authorized to be appropriated SSAN for FY2010 through FY2014 to carry out this subsection.

Subsection 4202(b) would require the Secretary to conduct an evaluation of community-based prevention and wellness programs, and, based on findings, develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries. The evaluation would include an evidence review of literature, best practices, and resources, and an evaluation of existing community prevention and wellness programs sponsored by the Administration on Aging. To fund the evaluation, the Secretary would be required to transfer to CMS \$50 million in total from the Part A and Part B Trust Funds, in whatever proportion the Secretary determines. Activities under this evaluation would not be subject to review under the Paperwork Reduction Act of 1995, which subjects collections of information from the public to clearance by the Office of Management and Budget.

### **Sec. 4204. Immunizations**

This section would amend **PHSA Sec. 317** to provide explicit authority to the Secretary to negotiate and enter into contracts with manufacturers for the purchase of vaccines for adults, and for states to purchase such vaccines at the prices negotiated by the Secretary. The section also would amend subsection 317(j) to permanently reauthorize the program of immunization grants to states.

In addition, the section would add a new **PHSA Section 317(m)**, which would require the Secretary, through the CDC Director, to conduct a demonstration program of grants to states to improve immunization coverage of children, adolescents, and adults. States would be required to use funds provided to implement recommendations of the TFCPS, or other evidence-based interventions. Grantees would be required to report to the Secretary within three years of receiving a grant regarding an evaluation of progress in improving immunization rates in high-risk populations. The Secretary would be required to report to Congress within four years regarding the effectiveness of the program, and recommendations regarding whether it should be extended or expanded. There would be authorized to be appropriated SSAN for FY2010 through FY2014 to carry out this subsection.

Finally, the section would require a GAO study of the impact of vaccine coverage under Medicare Part D on access to those vaccines by beneficiaries who are 65 years of age or older. It would appropriate \$1 million for FY2010 for this study. Nothing in the section or any other provision of the bill could be construed to decrease children's access to immunizations.

### **Sec. 4206. Demonstration Project Concerning Individualized Wellness Plan**

This section would create a new **PHSA Section 330(s)** requiring the Secretary to establish a pilot program in not more than 10 community health centers to test the impact of providing at-risk individuals who use the centers with individualized wellness plans, designed to reduce risk factors for preventable conditions as identified by a comprehensive assessment. A wellness plan could include one or more of the following, as appropriate to an individual's identified risk factors: (1) nutritional counseling; (2) a physical activity plan; (3) alcohol and smoking cessation counseling and services; (4) stress management; (5) dietary supplements that have health claims approved by the Secretary; and (6) compliance assistance provided by a community health center



employee. Risk factors would have to include weight, tobacco and alcohol use, exercise rates, nutritional status, and blood pressure. Wellness plans would have to make comparisons between the individual involved and a control group of individuals with respect to these risk factors. There would be authorized to be appropriated SSAN to carry out this subsection.

### **Sec. 4301. Research on Optimizing the Delivery of Public Health Services**

This section would require the Secretary, through the CDC Director, to fund research on public health services and systems, to include (1) examining evidence-based prevention practices relating to prevention, including comparing community-based public health interventions in terms of effectiveness and cost; (2) analyzing the translation of interventions from academic settings to real world settings; and (3) identifying effective strategies for organizing, financing, or delivering public health services in community settings, including comparing state and local health department structures and systems in terms of effectiveness and cost. Such research would have to be coordinated with the TFCPS.

### **Sec. 4304. Epidemiology and Laboratory Capacity Grants**

This section would amend **PHSA Title XXVIII**, National All-Hazards Preparedness for Public Health Emergencies, adding a new **Subtitle C**, Strengthening Public Health Surveillance Systems, consisting of a new **PHSA Sec. 2821**, Epidemiology-Laboratory Capacity Grants. The purpose would be to establish a grant program to strengthen national epidemiology, laboratory, and information management capacity for the response to infectious diseases and other conditions of public health importance. Eligible entities would be state, local, or tribal health departments, tribal jurisdictions, or academic centers that meet CDC-specified criteria. Grants would be subject to the availability of appropriations. There would be authorized to be appropriated for this program \$190 million for each of FY2011 through FY2013, of which at least \$95 million per fiscal year must be used to award grants for epidemiology and disease control capacity, at least \$60 million per fiscal year for grants for information management capacity, and at least \$32 million per fiscal year for laboratory capacity.

### **Sec. 4306. CHIPRA Childhood Obesity Demonstration Project**

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA; P.L. 111-3) included several quality of care provisions. One such provision instructed the Secretary to conduct a demonstration project to develop a comprehensive and systematic model for reducing child obesity. CHIPRA authorized the appropriation of \$25 million for the period FY2009 through FY2013 for the child obesity demonstration. This section would amend **SSA Sec. 1139A(e)** by replacing the authorization of appropriations with an appropriation of \$25 million for the period of FY2010 through FY2014.

### **Sec. 10407. Better Diabetes Care**

This section would require the Secretary, in collaboration with CDC, to prepare and publish a biennial national diabetes report card, and, to the extent possible, a report card for each state. Report cards would aggregate information related to diabetes and prediabetes, including preventive care, risk factors, and outcomes. The section also would require the Secretary, acting through the CDC Director, to promote the education and training of physicians on the importance

of birth and death certificate data, encourage state adoption of the latest standard revisions of birth and death certificates, and work with states to re-engineer their vital statistics systems. This section also would allow the Secretary to promote improvements to the collection of diabetes mortality data. The Secretary would also be required, in collaboration with IOM, to study, and report within two years of enactment, regarding the impact of diabetes on medical practice, and the appropriateness of medical education regarding diabetes. There would be authorized to be appropriated SSAN to carry out this section.

### **Sec. 10411. Congenital Heart Disease Programs**

Subsection 10411(b)(1) would amend Part P of Title III of the PHSa, as amended by Sec. 5405, adding a new **PHSA Sec. 399V-2**. This new section would authorize the Secretary, acting through the CDC Director, to enhance and expand infrastructure to track the epidemiology of congenital heart disease; to organize such information into a nationally representative surveillance system; or award a grant to one eligible entity to undertake these activities. Sec. 399V-2(d) would require that this surveillance system be made available to the public and Sec. 399V-2(e) would require the Secretary to ensure that the surveillance system is maintained in a manner that complies with the HIPAA Privacy Rule. Sec. 399V-2(c) allows that the surveillance system may include certain content, including, for example, information concerning the incidence and prevalence of congenital heart disease.

Subsection 10411(b)(2) would amend Subpart 2 of Part C of Title IV of the PHSa by adding at the end a new **PHSA Sec. 425**. Sec. 425(a) would authorize the Director of the NIH National Heart, Lung, and Blood Institute to expand, intensify and coordinate research with respect to congenital heart disease. Sec. 425(b) would authorize the Director of the Institute to coordinate research efforts related to congenital heart disease and may develop research networks, and Sec. 425(c) would require the Director of the Institute to consider, in carrying out the activities under this section, the application of this research to minority and medically underserved populations.

Subsection 10411(c) would authorize to be appropriated SSAN for each of FY2011 through FY2015.

### **Sec. 10413. Young Women's Breast Health Awareness**

This section would add a new Part V to PHSa Title III, *Programs Relating to Breast Health and Cancer*, consisting of a new **PHSA Sec. 399NN**, which would require the Secretary, through the CDC, to conduct a national evidence-based education campaign to increase awareness among young women about breast cancer. This campaign would be required to provide evidence-based messages and materials developed by the CDC and an advisory committee established under this section. As part of this campaign, the Secretary would be required to award grants to entities to establish national multimedia campaigns oriented to young women. Finally, Sec. 399NN(a) would require the Secretary, within 60 days of enactment, to establish an advisory committee to assist in conducting the education campaign.

Sec. 399NN(b) would require the Secretary, through the CDC, to conduct an education campaign among health care professionals to increase awareness of breast health; on how to provide counseling to young women about their breast health; concerning the importance of discussing healthy behaviors; on when to refer patients to a genetics health professional; on how to provide

counseling that addresses long-term survivorship of young women diagnosed with breast cancer; and on when to provide referrals to credible organizations.

Sec 399NN(c) would require the Secretary, through the CDC, to conduct prevention research on breast cancer in younger women, as specified. The NIH Director would be required to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women. Sec. 399NN(d) would require the Secretary to award grants to organizations to provide health information from credible sources to young women diagnosed with breast cancer. Sec. 399NN(e) would provide that the Secretary not duplicate other existing federal breast cancer education efforts. Sec. 399NN(f) would require the Secretary to measure young women's awareness regarding breast health; the number of young women using information regarding lifestyle interventions that foster healthy behaviors; the number receiving regular clinical breast exams; and the number who perform breast self exams. The Secretary would be required to measure such activities at least every three years and report to Congress on the findings. Sec. 399(h) would define young women as meaning between the ages of 15 and 44.

Sec. 399NN(h) would authorize the appropriation of \$9 million for each of FY2010 through FY2014.

### **Sec. 10501(g). National Diabetes Prevention Program**

This section would create a new **PHSA Sec. 399V-3** requiring the Secretary, through the CDC, to establish a national diabetes prevention program, targeted at high-risk adults, with specified program components. Entities eligible for program grants would be state or local health departments, tribal organizations, national networks of community-based non-profits focused on health and well-being, academic institutions, or other entities, as the Secretary determines. There would be authorized to be appropriated SSAN for FY2010 through 2014.

## **Stricken Provision**

### **Secs. 4401 and 10405. Sense of the Senate Concerning CBO Scoring**

Sec. 10405 strikes Sec. 4401 from the Senate-passed bill. Sec. 4401 (which remains in the Senate-passed version of the bill, although it is stricken) states that the Senate finds that the costs of prevention programs are difficult to estimate, in part because prevention initiatives are hard to measure, and because results may occur outside the 5- and 10-year budget windows currently considered by the CBO. Sec. 4401 further states that it is the sense of the Senate that Congress should work with CBO to develop better methodologies for scoring progress to be made in prevention and wellness programs.

## **Maternal and Child Health**

### **Maternal and Early Childhood Home Visitation**

Home visitation is used to deliver support and services to families or individuals in their homes. Early childhood home visitation programs typically seek to improve maternal and child health; early childhood social, emotional, and cognitive development; and family/parent functioning.

Depending on the particular model of early home visitation being used, the visitors may be specially trained nurses, other professionals, or paraprofessionals. Visits, which often occur weekly, may begin during a woman's pregnancy or some time after the birth of a child and may continue until the child reaches his/her second birthday (in some cases) or enters kindergarten. Participation of families is voluntary. Early childhood home visitation programs are in operation in all 50 states and the District of Columbia. In addition to private and state and local public funds provided for early childhood home visitation, a number of federal programs have been used to support home visitation programs. Among others, these include Medicaid, the Temporary Assistance for Needy Families (TANF) block grant, the Social Services Block Grant, Community-Based Grants to Prevent Child Abuse and Neglect, the Maternal and Child Health (MCH) block grant, Healthy Start, and Early Head Start. However, there is no dedicated federal program that provides grant funds to support home visitation programs for families with young children and those expecting children. As part of the FY2010 President's Budget, the Administration sought legislative authorization and requested mandatory funding for such a program.<sup>48</sup>

SSA Title V authorizes the MCH block grant program. The MCH block grant, which is administered by HRSA, allocates funding to states based on their relative share of children in the nation who live in families with income below the federal poverty level and certain other factors. States use the Title V funds to design and implement a wide range of maternal and child health programs. States must submit annual reports on Title V-funded activities and demonstrate progress made towards standardized MCH status indicators (e.g., live birth rate, low birth weight, maternal death rates, and poverty levels) in order to facilitate comparison between states. The Secretary compiles the data submitted by the states in an annual report to Congress. States are required to audit and report on the use of their funds at least once every two years.

### **Sec. 2951. Home Visitation Grant Program**

This section would amend Title V to add a new **SSA Sec. 511, *Early Childhood Home Visitation Programs***. The new provision would require states, as a condition for receiving the MCH block grant funds for FY2011, to conduct a needs assessment, separate from but coordinated with the assessment currently required to receive that block grant, and those required under the Head Start Act, and the Child Abuse Prevention and Treatment Act. The needs assessment would identify (1) communities that have concentrations of poverty, crime, domestic violence, high school drop-outs, substance abuse, unemployment, child maltreatment and a range of maternal and child health risk factors (such as premature births, low-birth weight infants, and high infant mortality); (2) the quality and capacity of existing early childhood home visitation activities in the state, including the number and types of individuals and families receiving these services, gaps in those services, and the extent to which the current programs meet the needs of parents and caregivers of young children and individuals expecting to be parents; and (3) the state's capacity for providing substance abuse treatment and counseling services to those who need them.

In addition, this section would direct the HHS Secretary to award grants to states, Indian tribes and certain other tribal entities, and, in limited circumstances, non-profit organizations for support of early childhood home visitation programs. Families eligible to receive these services would include pregnant women, men expecting to become fathers, and parents and other

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<sup>48</sup> For more information, see CRS Report R40705, *Home Visitation for Families with Young Children*, by Emilie Stoltzfus and Karen E. Lynch.

caregivers of children who haven't yet entered kindergarten. Grantees of this new program would be required to establish quantifiable three- and five-year benchmarks to measure improvements for the families participating in the program in the following areas: maternal and newborn health; childhood injury prevention, reduction of emergency department visits, and prevention of child maltreatment; school readiness and achievement; reductions in crime or domestic violence; family economic self-sufficiency, and coordination and referrals to community resources and supports. Grantees that failed to meet the three-year benchmarks in at least four of the specified areas would have to develop and implement a plan to improve outcomes. Grantees that continued to show a lack of improvement, or that failed to report on benchmarks, could have their grant terminated. By December 31, 2015, the grantees would be required to submit a report to the Secretary demonstrating progress on the three- and five-year benchmarks.

To receive funds grantees would be required to submit an application seeking early childhood home visitation funds and to assure that they would establish procedures to ensure participation of families in the program is voluntary and that services are provided to each family based on an individual assessment for that family. Further they would need to describe the service delivery model they intend to support. In general, a grantee would only be permitted to use these funds to support early childhood home visitation programs that adhere to clear evidence-based models of service delivery that, among other criteria, have been rigorously evaluated. However, they would be permitted to use no more than 25% of the award to support promising new approaches to achieving the desired improvements for families served. Among other things, grantees would also need to assure that they give priority to providing services to families who are determined to be at-risk by the needs assessment and other indicators, including low-income, young maternal age, and involvement with child welfare.

The HHS Secretary would be required to provide technical assistance to grantees receiving early childhood home visitation and to support an ongoing research program designed to increase knowledge about the implementation and effectiveness of home visiting programs. Further the HHS Secretary would need to appoint an expert panel to design an evaluation of the home visitation grant program, including an analysis of the state needs assessments and the impact of early childhood home visitation programs on various child and parent outcomes and by grant or contract, would be required to conduct such an evaluation and report the results to Congress no later than March 31, 2015. The Secretary also would be required to submit to Congress, by December 31, 2015, a final report on the activities conducted with funding from this grants program. The report would include information on: (1) the extent to which grantees demonstrated improvement, (2) any technical assistance provided to grantees implementing corrective action plans, and (3) recommendations for any further legislative or administrative action.

This section would appropriate a total of \$1.5 billion for FY2010 through FY2014 for the home visitation grant program: \$100 million for FY2010; \$250 million for FY2011; \$350 million for FY2012; \$400 million for FY2013; and \$400 million for FY2014. Of the amount appropriated for this program, 3% would be reserved for research and evaluation, and 3% would be reserved for making grants to tribal entities for home visitation services to Indian families. The grant program supported by these appropriated funds would be collaboratively administered by two HHS agencies: the ACF and the MCH Bureau, which is within HRSA.

## Postpartum Depression

### Sec. 2952. Support, Education, and Research for Postpartum Depression

This section would encourage the Secretary to expand and intensify specified types of research—including epidemiology, improved screening and diagnosis, clinical research, and public education—to expand our understanding of the causes and treatments for postpartum depression and related conditions. The section also states that it is the sense of Congress that the Director of the National Institute of Mental Health (NIMH) may conduct a nationally representative longitudinal study (during the period FY2010-FY2019) on the relative mental health consequences for women of resolving a pregnancy, intended and unintended, in various ways (e.g., carrying the pregnancy to term and placing the child for adoption, miscarriage, abortion). The study could assess the incidence, timing, magnitude and duration of the immediate and long-term mental health consequences of these pregnancy outcomes. Subject to the completion of such a study, beginning within five years of enactment and periodically thereafter for the duration of the study, the NIMH Director could submit to Congress reports on the study's findings.

Additionally, this section would create a new **SSA Sec. 512, *Services to Individuals with a Postpartum Condition and their Families***. The new section would authorize the Secretary to award grants, in addition to any other funds that would be provided to states under Title V, to eligible entities to establish, operate and coordinate effective and cost-efficient systems for the delivery of essential services and support services to individuals with postpartum conditions and their families. Grant funds could be used to carry out certain activities that provide education and services with respect to the diagnosis and management of postpartum conditions, such as delivering or enhancing outpatient and home-based services, inpatient care management, improving quality, availability and organization of health care and social services, and providing earlier diagnosis and treatment. Grantees would have to agree to various requirements that the Secretary would establish, and some other general requirements of the title. The Secretary could integrate this program with other grant programs within Sec.330 of the PHSA.

Eligible entities would include public or nonprofit private entities, state or local government public-private partnerships, recipients of Healthy Start grants, public or nonprofit private hospitals, community-based organizations, hospices, ambulatory care facilities, CHCs, migrant health centers, public housing, primary care centers, and homeless health centers. The section would authorize the appropriation of \$3 million for FY2010, and SSAN for FY2011 and FY2012 to carry out the grant program. The Secretary would be required to study the benefits of screening for postpartum conditions and, within two years of enactment, submit a report to Congress.

## Personal Responsibility Education and Abstinence Education

SSA Sec. 510 authorizes a state formula grant program to support abstinence education programs. Funds are awarded to states based on the proportion of low-income children in each state compared to the national total, and may only be used for teaching abstinence. To receive funding, a state must match every \$4 in federal funds with \$3 in state funds. Sec. 510 provided \$50 million for each of five years (FY1998-FY2003). Although the program has not been reauthorized, the latest of several extensions, which was included in the Medicare Improvements for Patients and Providers Act (MIPAA) of 2008, continued funding at the \$50 million annual rate through June

30, 2009.<sup>49</sup> Funds are administered by the Administration for Children and Families (ACF) within HHS.

