
# Public Health, Workforce, Quality, and Other Provisions in the Affordable Health Choices Act (S. 1679)

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# Summary

Health care reform is at the top of the domestic policy agenda for the 111th Congress, driven by concerns about the growing ranks of the uninsured and the unsustainable growth in spending on health care and health insurance. But efforts to improve access to care and control rising health care costs also will require changes to the health care delivery system. Experts point to a growing body of evidence of the health care system's failure to consistently provide high-quality care to all Americans. Major challenges to the delivery of high-quality care include improving patient safety by eliminating medical errors, eradicating disparities in care, reducing the burden of chronic disease, and eliminating unnecessary and ineffective care that compromises quality, drives up costs, and neglects the needs of patients.

The health reform debate has embraced 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 expanding the primary care workforce, encouraging the use of clinical preventive services, and strengthening the role of chronic care management. However, health care delivery reform cannot happen unless mechanisms are in place 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 importantly, the alignment of payment incentives with high-quality care.

Congress took an important first step 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 included $1.1 billion for comparative effectiveness research and established an interagency advisory panel to help coordinate and support the research. It also 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.

Both the House and the Senate are now considering health reform legislation. America's Affordable Health Choices Act of 2009 (H.R. 3200), introduced in the House and approved by the Committees on Ways and Means, Energy and Commerce, and Education and Labor, includes numerous provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things. In the Senate, the Health, Education, Labor, and Pensions (HELP) Committee has approved the Affordable Health Choices Act (S. 1679), which addresses health care delivery reform issues such as expanding private health insurance coverage, improving health care quality and strengthening quality measurement, encouraging preventive services, expanding the health care workforce, preventing health care fraud and abuse, and improving access to medical therapies. This report summarizes the workforce, quality, prevention, and other selected provisions in S. 1679, as amended and adopted by the Senate HELP Committee. It will be updated to reflect future legislative actions. A companion product, CRS Report R40745, *Public Health, Workforce, Quality, and Other Provisions in H.R. 3200*, summarizes comparable provisions in the House health reform legislation, American's Affordable Health Choices Act of 2009 (H.R. 3200).

# Contents

## Appendixes



## Contacts

# Introduction

Health care reform is at the top of the domestic policy agenda for the 111th Congress, driven by concerns about the growing ranks of the uninsured and the unsustainable growth in spending on health care and health insurance. Improving access to care and controlling rising costs will 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.

In a November 2008 report outlining its goals for health reform, the National Priorities Partnership, representing all the major stakeholder groups in the health sector, identified four major challenges to the delivery of high-quality care.[1] 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 (IOM), an estimated 30%-40% of health care spending is wasted on unnecessary and even unsafe care.[2]

## Health Care Delivery Reform

While primarily focused on health care financing issues, the health reform debate has embraced 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—will require significant changes in health professions education and training. While some advisory

[1] 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/.

[2] Institute of Medicine, National Academy of Engineering, *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Washington, DC: National Academies Press, 2005.

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.[3] Instead of focusing on overall physician supply, health policy analysts recommend a 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.[4]

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. 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, 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 cannot happen unless mechanisms are in place 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, perhaps most importantly, 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. Policymakers are interested in expanding these pay-for-performance initiatives to incentivize other changes to the health care delivery system.

[3] 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.

[4] 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.

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.

## American Recovery and Reinvestment Act

Congress took one step 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 included $17 billion in supplemental funding for biomedical research, public health, and other health-related programs within the Department of Health and Human Services (HHS), including $1.1 billion for comparative effectiveness research. It also established an interagency advisory panel to help coordinate and support the research. In addition, 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. Included in the ARRA health funding was $2 billion to fund HIT grant programs authorized by the HITECH Act.[5]

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. Moreover, 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

On September 17, 2009, Senator Harkin introduced a comprehensive health care reform bill entitled the Affordable Health Choices Act (S. 1679). The legislation is identical to the unnumbered health reform bill that was marked up and, on July 15, 2009, approved by the Senate Committee on Health, Education, Labor, and Pensions (HELP). The Affordable Health Choices Act (hereinafter referred to as the Senate HELP bill) consists of six titles. Title I addresses private health insurance, including the establishment of an insurance exchange and the creation of a public option. Title II includes provisions related to improving health care quality and service delivery, including strengthening quality measurement. Title III promotes preventive services.

[5] See P.L. 111-5; for more information, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by (name redacted), and CRS Report R40161, *The Health Information Technology for Economic and Clinical Health (HITECH) Act*, by (name redacted).

Title IV includes provisions to increase the primary care and public health workforce. Title V includes a series of provisions intended to prevent health care fraud and abuse. And Title VI addresses access to medical therapies, including creating a regulatory pathway for approving biosimilars and expanding participation in the Public Health Service Act (PHSA) 340B drug pricing program.

This report summarizes the workforce, quality, prevention, and other provisions in Titles I, II, III, IV, and VI of the Senate HELP bill, as amended and adopted by the HELP Committee. The report groups the bill's provisions under the following headings: (1) health centers; (2) health workforce, including programs authorized under the PHSA and under other statutes; (3) health care quality; (4) prevention and wellness; (5) Food and Drug Administration; (6) emergency care; (7) behavioral health care; (8) pain care and management; (9) PHSA 340B drug pricing program; and (10) miscellaneous. In most instances, each section begins with some background on current law and practice so as to provide context for the subsequent brief descriptions of the bill's provisions. Unless otherwise stated, references to "the Secretary" refer to the Secretary of HHS. A list of all the acronyms used in the report is in the **Appendix**. This report will be updated to reflect future legislative actions.

A companion report, CRS Report R40745, *Public Health, Workforce, Quality, and Other Provisions in H.R. 3200*, summarizes comparable provisions in the House health reform legislation, American's Affordable Health Choices Act of 2009 (H.R. 3200). This legislation was jointly developed by the House Committees on Ways and Means, Energy and Commerce, and Education and Labor, which share jurisdiction over the federal health statutes. All three committees have held markups—in each case focusing on the titles in the bill that fall under the committee's jurisdiction—and ordered the legislation to be reported, as amended.

# Health Centers

## Background and Issues

PHSA Sec. 330 authorizes the health center program, which provides grants to Community Health Centers (CHCs), migrant health centers, health centers for the homeless, and health centers for residents of public housing. Health centers are a key component of the nation's health care safety net and provide primary care and preventive services to the 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 areas that are medically underserved and target populations with insufficient health care access.

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.[6] The program was reauthorized by the Health Care Safety Net Act of 2008.[7] The Act also included the requirement that the Government Accountability Office (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

[6] An individual health center may operate multiple sites.

[7] The health centers program is administered by HRSA. For more information, see http://bphc.hrsa.gov.

the general authority to establish community health centers. Studies show that health centers increase access to primary health care services, which helps reduce disparities and reduce costs by averting more expensive emergency room visits.[8]

## Sec. 171. Spending for Community Health Centers

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 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 should be construed to prevent a 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. This section also specifies the criteria that the entities must meet in order to be eligible to receive contract funds from a CHC.

## Sec. 172. Administrative Changes

This section would amend **PHSA Sec. 330** to make several administrative changes to the health center programs. Among other changes, it would (1) expand the definition of health center to allow facilities to provide services at either facilities operated directly by the center and at other inpatient and outpatient settings; (2) allow facilities to be located outside of a medically underserved area if the location is accessible to and meets the needs of the service population; (3) allow the Secretary to permit grant applications for additional centers in an established center's catchment area provided that certain specified criteria are met; (4) amend several grant application requirements as specified; (5) provide centers with greater flexibility to modify their budgets; (6) authorize the Secretary to carry out projects that allow centers to collaborate to establish joint purchasing agreements in order to reduce the costs of supplies; and (7) specify the procedures through which centers can correct a failure to meet grant conditions.

## Sec. 312. School-Based Health Clinics

This section would create a new **PHSA Sec. 399Z-1** requiring the Secretary to establish a SBHC grant program. 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 nonfederal sources unless granted a waiver by the Secretary, agree to use grant funds for certain specified purposes (which may include facility construction), and agree to use grant funds to supplement and not supplant funds received from other sources. Additionally, SBHCs would only be permitted to provide age-appropriate services. The Secretary would be authorized to give preference to applicants who demonstrate ability to serve communities with specified barriers to

[8] 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.

access. When determining grant amounts, the Secretary would be required to take into account the financial need of the SBHC, other funding sources available to the SBHC, and other factors determined appropriate by the Secretary. The section would authorize to be appropriated such sums as may be necessary (SSAN) for FY2010 through FY2014.

### Sec. 428. Nurse-Managed Health Clinics

This section would create a new **PHSA Sec. 330A-1** requiring the Secretary to establish a grant program to fund the development and operation of Nurse-Managed Health Clinics (NMHCs) that provide comprehensive primary health care and wellness services to vulnerable populations living in medically underserved communities, and to reduce the level of health disparities experienced by vulnerable populations. To be eligible to receive a grant, a 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 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.[9]

[9] For more information on the NHSC program, see CRS Report R40533, *Health Care Workforce: National Health Service Corps*, by (name redacted).

# National Health Service Corps

## Sec. 173. 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. 427. National Health Service Corps

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.

# Promotion of Primary Care and Dentistry

PHSA Title VII, Part A, comprising Secs. 701-735, authorizes student loan programs for health professions students. 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. The Senate HELP bill includes the following sections that would establish or amend existing programs to increase the supply of primary care providers.

## Sec. 421. 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.

## Sec. 423. 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 pediatric medicine or surgery, or in child and adolescent mental and behavioral health care (which could include substance abuse prevention and treatment). Eligible individuals, including 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. 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. 431. 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, accredited 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 the grants or contracts, the Secretary would be required to give preference to qualified applicants proposing certain specified activities. 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. 432. 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 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 in courses provided by an eligible entity. Individuals receiving assistance under this section would be required to work in one of the specified fields for a minimum of two years. There would be authorized to be appropriated $10 million for each of FY2011 through FY2013.

## Sec. 433. Training in General, Pediatric, and Public Health Dentistry

This section would redesignate **PHSA Sec. 748**, as amended by Sec. 413 of this 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 conduct 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, including those eligible for Medicaid and the Children's Health Insurance Program (CHIP), or to entities that in the two fiscal years prior to receiving the award had an increased rate of placing its 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.