PHSA Title XX, Adolescent Family Life (AFL) Demonstration Projects, authorizes a number of voluntary teen pregnancy prevention, counseling, and related programs. The HHS Secretary may award demonstration grants to public or nonprofit private entities to provide care and/or prevention services (including educational services) according to specified requirements. Grantees are required to evaluate program results and report to the Secretary, and the Secretary is authorized to support research on teen pregnancy prevention. Title XX AFL funds are administered by the Office of Population Affairs within HHS. PHSA Title X, Population Research and Voluntary Family Planning Programs, authorizes grants for comprehensive voluntary family planning services, education, and research, including such activities for adolescents. Title X Family Planning funds also are administered by the Office of Population Affairs within HHS. PHSA Sections 318 and 318A authorize grants for technical assistance and voluntary services (including screening, treatment, counseling, and education) to address sexually-transmitted diseases in women (these provisions do not explicitly address adolescents). These funds are administered by the Centers for Disease Control and Prevention within HHS. In addition, there are several other federally-funded programs that provide pregnancy prevention information and/or services to teens.<sup>50</sup>

### **Sec. 2953. Personal Responsibility Education**

This section would add a new **SSA Sec. 513**, *Personal Responsibility Education*, to be administered by the ACF. The new section would establish a state formula grant program of \$75 million for each of the fiscal years FY2010 through FY2014 to enable states to operate a new Personal Responsibility Education program. Under the funding allocation formula, each state would receive an amount based on the size of its youth population (persons ages 10 through 19) as a percentage of the national youth population. However, each state would receive a minimum allotment of at least \$250,000 for each of FY2010 through FY2014.

The section defines a Personal Responsibility Education program as a program that is designed to educate adolescents on both abstinence and contraception for prevention of pregnancy and sexually transmitted infections, including HIV/AIDS, and at least three of the six stipulated adulthood preparation subjects. The adulthood preparation subjects are: (1) healthy relationships, including marriage and family interactions; (2) adolescent development, including the development of healthy attitudes and values about adolescent growth and development, body image, racial and ethnic diversity, and other related subjects; (3) financial literacy; (4) parent-child communication; (5) educational and career success, including developing skills for employment preparation, job seeking, independent living, financial self-sufficiency, and workplace productivity; and (6) healthy life skills, including goal-setting, decision making, negotiation, communication and interpersonal skills, and stress management.

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<sup>49</sup> For more information, see CRS Report RS20873, *Reducing Teen Pregnancy: Adolescent Family Life and Abstinence Education Programs*, by Carmen Solomon-Fears.

<sup>50</sup> These programs include Medicaid Family Planning, the Maternal and Child Health block grant, the Temporary Assistance for Needy Families (TANF) program, the Title XX Social Services block grant, and a couple of teen pregnancy prevention programs administered by the Centers for Disease Control and Prevention.

A Personal Responsibility Education program would be required to: (1) replicate evidence-based effective programs or substantially incorporate elements of effective programs that have been proven through rigorous scientific evaluation to delay sexual activity, increase condom or contraceptive use for sexually active youth, or reduce pregnancy among youth; (2) be medically accurate and complete; (3) include activities that educate youth who are sexually active about responsible sexual behavior with regard to both abstinence and the use of contraception; (4) place substantial emphasis on both abstinence and contraception for the prevention of pregnancy among youth and sexually transmitted infections; (5) provide age-appropriate information and activities; and (6) provide the acceptable activities within the cultural context that is most appropriate for individuals in the particular population group to which they are directed.

In order to receive its allotment, a state would be required to submit an application to the HHS Secretary that includes (1) youth pregnancy rates and youth birth rates for the state for the most recent year for which data are available (and trend data for the most recent five years); (2) state-established goals for reducing youth pregnancy rates and youth birth rates; and (3) a description of the state's plan for using its allotment to achieve the state-established goals to reduce youth pregnancy rates and youth birth rates in the state, especially among youth populations that are the most high-risk or vulnerable for pregnancies or otherwise have special circumstances.

This section would provide that a state's allotment would remain available for expenditure by the state through the end of the second succeeding fiscal year. States that did not apply for the funds in FY2010 or FY2011 would not be eligible to apply for the funds allotted for the period FY2010 through FY2014. The HHS Secretary would be required to use unexpended funds resulting from states not submitting an application, or states not expending their allotments for the Personal Responsibility Education program, for three-year grants to local organizations and entities (including faith-based organizations or consortia) to conduct Personal Responsibility Education programs in states that chose not to apply for Personal Responsibility Education program funding. Grantees of these three-year (FY2012-FY2014) awards would be required to agree to participate in a rigorous federal evaluation of their programs.

The HHS Secretary would be required to annually reserve \$10 million (out of the \$75 million annual appropriation) for grants to entities to implement innovative youth pregnancy prevention strategies and target services to high-risk, vulnerable, and culturally under-represented youth populations. An entity that is awarded a grant would be required to participate in a rigorous federal evaluation of the activities funded by the grant.

The HHS Secretary would be required to reserve 5% of remaining funds for allotments to Indian tribes and tribal organizations. The HHS Secretary would be required to reserve 10% of remaining funds for expenditures by the Secretary to (1) provide (directly or through a competitive grant process) research, training, and technical assistance for the programs and activities funded by the Personal Responsibility Education program allotments or grants, and (2) evaluate the program and activities funded by the Personal Responsibility Education program allotments or grants.

## **Sec. 2954. Restoration of Funding for Abstinence Education**

This section would amend **SSA Sec. 510** by appropriating \$50 million for each of FY2010 through FY2014 for the abstinence education grant program.



## **Support for Pregnant and Parenting Teens and Women**

### **Secs. 10211-10214. Pregnancy Assistance Fund**

These sections would create and fund a new competitive grant program to states to help pregnant and parenting teens and women. Sec. 10211 would define several words and terms that are associated with the new pregnancy assistance fund. Sec. 10212 would create a new Pregnancy Assistance Fund that would require the HHS Secretary (in collaboration and coordination with the Secretary of Education) to establish a competitive grant program to states to help pregnant and parenting teens and women. To qualify for a grant, a state must submit an application to the HHS Secretary, containing prescribed information, including the name of the state agency designated to receive and administer grant funds.

Sec. 10213 would allow states to make pregnancy assistance grant funds available to (1) institutions of higher education, (2) high schools and community service centers, (3) a state's attorney general, (for services or technical assistance and training pertaining to violence against eligible pregnant women), and/or (4) to increase public awareness and education.

Pursuant to the bill, a state would be able to make grant funds available to eligible institutions of higher education to enable them to establish, maintain, or operate pregnant and parenting student services. Such services would include a needs assessment on campus and within the local community to determine pregnancy and parenting resources and to set goals for improving such resources for pregnant, parenting, and prospective parenting students, and improving access to such resources. An institution of higher education that receives grant funds would have to annually assess its performance in meeting the following needs of pregnant or parenting students: (1) inclusion of maternity coverage and the ability to include additional family members in student health care; (2) family housing; (3) child care; (4) flexible academic scheduling; (5) education to improve parenting skills; (6) maternity and baby clothing, baby food, baby furniture, and similar material items; and (7) post-partum counseling. Among other things, higher education institutions that receive grant funds would be required to identify public and private service providers (located on campus or within the local community), establish programs with such providers to meet the specified needs of pregnant or parenting students, assist eligible persons in locating and obtaining appropriate services, and make necessary referrals for prenatal care and delivery, infant or foster care, or adoption.

Higher education institutions that receive grant funds would be required to submit an annual report to the state. The state would be required to prepare and submit a report to the Secretary on findings related to the grant funds. Institutions of higher education that receive grant funds would have to match 25% of the grant amount from non-federal funds.

Under the bill, a state would be able to make grant funds available to eligible high schools and community service centers to enable them to establish, maintain, or operate pregnant and parenting student services in the same general manner and in accordance with the conditions and requirements imposed on institutions of higher education (described above), except that matching funds would not be required.

In addition, the bill stipulates that a state would have the flexibility to provide grant funds to its attorney general (if the attorney general applies for grant funds) to help statewide offices provide intervention services and supportive services for eligible pregnant women who are victims of domestic violence, sexual violence, sexual assault, or stalking. Under the bill, a state's attorney

general would be allowed to provide technical assistance and training to (1) federal, state, tribal, territorial, and local governments, law enforcement agencies, and courts; (2) professionals working in legal, social service, and health care settings; (3) nonprofit organizations; and (4) faith-based organizations. A state would have the authority to use grant funds to increase public awareness and education concerning any of the new services available to eligible pregnant and parenting teens and women or other relevant resources available to such persons.

Sec. 10214 would authorize and appropriate \$25 million annually for ten years (FY2010-FY2019) for the new pregnancy assistance fund.

## **Health Care Needs of Youth Aging Out of Foster Care**

Under the federal foster care program (SSA Title IV-E) a state is required to have in place a case review system for each child in foster care to, among other things, periodically review the child's status in foster care and to develop and carry out a permanency plan for the child. The case review system must ensure that a transition plan is developed for (and with) any youth in foster care for whom the state's responsibility is expected to end because the youth has reached the age of majority (i.e., 18 years of age or a later age, up to age 21, if elected by the state). The plan must be developed during the 90-day period immediately prior to date on which the youth is expected to age out of foster care and it must include specific options on housing, health insurance, education, local opportunities for mentors and continuing support services, and workforce supports and employment services. Under the Chafee Foster Care Independence Program (CFCIP; SSA Sec. 477), states receive funds to provide independent living services for youth who are expected to age out of foster care and for those who have already aged out of care. As part of their application for these funds, states must provide certain certifications regarding how the programs will be carried out. Finally, under the Stephanie Tubbs Jones Child Welfare Services Program (SSA Title IV-B, Subpart 1), states are required to develop a plan for the ongoing oversight and coordination of health care services for children in foster care. The state child welfare agency and the state agency that administers Medicaid must coordinate and collaborate in the development of this plan, and the plan must outline specific steps to ensure that children in foster care have their health care needs identified and appropriately met and that medical information for children in foster care is updated and appropriately shared.

### **Sec. 2955. Health Care Power of Attorney**

This section would amend **SSA Sec. 475(5)(H)** to require that the mandatory transition plan for a youth who is about to age out of foster care include information about the importance of designating another individual to make health care treatment decisions on behalf of the youth if he or she becomes unable to participate in these decisions and either does not have a relative who would be authorized to make these decisions under state law or does not want that relative to make those decisions. In addition, the transition plan would also be required to provide the youth with the option to execute a health care power of attorney, health care proxy, or other similar document recognized under state law.

This section also would amend **SSA Sec. 477(b)(3)** to require states, as part of their application for CFCIP funds, to certify that foster care or former foster care adolescents receiving these independent living services receive education about: (1) the importance of designating an individual to make health care treatment decisions for them if appropriate; (2) whether a health

care power of attorney, health care proxy, or other similar document is recognized under state law; and (3) how to execute such a document if desired.

Finally this section would amend **SSA Sec. 422(b)(15)(A)** to require that the health care oversight plan developed collaboratively between the state child welfare agency and the state Medicaid agency outline steps to ensure that the health-care related components of the transition plan for youth aging out of foster care are met. These would include options for health insurance, information about a health care power of attorney, health care proxy, or other similar document recognized by state law, and the option to execute such a document. All of these requirements would become effective on October 1, 2010.

## **Behavioral Health**

### **Background and Issues**

Existing behavioral health programs authorized under PHS A Title V and Title IX provide funding for prevention and treatment of mental health and substance abuse problems. This funding is provided through the HHS Substance Abuse and Mental Health Services Administration (SAMHSA). Appropriations authorities for most of the Title V programs have expired, though many of them continue to receive funding.<sup>51</sup> Schools and training programs in social work are generally not eligible for funding under PHS A Title VII, with the exception of training programs in health administration under Sec. 769. In contrast, most graduate programs in mental and behavioral health are generally eligible for broad health professions training grants under Title VII. PHS A Title XXVII, Sec. 2705 requires insurers who choose to offer coverage for behavioral health to provide it on par with their coverage for physical health conditions.

In 2007, about 11% of Americans aged 18 or older (23.7 million) in the United States experienced serious psychological distress, such as anxiety and mood disorders, that resulted in functional impairment that impeded one or more major life activities. During the same year, an estimated 8% of Americans aged 12 or older (19.9 million) were current users<sup>52</sup> of illicit drugs.<sup>53</sup> The behavioral health care system confronts numerous issues including access to and availability of services, quality of care, insurance coverage and payment, and coordination of care.<sup>54</sup>

H.R. 3590, as passed by the Senate, would address behavioral health issues primarily in the following areas: coordinated care for individuals with mental disorders and co-occurring physical illness, education and training of mental and behavioral providers, mental health parity, and establishing centers of excellence to treat depression.

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<sup>51</sup> For more information on SAMHSA, see CRS Report RL33997, *Substance Abuse and Mental Health Services Administration (SAMHSA): Reauthorization Issues*, by Ramya Sundararaman.

<sup>52</sup> A “current user” is defined as someone who used an illicit drug during the month prior to the survey interview.

<sup>53</sup> Department of Health and Human Services: Substance Abuse and Mental Health Services Administration, *National Survey on Drug Use and Health*, 2007, <http://www.oas.samhsa.gov/NSDUHlatest.htm>.

<sup>54</sup> For more information on issues related to the mental health care delivery system, see CRS Report R40536, *The U.S. Mental Health Delivery System Infrastructure: A Primer*, by Ramya Sundararaman.

### **Sec. 1311(j). Applicability of Mental Health Parity to Qualified Plans**

This paragraph would apply existing mental health parity rules in **PHSA Sec. 2726** to qualified health benefits plans<sup>55</sup> in the same manner and to the same extent as they apply to health insurance issuers and group health plans.

### **Sec. 5604. Co-locating Care in Community-Based Mental Health Settings**

This section would create a new **PHSA Sec. 520K**, *Grants for Co-Locating Primary and Specialty Care in Community-Based Mental Health Settings*, requiring the Secretary to fund demonstration projects for providing coordinated care to individuals with mental illness and co-occurring primary care conditions and chronic diseases. Primary and specialty care services would be co-located in community-based mental health settings. Grantees would be required to use the grant funds to provide specific services such as primary care services, diagnostic and laboratory services, and screenings for the defined special populations, and certain specialty care services. Not more than 15% of the funds could be used for information technology or facility improvements or modifications. Within 90 days of expiry of the grant, grantees would have to submit to the Secretary an evaluation of the effectiveness of the activities carried out under the grant. There would be authorized to be appropriated \$50 million for FY2010 and SSAN for each of FY2011 through FY2014 to carry out this section.

### **Sec. 5306. Mental and Behavioral Health Education and Training Grants**

This section would amend **PHSA Title VII, Part D** by deleting Sec. 757 (authorizing appropriation for Part D through FY2002), redesignating Sec. 756 (as amended by Sec. 5103 of the bill) as Sec. 757, and adding a new **PHSA Sec. 756**, *Mental and Behavioral Health Education and Training Grants*. The new section would authorize the Secretary to award grants to: (1) eligible institutions of higher education to support the recruitment and education of students in social work programs, interdisciplinary psychology training programs, and internships or field placement specified types of programs related to child and adolescent mental health; and (2) state licensed mental health organizations to train paraprofessional child and adolescent mental health workers.

The section would require at least four of the grant recipients to be historically black colleges or universities, or other minority-serving institutions. For grants for education and training in social work, priority would be given to applicants that are accredited by the Council on Social Work Education, have a graduation rate of at least 80% for social work students, and are able to recruit from and place social workers into areas with a high need and high demand population. For grants in graduate psychology, priority would be given to institutions that focus on the needs of specified vulnerable groups. For grants to train child and adolescent mental health professionals, priority would be given to applicants that, among other things: (1) have shown they are able to collect data on their students who are trained in child and adolescent mental health and the populations served by those students after graduation; (2) are familiar with evidence-based methods; and (3) have programs designed to increase the number of professional serving and coming from high-priority populations, and who plan to serve in HPSAs, medically underserved areas, or medically underserved populations.

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<sup>55</sup> A qualified health benefits plan is one that meets the requirements set forth Sec. 1301 of S. 3590.

For grants to train paraprofessional child and adolescent mental health workers, priority would be given to applicants that, among other things: (1) have demonstrated the ability to collect data on the number of child and adolescent mental health workers trained and the populations they serve upon completion of the training; (2) are familiar with evidence-based methods; (3) have programs designed to increase the number of child and adolescent mental health workers serving high-priority populations; (4) offer curriculum taught collaboratively with a family; and (5) provide services through a community mental health program described in PHSA Sec. 1913(b)(1).

For FY2010 through FY2013, the section would authorize to be appropriated \$8 million for training in social work, \$12 million for training in graduate psychology, \$10 million for training in professional child and adolescent mental health, and \$5 million for training in paraprofessional child and adolescent work.

### **Sec. 10410. Centers of Excellence for Depression**

This section would add a new **PHSA Sec. 520B**, requiring the Secretary, acting through the SAMHSA Administrator, to award five-year grants on a competitive basis to eligible entities to establish national centers of excellence for depression. These Centers would be required to engage in activities related to the treatment of depressive disorders, as defined. If funds authorized are appropriated in the amounts provided, the Secretary would be required to establish no more than 20 Centers no later than one year after enactment; and no more than 30 Centers no later than September 30, 2016. One grant recipient would be designated as the coordinating center, as specified. The Secretary would be prohibited from funding an entity unless they agree to make non-federal contributions toward grant activities equal to \$1 for every \$5 of federal grant funds. Each Center would be required to carry out specified activities, including developing improved treatment standards, clinical guidelines, diagnostic protocols, and care coordination practices; and expanding translational research through collaboration of Centers and community-based organizations. The coordinating Center would be required to establish and maintain a national database. The Secretary, acting through the SAMHSA Administrator, would be required to establish performance standards for each Center and the network of Centers and would issue Center report cards, as described. Based upon the report cards, the Secretary would be required to make recommendations to (1) the Centers regarding improvements; and (2) Congress for expanding the Centers. The Secretary would be required to arrange for an independent third party review to conduct an evaluation of the network of Centers. To carry out this section, there would be authorized to be appropriated \$100 million for each of FY2011 through FY2015, and \$150 million for each of FY2016 through FY2020. Of the amount appropriated for a fiscal year, the Secretary would be required to determine the allocation for each Center which may not be more than \$5 million to each Center, and no more than \$10 million to the coordinating center.