## Sec. 434. Alternative Dental Health Care Provider Demonstration

This section would add a new **PHSA Sec. 340H** 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, primary care physicians, and dental therapists. Entities eligible for this grant program include institutions of higher education, public-private partnerships, FQHCs, Indian tribes, Indian Health Service (IHS) or tribally operated facilities and Urban Indian organizations as specified, 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, to include baseline and comparison data from each project funded by this program. Nothing in this 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. 456. Definition of Economic Hardship

This section would amend the **Higher Education Act Sec. 435** by inserting new language restoring the "20/220 pathway," which provides deferments of federal student loans to borrowers who are working full-time, have a federal educational debt burden that equals or exceeds 20% of their adjusted gross income, and where the difference between the borrower's adjusted gross

income minus the borrower's federal education debt burden is less than 220% of the greater of (1) minimum wage earnings, as defined, or (2) 150% of the poverty line adjusted for the borrower's family size.[10]

## 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. The Senate HELP bill would modify and reauthorize several of these existing programs.

### Sec. 422. 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 non-profit settings who received loan funds before September 29, 1995.

### Sec. 435(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 435(a) and (b) of this bill amend the geriatric education and training provisions in PHSA Sec. 753; see below.)

### Sec. 438. 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.

[10] The College Cost Reduction and Access Act of 2007 (P.L. 110-84) made changes to the definition of "economic hardship" by repealing the 20/220 pathway, a specific type of economic hardship deferment (i.e., the temporary suspension of a borrower's obligation to make payments on the principal of a loan for a period of time) that was commonly used by medical residents who were middle-income borrowers with large amounts of federal student loan debt. As of July 1, 2009, this deferment was no longer available. Medical residents and other eligible borrowers were able to obtain forbearance, whereby loan payments are temporarily suspended or reduced for a specified period of time; however, unlike a deferment, interest still accrues during the period of forbearance and the borrower is ultimately responsible for paying this interest.

## Sec. 439. 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. 440. 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.

## Sec. 441. 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. 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 the Health Resources and Services Administrator (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. Support of doctoral students would receive funding priority. There would be authorized to be appropriated SSAN for each of FY2010 through FY2014.

## Sec. 442. Authorization of Appropriations

This section would amend **PHSA Sec. 841** 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.

## 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. 424. 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. 426. 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. 429. 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.[11] This section would amend Sec. 202 of P.L. 102-394 by eliminating the cap.

[11] The ceiling was raised to 4,000 in Sec. 222 of P.L. 111-8, the Omnibus Appropriations Act, 2009.

## Sec. 430. 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. 443. Grants to Promote the Community Health Workforce

This section would create a new **PHSA Sec. 399U**, requiring the Centers for Disease Control and Prevention (CDC) Director to award grants to eligible entities to serve medically underserved communities (as defined) through the use of community health workers (CHWs, as defined). Among other things, the Secretary would be required to establish guidelines for training and supervision of CHWs, monitor programs that receive grants, and provide technical assistance. The section would authorize the appropriation of SSAN through FY2014.[12]

## Sec. 444. Youth Public Health Program

This section would amend **PHSA Sec. 751** with respect to an Area Health Education Center (AHEC) infrastructure development awards (as established by Sec. 453 of this bill, see below), by adding to the list of eligible activities programs to expose and recruit high school students into health careers, with a focus on public health.

## Sec. 445. 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. 446. 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, as follows. 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

[12] This section would also redesignate two existing PHSA sections sharing duplicate designations as Sec. 399R. Namely, Sec. 399R regarding an ALS registry would be redesignated as Sec. 399S, and Sec. 399R regarding prenatally and postnatally diagnosed conditions would be redesignated as Sec. 399T.

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 U.S. Surgeon General (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 regarding 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 give priority to 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.[13]

## Workforce Diversity, Cultural Competency, and Interdisciplinary Care

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 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 nonfederal expenditures, and must first expend other federal funds before expending

[13] 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.

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. 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.

The Senate HELP bill includes the following sections that would amend and expand existing workforce diversity and interdisciplinary, community-based training programs.

## Sec. 435(a) and (b). Geriatric Education and Training

Section 435(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 that 24 GECs authorized to receive an award. There would be authorized to be appropriated $10.8 million for 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 FY2011 through FY2013.

Sec. 435(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. 437. Cultural Competency, Prevention, and Disability Training

This section would amend Title VII, Part B by adding at the end a new **PHSA Sec. 742**—Cultural Competency, Prevention and Public Health, and Individuals with Disabilities Training. The new section would require the Secretary to support the development and evaluation of model curricula for use in health professions schools and continuing education programs for providing training in cultural competency, prevention and public health proficiency, and working with individuals with disabilities. The Secretary would be required to evaluate the adoption and implementation of these curricula, which would be available through the Internet. To carry out the section, there would be authorized to be appropriated SSAN for each of FY2010 through FY2015.

## Sec. 451. Centers of Excellence

This section would amend **PHSA Sec. 736**, modifying the COE funding formula by adding 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. 452. Health Care Professionals Training for Diversity

This section would amend **PHSA Sec. 738** 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. 453. 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 nonfederal 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 year.

### Sec. 454. Nursing Workforce Diversity

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. 455. Primary Care Extension Program

This section would add a new **PHSA Sec. 399V**—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.

## 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 (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 Senate HELP 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 a 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.

### Sec. 411. National Health Care Workforce Commission

This section 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 Comptroller General of the United States. It would (1) review specified health care workforce supply and distribution information and make two annual reports with recommendations to Congress; (2) review implementation progress reports and report on the state health care workforce development grants program (established by Sec. 412 of this bill); (3) study effective mechanisms for financing education and training for careers in health care; (4) make recommendations about improving health care workers' safety and protections; and (5) assess reports from the NCHWA (established by Sec. 413 of this bill). This section would authorize to be appropriated SSAN.

### Sec. 412. 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. 411 of this 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. 413. 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: (1) for National Centers, $5 million for each of FY2010 through FY2011, $10 million for each of FY2012 through FY2014, and SSAN for each subsequent fiscal year; (2) for State and Regional Centers, $4.5 million for each of FY2010 through FY2014, and SSAN for each subsequent fiscal year; and (3) for grants for longitudinal evaluations, SSAN for each of FY2010 through FY2014. 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. This section

also 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 amends **PHSA Sec. 791** by adding new language that would require 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 would also 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.

## Other Workforce Provisions

### Sec. 425. 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. 461. Reports

This section would require the Secretary to submit an annual report to the appropriate congressional committees. The report would include the activities carried out under the amendments made by Title IV of this bill, and their effectiveness. The Secretary would be authorized to require, as a condition of receiving funds under the amendments made by Title IV, that recipients of such funds submit reports on activities carried out under the amendments and the effectiveness of those activities.

# 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 the Senate HELP bill that would address the issues of quality measurement, patient safety/quality improvement, care coordination, and comparative effectiveness research.

## 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 the Agency for Healthcare Research and Quality, 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 the Centers for Medicare and Medicaid's (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.

The Senate HELP bill includes the following five sections addressing quality measurement, which would require the development of an explicit 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 quality measure endorsement, data collection methods, and public reporting of quality information.

### Sec. 201. 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 the adoption of strategies for quality improvement that represent best practices; 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. The Secretary would also be required

to publish an annual national health care quality report card and create a website to make public the national priorities, the annual national health care quality report card, and other information the Secretary deems appropriate.

## Sec. 202. 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, and developing a streamlined process for quality reporting and compliance requirements. 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. 203. 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 a qualified consensus-based entity under **Sec. 399JJ**. 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 also require the Director to fund or enter into agreements with eligible entities for purposes of developing, improving, updating, or expanding quality measures in 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 continuity, management, and coordination of health care and care transitions; health disparities; and the appropriate use of health care resources and services, 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 a qualified consensus-based entity. This section would authorize to be appropriated $75 million for each fiscal year through FY2014.

## Sec. 204. Quality Measure Endorsement; Public Reporting; Data Collection

This section would create in Title III, Part S, a new **Subpart II**, "Health Care Quality Programs." It would include **Secs. 399JJ, 399KK, and 399LL,** as described below.

**Sec. 399JJ** would permit a qualified consensus-based entity to receive a grant or contract to make recommendations to the Secretary for national priorities for performance improvement; identify gaps in endorsed quality measures; identify and endorse quality measures, including measures that address gaps; update endorsed measures; make endorsed measures publicly available and have a plan for wide-spread dissemination; and transmit endorsed measures to the Secretary. An

entity that receives funding under this section would be required to convene multi-stakeholder groups to make recommendations for national priorities for performance improvement and to provide guidance on the selection of individual or composite measures for use in reporting performance information to the public or for use in federal health programs. This section would permit the Secretary to make a determination under regulation or otherwise to use a quality measure that has been endorsed by the qualified consensus-based entity only after taking into account the guidance of multi-stakeholder groups. The Secretary would be permitted to make a determination to use a quality measure that has not been endorsed under certain circumstances, and if there is no adequate alternative, the Secretary would be required to support the development of such an alternative measure. This section would require the Secretary to review quality measures used by the Secretary and determine whether to maintain or phase out each measure. This section would authorize to be appropriated $50 million for each fiscal year through FY2014.

**Sec. 399KK** would require the Secretary to implement a system for the reporting of quality measures that protects patient privacy and, where appropriate, assesses health outcomes and functional status of patients; coordination of care; patient experience and patient caregiver and family engagement; the safety, effectiveness, and timeliness of care; and health disparities. This section would require the Secretary to make available to the public performance information summarizing data on quality measures through a series of standardized websites. Performance information on these websites would be required to be made available by clinical condition and, where appropriate, would be provider-specific to meet the needs of patients with different clinical conditions.

**Sec. 399LL** would require the Comptroller General of the United States to conduct periodic evaluations of the implementation of the data collection processes for quality measures to be used by the Secretary.