## **Quality**

### **Background and Issues**

Numerous stakeholders, including policymakers, have engaged in a wide range of efforts to try to address the issue of health care quality. These efforts have generally focused on improving and refining metrics for measuring the quality of care delivered in a number of settings; publicly reporting comparative information on quality performance; and, in some cases, using metrics as the basis for payment policies to demand provider accountability (value-based purchasing).

However, these efforts have not generally been guided by a single federal strategy, entity, or set of priorities or goals, nor have they benefitted from a coordinated infrastructure specifically devoted to improving health care quality. The following describes provisions in H.R. 3590, as passed by the Senate, that would address the issues of quality measurement, patient safety/quality improvement, care coordination, improvement of Medicare and Medicaid nursing homes and other long term care facilities, and comparative effectiveness research.

## **National Strategy to Improve Health Care Quality and Quality Measurement**

There are no provisions in current law that require the development of national priorities for performance improvement (directed either at the Secretary or AHRQ). However, the Secretary is required by law to have in effect a contract with a consensus-based entity to perform a number of duties, including to synthesize evidence and convene stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings.

AHRQ has significant existing statutory authorities under PHSA Title IX with respect to the development of quality measures. This includes promoting health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality. In addition, AHRQ's role includes the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes, and the compilation and dissemination of health care quality measures developed in the private and public sector.

Current law does not set forth a process for, or require, multi-stakeholder input into the selection of quality measures by the Secretary for use in CMS's quality programs, such as Medicare's Physician Quality Reporting Initiative (PQRI) or the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

H.R. 3590 includes the following five sections addressing quality measurement, which together would require the development of an explicit national effort to establish a national strategy for quality improvement; establish an interagency working group to advance quality efforts at the national level; develop a comprehensive repertoire of quality measures; and formalize processes for quality measure selection, endorsement, data collection and public reporting of quality information.

### **Sec. 3011. National Strategy**

This section would create in Title III a new **PHSA Part S, Health Care Quality Programs, Subpart I, National Strategy for Quality Improvement in Health Care**. It would include a new **Sec. 399HH**, which would require the Secretary to establish a national strategy for healthcare quality improvement to improve the delivery of health care services, outcomes, and population health, and to identify national priorities for quality improvement. This section would require the Secretary to ensure that the national priorities would address health care provided to patients with high-cost chronic diseases; improve federal payment policy to emphasize quality and efficiency; have the greatest potential for improving health outcomes, efficiency, and patient-centeredness of care; reduce health disparities; and address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggregation techniques, among others. The

national strategy would be required to include a comprehensive strategic plan to achieve the national priorities for quality improvement and would be required to address a number of issues, including coordination among agencies within the Department and strategies to align public and private payers with regard to quality and patient safety efforts, among others. The Secretary would also be required to create a health care quality website to make public the national priorities and other information the Secretary deems appropriate.

### **Sec. 3012. Interagency Working Group on Health Care Quality**

This section would require the President to convene a working group to be known as the Interagency Working Group on Health Care Quality. The goals of this group would include achieving collaboration, cooperation, and consultation between federal departments and agencies with respect to quality improvement activities; avoiding duplication of quality improvement efforts; developing a streamlined process for quality reporting and compliance requirements; and assessing alignment of quality efforts in the public sector with private sector initiatives. The Working Group would be composed of senior level representatives of specified federal agencies and departments; the Secretary would serve as the Chair; and Members would serve as Vice Chair, on a rotating basis. The Working Group would be required to submit a report describing its progress and recommendations to relevant Committees of Congress and to make this report publicly available.

### **Sec. 3013. Quality Measure Development**

This section would create in Title IX a new **PHSA Part D, Health Care Quality Improvement, Subpart I, Quality Measure Development**. It would include a new **PHSA Sec. 931**, which would require the Director of AHRQ to identify gaps where no quality measures exist or where existing measures need improvement, updating or expansion consistent with the national strategy under **Sec. 399HH**. In identifying these gaps, the Director would be required to consider the gaps identified by the entity with a contract under SSA Sec. 1890(a) and other stakeholders. The Director would be required to make a report on any gaps identified, and the process used to identify the gaps, available to the public. This section would require the Director to fund or enter into agreements with eligible entities for purposes of developing, improving, updating, or expanding quality measures in areas identified as gap areas. The Director would be required to give priority to the development of quality measures that allow for the assessment of health outcomes and functional status of patients; the management and coordination of health care across episodes of care and care transitions; health disparities; and the efficiency of care, among other things. An entity receiving funds under this section would be required to use the funds to develop quality measures that allow, to the extent practicable, data on measures to be collected using HIT, that are free of charge to users, and that are publicly available, among other things. The funds under this section would be able to be used by the Director to update and test quality measures endorsed by the entity with a contract under SSA Sec. 1890(a). This section, as amended by Sec. 10303(a) of the bill, would require the Secretary to develop, and periodically update, provider-level outcome measures for hospitals and physicians, and other providers as determined appropriate by the Secretary. The measures would be required to include outcome measurement for acute and chronic disease and primary and preventive care. In developing the outcome measures, the Secretary would be required to seek to address risk adjustment, accountability, and sample size issues; and include the full scope of services that comprise a cycle of care. This section would authorize to be appropriated \$75 million for each of FY2010 through FY2014.

### **Sec. 3014. Quality Measurement**

This section would amend **SSA Sec. 1890(b)** to outline new duties for a consensus-based entity. This section would require the entity to convene multi-stakeholder groups to provide input on the selection of quality measures and national priorities. The quality measures would be those used pursuant to specified SSA sections; those used in reporting performance information to the public; and those used in health care programs other than for use under this bill. Those data sets that are used for the purposes of classification systems used in establishing payment rates under this title would not be considered quality measures for purposes of this section. The entity would be required to transmit to the Secretary the input of multi-stakeholder groups no later than February 1<sup>st</sup> of each year, beginning in 2012. This section would amend **SSA Sec. 1890(b)(5)(A)** to require the entity to submit a report to Congress and the Secretary describing gaps in endorsed measures and areas where evidence is insufficient to support endorsement of quality measures in priority areas identified under the national strategy. This section would also amend the SSA by inserting, after section 1890, the following new **SSA Sec. 1890A**, Quality Measurement. This new section would require the Secretary to establish a pre-rulemaking process, to include a series of six steps to select quality measures, including gathering multi-stakeholder input; making measures under consideration available to the public; transmission to, and consideration by the Secretary of, the input of multi-stakeholder groups; and the publication of the rationale for the use of any quality measure in the Federal Register; among others. This section would also require the Secretary to establish a process for disseminating quality measures used by the Secretary and would require the Secretary to periodically review quality measures and determine whether to maintain the use of the measure or to phase it out.

This section would require the Secretary to provide for the transfer, from the Medicare Part A and Part B Trust Funds, \$20 million to the CMS Program Management Account for each of FY2010 through FY2014.

### **Sec. 3015. Data Collection; Public Reporting**

This section would amend PHS Title III by adding at the end the following new **PHSA Sec. 399II**, *Collection and Analysis of Data for Quality and Resource Use Measures*. This section, as amended by Sec. 10305 of the bill, would require the Secretary to establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in **new PHS Sec. 399JJ**, as added by this Act. In addition, the Secretary would be required to collect and aggregate consistent data on quality and resource use measures, and may award grants or contracts for this purpose, and to ensure that data collection, aggregation and analysis systems involve an increasingly broad range of patient populations, providers, and geographic areas over time. This section would allow the Secretary to award grants or contracts to eligible entities to support new, or improve existing, efforts to collect and aggregate quality and resource use measures. The Secretary, under this section, would only be permitted to award grants or contracts to entities that enable summary data that can be integrated and compared across multiple sources. This section would authorize the appropriation of SSAN for FY2010 through FY2014.

This section would also add a new **PHSA Sec. 399JJ**, *Public Reporting of Performance Information*. This section would require the Secretary to make available to the public, through standardized websites, performance information summarizing data on quality measures. This performance information would be required to include information regarding clinical conditions to the extent such information is available, and the information would, where appropriate, be



provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions. This section would require the Secretary to consult with the entity with a contract under SSA Sec. 1890(a) and other entities as appropriate to determine the type of information that is useful to stakeholders. In addition this section would require the entity with a contract under Sec. 1890(a) to convene multi-stakeholder groups to review the design and format of each website and to transmit the views of these groups to the Secretary. This section would authorize the appropriation of SSAN for FY2010 through FY2014.

## **Quality Improvement and Patient Safety**

The PHSA, Title IX, provides AHRQ with broad general authority to conduct and support research on health care quality, including ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, and the determinants and impact of their use of this information. In addition, AHRQ has the authority to provide financial assistance for meeting the costs of planning and establishing new centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis.

Under PHSA Sec. 301, the Secretary has general authority to conduct and promote the coordination of research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases impacting individuals and to award grants for public health purposes, including for training; to award grants for training of health professionals under Part C of Title VII; and to conduct research and disseminate information regarding health care quality under Title IX; among other things.

### **Sec. 3501. Health Care Delivery System Research; Quality Improvement**

This section would create a new **Subpart II, *Health Care Quality Improvement Programs***, and would include a new **PHSA Sec. 933**, to enable the Director of AHRQ to identify, develop, evaluate, and disseminate innovative strategies for quality improvement practices in the delivery of health care services that represent best practices, and to establish The Center for Quality Improvement and Patient Safety of AHRQ (hereinafter referred to as the “Center”). The general functions of this Center would include, among others: (1) identifying providers that deliver consistently high-quality, efficient health care services and employ best practices that are adaptable and scalable to diverse health care settings; (2) assessing research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery; (3) finding ways to translate such information rapidly and effectively; (4) creating strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variation in the delivery of health care; and (5) building capacity at the state and community level to lead quality and safety efforts through education, training and mentoring programs. The Center would be required to support research on health care delivery system improvement and the development of tools to facilitate the adoption of best practices. This section would require the Director to make the research findings of the Center available to the public, would ensure that research findings and results generated by the Center would be shared with the Office of the National Coordinator of Health Information Technology, and would require the Center to coordinate its activities with the Center for Medicare and Medicaid Innovation established by this Act. The Director would be required to identify a list of processes or systems on which to focus research and dissemination activities, and would be required to take into account a number of factors, including the cost to federal health programs

and provider assessment of such processes or systems, among others. This section would authorize to be appropriated \$20 million for FY2010 through FY2014.

This section would also add a new **PHSA Sec. 934**, which would require the Director, through the Center, to award technical assistance funding to specified eligible entities. Funds would provide technical support to institutions that deliver health care so that such institutions understand, adapt, and implement the models and practices identified by the research conducted by the Center. Funds would also support implementation awards to eligible entities to implement these models and practices. Sec. 3511 of this bill would authorize the appropriation of SSAN to carry out the activities in this section.

### **Sec. 3508. Quality and Patient Safety Training in Clinical Education**

This section would allow the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety into the clinical education of health professionals. A grant could be awarded under this section only if the receiving entity or consortium were to agree to make available non-Federal contributions toward the costs of the program in an amount that is not less than \$1 for each \$5 of Federal funds. This section would also require the Secretary to evaluate the projects funded under this section and publish, make publicly available, and disseminate the results of such evaluations on as wide a basis as is practicable. Finally, this section would require the Secretary to submit a report to specified Congressional Committees that would describe the specific projects supported under this section and provide recommendations to Congress. Sec. 3511 of this bill would authorize the appropriation of SSAN to carry out the activities in this section.

### **Sec. 10303(b). Hospital-Acquired Conditions**

Medicare pays acute care hospitals using the inpatient prospective payment system (IPPS), where each patient is classified into a Medicare severity adjusted diagnosis-related group (MS-DRG). Generally, except for outlier cases, a hospital receives a predetermined amount for a given MS-DRG regardless of the services provided to a patient. In some instances, Medicare patients may be assigned to a different MS-DRG with a higher payment rate based on secondary diagnoses. Starting October 1, 2008, hospitals did not receive additional Medicare payment for complications that were acquired during a patient's hospital stay for certain select conditions. These hospital-acquired conditions (HACs) are (1) high cost, high volume, or both; (2) identified though a secondary diagnosis that will result in the assignment to a different, higher paid MS-DRG; and (3) reasonably preventable through the application of evidence-based guidelines.

Sec. 10303(b) would amend SSA Sec. 1890A, as added by Sec. 3014(b), and as amended by Sec. 3013(b), to require the Secretary, to the extent practicable, to publicly report on measures for HACs that are currently utilized by CMS for the adjustment of payment to hospitals based on rates of hospital-acquired infections.

### **Sec. 10303(c). Clinical Practice Guidelines**

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Sec. 304(b)) required the Secretary to enter into a contract with the Institute of Medicine (IOM) requiring the IOM to conduct a study on the best methods used in developing clinical practice guidelines in

order to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent. The IOM is required to submit to the Secretary, and the appropriate committees of jurisdiction of Congress, a report containing the results of this study and recommendations for legislation and administrative action. Finally, stakeholders with expertise in making clinical recommendations are required to participate on the panel responsible for conducting this study and preparing the report.

Sec. 10303(c) would require the Secretary, following receipt of the report required under MIPPA Sec. 304(b), and not less than every three years thereafter, to contract with the IOM to employ the results of the study and the best methods identified for the purpose of identifying existing and new clinical practice guidelines that were developed using such best methods, including guidelines listed in the National Guideline Clearinghouse. This section would require the Secretary, in carrying out this identification process, to allow for consultation with professional societies, voluntary health care organizations, and expert panels.

## **Care Coordination**

Care coordination is seen as an important aspect of health care that helps avoid waste by reducing the over- and underuse of medications, diagnostic tests, and therapies. The current health care system places a high value on specialty care, rather than primary care, and patients with multiple chronic conditions often receive care from several providers in different settings. Among other things, this can compromise patients' understanding of their conditions and ways to manage them, and may also result in deficiencies in the quality of care provided to these patients. A number of provisions in H.R. 3490, as passed by the Senate, address issues relating to the coordination of care by supporting medical homes, medication management services, patient navigator services, and the empowerment of patients through education about methods for managing their chronic conditions.

Sec. 204 of the Tax Relief and Health Care Act of 2006 mandated a demonstration in up to eight states to provide targeted, accessible, continuous and coordinated care to Medicare beneficiaries with chronic or prolonged illnesses requiring regular medical monitoring, advising, or treatment. This model is commonly referred to as a medical home. MIPPA Sec. 133 allowed the Secretary to expand the demonstration project as appropriate (subject to certain limitations).

Currently, Medicare Part D sponsors are required to establish medication therapy management (MTM) programs, in cooperation with licensed pharmacists, to ensure that covered Part D drugs are used appropriately and reduce adverse drug interactions. Part D plans have significant flexibility in structuring their MTM programs and deciding which targeted populations are appropriate for MTM services. In a July 2008 study, CMS examined the attributes and features of MTM models currently in use and concluded that it is too soon to tell how the various MTM models contribute to clinical outcomes.

PHSA Sec. 340A authorizes the Secretary to make four-year grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services. Patient navigators must have direct knowledge of the communities they serve, and perform the following duties, among others: (1) facilitate involvement of community organizations in assisting individuals with chronic diseases to receive better access to high-quality health care services; (2) help patients to overcome barriers in the health care system to ensure prompt resolution of an abnormal finding of a chronic disease; and (3) coordinate with relevant health

insurance entities to provide information to individuals with chronic diseases about health coverage.

### **Sec. 3502. Community Health Teams to Support Medical Homes**

This section would require the Secretary to implement a grant program for the purpose of establishing health teams to provide support to primary care providers, and providing capitated payments to these providers. Eligible grantees would be a state (or designee), Indian tribe, or tribal organization that submits a plan for financial sustainability and for incorporating prevention initiatives, patient education, and care management resources into care delivery; ensures that the health team includes a multi-disciplinary team of specified providers; and agrees to provide services to Medicaid beneficiaries with chronic conditions, as described in SSA Sec. 1945 (as added by Sec. 2703 of this bill), in accordance with the payment methodology established under that section. “Medical home” would be defined as a mode of care that includes (1) personal physicians; (2) whole-person orientation; (3) coordinated and integrated care; (4) safe and high quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements; (5) expanded access to care; and (6) payment that recognizes added value from additional components of patient-centered care. A health team would be required to carry out 10 specific activities, including establishing contractual agreements with primary care providers to provide support services; developing plans that integrate preventive services for patients; providing 24-hour care management and support during transitions in care settings; and others. Primary care providers who contracted with these teams would be required to provide care plans for patient participants, provide access to participant health records and primary care practices, and meet regularly with the care team to ensure integration of care. Sec. 3511 of this bill would authorize the appropriation of SSAN to carry out the activities in this section.

### **Sec. 3503. Medication Management Services in Treatment of Chronic Disease**

This section would add a new **PHSA Sec. 935, *Grants of Contracts to Implement Medication Management Services in Treatment of Chronic Diseases***, which would require the Secretary, acting through the Patient Safety Research Center established in PHSA Sec. 933 (as added by Sec. 3501 of this bill), to provide grants to support MTM services provided by licensed pharmacists. Grantees would have to provide various specified MTM services to targeted individuals, such as (1) assessing patients’ health and functional status; (2) formulating a medical treatment plan; (3) administering appropriate medication therapy; (4) monitoring and evaluating patient response to therapy; (5) documenting the care delivered and communicating essential aspects to appropriate care providers; (6) providing education and training to enhance the appropriate use of medications; and (7) coordinating and integrating MTM services in broader health care management. MTM services provided by licensed pharmacists under this program would be targeted at individuals who take four or more prescribed medications, take high-risk medications, have two or more chronic diseases, or have undergone a transition of care or other factors that are likely to create a high risk of medication-related problems. The Secretary would be required to assess and evaluate specified aspects of the program and report to Congress. Sec. 3511 of this bill would authorize the appropriation of SSAN to carry out the activities in this section.