## Sec. 205(a). Data for Quality and Resource Use Measures

This subsection would add a new **PHSA Sec. 399MM**, which would provide for the development of reports to improve the quality and efficiency of health care and make available to the public provider-identifiable performance information. This section would require the Secretary to establish a process to collect, and validate, aggregate data on quality measures, as well as to ensure the collection and aggregation of consistent data on quality and resource use measures, to facilitate and implement public reporting of performance information, and would require the Secretary to award grants or contracts to eligible entities to support this activity. This section would also require the Secretary to support the development, validation, implementation, and refinement of nationally consistent methods used to support quality measurement and reporting through the awarding of grants or contracts to eligible quality data entities. The Secretary would be required to make aggregated data and reports on quality and resource use measures available to health care providers and the public. Finally, this section would require the Secretary to allow certain researchers to report on the performance of health care providers and suppliers, including in a provider-identifiable format. This section would authorize to be appropriated $90 million for each fiscal year through 2014.

## 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 affecting 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. 211. Patient Safety Research Center

This section would create a new **Subpart II**, "Health Care Quality Improvement Programs," and would include a new **PHSA Sec. 933**, which would establish the Patient Safety Research Center in AHRQ. 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 and to ensure that research findings and results generated by the Center would be shared with HHS Office of the National Coordinator for HIT (ONCHIT) section would authorize to be appropriated $20 million for each fiscal year through 2014.

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 in the research conducted by the Center. Funds would also support implementation awards to eligible entities to implement these models and practices.

### Sec. 216. Reducing and Reporting Hospital Readmissions

This section would add a new **PHSA Sec. 399NN**, with the purpose of improving the quality and value of inpatient hospital services in order to improve the coordination of care and appropriately reduce inefficiency and waste, such as unnecessary hospital readmissions. This section would

require the Secretary to analyze and calculate hospital-specific and national applicable readmissions rates and to establish procedures to provide for the confidential disclosure, to hospitals receiving funds under this proposed law, of information on the hospital-specific and national applicable readmission rates. No later than two years after enactment, the Secretary would also be required to make publicly available information on applicable readmission rates of hospitals receiving funds under the PHSA.

This section would require the Secretary to establish a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations. Eligible hospitals would be defined as a hospital that the Secretary would determine to have a severity adjusted readmission rate, for the selected conditions, among the highest 25% of all hospitals nationally. Eligible hospitals and patient safety organizations working with those hospitals would be required to report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates. This section would require the Secretary to identify and select at least eight high-volume and high-readmissions conditions or procedures to be analyzed under this section. It would also require the Secretary to select readmissions, for analysis under this section, that must have been reasonably preventable by the provision of care consistent with evidence-based guidelines during the prior admission or the post discharge follow-up period, and they must have been for a condition or procedure related to the care provided during the prior admission or post discharge follow-up period.

The Comptroller General of the United States would be required to conduct a study on the impact of this section on care furnished to consumers, expenditures under federal health programs, and the cost and quality of care furnished by hospitals. This section would also require the Secretary to seek to enter into an agreement with the IOM to submit a report to Congress with recommendations on how to reduce unnecessary hospital readmissions.

### Sec. 220. Health Professional Education

This section would allow the Secretary to award grants to eligible entities or consortia 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 nonfederal 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.

## 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. 187. 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 ensure 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 issues 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. 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 fiscal years 2011 through 2018, with amounts appropriated to remain available until expended.

## 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 the Senate HELP bill 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. Sec. 133 of the Medicare Improvements

for Patients and Providers Act of 2008 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.

Sec. 340A of the PHSA authorizes the Secretary to make 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. 212. Community Health Teams to Support Patient-Centered 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, and that ensures that the health team includes a multi-disciplinary team of specified providers. "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 though 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. 213. Medication Management Services in Treatment of Chronic Disease

This section would add a new **PHSA Sec. 935,** which would require the Secretary, acting through the Patient Safety Research Center established in **Sec. 933**, to provide grants to support MTM services provided by licensed pharmacists. The section would require the Secretary to establish an MTM grant program. 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. 217. Program to Facilitate Shared Decisionmaking

This section would add a new **PHSA Sec. 936** 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 a qualified consensus-based organization 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. Finally, the Secretary would be required to adopt quality measures for shared decision making. 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. 223. 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. This section would authorize the appropriation of $3.5 million for FY2010, and SSAN for each of fiscal years 2011 through 2015.

## Comparative 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.[14]

### Sec. 219. Center for Health Outcomes Research and Evaluation

The section would add a new **PHSA, Sec. 937**, which would require the Secretary to establish a Center for Health Outcomes Research and Evaluation ("Center") within AHRQ. This section would direct the Center to conduct research relevant to the comparative health outcomes and effectiveness of the full spectrum of health care treatments. Responsibilities would cover systematic reviews of clinical research, research to identify benefits and risks of treatments specific to individuals' genetic makeup and coexisting conditions, and research that leads to reduction in treatment disparities among populations. The Center would be required to use a broad range of methodologies, create informational tools, and develop a publicly available resource database to inform healthcare decision making. The section would direct the Center to use existing published and unpublished information, to carry out, or award grants or contracts for, original research and experimentation where existing information is inadequate, and to adopt procedures for interested parties to submit information, among other things.

The section would require the Secretary to establish, through AHRQ's National Advisory Council, an advisory council that includes representatives from the scientific research, patient, provider, and health industry committees. To insulate the research agenda and research conduct from undue political or stakeholder influence, the section would require that research use scientifically based methods, that all aspects of research be transparent to stakeholders, and that there be a process for involved stakeholders to review and comment on the research, among other things. The section would require the Center to disseminate to health care providers, patients, and other specified groups the findings of the research it supported, conducted, or synthesized. The section specifies that Center reports and recommendations would not be permitted to be construed as mandates for payment, coverage, or treatment.

# Health Information Technology

## HIPAA Administrative Simplification

To support the growth of electronic record keeping and claims processing in the nation's health care system, the Health Insurance Portability and Accountability Act's (HIPAA) Administrative Simplification provisions (Social Security Act, SSA Secs. 1171-1179) instructed the Secretary to adopt standards for the electronic transmission of certain routine administrative and financial health care transactions, including data elements and code sets for those transactions. The HIPAA-specified transactions include (1) health claims and (2) health care payment and remittance advice. A final rule, which adopted existing and already widely used standards for

[14] On June 30, 2009 FCCCER released its annual "Report to the President and the Congress." The report can be found at http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.

seven of the specified transactions as well as code sets to be used in those transactions, was published in 2000. The transactions standards included several Accredited Standards Committee X12 (ASC X12) standards for health care transactions. In January 2009, the Secretary published a final rule adopting updated versions of the HIPAA electronic transactions standards to replace the versions currently in use.

The HIPAA Administrative Simplification standards apply to health plans (including the Medicare program and state Medicaid plans), health care clearinghouses, and health care providers who transmit HIPAA-specified transactions electronically. HIPAA does not mandate that providers conduct these transactions electronically, though private health plans and state Medicaid programs 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. The Administrative Simplification Compliance Act of 2001 requires that Medicare claims be submitted electronically in the HIPAA standard format, with the exception of those from small providers and in other limited circumstances.

HIPAA further required the Secretary to issue national identification numbers for health care providers, health plans, employers, and individuals (i.e., patients) 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 development of a unique individual identifier.

### Sec. 222. Administrative Simplification

This section would require the Secretary, within two years of enactment and building on the existing HIPAA standards and related requirements, to adopt and regularly update a set of standards, implementation specifications, and operating rules for electronic financial and administrative transactions. The standards, implementation specifications, and operating rules would be required to (1) be unique with no conflicting or redundant standards; (2) be authoritative, requiring no additional standards; (3) be comprehensive and robust, requiring minimal augmentation by paper transactions; (4) enable real-time determination of a patient's financial responsibility at the point of service; (5) provide for timely acknowledgment; and (6) require that all data elements be described in unambiguous terms with no optional fields permitted. Further, the initial set of standards, implementation specifications, and operating rules must include requirements to clarify, refine, and expand the HIPAA Administrative Simplification standards. In addition, they must include requirements for acknowledgments (such as those for receipt of a claim) and to permit electronic funds transfers, as well as requirements for timely and transparent claim and denial management processes. The section outlines a set of procedures for expediting the adoption of additions and modifications to the initial set of standards, which the Secretary may choose to follow. Within two years of enactment of this Act, the Secretary would be required to submit to Congress a five-year implementation and enforcement plan for the new standards, implementation specifications, and operating rules.

Finally, the Secretary, within one year of enactment, would be required to promulgate a final rule to establish a unique health plan identifier.

## Legal Obstacles to HIT Adoption

The federal anti-kickback statute (SSA Secs. 1128A, 1128B) prohibits an individual or entity from knowingly or willfully offering or accepting remuneration of any kind to induce a patient

referral for, or purchase of, an item or service covered by any federal health care program. Violations of the law are subject to civil and criminal penalties, and exclusion from participation in federal health care programs. HHS issues regulations designating specific safe harbors for various payment and business practices that would otherwise be implicated by the anti-kickback statute and subject to its civil and criminal prosecution. The Medicare physician self-referral (Stark) law (SSA Sec. 1877) prohibits physicians from referring patients to any entity for certain health services if the physician has a financial relationship with the entity, and prohibits entities from billing for any services resulting from such referrals, unless an exception applies.

The Medicare Modernization Act of 2003 instructed the Secretary to establish a safe harbor from penalties under the anti-kickback statute and an exception to the Stark law for the provision of HIT and training services used in electronic prescribing. That would allow, for example, a hospital to provide e-prescribing software and training to its medical staff, and Medicare Advantage (MA) plans to provide such software and training to pharmacies and prescribing health care providers. The final rule, which was published in August 2006, created a safe harbor and Stark exception not just for e-prescribing software, but more broadly for EHR software, provided it includes e-prescribing.

## Secs. 231-233. Safe Harbor and Stark Exception for HIT Products and Services

Sec. 231 would create a safe harbor from civil monetary penalties under the anti-kickback statute for HIT and related services provided by a hospital or critical access hospital to a physician. It also would create a safe harbor from criminal penalties under the anti-kickback statute for HIT and related services provided to a physician by a hospital, group practice, prescription drug plan (PDP) sponsor, MA organization, or similar entity as specified by the Secretary. The provision of HIT and related services by such an entity would have to be pursuant to a written agreement between the physician and the entity specifying the goal of improved health care quality. An entity could not condition the provision of HIT and related services on the volume or value of referrals (or other business generated) by the physician to the entity, nor could it disable a hardware or software component that permits interoperability, or otherwise limit or restrict interoperability with other HIT systems.