### **Sec. 3506. Program to Facilitate Shared Decisionmaking**

This section would add a new **PHSA Sec. 936**, *Program to Facilitate Shared Decisionmaking*, to facilitate shared decision making between patients and caregivers and their clinicians by engaging the patient in clinical decision making, providing information on trade-offs among treatment options, and incorporating patient preferences and values into the medical plan. The Secretary would be required to enter into a contract with the consensus-based organization with a contract under SSA Sec. 1890 to develop and identify standards for patient decision aids, to review patient decision aids, and develop a certification process for determining whether patient decision aids meet those standards. The Secretary, acting through the Director of AHRQ, would be required to award grants or contracts to develop, update, and produce patient decision aids, to test such materials to ensure they are balanced and evidence-based, and to educate providers on their use. The Secretary would be required to award grants for establishing Shared Decision Making Resource Centers to develop and disseminate best practices to speed adoption and effective use of patient decisions aids and shared decision making. The Secretary also would be required to award grants to providers for the development and implementation of shared decision-making techniques. Providers receiving a grant would have to report to the Secretary data on those quality measures, and the Secretary would have to provide feedback to those providers. This section would authorize to be appropriated SSAN for FY2010, and each subsequent fiscal year.

### **Sec. 3510. Patient Navigator Program**

This section would amend **PHSA Sec. 340A** to prohibit the Secretary from awarding a grant to an entity under this section unless the entity provides assurances that patient navigators recruited, assigned, trained, or employed using these grant funds meet certain minimum core proficiencies. These proficiencies would be defined by the entity that submits the application and would be tailored for the main focus or intervention of the navigator involved. The section would authorize the appropriation of \$3.5 million for FY2010, and SSAN for each of FY2011 through FY2015.

### **Sec. 10333. Community-Based Collaborative Care Networks**

This section would add a **new PHSA Sec. 340H**, authorizing the Secretary to award grants to eligible entities to support community-based collaborative care networks (CCNs). Eligible CCNs would be required to be a consortium of health care providers with a joint governance structure that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations. Networks would include a safety net hospital and all FQHCs in the community. Grant funds could be used to assist low-income individuals, as described; provide case management and care management; perform health outreach; provide transportation; expand capacity; and provide direct patient care services. The Secretary would be authorized to limit the percent of grant funding that may be spent on direct care services provided by HRSA grantees or impose other requirements on such grantees deemed necessary. There would be authorized to be appropriated SSAN for each of FY2011 through FY2015.

## **Nursing Homes and other Long-Term Care Facilities and Providers**

### **Secs. 6101- 6121. Nursing Home Transparency, Enforcement and Staff Training**

These sections include a number of provisions that would enhance certain accountability requirements for Medicare certified skilled nursing facility (SNF) and Medicaid certified nursing facility (NF). The changes in these sections would require SNFs and NFs to maintain and make available additional information on facility ownership and organizational structure, as well as to establish new staff compliance and ethics training programs. The changes in these sections also would require the Secretary to establish additional requirements for SNFs and NFs to develop and implement compliance and ethics programs.

The Secretary would further be required to enhance the SNF and NF information available on the Medicare Nursing Home Compare website, and to ensure that information is prominent, easily accessible, searchable, and readily understandable to long-term care consumers. SNFs would be required to report wage and benefit expenditures for direct care staff. In addition, the Secretary, in consultation with private sector experts, would be required to redesign Medicare and Medicaid cost reports to capture wage and benefit reporting by SNFs and NFs. The Secretary would be required to develop a new standardized complaint form that facilities and states would be required to make available to all stakeholders and consumers. The changes in these sections would require SNFs and NFs to electronically report direct staffing information to the Secretary following specifications the Secretary would establish in consultation with stakeholders. The GAO would be required to conduct a study of the CMS Five-Star rating system.

Additional civil money penalties would be established that both the Secretary and states could impose on SNFs or NFs found to have quality of care issues and other deficiencies that jeopardized residents' safety. The Secretary would be required to develop, test, and implement a national independent monitoring demonstration for large interstate and intrastate SNF and NF chains. Further, these sections would establish new requirements for SNF and NF administrators to inform residents and their representatives, as well as the Secretary, states, and other stakeholders of planned facility closures. SNF and NF administrators who failed to comply with the closure notice requirements could be subject to penalties up to \$100,000 and exclusion from federal health program participation. The Secretary also would be required to conduct demonstration projects on best practices for culture change and use of information technology in SNFs and NFs. The changes in these sections would require the Secretary to revise initial nurse aide training, competency, and evaluation requirements to include dementia and abuse prevention. Finally, the Secretary also could revise dementia management training and patient abuse prevention in ongoing nurse training, competency, and evaluation requirements.

### **Sec. 6201. Background Checks on Employees of Long-Term Care Facilities**

This section would require the Secretary to establish a nationwide program for national and state background checks on direct patient access employees of certain long-term care (LTC) facilities or providers and provide federal matching funds to states to conduct these activities. The Secretary would be required to carry out the nationwide program under similar terms and conditions as the Background Check Pilot program under Sec. 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) which established the framework for such a program. From January 2005 through September 2007, CMS administered the Background Check Pilot program, in consultation with the Department of Justice (DoJ), in

seven states (Alaska, Idaho, Illinois, Michigan, Nevada, New Mexico, and Wisconsin) selected to participate.

Under the nationwide program, the Secretary would be required to enter into agreements with newly participating states and previously participating states. Certain LTC providers would be required to obtain state and national criminal history background checks on their prospective employees as the Secretary determines appropriate, efficient, and effective. The section would require the Secretary of the Treasury to transfer to HHS an amount specified by the HHS Secretary as necessary (not to exceed \$160 million) to carry out the nationwide program for FY2010 through FY2012. Such amounts would be required to remain available until expended. The Secretary would be authorized to reserve no more than \$3 million of the amount transferred to conduct the evaluation.

## **Comparative Clinical Effectiveness Research**

ARRA provided \$1.1 billion for comparative effectiveness research and created the Federal Coordinating Council for Comparative Effectiveness Research (FCCCER), an interagency advisory group that is required to report to the President and Congress annually.<sup>56</sup> H.R. 3590, as passed by the Senate, has two comparative effectiveness research provisions. The first would establish a new private, non-profit corporation to be called the Patient-Centered Outcomes Research Institute; the second would terminate the FCCCER.

### **Sec. 6301. Patient-Centered Outcomes Research**

This section would add a new **SSA Part D**, *Comparative Clinical Effectiveness Research*. New **Sec. 1181** would authorize the establishment of a private, nonprofit, tax-exempt (by amending Sec. 501(l) of the Internal Revenue Code (IRC)) corporation called the Patient-Centered Outcomes Research Institute (the Institute). The Institute would assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of clinical evidence through research and evidence synthesis. The Institute would identify national priorities for research, including attention to chronic conditions, gaps in evidence, quality of care, patient health and well-being, the effect on national expenditures associated with interventions or conditions, among other concerns. It would establish and update a research agenda, which it would carry out by systematic reviews and assessment so existing and future research, primary research, and other appropriate methodologies. This section would require the Institute to enter into contracts with federal agencies as well as with appropriate academic, private sector research, or study-conducting entities for the management of funding and conduct of research.

The Institute's 19-member board would include the directors (or their designees) of the AHRQ and the National Institutes of Health (NIH), along with others appointed by the U.S. Comptroller General to include representation of a broad range of groups, including patients and health care consumers; physicians and providers; private payers; pharmaceutical, device, and diagnostic manufacturers; quality improvement or independent health services researchers, and government representatives. The Institute would, as appropriate, appoint expert advisory panels to assist in

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<sup>56</sup> The Council released its initial report on June 30, 2009. The report can be found at <http://www.hhs.gov/recovery/programs/ce/annualrpt.pdf>.

identifying research priorities and establishing the research project agenda. The section would direct appointment of panels for clinical trials and rare diseases.

The Institute would also be required to establish a methodology committee, consisting of no more than 15 members appointed by the Comptroller General plus the directors of AHRQ and NIH, which would have responsibility for developing and improving the science and methods of comparative clinical effectiveness research. The methodology committee would establish, with outside input and with public comment, and periodically update research design standards regarding clinical outcomes measures, risk-adjustment, subpopulation analysis, and other aspects of research and assessment. The methodology committee would also be able to consult and contract with the IOM and other private and governmental entities.

This section would require extensive procedures regarding conflict-of-interest, data privacy, peer-review, and the public availability of information.

A new **PHSA Sec. 937** would require AHRQ to broadly disseminate research findings published by the Institute and other government-funded CCER research; create information tools; develop a publicly available database of government-funded evidence. Dissemination materials would identify researchers; describe research methodology, limitations, and subpopulation-specific considerations; and not be construed as mandates, guidelines, or recommendations for payment, coverage or treatment. This section would also require training of researchers, building of data capacity in coordination other federal health programs, and authorize federal agencies to contract with the Institute for the conduct and support of relevant research.

This section would add a new **SSA Sec. 1182** to limit certain uses of evidence and findings from research conducted under these provisions: the Secretary could only use the findings to make coverage determinations if the use is through an iterative and transparent process that includes public comment and considers the effect on subpopulations. This section would prohibit the Secretary from using these research findings in determining Medicare coverage that in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill; or that would preclude or discourage an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability. It also prohibits the Institute from using values that discount the value of life because of an individual's disability or to use such measures in determining coverage.

New **IRC Sec. 9511** would establish a new Patient-Centered Outcomes Research Trust Fund (PCORTF) in the U.S. Treasury to fund the Institute and its activities. The Fund would receive the following amounts: (1) specified annual appropriations over the period FY2010-FY2019 totaling \$1.26 billion; (2) additional annual appropriations over the period FY2013-FY2019 equal to the net revenues from a new fee levied on health insurance policies and self-insured health plans through FY2019; and (3) transfers from the Medicare Trust Funds through FY2019. The new fee would equal \$1 per covered life in FY2013 and \$2 per covered life in FY2014 through FY2019 (updated annually by the rate of medical inflation). Similarly, the transfers from the Medicare Trust Funds would equal \$1 per beneficiary in FY2013 and \$2 per beneficiary in FY2014 through FY2019 (updated annually by the rate of medical inflation).

## **Sec. 6302. Federal Coordinating Council, Comparative Effectiveness Research**

This section would terminate the FCCCER upon enactment.



## **Key Health Indicators**

There are a number of current efforts, some required by law, to collect and disseminate health statistics on the U.S. population. Those activities are primarily directed by AHRQ and the CDC National Center for Health Statistics (NCHS). AHRQ is required to submit two annual reports to Congress: one on national trends in the quality of health care provided to the American people, and the other on prevailing disparities in health care delivery as they relate to racial and socioeconomic factors in priority populations. NCHS conducts and supports statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States. NCHS collects statistics on (1) the extent and nature of illness and disability in the U.S. population; (2) the impact of illness and disability of the population on the U.S. economy; (3) environmental, social, and other health hazards; (4) determinants of health; (5) health resources; (6) utilization of health care; (7) health care costs and financing; and (8) family formation, growth, and dissolution.

### **Sec. 5605. Key National Indicators**

This section would establish the Commission on Key National Indicators (“Commission”) appointed equally by the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives. The Commission would have the following responsibilities: (1) conduct comprehensive oversight of the newly established key national indicator system; (2) make recommendations on how to improve the key national indicator system; (3) coordinate with federal government users and information providers to assure access to relevant and quality data; and (4) enter into contracts with the National Academy of Sciences (“Academy”). The Commission would be required to enter into an arrangement with the Academy to review available public and private sector research on key national indicator set selection and determine how to best establish a key national indicator system. The Academy would establish the key national indicator system by either creating its own institutional capability, or partnering with an independent, private, non-profit organization as an Institute. The Academy would be required to identify and select all criterion and methodologies to establish and operate the key national indicator system. This entails issue areas to be represented, measures to utilize, and data to populate the system. The Academy would be required to design, publish, and maintain a public website for public access to key national indicators. Also, the Academy would develop a quality assurance framework to ensure rigorous and independent processes and quality data selection, and would be required to submit a report not later than 270 days after enactment of this Act, and annually thereafter, to the Commission outlining the findings and recommendations of the Academy. The Comptroller General of the United States would be required to conduct a study of previous work conducted by a range of entities with respect to best practices for a key national indicator system, and would be required to submit this study to the appropriate authorizing committees of Congress. This section would authorize to be appropriated \$10 million for FY2010, and \$7.5 million for each of FY2011 through FY2018, with amounts appropriated to remain available until expended.

# Health Disparities

## Data on Health Disparities

Federal initiatives such as the National Healthcare Disparities Report<sup>57</sup> and HealthyPeople 2010<sup>58</sup> examine health status, access to care, quality of care, and health disparities for the nation as a whole and for population subgroups. These initiatives depend mainly on existing federally sponsored data.

The OMB issues statistical policy guidance for the collection of data from federally sponsored surveys, administrative forms and other records.<sup>59</sup> Agency data collection efforts may use categories beyond this minimum set (for example, collect information on Hispanic subpopulations); however, categories must be aggregated into the established minimum set for reporting purposes. Another OMB guidance document addresses how to allocate multiple race responses to the categories established in the 1997 standards for civil rights monitoring and enforcement.<sup>60</sup> OMB standards do not apply to state and municipal public health departments or to Medicaid. While the standards do apply to CHIP, they are not binding on states that opt to use CHIP funding to finance a Medicaid expansion or that employ a combined approach. The OMB standards do not address primary language; however, CMS mandates that this information be reported for Medicaid beneficiaries. CMS does not require the collection of primary language data from CHIP enrollees, their parents or legal guardians.

Current law does not require the collection of data on access to care for disabled individuals for any federal health care program or other federally sponsored entities. Data on access to care by the disabled are collected in federally sponsored surveys such as the National Health Interview Survey, the Medical Expenditure Panel Survey, the Behavioral Risk Factor Surveillance System, and the Medicare Current Beneficiary Survey; however, analysis of survey data is limited by the number and type of survey items included, variation in the items across surveys, and limitations in the sample and sample size for individuals with disabilities.

## Required Collection of Data

Many federal data collection efforts include items for measuring race and ethnicity or subpopulations such as those whose primary language is not English or persons with disabilities. However, sample surveys are often of insufficient sample size to ensure reliable estimates with

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<sup>57</sup> U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2008 National Healthcare Disparities Report. AHRQ Publication No. 09-001. March 2009. <http://www.ahrq.gov/qual/nhqr08/nhqr08.pdf>

<sup>58</sup> HealthyPeople 2010 Fact Sheet. <http://www.healthypeople.gov/About/hpfact.htm>

<sup>59</sup> See, e.g., Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity; *Federal Register*, Thursday October 30, 1997, pp. 58782. [http://www.whitehouse.gov/omb/fedreg\\_1997standards/](http://www.whitehouse.gov/omb/fedreg_1997standards/); Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity December 15, 2000. [http://www.whitehouse.gov/omb/assets/information\\_and\\_regulatory\\_affairs/re\\_guidance2000update.pdf](http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf); and “Guidance on Aggregation and Allocation of Multiple Race Responses for Use in Civil Rights Monitoring and Enforcement”. OMB Bulletin No. 00-02. March 9, 2000. [http://www.whitehouse.gov/omb/bulletins\\_b00-02/](http://www.whitehouse.gov/omb/bulletins_b00-02/).

<sup>60</sup> “Guidance on Aggregation and Allocation of Multiple Race Responses for Use in Civil Rights Monitoring and Enforcement”. OMB Bulletin No. 00-02. March 9, 2000. [http://www.whitehouse.gov/omb/bulletins\\_b00-02/](http://www.whitehouse.gov/omb/bulletins_b00-02/).

appropriate precision for small subpopulations. Sample size also influences the level of analysis that can be conducted. For example, larger sample sizes may be needed to study a specific medical condition among subgroups of a population. Some surveys use oversampling to increase the precision of subpopulation estimates. Other times, data from multiple years are combined to produce stable estimates. The need for and size of a sample is tied, in part, to the cost of the data collection effort.

Current law requires the evaluation of data collection approaches under Medicare that facilitate the collection and evaluation of disparities data. In addition, the Secretary is required to develop reports for Congress identifying best approaches for the collection of disparities data and recommending ways to improve the care delivered to Medicare beneficiaries based on the analysis of disparities data.

### **Sec. 4302. Understanding Health Disparities: Data Collection and Analysis**

This section would add a new **PHSA Title XXXI, *Data Collection and Analysis***. New **Sec. 3101** would require the Secretary to establish procedures to ensure that all data collected on race, ethnicity, sex, and primary language by any federally conducted or supported health care or public health program does so in compliance with OMB directives and guidance.

Sec. 3101 would require that federally funded population surveys collect sufficient data relating to race, ethnicity, sex, primary language, and type of disability to generate statistically reliable estimates in studies comparing health disparities among populations. It would ensure that quality reporting requirements under federal health care programs would include the collection of data on individuals receiving health care items or services under these programs by race, ethnicity, sex, primary language, and type of disability.

Sec. 3101 would further require the Secretary to develop OMB-compliant standards for the collection of data on race, ethnicity, sex, primary language, and disability status. It would also mandate that the Secretary survey health care providers to identify where people with disabilities receive primary, acute and long-term care; the number of providers with accessible facilities and equipment (according to criteria set forth in Sec. 510 of the Rehabilitation Act of 1973); and the number of health care professionals trained in disability awareness and in caring for patients with disabilities.<sup>61</sup>

The Secretary, working through the National Coordinator for Health Information Technology, would be required to develop national interoperability and security standards for the management of the aforementioned data.

Sec. 4302 would require the Secretary to establish procedures for sharing data collected under a federal health care or insurance program on race, ethnicity, gender, primary language, and type of disability, and relevant analyses of such data, with other federal and state agencies, as well as agencies within HHS. This section would also require the Secretary to ensure all appropriate

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<sup>61</sup> This section would apply to any Federal health care program, funded directly, in whole or in part, by the United States Government, as well as state health care programs (Title XIX, Medicaid; Title V, the Maternal Child Health Services Block Grant program; Title XX, block grants to states for social services; Title XXI, Children's Health Insurance Program). It would apply to any plan or program that provides health benefits, whether directly, through insurance, or otherwise.

privacy and security safeguards are followed for the collection, analysis, and sharing of these data.