Sec. 232 would create an exception to the Stark law for HIT and related services provided to a physician by a hospital, group practice, PDP sponsor, MA organization, or similar entity as specified by the Secretary, subject to the same requirements as above. For the purposes of the safe harbors and the Stark exception, HIT includes hardware, software, license, intellectual property, equipment, or other information technology used primarily for the electronic creation, maintenance, and exchange of clinical health information.

The HIT safe harbors and Stark exception would take effect 120 days after enactment. Both provisions would preempt state laws that would otherwise penalize the provision of HIT and related services as described in this section. Within three years of enactment, the Secretary would have to report to Congress on the impact of each of the safe harbors and the Stark exception on increasing HIT adoption and on the business relationships between providers. The Secretary would be required to include in the report recommendations for changes in the safe harbors and Stark exception, as may be appropriate.

Sec. 233 would further amend the HIT safe harbors and Stark exception by stating that nothing in the provisions could be construed as preventing a specified entity from forming a consortium of

health care providers, payers, and employers to collectively purchase and donate HIT, or from offering health care providers a choice of HIT products.

## Other HIT Provisions

Among its provisions, the HITECH Act[15] codified ONCHIT and established a process for the development of interoperability standards that support the nationwide electronic exchange of health information among doctors, hospitals, patients, health plans, the federal government, and other health care stakeholders. The Act established an HIT Policy Committee to make policy recommendations to the National Coordinator relating to the implementation of a nationwide HIT infrastructure, including recommending areas in which standards are needed for the electronic exchange and use of health information. It also established an HIT Standards Committee to develop, harmonize, and pilot test standards, implementation specifications, and certification criteria for the electronic exchange of health information, based on the recommendations of the HIT Policy Committee.

### Sec. 185. 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.

### Sec. 205(b). Quality Measures

This subsection would amend **PHSA Sec. 3002(b)**, requiring the HIT Policy Committee to make recommendations for standards that enable certified EHRs to collect and report quality measures.

[15] See footnote 5.

# Prevention and Wellness

## Background and Issues

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-provided "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.[16] 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.

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 wellness programs, in order to strike a balance between flexibility and compliance with current federal privacy, civil rights, and other laws.[17]

Under current federal law, private insurance providers are not required to cover preventive services. The Senate HELP bill does not propose changes to Medicare or Medicaid law, but would establish new coverage requirements for the private insurance market. Proposed new requirements regarding disease prevention and health promotion are summarized below.

In addition, the Senate HELP bill proposes a number of community-based research, disease prevention, and health promotion activities, which are also summarized below. These activities include strategic planning, education campaigns, and pilot programs to study models of service delivery, among many others. Also, proposals to bolster the workforce in public health and primary care, which many believe can improve the quality and effectiveness of clinical and community prevention efforts, are summarized in an earlier section of this report (see "Health Workforce").

Furthermore, the federal government supports the development of evidence-based recommendations for the use of clinical and community preventive services through three advisory committees.[18] The U.S. Preventive Services Task Force (USPSTF) is established in

[16] See, for example, Louise B. Russell, "Preventing Chronic Disease: An Important Investment, But Don't Count On Cost Savings," *Health Affairs*, vol. 28, no. 1 (January/February 2009), pp. 42-45; and 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.

[17] CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by (name redacted); and CRS Report R40791, *Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act*, by (name redacted).

[18] See the U.S. Preventive Services Task Force, http://www.ahrq.gov/clinic/uspstfix.htm; the Task Force on Community Preventive Services, http://www.thecommunityguide.org/index.html; and the Advisory Committee on (continued...)

PHSA Sec. 915(a), and is required to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations." It is administered by AHRQ. The Task Force on Community Preventive Services (TFCPS) conducts similar evidence reviews of community (i.e., population-based) interventions. The Advisory Committee on Immunization Practices (ACIP) develops science-based recommendations for the use of vaccines in the U.S. population. The latter two committees are administered by CDC, and are not explicitly authorized; rather, they are conducted under general authorities of the Secretary in the PHSA. The Senate HELP bill would amend authority for the USPSTF, and codify the TFCPS.

Beneficiary cost-sharing has been shown to decrease utilization of certain clinical 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.[19]

As employers and insurers have struggled with rising health care costs, there has been significant interest in reducing these costs by incentivizing health behaviors through wellness programs. These programs take many forms, from providing a gym at the workplace to subsidizing the co-pays of certain medications and linking health care benefits or discounts to certain healthy lifestyles. Wellness programs offered by employers may be subject to a number of federal laws. Among these laws is the Health Insurance Portability and Accountability Act (HIPAA), which amended the Employee Retirement Income Security Act (ERISA), the PHSA, and the Internal Revenue Code in order to improve portability and continuity of health coverage. HIPAA established certain nondiscrimination requirements that are intended to prevent group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on a health status-related factor.[20] In particular, HIPAA prohibits a group health plan or 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. 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]." On December 13, 2006, the Departments of Labor, Treasury, and HHS issued joint final regulations on the nondiscrimination provisions of HIPAA that provide a framework for structuring wellness programs.[21]

(...continued)

Immunization Practices, http://www.cdc.gov/vaccines/recs/acip/default.htm.