This provision would also ensure that any federally-funded data which are collected regarding race and ethnicity include underserved rural and frontier populations.

A new **SSA Sec. 1946**, *Addressing Health Care Disparities*, would require the Secretary to evaluate approaches for the collection of data that allow for the collection and evaluation of data on health care disparities. In conducting this evaluation, the Secretary would be required to consider several objectives, including protecting patient privacy, minimizing the administrative burden of data collection and reporting, and improving program data on race, ethnicity, sex, primary language, and type of disability. This new section would require the Secretary to submit a report on the evaluation of data collection methodologies conducted pursuant to this section, and would include approaches for identifying, collecting, and evaluating health disparities data under Medicaid and CHIP. The Secretary would also be required to submit a series of reports that would include recommendations for improving the identification of health disparities for Medicaid and CHIP beneficiaries and then implement the most promising data collection approaches identified by these reports within 24 months of the enactment of this Act.

The new SSA Sec. 1946 would require the Secretary to report data and analyses on race, ethnicity, sex, primary language, and disability, which were collected or conducted using federal funding by posting them on publically available HHS websites and/or by disseminating them using other mechanisms deemed appropriate by the Secretary.

The provision would authorize the appropriation of SSAN for FY2010 through FY2014 for the purpose of carrying out Sec. 4302.

### **Sec. 10334. Office of Minority Health**

This section would amend **PHSA Sec. 1707**, elevating the existing Office of Minority Health (“the Office”) within the HHS Office of Public Health and Science by placing it within the Office of the Secretary. The Office would be headed by a Deputy Assistant Director for Minority Health (DAD) who would report directly to the Secretary. The Secretary, acting through the DAD, would be required to award grants, contracts, and enter into certain types of agreements with certain types of entities to assure improved health status of racial and ethnic minorities, and to develop measures to evaluate the effectiveness of activities aimed at reducing health disparities and supporting the local community, as specified. The Secretary would be required to prepare and submit biennial reports to appropriate congressional committees describing the activities carried out under PHSA Sec. 1707. A similar requirement would be placed on HHS agency heads, regarding their respective Offices of Minority Health, which would be required to be created as described below. The section would authorize the appropriation of SSAN for each of FY2011 through FY2016 for the Office.

The section also would add a new **PHSA Sec. 1707A**, requiring each of the heads of CDC, HRSA, SAMHSA, AHRQ, FDA, and CMS to create an Office of Minority Health within their respective agency. Each office’s director would be appointed by and report directly to the agency head. The Secretary would be required to designate as specified, for carrying out the activities of the section, an appropriate amount of funds appropriated for each agency for a fiscal year.

Finally, the section would amend **PHSA Title IV**, redesignating the National Center on Minority Health and Health Disparities as an Institute. It would expand the Institute Director's authority to make research endowments to include those made to certain centers of excellence for research education and training. It would change eligibility requirements for centers eligible to receive certain endowments, making the calculation based upon the national median of endowment funds. The section would require the Director of the Institute, as the primary federal official responsible for coordinating all research and activities conducted and supported by NIH on minority health and health disparities, to plan, coordinate, review and evaluate research and other activities conducted or supported by NIH's Centers and Institutes.

## **Health Information Technology**

### **HIPAA Administrative Simplification**

To promote the growth of electronic record keeping and claims processing in the nation's health care system, HIPAA's 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, 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. In September 2005, CMS proposed a standard for health care claims attachments, one of the two remaining transactions standards that must be adopted. A claims attachment transaction is used to request and provide additional clinical data necessary to adjudicate a claim.

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.

### **Sec. 1104. Administrative Simplification**

This section would amend **SSA Sec. 1173** to establish a timeline for the development, adoption and implementation of a single set of 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. The standards and associated operating rules would be required to meet certain requirements. They would have to (1) enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care; (2) be comprehensive, requiring minimal augmentation with paper; and (3) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process. Operating rules are 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 be required to consider the recommendations of a qualified nonprofit entity that uses a multi-stakeholder, consensus-based process for developing such rules. Also, the section would add EFT for the payment of health claims as a HIPAA transaction and require the Secretary to adopt an EFT standard no later than January 1, 2012, to take effect by January 1, 2014.

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 (i.e., health claims, plan enrollment and disenrollment, health plan premium payments, and prior authorization and referral) by July 1, 2014, to take effect by January 1, 2016. The Secretary also would have 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 and associated 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, 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.

The section 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. In addition, the Secretary would be required to adopt a transaction standard and single set of associated operating rules for health claims attachments no later than January 1, 2014, to take effect by January 1, 2016.

In addition to the above provisions, the section would amend **SSA Sec. 1862(a)** to 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 standard.

### **Sec. 1561. Standards for Enrollment in Federal and State Programs**

This section would add a new **PHSA Title XXX, Subtitle C**, comprising **Sec. 3021**. The Secretary, within 180 days of enactment and in consultation with the HIT Policy Committee and the HIT Standards Committee, would be required to develop interoperable and secure standards that facilitate enrollment of individuals in federal and state health and human services programs. The standards and protocols would have to allow for the following functions: (1) electronic matching against existing federal and state data that provide evidence of eligibility; (2) simplification and submission of electronic documentation, digitization of documents, and systems verification of eligibility; (3) reuse of stored eligibility information; (4) capability of individuals to manage their eligibility information online; (5) ability to expand the enrollment system to integrate new programs; (6) notification, including by e-mail and phone, of eligibility, recertification, and other information regarding eligibility; and (7) other functionalities to streamline the enrollment process. The Secretary would be required to notify states upon approval of the standards and protocols and would be authorized to require that states and other entities incorporate such standards and protocols as a condition of receiving federal HIT funds.

The Secretary would be required to award grants to states and localities to develop new or upgrade existing IT systems to implement the enrollment standards and protocols. Eligible grantees would be required to submit an adoption and implementation plan that includes, among other things, demonstrated collaboration with other grantees. The Secretary also would be required to ensure that the enrollment IT adopted by grantees be shared at no cost to other qualified states, localities, and others.

## **Emergency Care**

### **Background and Issues**

PHSA Title XII authorizes the Secretary, acting through HRSA, to fund trauma care research, training, evaluations, and demonstration projects. Title XII, Part A, comprising Secs. 1201-1203, authorizes the Secretary to fund research and demonstration projects for improving trauma care in rural areas, and to award grants to states to develop and improve trauma care systems. Part B, comprising Secs. 1211-1222, mandates a state formula grant program for modifying and strengthening the trauma care component of states' plans for emergency medical services. Part D, comprising Secs. 1241-1245, authorizes grants to trauma centers operating in areas severely affected by drug-related violence that have incurred substantial costs for providing uncompensated care.

Many trauma experts consider the first 60 minutes after an injury to be a so-called “golden hour” when trauma care is most effective in saving lives. Given that the risk of death for severely injured patients rises significantly after one hour, trauma systems strive to offer access within that time period, from receipt of the initial emergency call to arrival at a trauma center. The geographic distribution of trauma centers varies widely across states and regions. Many areas of the country are not well served by trauma centers, while other areas may have a surplus of centers, possibly leading to inefficiencies, lower patient volumes per center, and reduced quality of care. More than 84% of U.S. residents can reach a level I or II trauma center within an hour, but access lags in rural areas.<sup>62</sup>

### **Sec. 3504. Regionalized Systems for Emergency Care**

This section would amend **PHSA Sec. 1203**, which provides grants to states and localities to improve access to and enhance the development of trauma care systems, by modifying the section heading to read “Competitive Grants for Trauma Systems for the Improvement of Trauma Care” and by transferring administration of the program from HRSA to the Assistant Secretary for Preparedness and Response.

In addition, the section would add a new **PHSA Sec. 1204**, requiring the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award no fewer than four multiyear contracts or competitive grants for pilot projects to improve regional coordination of emergency services. Funding would be awarded to eligible entities (including states and Indian tribes) that propose a pilot project to design, implement, and evaluate certain emergency medical and trauma systems. Grants would have to be matched, cash or in-kind, at a rate of \$1 for every \$3 of federal funds, and priority would be given to entities in medically underserved areas. Within 90 days of completing a pilot project, the grantee would be required to submit to the Secretary a detailed evaluation of the program’s characteristics and impact. The Secretary would be required, as appropriate, to disseminate that information to the public and to Congress. In addition, the section would authorize to be appropriated for Title XII Parts A and B trauma care grant programs \$24 million for each of FY2010 through FY2014, and would transfer authority for administering those grants and related authorities to the Assistant Secretary for Preparedness and Response.

Finally, the section would add a new **PHSA Sec. 498D**, directing the Secretary to expand and accelerate basic science, translational and service delivery research on emergency medical care systems and emergency medicine, including pediatric emergency medical care. The Secretary also would be required to support research on the economic impact of coordinated emergency care systems. There would be authorized to be appropriated SSAN for each of FY2010 through FY2014 to carry out the new section.

### **Sec. 3505. Trauma Care Centers**

This section would amend **PHSA Secs. 1241-1245** by replacing the existing language with the following new provisions. Sec. 1241 would require the Secretary to establish three programs to award grants to qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers to (1) help defray substantial uncompensated care costs, (2) further the core

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<sup>62</sup> Charles C. Branas, *No Time to Spare: Improving Access to Trauma Care*, University of Pennsylvania, Leonard David Institute of Health Economics, September 2005, [http://www.upenn.edu/ldi/issuebrief11\\_1.pdf](http://www.upenn.edu/ldi/issuebrief11_1.pdf).



missions of such centers, and (3) provide emergency relief to ensure the continued availability of trauma services. In states with a trauma care system, a trauma center would not be eligible for a grant unless it is part of the trauma care component of the state plan for the provision of emergency care services. The maximum grant amount would be \$2 million per fiscal year.

To receive a substantial uncompensated care grant, qualified trauma centers would be categorized based on the percentage of emergency department visits that were charity, self-pay, and Medicaid patients. Trauma centers in each category would be eligible for grants up to some specified percentage of their uncompensated care costs. For example, category A centers—those with highest percentage of charity or self-pay patient visits—would be eligible for grants covering 100% of their uncompensated care costs. The Secretary would also award core mission grants to certain qualified trauma centers, and make emergency grant awards.

Funding allocated for core mission grants would be distributed among the different levels of trauma centers, as specified. Preference in awarding emergency relief grants would be given to applications from trauma centers in areas in which the availability of trauma care is declining or would significantly decrease if the center was forced to scale back or close. The Secretary would be authorized to require that grantees (1) maintain access to trauma care services at comparable levels to the prior year during the grant program and (2) provide data to a national and centralized registry of trauma cases, in accordance with American College of Surgeons (ACS) guidelines.

The section would authorize to be appropriated \$100 million for FY2009 and SSAN for each of FY2010 through FY2015 to carry out the three grant programs. Seventy percent of the total amount appropriated for a fiscal year would be for substantial uncompensated care awards unless the appropriation was less than \$25 million, in which case all the funding would be used for such awards. The Secretary would be required to submit a biennial report to Congress on the status of the grant programs.

Additionally, this section would add a new **PHSA Sec. 1281**, requiring the Secretary to award grants to states for the purpose of supporting trauma-related physician specialties and broadening access to and availability of trauma care services. Distribution of grant funds among the states would be based on the program's annual appropriation level. The lower the appropriation amount, the more the distribution of funds would be restricted to those states with trauma centers that provide a substantial amount of uncompensated care. If the appropriation was less than \$10 million, the lowest amount specified, then the funds would be distributed among only those states with one or more category A centers. There would be authorized to be appropriated \$100 million for each of FY2010 through FY2015 to provide for the state grants.

### **Sec. 5603. Emergency Medical Services for Children**

This section would amend **PHSA Sec. 1910**, which authorizes demonstration grants to expand emergency services for children, to lengthen the grant period to four years (with an optional fifth year). It also would authorize \$25 million for the program for FY2010, \$26.3 million for FY2011, \$27.6 million for FY2012, \$28.9 million for FY2013, and \$30.4 million for FY2014.

## **Pain Care and Management**

Under general authorities in PHS Title III and Title IV, NIH established the Pain Consortium to enhance pain research and promote collaboration among researchers across various NIH Institutes

and Centers that have programs and activities addressing pain. In addition, PHS Sec. 403 requires the NIH Director to submit to the President and Congress a biennial report that includes, among other things, a summary of the research activities throughout the agency organized by category; the chronic disease category includes pain and palliative care. The bill includes the following section that would address pain research and education for the purposes of recognizing pain as a national public health problem and would establish a health professionals training program in pain care.

### **Sec. 4305. Advancing Research and Treatment for Pain Care Management**

This section would require the Secretary to seek an agreement with the IOM (or another appropriate entity if the IOM declines) to convene a Conference on Pain, no later than one year after the appropriation of funds, for the purposes of increasing the recognition of pain as a significant public health problem in the United States, among other purposes. It also would require a report summarizing the Conference's findings to be submitted to Congress. For the purpose of carrying out this section, the bill would authorize to be appropriated SSAN for each of FY2010 and FY2011.

This section would add a new **PHSA Sec. 409J** to Title IV, Part B, which would encourage the NIH Director to continue and expand an aggressive program of research on the causes of and potential treatment for pain through the Pain Consortium. The Pain Consortium, no less than annually, would develop and submit to the NIH Director recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under the NIH Common Fund or otherwise available for such initiatives. The Secretary also would be required to establish, no later than one year after enactment, and as necessary maintain, the Interagency Pain Research Coordinating Committee to coordinate all efforts within HHS and other federal agencies that relate to pain research, among other duties.

This section would add a new **PHSA Sec. 759** to Title VII, Part D, authorizing the Secretary to establish a program to train health professionals in pain care. The Secretary could fund health professions schools, hospices, and other entities for the development and implementation of education and training programs to health care professionals in pain care. Award applicants would be required to agree to include information and education on the following topics: (1) recognized means for assessing, diagnosing, treating, and managing pain and related signs and symptoms; (2) applicable laws, regulations, rules, and policies on controlled substances; (3) interdisciplinary approaches to the delivery of pain care; (4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations; and (5) recent findings, developments, and improvements in the provision of pain care. The Secretary would also be required to provide for an evaluation of the implemented programs. For the purposes of carrying out this section, there would be authorized to be appropriated SSAN for each of FY2010 through FY2012 with amounts remaining available until expended.

## **Elder Justice**

### **Background and Issues**

Abuse, neglect, and exploitation of older individuals in domestic and institutional settings, such as nursing homes, affects hundreds of thousands of older Americans every year, according to

national experts. Precisely how many older individuals are mistreated by someone on whom they depend for care or protection is unknown. Efforts to collect data on elder abuse, neglect, and exploitation at the national level are hampered by the variation in state statutory definitions of elder abuse that make it difficult to identify actions that constitute abuse and neglect and by the absence of a uniform reporting system across states. The most recent study to estimate the occurrence of elder abuse and neglect nationally, concluded that about 450,000 persons age 60 or older experienced abuse or neglect in domestic settings in 1996.<sup>63</sup> In 2003, a National Research Council Study estimated that between 1 and 2 million Americans age 65 and older had been injured, exploited, or mistreated.<sup>64</sup> Other evidence and anecdotal reports indicate that the problem is serious and that many incidents are never reported.<sup>65</sup>

Congress has taken a number of modest steps towards addressing elder justice, including federal assistance to state Adult Protective Services programs through the Social Security Block Grant and amendments to the Older Americans Act (OAA) to provide separate funding for elder abuse prevention and vulnerable elder rights protection activities, including establishment of the Long-Term Care Ombudsman Program. While Congress has enacted comprehensive legislation to address child abuse and neglect (P.L. 93-247, Child Abuse Prevention and Treatment Act) and domestic violence (P.L. 103-322, Violence Against Women's Act), legislation addressing abuse, neglect, and exploitation of the elderly at a national level has not been enacted.

The Elder Justice Act, first introduced in 2002 and periodically since that time, represents an effort to produce a coordinated federal effort with a multidisciplinary approach that combines law enforcement, public health, and social services to combat abuse, neglect, and exploitation of the elderly. Some provisions regarding elder justice were incorporated in the 2006 reauthorization of the OAA (P.L. 109-365). Other provisions from the Elder Justice Act of 2009 (S. 795) have been incorporated into H.R. 3590, as passed by the Senate.

## **Sec. 6703. Elder Justice**

This section includes the following provisions divided into three subsections: (a) elder justice provisions amended to Title XX of the SSA; (b) various provisions related to protecting residents of long-term care facilities; and (c) establishing a national nurse aide registry.

### ***Elder Justice***

Subsection (a) of Sec. 6703 would amend Title XX of the SSA to insert new Elder Justice provisions to a newly entitled Block Grants to States for Social Services and Elder Justice. This subsection would insert a new Subtitle A—Block Grants to States for Social Services before SSA Sec. 2001 and add new sections with various Elder Justice provisions under a new Subtitle B—Elder Justice. The Elder Justice provisions under Subtitle B would be composed of two parts: Part

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<sup>63</sup> National Center on Elder Abuse at American Public Human Services Association, *National Elder Abuse Incidence Study*, prepared for the U.S. Department of Health and Human Services. The Administration for Children and Families and the Administration on Aging, Washington, DC, 1998.

<sup>64</sup> Richard J. Bonnie and Robert B. Wallace, eds., *Elder Mistreatment: Abuse, Neglect and Exploitation in an Aging America*, National Research Council of the National Academies, National Academy Press, Washington, DC, 2003.

<sup>65</sup> Richard J. Bonnie and Robert B. Wallace, eds., *Elder Mistreatment: Abuse, Neglect and Exploitation in an Aging America*, National Research Council of the National Academies, National Academy Press, Washington, DC, 2003.

I—National Coordination of Elder Justice Activities and Research and Part II—Programs to Promote Elder Justice.

### **Part I—National Coordination of Elder Justice Activities and Research**

The proposed Title XX, Subtitle B, Part I would be divided into two subparts—**Subpart A** would establish an Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation comprised of new **SSA Secs. 2021-2024**; **Subpart B** would add a new **Sec. 2031** awarding grants to establish and operate stationary and mobile forensic centers. These sections and activities are described in further detail below.

**Subpart A—Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation.** Subpart A would add a new **Sec. 2021**, *Elder Justice Coordinating Council*, establishing such a Council in the Office of the Secretary. The Council would include the Secretary who would chair the Council and the U.S. Attorney General as well as the head of each federal department or agency, identified by the Chair, as having administrative responsibility or administering programs related to elder abuse, neglect, and exploitation. The Council would be required to make recommendations to the Secretary regarding coordination of activities of HHS, DoJ, and other relevant federal, state, local, and private agencies and entities, relating to prevention of elder abuse, neglect, and exploitation and other crimes against elders. The Council would be required to submit a report to the appropriate committees of Congress within two years of enactment and every two years thereafter that describes its activities and challenges; and make recommendations for legislation, model laws, and other actions deemed appropriate. There would be authorized to be appropriated SSAN to carry out the Council’s functions.

Subpart A would also add a new **Sec. 2022**, *Advisory Board on Elder Abuse, Neglect, and Exploitation*, establishing an Advisory Board to create a short- and long-term multidisciplinary plan for development of the field of elder justice and make recommendations to the Elder Justice Coordinating Council. The Advisory Board would be composed of 27 members from the general public appointed by the Secretary to serve for staggered three-year terms, and must have experience and expertise in prevention of elder abuse, neglect, and exploitation. The Advisory Board would be required to develop collaborative approaches to improving the quality of LTC and to establish multidisciplinary panels to address these subjects by examining relevant research and identifying best practices, among other things. The Advisory Board would be required to submit a report to the Elder Justice Coordinating Council and the appropriate committees of Congress within 18 months of enactment and annually thereafter that contains information on the status of federal, state, and local elder justice activities; and make specified recommendations. There would be authorized to be appropriated SSAN to carry out the functions of the Advisory Board.

The proposed Subpart A would add a new **Sec. 2023**, *Research Protections*, requiring the Secretary to promulgate guidelines to assist researchers working in the areas of elder abuse, neglect, and exploitation with issues relating to human subjects protections. For the purposes of the application of certain specified federal regulations to research conducted under Subpart A it would define “legally authorized representative” to mean, unless otherwise provided by law, the individual, or judicial or other body authorized under the applicable law to consent to medical treatment on behalf of another person.

To carry out the functions under the proposed Subpart A, a new **Sec. 2024**, *Authorization of Appropriations*, would authorize to be appropriated \$6.5 million for FY2011, and \$7.0 million for each of FY2012 through FY2014.

**Subpart B—Elder Abuse, Neglect, Exploitation Forensic Centers.** Subpart B would add a new **Sec. 2031**, *Establishment and Support of Elder Abuse, Neglect, and Exploitation Forensic Centers*, requiring the Secretary, in consultation with the U.S. Attorney General, to award grants to eligible entities to establish and operate both stationary and mobile forensic centers and to develop forensic expertise pertaining to elder abuse, neglect, and exploitation. Funding would be authorized for the centers to: (1) develop forensic markers that would determine whether abuse or neglect occurred and whether a crime was committed, and determine methodologies for how and when intervention should occur; (2) develop forensic expertise with respect to elder abuse, neglect, and exploitation in order to provide relevant evaluation, intervention, support and advocacy, case review and tracking; and (3) in coordination with the U.S. Attorney General, use data made available by grant recipients under this section to develop the capacity of geriatric health care professionals and law enforcement to collect forensic evidence. It would authorize to be appropriated \$4 million in FY2011, \$6 million in FY2012, and \$8 million for each of FY2013 and FY2014 to carry out these activities.

## **Part II—Programs to Promote Elder Justice**

The proposed Title XX, Subtitle B, Part II would establish several grant programs and other activities to promote elder justice. These provisions would be established in the following new **Secs. 2041- 2046** and are described below.

**Sec. 2041. Enhancement of Long-Term Care.** The section would require the Secretary, in coordination with the Secretary of Labor, to carry out activities that provide incentives for individuals to train for, seek, and maintain employment providing direct care in LTC. The Secretary would be required to award grants to eligible entities to conduct programs that offer direct care employees continuing training and varying levels of certification. Grants would also be used to provide for or make arrangements with employers to pay bonuses, or other increased compensation or benefits, to employees who obtain certification. The Secretary would also be required to award grants to eligible entities for training and technical assistance regarding management practices using methods that are demonstrated to promote retention. The Secretary would be required to develop accountability measures to ensure that funded activities under this subsection benefit direct care workers and increase the stability of the LTC workforce.

The Secretary would also be authorized to make grants to LTC facilities for specified activities that would assist such entities in offsetting costs related to purchasing, leasing, developing, and implementing certified EHR technology designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors. A LTC facility that receives a grant would be required, where available, to participate in state health exchange activities conducted by a state or qualified entity under PHSA Sec. 3013, regarding state grants to promote HIT, to coordinate care and for other purposes the Secretary determines appropriate. The Secretary would be required to develop accountability measures to ensure that these activities help improve patient safety and reduce adverse events and health care complications resulting from medication errors.

The Secretary would be required to adopt electronic standards for the exchange of clinical data by LTC facilities to the Secretary. The standards adopted would have to be compatible with

standards established under current law, as specified, and with general HIT standards. Within 10 years after the date of the proposed law's enactment, the Secretary would be required to have procedures in place to accept the optional electronic submission of clinical data by LTC facilities. The Secretary would be required to promulgate regulations to carry out the adoption of standards for transactions involving clinical data by LTC facilities. Such regulations would require a state, as a condition of the receipt of funds under Part II, to conduct such data collection and reporting as the Secretary determines necessary.

It would authorize to be appropriated \$20 million for FY2011, \$17.5 million for FY2012, and \$15 million for each of FY2013 and FY2014 to carry out the activities under this section.

**Sec. 2042. Adult Protective Service Functions and Grant Program.** The section would require the Secretary to ensure that the Department: (1) provides authorized funding to state and local adult protective services (APS) offices that investigate reports of elder abuse, neglect, and exploitation of elders; (2) collects and disseminates data in coordination with DoJ; (3) develops and disseminates information on best practices regarding, and provides training on, carrying out APS; (4) conducts research related to the provision of APS; and (5) provides technical assistance to states and other entities that provide or fund APS. To carry out these functions, the section would authorize to be appropriated \$3 million for FY2011, and \$4 million for each of FY2012 through FY2014.

The section would also require the Secretary to establish two grant programs. The first would award annual grants to enhance APS programs provided by states and local governments. The second would award grants to states for APS demonstration programs. Annual grants awarded to states to enhance APS programs would be distributed to states based on a formula that takes into account the number of individuals aged 60 or older residing in a state relative to the total U.S. population aged 60 or older. States would receive no less than 0.75% of the grant program's annual appropriation. The District of Columbia and U.S. territories would receive no less than 0.1% of the annual appropriation. In order to comply with these minimum amounts, the Secretary would be required to make pro rata reductions in allotments. Grant awards for APS demonstration programs may be used by state and local governments to test: training modules developed for the purpose of detecting or preventing elder abuse; methods to detect or prevent financial exploitation and elder abuse; whether training on elder abuse forensics enhances the detection of abuse by employees of state or local government; and other related matters. For each of FY2011 through FY2014, it would authorize to be appropriated \$100 million for annual grants to enhance APS programs and \$25 million for the APS demonstration grants.

**Sec. 2043. Long-Term Care Ombudsman Program Grants and Training.** The section would require the Secretary to award grants to eligible entities with relevant expertise and experience in abuse and neglect in LTC facilities or state LTC ombudsman programs to: (1) improve the capacity of state LTC ombudsman programs to respond to and resolve abuse and neglect complaints; (2) conduct pilot programs with state or local LTC ombudsman offices; and (3) provide support for such state LTC ombudsman programs and such pilot programs. The provision would authorize to be appropriated \$5 million for FY2011, \$7.5 million for FY2012, and \$10 million for FY2013 and FY2014. The provision would also require the Secretary to establish programs to provide and improve ombudsman training with respect to elder abuse, neglect, and exploitation for national organizations and state LTC ombudsman programs. The provision would authorize to be appropriated \$10 million for each of FY2011 through FY2014.

**Sec. 2044. Provision of Information Regarding, and Evaluation of, Elder Justice Programs.**

To be eligible to receive a grant under Part II, the section would require an applicant to (1) agree to provide the required information to eligible entities conducting an evaluation of the activities funded through the grant; and (2) in the case of an applicant for a certified EHR technology grant, to provide the Secretary with such information as the Secretary may require. It would require the Secretary to reserve a portion of the funds appropriated in each program under Part II (no less than 2%) to be used to provide assistance to eligible entities to conduct validated evaluations of the effectiveness of the activities funded under each program under Part II. This provision would not apply to the certified EHR technology grant program, instead the Secretary would be required to conduct an evaluation of the activities funded under this grant program and appropriate grant audits.

**Sec. 2045. Report.** No later than October 1, 2014, the section would require the Secretary to submit a report to the Elder Justice Coordinating Council and the appropriate committees of Congress compiling, summarizing and analyzing state reports submitted under the APS grant programs and recommendations for legislative or administrative action, as the Secretary determines appropriate.

**Sec. 2046. Rule of Construction.** The section states that nothing in Subtitle B would be construed as (1) limiting any cause of action or other relief related to obligations under this subtitle that are available under the state law; or (2) creating a private cause of action for a violation of this subtitle. The section would also amend **SSA Sec. 402(a)(1)(B)** to require a state's TANF state plan to indicate whether the state intends to assist individuals to train for, seek, and maintain employment providing direct care in a LTC facility or in other occupations related to elder care. States that add this option would be required to provide an overview of such assistance. The amendment would take effect on January 1, 2011.

### *Protecting Residents of Long-Term Care Facilities*

Subsection (b) of Sec. 6703 would establish (1) a National Training Institute for Surveyors and grants to state survey agencies; and (2) requirements for reporting crimes in federally funded LTC facilities.

Specifically, this subsection would require the Secretary to enter into a contract to establish and operate the National Training Institute for federal and state surveyors to carry out specified activities that provide and improve the training of surveyors investigating allegations of abuse, neglect, and misappropriation of property in programs and LTC facilities that receive payments under Medicare or Medicaid. It would authorize to be appropriated \$12 million for each of FY2011 through FY2014 to carry out these activities. The HHS Secretary would also be required to award grants to state survey agencies that perform surveys of Medicare or Medicaid participating facilities to design and implement complaint investigation systems. It would authorize \$5 million for each of FY2011 through FY2014 to carry out these activities.

This subsection would also amend **SSA Title XI, Part A** (as amended by Sec. 6005 of the bill) by adding the following new section, Reporting to Law Enforcement of Crimes Occurring in Federally Funded Long-Term Care Facilities, with a new **Sec. 1150B** requiring the reporting of crimes occurring in federally funded LTC facilities that receive at least \$10,000 during the preceding year. It would require the owner or operator of these facilities to annually notify covered individuals (defined as an owner, operator, employee, manager, agent, or LTC facility contractor) that they are required to report any reasonable suspicion of a crime against a resident

or individual receiving care from the facility. Suspected crimes would have to be reported to the Secretary and one or more law enforcement entities. The timing for reporting suspected crimes would be subject to certain reporting requirements. Failure of a covered individual to report suspicion of a crime would result in a civil money penalty and the Secretary may make a determination to exclude the covered individual from participation in any federal health care program. If an individual is classified as an “excluded individual,” a LTC facility that employs them would not be eligible to receive federal funds under the SSA. The Secretary would be authorized to take into account the financial burden on providers with underserved population in determining any penalty to be imposed. A LTC facility would be prohibited from retaliating against an employee for making a report. If retaliation occurred, the LTC facility would be subject to a civil money penalty or the Secretary could exclude them from participation in any federal health care program for a period of two years, or both. In addition, each LTC facility would be required to post conspicuously, in an appropriate location, a sign specifying the rights of employees under this section.

### *National Nurse Aide Registry*

Subsection (c) of Sec. 6703 would require the Secretary, in consultation with appropriate government agencies and private sector organizations, to conduct a study on establishing a national nurse aide registry. The study would include an evaluation of (1) who should be included in the registry; (2) compliance with federal and state privacy laws; and (3) how data would be collected, among other things. In conducting the study and preparing the report, the Secretary would be required to take into consideration the findings and conclusions of relevant reports and resources. No later than 18 months after the date of enactment, the Secretary would be required to submit a report to the Elder Justice Coordinating Council and appropriate congressional committees containing the findings and recommendations of the study. Based on the recommendations contained in the report, the appropriate congressional committees would be required to take action as determined appropriate. It would authorize to be appropriated SSAN to carry these activities, with funding for the study not to exceed \$500,000.

## **Food and Drug Administration**

### **Background and Issues**

The Food and Drug Administration (FDA) is responsible for the safety of most foods, as well as the safety and the effectiveness of human drugs, biologics (e.g., vaccines, blood, and blood components), and medical devices, among other things.<sup>66</sup> FDA’s regulation of medical products affects aspects of the cost, quality, and accessibility of health care. Medical products comprise a large percentage—over 15%—of health care costs.<sup>67</sup> The products’ effectiveness, which FDA

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<sup>66</sup> For further information about FDA, see CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*, by Erin D. Williams.

<sup>67</sup> This percentage is based upon the CMS data from 2007. It was generated by dividing \$289 billion (Retail Outlet Sales of Medical Products) by \$1,878 billion (Personal Health Care). The number does not reflect all of the costs of FDA regulated medical products associated with health care spending, because it does not include those purchased by hospitals (such as pacemakers and other implantable devices), dentists offices (such as fillings), or other health care facilities. “Table 4 - National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2002 - 2007,” CMS website, at <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>.



evaluates, is a major component of health care quality. Their availability to consumers, which FDA regulates, is one component of access to health care. In the context of health care, adding regulatory requirements may increase the quality of medical products that reach the market, but may also raise the cost of those products or delay consumer access to them. FDA's regulation of food, in particular its nutrition labeling requirements, may have an effect on the health of individuals as well. This regulatory authority is particularly relevant given links between obesity and chronic diseases that may drive up health care costs.

H.R. 3590, as passed by the Senate, contains eight FDA-related provisions that would affect the agency's regulation of four types of products. For prescription drugs, one provision would require the Secretary to determine whether adding certain information to a prescription drug's labeling and advertising would improve health care decision making, and a second would change certain drug labeling requirements. For foods, a third provision would require nutrition labeling at certain restaurants and vending machines. For biologics, a fourth, fifth, and sixth provision would create a licensure pathway for biosimilars (generic biologics) and authorize the agency to collect associated fees. For drugs and devices, a seventh and eighth provision would create a tax on certain medical products. Each of these provisions is described in more detail below.

## **Prescription Drug Labeling**

The introduction or delivery for introduction of a misbranded drug into interstate commerce is a prohibited act for which certain penalties may be imposed, according to the Federal Food Drug and Cosmetic Act (FFDCA) Secs. 301(a) and 303. A drug is deemed to be misbranded if it does not meet the requirements of FFDCA Sec. 502. The section lists the items of information that must be listed in a drug's labeling (such as established name, quantity, active and inactive ingredients, adequate directions for use, and adequate warnings). The section also requires that each of these items be included prominently and conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In addition, the section requires that all advertisements and other descriptive printed matter include information in brief summary relating to side effects, contraindications, and effectiveness, as specified in regulation.<sup>68</sup>

FFDCA Sec. 505(j) requires an abbreviated application for a new drug (ANDA) to "show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug."

### **Sec. 3507. Presentation of Prescription Drug Benefit and Risk Information**

This section would require the Secretary to determine whether the addition of information about the health benefits and risks of a prescription drug to that drug's labeling and advertising would improve health care decision-making by clinicians, patients, and consumers. To reach this determination, the Secretary would be required to review all available scientific evidence and research on decision-making and social and cognitive psychology and consult with a wide range of stakeholders. If such a determination is made, the bill would require the Secretary to promulgate proposed regulations within three years to implement such format. Sec. 3511 of this bill would authorize the appropriation of SSAN to carry out the activities in this section.

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<sup>68</sup> For further information see 21 CFR 201 (regarding labeling), and 21 CFR 202 (regarding prescription drug advertising).

## **Sec. 10609. Labeling Changes**

This section would amend **FFDCA Sec. 505(j)** to allow ANDA approval of a drug otherwise qualified whose labeling reflects the labeling approved for the listed referent drug that had been in effect until the listed drug changed labeling within 60 days of the anticipated ANDA approval. The ANDA sponsor would be required to agree to the submission of revised labeling within 60 days of the Secretary's requiring changes. This provision would not be applicable if the Secretary were to determine that continued use of the unrevised labeling of the listed drug would adversely impact the safe use of the drug or if the revisions changed the "Warnings" section of the label.

## **Nutrition Labeling**

Concern about the rising rates of obesity and the resulting effect on individuals' health and health care costs have prompted Congress to consider options for promoting healthy eating. One option is to require nutrition labeling for some foods currently exempted from such regulations. (See FFDCA Secs. 301(a) and 403(q)(5)(A)). Food served in restaurants is currently among the types exempted from FDA's nutrition labeling requirements.

FFDCA Sec. 403 lists the circumstances that would cause a food to be deemed misbranded, which include the failure to adhere to the Act's nutrition labeling requirements. FFDCA Sec. 403A prohibits states and localities from establishing their own nutrition labeling that is not identical to the Act's requirements, except for food such as food sold in restaurants, that is presently exempt from nutrition labeling requirements. States and localities may petition the Secretary of HHS for an exemption from the preemption clause in FFDCA Sec. 403A.

## **Sec. 4205. Chain Restaurant Menus and Vending Machines**

This section would insert a new **paragraph H** into **FFDCA Sec. 403(q)(5)**, requiring nutrition labeling for standard menu items offered for sale in chain restaurants or similar retail food establishments with 20 or more locations. These establishments would be required, for standard menu items, to disclose as specified (1) the number of calories contained in the item and (2) the suggested daily caloric intake, as specified by the Secretary by regulation. Such establishments would also be required to make available, at the premises upon request, certain detailed written nutritional information.

The establishments would be required to have a reasonable basis for their nutrient content disclosures. The Secretary would be required to establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but that are listed as a single menu item.

The section would require certain vending machine operators that own or operate 20 or more machines to provide specified signs disclosing the number of calories contained in each article of food, so that the information is accessible to consumers before they make their purchases.

The Secretary would be required to promulgate proposed regulations as specified to carry out the requirements of the section, and to provide quarterly reports to Congress describing progress toward promulgating final regulations.

The section would amend **FFDCA Sec. 403A** to preempt states and localities from establishing or continuing in effect any requirement for nutrition labeling of a food that is not identical to the requirements of FFDCA Sec. 403(q), including the new requirements for foods served in certain restaurants and retail food. The section also would prohibit the amendments it made from being construed as (1) preempting any provision of state or local law unless the state or local law creates or continues nutrition disclosures of the type that would be required by this section and those disclosures would be expressly preempted; (2) applying to any state or local requirement about food labeling that provides for safety warnings concerning the food or a component of the food; or (3) applying to any restaurant or similar retail food establishment other than those described in this proposal and offering for sale substantially the same menu items.

## **Biosimilars**

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.<sup>69</sup>

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 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.

## **Sec. 7001. Short Title**

This section provides the title, “Biologics Price Competition and Innovation Act of 2009,” and the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

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<sup>69</sup> For additional information, see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

## Sec. 7002. Approval Pathway for Biosimilar Biological Products

This section would amend **PHSA Sec. 351** by opening 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).

The section 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.

The section would provide a 12-year data exclusivity period (from the date on which the reference product was first approved) for the reference product. If a reference product has been designated an orphan drug, an application for a biosimilar or interchangeable product may not be filed until the later of (1) the 7-year period of orphan drug exclusivity described in the FFDCA, or (2) the 12-year period established by this section. The section also 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.<sup>70</sup>

The Secretary would be authorized to 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 section 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 section would further require that all biological product applications be submitted under PHSa Sec. 351. For the small number of biological products that have been approved under FFDCA Sec. 505, the approved application would be deemed to be a license for the biological product under Sec. 351 as of 10 years after enactment.

The section would allow for the collection of user fees for the review of applications for approval of biosimilars. The Secretary would have to develop recommendations regarding goals for the review of biosimilar product applications for FY2013 through the end of FY2017 and present them to Congress. The recommendations must be published in the *Federal Register* with a 30-day public comment period, and a public meeting must be held. The revised recommendations would be presented to Congress by January 15, 2012. Based on those recommendations, it is the sense of the Senate that Congress should authorize a user fee program effective October 1, 2012. Through

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<sup>70</sup> For more information on exclusivity and patents, see CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

October 1, 2010, the Secretary must collect data on the cost of biosimilar product application review as conducted according to the prescription drug user fee program. Two years after receiving the first user fee for a biosimilar product application, and every two years thereafter until October 1, 2013, the Secretary must perform an audit of the application review costs. An alteration of the user fee would occur depending on results of the audit, as specified in this section.

An extra six months of data (market) exclusivity would be provided for a new biologic drug if pediatric studies are conducted prior to FDA approval of the drug. An extra six months of data (market) exclusivity is provided for a biologic drug already on the market if pediatric studies are conducted and the request for the extension is made not less than nine months before the expiration of the original exclusivity period. The section would require an IOM study that would review and assess the number and importance of biological products for children that are being tested as a result of amendments made by the Biologics Price Competition and Innovation Act of 2009, as well as biological products that are not being tested for pediatric use, and offer recommendations for ensuring pediatric testing of biological products.

### **Sec. 7003. Savings**

This section would require that the HHS Secretary and the Treasury Secretary determine for each fiscal year the amount saved to the federal government as a result of enactment of the approval pathway for biosimilar biological products. Notwithstanding any other provision, the savings to the federal government as a result of enactment of the biosimilars approval pathway shall be used for deficit reduction.

## **Drug and Device Taxes**

H.R. 3590, as passed by the Senate, includes measures designed to generate revenue by imposing taxes related to branded prescription drugs and medical devices. These have generated controversy within the device industry, with device manufacturers voicing their concern that smaller companies may suffer, and that all companies may be less able to capitalize research into the development of future devices.<sup>71</sup> There is currently no special tax on branded prescription drugs or medical devices; however, manufacturers do pay user fees to the FDA.<sup>72</sup>

### **Sec. 9008. Annual Fee for Branded Prescription Pharmaceuticals**

This section would impose an annual fee on *covered entities*: certain manufacturers and importers of branded prescription drugs (including biological products and excluding orphan drugs). Covered entities would pay annually to the Secretary of the Treasury a total of \$2.3 billion, which would be transferred to the Medicare Part B trust fund.

Each covered entity would pay a proportion of the \$2.3 billion, calculated by the Secretary, equal to the proportion that specified amounts of each entity's branded prescription drug sales for

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<sup>71</sup> See, e.g., Alicia Mundy, "Drug Makers Face Tougher Measures," *The Wall Street Journal*, October 30, 2009, p. A4.

<sup>72</sup> For further information about user fees, see CRS Report RL34571, *Medical Device User Fees and User Fee Acts*, by Erin D. Williams; and CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul.

specified government programs bore to the total such sales of all covered entities for the previous year. The specified amounts of total that would be taken into account are as follows. For sales of not more than \$5 million, none would be taken into account. For sales of more than \$5 million and not more than \$125 million, 10% would be taken into account. For sales of more than \$125 million and not more than \$225 million, 40% would be taken into account. For sales of more than \$225 million and not more than \$400 million, 75% would be taken into account. For sales of more than \$400 million, 100% would be taken into account.

The Secretary of the Treasury would calculate the proportion to be paid by each covered entity based upon annual reports made by the Secretaries of HHS, Veterans Affairs, and Defense. Reports would contain the total branded prescription drug sales for each covered entity with respect to Medicare Parts B and D, Medicaid, the Department of Veterans Affairs programs, and the Department of Defense programs and TRICARE.

### **Sec. 9009. Annual Fee for Medical Devices**

This section, as amended by Sec. 10904 of the bill, would impose an annual fee on *covered entities*: certain manufacturers and importers of medical devices with sales in United States. Sales would exclude those of class II devices typically sold to consumers for less than \$100, and those of class I devices.<sup>73</sup>

Beginning in 2011, covered entities would pay annually to the Secretary of the Treasury a total of \$2 billion (\$3 billion after 2017). Each covered entity would pay proportion of the total, calculated by the Secretary, that is equal to the proportion that specified amounts of its gross receipts from medical device sales bore to the total gross receipts of all covered entities for the previous year. The specified amounts of total that would be taken into account are as follows. For sales of not more than \$5 million, none would be taken into account. For sales of more than \$5 million and not more than \$25 million, 50% would be taken into account. For sales of more than \$25 million, 100% would be taken into account.

The Secretary of the Treasury would calculate the proportion to be paid by each covered entity based upon annual reports made by covered entities. Penalties could be imposed for a failure to make required reports.

## **340B Drug Pricing**

### **Background and Issues**

Under PHS Act Sec. 340B, pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program are required to enter into pharmaceutical pricing agreements that provide discounts on covered outpatient drugs purchased by certain public health facilities (covered entities). HRSA, the agency that administers the 340B program, indicates that approximately

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<sup>73</sup> Under the Federal Food, Drug and Cosmetic Act, medical devices are categorized as class I, class II, or class III according to the amount of controls necessary to ensure their safety and effectiveness. Class I devices (e.g., cotton swabs) require the least controls. Class III devices (e.g., pacemakers) require the most controls. For further information see CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

14,000 covered entities and 800 pharmaceutical manufacturers participate in the program.<sup>74</sup> Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers. These entities include hospitals owned or operated by state or local government that serve a higher percentage of Medicaid beneficiaries, as well as federal grantees such as FQHCs, FQHC look-alikes, family planning clinics, state-operated AIDS drug assistance programs, Ryan White CARE Act grantees, family planning and sexually transmitted disease clinics, and others, as identified in the PHSA. Covered entities may not receive discounts on inpatient drugs under the 340B program.

Under the 340B program, covered entities are prohibited from diverting drugs purchased under the program to other organizations and from obtaining multiple discounts, including participation in outpatient group purchasing arrangements. The 340B discount is determined by dividing the average total Medicaid rebate percentage of 15.1% for single source and innovator multiple source drugs, and 11% for non-innovator multiple source drugs by the average manufacturer price (AMP) for each dose and strength. Medicaid statute defines AMP as the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers are required to report AMP and their best price to the Secretary, but subject to verification, manufacturers calculate the maximum price (“ceiling price”) they may charge 340B entities. Manufacturers are permitted to audit covered entity records if they suspect product diversion or multiple discounts are taking place.

Sec. 6004 of the Deficit Reduction Act of 2005 added children’s hospitals that are exempt from the Medicare prospective payment system to the list of covered entities, provided that these facilities meet other 340B participation requirements. A final rule for participation of children’s hospitals in the 340B program was issued on September 1, 2009.

### **Sec. 7101. Expanded Participation in 340B Program**

This section would amend **PHSA Sec. 340B** to add the following to the list of covered entities that would be entitled to discounted drug prices under the 340B program: (1) certain children’s and free-standing cancer hospitals excluded from the Medicare prospective payment system, (2) critical access and sole community hospitals, and (3) rural referral centers. These new 340B-eligible facilities also would need to meet the specified 340B participation requirements. In addition, the provision would expand 340B discounts to inpatient drugs for participating hospital entities. Further, hospitals that participate in the 340B program would be permitted to participate in group purchasing arrangements for inpatient drugs. However, the prohibition on hospital participation in outpatient drug group purchasing agreements would remain.

The Secretary would be required to provide for reasonable exceptions to the outpatient drug group purchasing prohibition; namely (1) for outpatient drugs that are unavailable due to supply shortages or other circumstances beyond the hospital’s control; (2) when generic drugs are available at lower prices; and (3) to reduce the administrative burden in managing inventories of 340B-covered and uncovered drugs (as long as duplicate discounts or drug diversion would be avoided). The Secretary would ensure that 340B hospitals (and particularly small and rural hospitals) have multiple options for purchasing covered inpatient drugs under this program. As determined by the Secretary, 340B hospitals would be required within 90 days after filing their

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<sup>74</sup> See HRSA “2009 Quarter 3 Statistics for 340B Covered Entities, Record Counts as of 7/01/2009” at [ftp://ftp.hrsa.gov/bphc/pdf/opa/Stats\\_2009\\_QTR\\_3.pdf](ftp://ftp.hrsa.gov/bphc/pdf/opa/Stats_2009_QTR_3.pdf).

most current Medicare cost report to issue a credit to the state Medicaid program for inpatient drugs provided to Medicaid beneficiaries. The changes in this provision and Sec. 612 would be used to determine whether manufacturers met 340B participation requirements.

### **Sec. 7102. Improvements to 340B Program Integrity**

This section would amend **PHSA Sec. 340B** to require the Secretary to develop systems to improve compliance and program integrity activities for manufacturers and covered entities, as well as administrative procedures to resolve disputes. The system would include a number of specifications that would increase transparency and strengthen the monitoring, oversight, and investigation of the prices manufacturers charge covered entities, as well as additional improvements to ensure covered entities are not diverting drugs or obtaining multiple discounts. The administrative dispute resolution process would mediate and provide final resolution to covered entity overpayment claims and manufacturer claims against covered entities for drug diversion or multiple discounts.

The section would authorize the appropriation of SSAN to carry out the improvements to the 340B program for FY2010 and each succeeding fiscal year. Manufacturers would be required to report to the Secretary quarterly ceiling prices for each covered drug and to offer these drugs to covered entities at or below these prices.

### **Sec. 7103. GAO Study on Improving the 340B Program**

This section would require GAO to submit a report to Congress that examines whether individuals receiving services through 340B-covered entities are receiving optimal health care services. The report would be due within 18 months of enactment and would at least make recommendations on (1) whether the 340B program should be expanded; (2) whether mandatory 340B sales of certain products could hinder patients' access to those therapies through any provider; and (3) whether 340B income is being used by covered entities to further program objectives.

## **Veterans Health Care**

### **Background and Issues**

The Department of Veterans Affairs (VA), through the Veterans Health Administration (VHA), operates the nation's largest integrated direct health care delivery system.<sup>75</sup> While Medicare, Medicaid, and the CHIP are also publicly funded programs, most health care services under these programs are delivered by private providers in private facilities. In contrast, the VA health care

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<sup>75</sup> U.S. Department of Veterans Affairs, *FY 2008 Performance and Accountability Report*, Washington, DC, November 17, 2008, p. 10; Established on January 3, 1946 as the Department of Medicine and Surgery by P.L. 79-293, succeeded in 1989 by the Veterans Health Services and Research Administration, renamed the Veterans Health Administration in 1991.



system is a truly public health care system in the sense that the federal government owns the medical facilities and employs the health care providers.<sup>76</sup>

In general, eligibility for VA health care is based on veteran status,<sup>77</sup> service-connected disabilities<sup>78</sup> or exposures,<sup>79</sup> income,<sup>80</sup> and other factors such as status as a former prisoner of war or receipt Purple Heart.<sup>81</sup>

The VHA also pays for care provided to veterans by private-sector providers on a fee basis under certain circumstances. Inpatient and outpatient care are also provided in the private sector to eligible dependents of veterans under the Civilian Health and Medical Program of the Department of Veterans Affairs.<sup>82</sup> All enrolled veterans are offered a standard medical benefits package.<sup>83</sup>

Veterans do not pay premiums or enrollment fees. However, under current law most veterans are required pay copayments for the treatment of nonservice-connected conditions.<sup>84</sup> It should be noted that those veterans who are rated 50% or more service-connected disabled and enrolled in the VA health care system do not pay copayments even for nonservice-connected care. Moreover, VA is required to collect reasonable charges for medical care or services (including prescription drugs) from a third party insurer to the extent that the veteran or the provider of the care or services would be eligible to receive payment from a third party insurer for a nonservice-connected disability for which the veteran is entitled to care (or the payment of expenses of care) under a health insurance plan.<sup>85</sup>

This bill contains several provisions related to the VA. Specifically, it includes a provision that would require the VA to report to Congress on the effect on VA health care because of fees charged to drug and medical device manufactures (described below). Furthermore, among other things, it would require VA to participate in the Interagency Working Group on Health Care Quality (Sec. 3012); would exempt the VA from a fee on all health insurers based on their market

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<sup>76</sup> U.S. Congress, House, *Economic Report of the President*, 110<sup>th</sup> Cong., 2<sup>nd</sup> sess., February 2008, H. Doc. 110-83 (Washington: GPO, 2008), p. 106.

<sup>77</sup> Veteran's status is established by active-duty status in the U.S. Armed Forces, and an honorable discharge or release from active military service. Generally, persons enlisting in one of the armed forces after September 7, 1980, and officers commissioned after October 16, 1981, must have completed two years of active duty or the full period of their initial service obligation to be eligible for VA health care benefits. Servicemembers discharged at any time because of service-connected disabilities are not held to this requirement.

<sup>78</sup> A service-connected disability is a disability that was incurred or aggravated in the line of duty in the U.S. Armed Forces (38 U.S.C. § 101 (16)). VA determines whether veterans have service-connected disabilities, and for those with such disabilities, assigns ratings from 0% to 100% based on the severity of the disability. Percentages are assigned in increments of 10% (38 C.F.R. §§ 4.1-4.31).

<sup>79</sup> For example, veterans who may have been exposed to Agent Orange during the Vietnam War or veterans who may have diseases potentially related to service in the Gulf War may be eligible to receive care.

<sup>80</sup> Veterans with no service-connected conditions and who are Medicaid eligible, or who have an income below a certain VA means-test threshold and below a median income threshold for the geographic area in which they live are also eligible to enroll in the VA health care system.

<sup>81</sup> For a complete discussion on eligibility for VA health care, priority groups, and enrollment see, CRS Report R40737, *Veterans Medical Care: FY2010 Appropriations*, by Sidath Viranga Panangala.

<sup>82</sup> For further information on CHAMPVA, see CRS Report RS22483, *Health Care for Dependents and Survivors of Veterans*, by Sidath Viranga Panangala.

<sup>83</sup> A detail listing of VHA's standardized medical benefits package is available at 38 C.F.R. § 17.38 (2008).

<sup>84</sup> 38 U.S.C. § 1729.

<sup>85</sup> 38 U.S.C. § 1729(a)(2)(D); 38 C.F.R. § 17.101(a)(1)(i).

share (Sec. 4375); and would provide VA access to the National Practitioner Data Bank without a charge (Sec. 6403).

### **Sec. 9011. Study and Report of Effect on Veterans Health Care**

This provision would require the Secretary of Veterans Affairs to conduct a study on the effect of provisions in Title IX of the bill—in particular the new fees on drug and device manufacturers—on the cost of medical care provided to veterans, and veterans’ access to medical devices and branded prescription drugs. The Secretary would be required to report the results of such a study to the House Committee on Ways and Means and the Senate Committee on Finance. The report would be required by December 31, 2012.

## **Miscellaneous**

### **Sec. 3509. Offices of Women’s Health**

This section would create a new **PHSA Sec. 229**, establishing in the Office of the Secretary an Office on Women’s Health, for the establishment of goals and objectives, expert consultation, and other specified duties. Among them, the Secretary would be required to establish a National Women’s Health Information Center and an HHS Coordinating Committee on Women’s Health. The Secretary would be authorized to provide funding and make interagency agreements as necessary to carry out these duties, and would be required to conduct evaluations of such activities and provide periodic reports to Congress. There would be authorized to be appropriated SSAN for FY2010 through FY2014. The section would transfer to this new office all functions of the existing Office on Women’s Health of the Public Health Service.

In addition, the section would establish new offices of women’s health, with specified duties, in CDC (new **PHSA Sec. 310A**), AHRQ (redesignated **PHSA Sec. 925**), HRSA (new **PHSA Sec. 713**), and the FDA (new **FFDCA Sec. 1011**). For each of these offices there would be authorized to be appropriated SSAN for FY2010 through FY2014. The section would also amend current authority for offices of women’s health in the NIH and SAMHSA, to establish that the director of each office would report to the senior official of the respective agency. Sec. 3511 of the bill would authorize the appropriation of SSAN for the NIH and SAMHSA offices.

This section and amendments made by it would not alter existing regulatory authority; terminate, reorganize, or transfer authority away from women’s health offices in existence as of enactment without the approval of Congress; or change existing administrative activities at HHS regarding women’s health.

### **Sec. 4203. Wellness for Individuals with Disabilities**

This section would add a new **Sec. 510 of the Rehabilitation Act** requiring the Architectural and Transportation Barriers Compliance Board, in consultation with FDA, to issue regulatory standards for minimal technical criteria for medical diagnostic equipment (as specified) used in medical settings.<sup>86</sup> The standards must ensure that individuals with disabilities can use, enter, and

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<sup>86</sup> Section 502 of the Rehabilitation Act established the Architectural and Transportation Barriers Compliance Board to (continued...)

exit such equipment independently, to the maximum extent possible. The Board would be required periodically to review the standards and amend them as necessary.

### **Sec. 4207. Reasonable Break Time for Nursing Mothers**

This section would amend **Sec. 7 of the Fair Labor Standards Act of 1938**,<sup>87</sup> to require employers to provide a reasonable break time for an employee to express breast milk for her nursing child for one year after the child's birth each time such employee has need to express the milk, and a place to do so, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public. An employer would not be required to compensate an employee for such break time. Employers of fewer than 50 employees would not be subject to these requirements if they would impose an undue hardship by causing the employer significant difficulty or expense when considered in relation to the size, financial resources, nature, or structure of the employer's business. This provision would not preempt a state law that provides greater protections to employees.

### **Secs. 6801 and 10607. Medical Liability**

Sec. 6801 expresses the Sense of the Senate that (1) health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test litigation alternatives while preserving an individual's right to seek redress in court; and (3) Congress should consider establishing a state demonstration program to evaluate alternatives to the existing civil litigation system with respect to medical malpractice claims.

Sec. 10607 would create a new **PHSA Sec. 933V-4**, authorizing the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or organizations. These grants would exist for no more than five years. State grantees would be required to develop an alternative that (1) allows for the resolution of disputes caused by health care providers or organizations; and (2) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data. Each state would have to identify the sources from and methods by which compensation would be paid, and demonstrate that its proposed alternative to tort litigation meets certain goals and criteria. The Secretary would have to provide to the states that are applying for the grants technical assistance, including guidance on common definitions, non-economic damages, avoidable injuries, and disclosure to patients of health care errors and adverse events.

The Secretary would be required to consult with a review panel composed of relevant experts appointed by the Comptroller General when reviewing states' applications. Furthermore, each state receiving a grant would be required to submit a report to the Secretary covering the impact of the activities funded on patient safety and on the availability and price of medical liability

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(...continued)

develop design standards for, and to assure compliance by, facilities designed, built, altered, or leased with federal funds, in order to improve access for people with disabilities.

<sup>87</sup> The Fair Labor Standards Act is the primary federal statute dealing with the issue of overtime pay. Section 7 of the law regards maximum work hours.

insurance. The Secretary would be required to submit a report to Congress that examines any differences that may result in the areas of quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance. Additionally, the Secretary, in consultation with the review panel, would be required to conduct an overall evaluation of the effectiveness of grants awarded, and to submit the findings of such evaluation to Congress. The Medicare Payment Advisory Commission would be required to conduct an independent review of the impact of state-implemented alternatives to tort litigation on the Medicare program and its beneficiaries. The Medicaid and CHIP Payment and Access Commission would be required to conduct a similar evaluation with respect to the Medicaid and CHIP programs and their beneficiaries.

The section would not limit any prior, current, or future efforts of any state to establish any alternative to tort litigation. It would appropriate \$50 million for the five-fiscal year period beginning FY2011 to carry out this section.

### **Sec. 9017. Excise Tax on Elective Cosmetic Medical Procedures**

This section would add a new **IRC Sec. 5000B** (in a new Chapter 49). It would impose a 5% tax on amounts paid for certain cosmetic surgeries and medical procedures performed by licensed medical professionals. Not included would be surgeries and procedures necessary to ameliorate deformities from congenital abnormalities, personal injury, or disfiguring diseases. The person receiving payment for the service would collect the amount of the tax from the individual on whom the procedure is performed, and would be responsible for the tax amount if the patient did not submit the payment. The provider would submit the tax to the Treasury Secretary quarterly. Note: Sec. 10907 of the bill, described below, would nullify this provision.

### **Sec. 10407(c). Vital Statistics**

This subsection would require the Secretary, acting through the CDC Director, to promote the education and training of physicians on the importance of birth and death certificate data, encourage state adoption of the latest standard revisions of birth and death certificates, and work with states to re-engineer their vital statistics systems. This section also would authorize the Secretary to promote improvements to the collection of diabetes mortality data. (Note: Sec. 10407 in its entirety is discussed earlier in this report under “Community Prevention Grants and Related Activities.”)

### **Sec. 10409. Cures Acceleration Network**

This section would amend **PHSA Sec. 402(b)** to require the NIH Director to implement the new Cures Acceleration Network (CAN), described below. It also would amend **PHSA Sec. 499(c)(1)** to enable the Foundation for the National Institutes of Health to accept charitable gifts to support the CAN.

The section would add a new **PHSA Sec. 402C**, *Cures Acceleration Network*, containing definitions, establishing CAN within the Office of the Director, specifying CAN’s functions, establishing CAN’s Board, and requiring the Director to award grants, contracts, or cooperative agreements to carry out the purposes of the section.

The NIH Director would determine which medical products (drugs, devices, biological products, or combinations thereof) were “high need cures,” based upon (1) their ability to diagnose, prevent, or treat harm from a disease or condition; and (2) the lack of market incentives for their adequate or timely development. The Director would award, as specified, grants, contracts, or cooperative agreements to accelerate the development of high need cures. The Cures Acceleration Partnership Awards would, among other things, provide up to \$15 million for the first year, payable in a lump sum, with a matching requirement. The Cures Acceleration Grant Awards would be similar but have no matching requirement. The Cures Acceleration Flexible Research Awards would be available if the Director determined that the goals of the section could not be met otherwise, and would consist of awards not to exceed 20% of the total funds appropriated under this section (see below).

The CAN would seek to support revolutionary advances in basic research, facilitate FDA review for CAN-funded cures, as specified, and carry out other specified functions. A CAN Review Board would be established to advise the Director on the activities of CAN. The Board also would advise the Director on significant barriers to the translation of basic science into clinical applications, among other things, and would submit to the Secretary reports regarding any barrier identified. The Director would be required to respond to such recommendations in writing.

There would be authorized to be appropriated \$500 million for FY2010, and SSAN for subsequent fiscal years. A limitation would prohibit other funds appropriated under the PHS Act from being allocated to the CAN.

### **Sec. 10412. Automated Defibrillation in Adam’s Memory Act**

PHSA Sec. 312(a) requires the Secretary to award grants to States, political subdivisions of States, and others to develop and implement public access defibrillation programs. Sec. 312(c)(6) authorizes grant recipients to use the funds received through such grants to establish an information clearinghouse that provides information to increase public access to defibrillation in schools. Sec. 312(e) authorizes \$25,000,000 for FY2003, and SSAN for each of the FY2004 through FY2006.

This section would amend **PHSA Sec. 312** so that the information clearinghouses that grant recipients are authorized to establish with grant funds would be required to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death. The section also would authorize the appropriation of \$25 million for each of FY2003 through FY2014.

### **Sec. 10907. Excise Tax on Indoor Tanning Services**

This section would add a new **IRC Sec. 5000B** (in a new Chapter 49), imposing a 10% tax on amounts paid for indoor tanning services. Not included would be phototherapy services performed by licensed medical professionals. The person receiving payment for the service would collect the amount of the tax from the individual on whom the procedure is performed, and would be responsible for the tax amount if the client did not submit the payment. The provider would submit the tax to the Treasury Secretary quarterly. This section also would nullify Sec. 9017 of the bill (Excise Tax on Elective Cosmetic Medical Procedures).

### **Sec. 10909. Expansion of Adoption Credit and Adoption Assistance Programs**

This section would increase the qualified expense limitation for the adoption tax credit and the income exclusion for qualified employer-provided adoption expense programs to \$13,170 for tax year 2010 (for tax year 2009, the qualified expense limitation is \$12,150). It also would index this new qualified expense limitation amount to inflation for tax year 2011. The adoption tax credit would be made refundable for tax years 2010 and 2011. In addition, the expiration of the Economic Growth and Tax Relief Reconciliation Act (EGTRRA, P.L. 107-16) changes to the adoption tax credit and the income exclusion for employer-provided adoption expense programs would be delayed by one year (from December 31, 2010, to December 31, 2011).<sup>88</sup>

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<sup>88</sup> For further information on the adoption tax credit, see CRS Report RL33633, *Tax Benefits for Families: Adoption*, by Christine Scott.

**Table I. Crosswalk of Public Health, Workforce, Quality, and Related Provisions in H.R. 3962 and H.R. 3590**

Topic	Sections in H.R. 3962 (as passed by the House)	Sections in H.R. 3590 (as passed by the Senate) <sup>a</sup>
Public Health Investment Fund (House); Prevention and Public Health Fund & Community Health Center Fund (Senate)	2002, 2003, 2101, 2202, 2216, 2221, 2235, 2281, 2301, 2403	4002, 10503
Health Centers	2101, 2511, 2512, 2586	4101 [10402(a)], 5208, 5601, 10503, 10608
Health Workforce		
National Health Service Corps	2201, 2202, 2596	5207, 5508(b), 5602, 10501(n), 10503, 10908
Primary Care and Dentistry	2211–2217	5201, 5203, 5301–5304, 5508(a) & (c)
Nursing Workforce	2221, 2521, 2536	5202, 5305(c), 5308–5312, 5509, 10501(e)
Public Health Workforce	2231–2235	5204, 5206, 5209, 5210, 5313 [10501(c)], 5314, 5315, 10501(m)
Workforce Diversity, Cultural Competency, Interdisciplinary and Community-Based Training	2241–2243, 2251, 2252, 2281	5305(a) & (b), 5307, 5401–5404, 5405 [10501(f)], 10501(d) & (l)
Health Workforce Evaluation and Assessment	2261, 2271, 2281	5101 [10501(a)], 5102, 5103, 10501(b)
Medicare Graduate Medical Education Payments	1501–1505	5503, 5504, 5505 [10501(j)], 5506
Other Workforce Provisions	2533, 2539, 2589–2591	5205, 5507, 5701, 8002(c), 10501(g) & (k), 10502, 10504
Prevention and Wellness		
Coverage of Clinical Preventive Services	222, 1305, 1306, 1310, 1311, 1313, 1711, 1712, 1725	1001, 1302, 4103 [10402(b)], 4104 [10406], 4105–4108
Employer-Provided Wellness Programs	112	1001, 1201, 4303 [10404], 4402, 10408
Community-based Prevention Strategy and Funding	2301	4001 [10401], 4002–4004
Community-based Preventive Services	2524, 2525, 2530, 2535, 2594	4102, 4201 [10403], 4202, 4204, 4206, 4301, 4304, 4306, 10407, 10411, 10413, 10501(g)
Stricken Provision Concerning CBO Scoring	np <sup>b</sup>	4401, 10405
Maternal and Child Health		
Maternal and Early Childhood Home Visitation	1904	2951
Postpartum Depression	2529	2952
Teen Pregnancy Prevention	2526	2953, 2954

Topic	Sections in H.R. 3962 (as passed by the House)	Sections in H.R. 3590 (as passed by the Senate) <sup>a</sup>
Support for Pregnant and Parenting Teens and Women	np	10211–10214
Infant Mortality	2532	np
Youth Aging out of Foster Care	np	2955
Behavioral Health	214, 222, 2513, 2522, 2538	1311(j), 5604, 5306, 10410
Quality		
National Strategy to Improve Health Care Quality and Quality Measurement	1441–1446	3011 [10302], 3012, 3013 [10303(a)], 3014 [10304], 3015 [10305]
Quality Improvement and Patient Safety	1461, 2401, 2403	3501, 3508, 10303(b) & (c)
Care Coordination	2528, 2534, 2537	3502, 3503, 3506, 3510, 10333
Key Indicators	2402, 2403	5605
Comparative Clinical Effectiveness Research	1401, 1802	6301 [10602], 6302
Medicare and Medicaid Nursing Homes	1411–1432	6101–6121, 6201
Health Disparities	1221–1224, 2588A	4302, 10334
Health Information Technology		
HIPAA Administrative Simplification	115, 237, 328	1104, 1561
Electronic Health Records	263	np
Telehealth	2523	np
Emergency Care	1908, 2551–2556	3504, 3505, 5603
Pain Care and Management	2561–2563	4305
Elder Justice	np	6703
Food and Drug Administration		
Medical Products	552, 2571, 2573	3507, 9008, 9009 [10904], 10609, 10907
Nutrition Labeling	2572	4205
Biosimilars	2575–2577	7001–7003
340B Drug Pricing	2501–2503	7101–7103
Veterans' Health	np	9011



Topic	Sections in H.R. 3962 (as passed by the House)	Sections in H.R. 3590 (as passed by the Senate) <sup>a</sup>
Miscellaneous	1451 (Physician Payment Sunshine), 2527 (Autism), 2531 (Medical Liability), 2585 (State Employers), 2587 (Diseases of Poor Americans), 2588 (Offices of Women's Health), 2592 (Disabilities), 2593 (Duplicative Grant Programs), 2595 (Vital Statistics)	3509 (Offices of Women's Health), 4203 (Disabilities), 4207 (Nursing Mothers), 6801 & 10607 (Medical Liability), 9017 (Elective Cosmetic Procedures), 10407(c) (Vital Statistics), 10409 (Cures Acceleration Network), 10412 (Defibrillators), 10907 (Indoor Tanning), 10909 (Adoption Tax Credit and Assistance)

**Source:** Table prepared by the Congressional Research Service based on the text of H.R. 3962, as passed by the House, and H.R. 3590, as passed by the Senate.

- a. Title X of the Senate-passed bill, which was incorporated as a manager's amendment to the underlying legislation, amends numerous provisions in Titles I through IX and adds several new sections. The Title X amendments appear italicized in square brackets immediately following the number of the section that they amend.
- b. No provision.

## **Appendix. Acronyms Used in the Report**

<b>ACF</b>	Administration for Children and Families
<b>ACIP</b>	Advisory Committee on Immunization Practices
<b>AFL</b>	Adolescent Family Life
<b>AHEC</b>	Area Health Education Center
<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>AMP</b>	average manufacturer price
<b>APS</b>	adult protective services
<b>ARRA</b>	American Recovery and Reinvestment Act
<b>CBO</b>	Congressional Budget Office
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CFCIP</b>	Chafee Foster Care Independence Program
<b>CHC</b>	Community Health Center
<b>CHIP</b>	Children's Health Insurance Program
<b>CHIPRA</b>	Children's Health Insurance Program Reauthorization Act of 2009
<b>CHW</b>	community health worker
<b>CMS</b>	Centers for Medicare and Medicaid Services
<b>COE</b>	Center of Excellence
<b>DoJ</b>	Department of Justice
<b>EFT</b>	electronic funds transfer
<b>EIS</b>	Epidemic Intelligence Service
<b>EHR</b>	electronic health record
<b>ERISA</b>	Employee Retirement Income Security Act
<b>FACA</b>	Federal Advisory Committee Act
<b>FCCCR</b>	Federal Coordinating Council for Comparative Effectiveness Research
<b>FDA</b>	Food and Drug Administration
<b>FFDCA</b>	Federal Food, Drug, and Cosmetic Act
<b>FQHC</b>	Federally Qualified Health Center
<b>GAO</b>	Government Accountability Office
<b>GEC</b>	Geriatric Education Center
<b>HELP</b>	Senate Committee on Health, Education, Labor, and Pensions
<b>HHS</b>	Health and Human Services
<b>HIT</b>	Health Information Technology
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>HITECH</b>	Health Information Technology for Economic and Clinical Health Act
<b>HRSA</b>	Health Resources and Services Administration
<b>HPSA</b>	Health Professional Shortage Area
<b>IHS</b>	Indian Health Service
<b>IOM</b>	Institute of Medicine

<b>IPPE</b>	initial preventive physical examination
<b>IRC</b>	Internal Revenue Code
<b>LTC</b>	long term care
<b>MA</b>	Medicare Advantage
<b>MCH</b>	Maternal and Child Health
<b>MEPS</b>	Medical Expenditures Panel Survey
<b>MIPPA</b>	Medicare Improvements for Patients and Providers Act of 2008
<b>MTM</b>	medication therapy management
<b>NCHS</b>	National Center for Health Statistics
<b>NCHWA</b>	National Center for Health Workforce Analysis
<b>NF</b>	nursing facility
<b>NHSC</b>	National Health Service Corps
<b>NIH</b>	National Institutes of Health
<b>NIMH</b>	National Institute of Mental Health
<b>NHANES</b>	National Health and Nutrition Examination Survey
<b>NMHC</b>	Nurse-Managed Health Clinic
<b>NOHSS</b>	National Oral Health Surveillance System
<b>OAA</b>	Older Americans Act
<b>OMB</b>	Office of Management and Budget
<b>ONCHIT</b>	Office of the National Coordinator for Health Information Technology
<b>PCORTF</b>	Patient-Centered Outcomes Research Trust Fund
<b>PDP</b>	prescription drug plan
<b>PHSA</b>	Public Health Service Act
<b>PQRI</b>	Physician Quality Reporting Initiative
<b>PRAMS</b>	Pregnancy Risk Assessment Monitoring System
<b>QHBP</b>	Qualified Health Benefits Plan
<b>RHQDAPU</b>	Reporting Hospital Quality Data for Annual Payment Update
<b>SAMHSA</b>	Substance Abuse and Mental Health Services Administration
<b>SBHC</b>	School-Based Health Clinic
<b>SG</b>	U.S. Surgeon General
<b>SNF</b>	skilled nursing facility
<b>SSA</b>	Social Security Act
<b>SSAN</b>	such sums as may be necessary
<b>TANF</b>	Temporary Assistance for Needy Families
<b>TFCPS</b>	Task Force on Community Preventive Services
<b>USPSTF</b>	U.S. Preventive Services Task Force
<b>VA</b>	Department of Veterans Affairs
<b>VHA</b>	Veterans Health Administration

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