[19] 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.

[20] 29 U.S.C. § 1182; 42 U.S.C. § 300gg-1; 26 U.S.C. § 9802.

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

# Health Insurance Reform

## Sec. 101. Amendments to the PHSA Regarding Insurance Coverage

Among other things, this section would create three new PHSA sections that address aspects of prevention and wellness, as follows:

New **PHSA Sec. 2706** would supplement HIPAA's current nondiscrimination requirements to prohibit a group health plan or a group health insurance issuer, as well as an insurer providing individual health insurance coverage, from basing eligibility rules on any of a number of stated health status-related factors. In addition, the section creates new statutory requirements relating to wellness programs offered through group health plans, as well as insurers offering group or individual insurance coverage. The section would, in large part, codify provisions of the HIPAA wellness program regulations, subject to certain exceptions. Accordingly, wellness programs under this section may be classified into two basic types. First, if a program does not condition a premium discount, rebate, or other reward based on an individual satisfying a health status factor (or does not provide a reward), the program complies with the section as long as the program is made available to all similarly situated individuals. Alternatively, if a wellness program is structured so that the conditions for receiving a reward are based on an individual satisfying a standard that is related to a health status factor, then the program must meet certain additional requirements. Among these requirements, the reward offered by this type of wellness program must not exceed 30% of the cost of employee-only coverage under the plan, which may be increased to 50% by the Secretaries of HHS and Treasury if they determine an increase is appropriate. This section differs from the current HIPAA wellness program regulations, under which a reward offered by this type of wellness program must not exceed 20% of the cost of employee coverage under the plan.

In addition, similar to the current regulations, a wellness program that conditions receipt of a reward based on an individual's satisfying a standard relating to a health status factor must be reasonably designed to promote health or prevent disease. Also, the reward under the program must be available to all similarly situated individuals. As part of this requirement, a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward must be available for any individual for whom it is "unreasonably difficult" due to a medical condition or "medically inadvisable" to satisfy the otherwise applicable standard.

New **PHSA Sec. Sec. 2708** would require a group health plan and a health insurance issuer offering group or individual health insurance coverage to cover the following preventive services, with minimal or no 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; and (3) for infants, children and adolescents, preventive care and screenings provided for in comprehensive guidelines supported by HRSA.

New **PHSA Sec. 2709** would require a group health plan and a health insurance issuer offering group or individual health insurance coverage to provide coverage for women, with minimal or no cost-sharing requirements, for additional preventive care and screenings not covered under Sec. 2708 (as established by this bill), as provided for in HRSA guidelines.

### Sec. 142. Affordable Health Choices

This section would create a new **PHSA Sec. 3103**, specifying certain types of health benefits that must be provided in order for a plan to participate in an American Health Benefit Gateway (as required under Sec. 3101 of the bill).[22] Among these requirements, plans would have to cover prevention and wellness services, among other services comprising a minimum package of required benefits. The Secretary would be required to determine the specific elements of such coverage.

### Sec. 326. Encouraging Employer-Sponsored Wellness Programs

This section states that a group health plan and a health insurance issuer offering health insurance coverage in connection with a group health plan may offer incentives to an individual who voluntarily participates in a wellness program that is reasonably designed to promote health or prevent disease. It further states that nothing in this bill (or an amendment made by this bill) should be construed to limit the ability of a group health plan or health insurance issuer, under regulations in effect on the date of enactment, to offer participants variations in employee contributions towards the cost of coverage for participation in wellness programs.[23]

## Public Health Systems

### Sec. 301. National Prevention, Health Promotion and Public Health Council

This section 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, public health, and integrative health care strategy; report to the President and Congress on activities under the strategy and progress toward identified goals; and other activities as specified.

### Sec. 302. 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: $2 billion for FY2010; $4 billion for FY2011; $6 billion for FY2012; $8 billion for FY2013; $10 billion for each of FY2014 through FY2019; and $10 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

[22] An American Health Benefit Gateway, as referred to in this bill, is another name for what is commonly referred to as a health insurance exchange or connector. Such gateways or exchanges are not authorized in federal law at this time.

[23] It should be noted that questions may exist as to how to reconcile Sec. 326 with the wellness program provisions added under proposed new PHSA Sec. 2706, summarized earlier in this report. For example, it may be questioned whether the "incentives" provided under section 326 may differ from the requirements for a reward for certain wellness programs under the proposed Sec. 2706. See discussion above.

PHSA for prevention, wellness, and public health activities, including prevention research and health screenings. Such transfers would be subject to the transfer authority provided for in the annual appropriations Act for the fiscal year in which the funds become available. The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives could provide for the transfer of funds in the Fund to eligible activities under this section.

## Sec. 303. Clinical and Community Preventive Services Task Forces

Subsection (a) of this section would strike and replace **PHSA Sec. 915(a)**, the current authority for the U.S. Preventive Services Task Force, 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 the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical 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 target setting 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, shall 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 the activities of this Task Force.

Subsection (b) of this section would create a new **PHSA Sec. 399S**, requiring the CDC Director to establish 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, 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 Advisory Committee on Immunization Practices. In addition, neither Task Force would be subject to requirements of the Federal Advisory Committee Act (FACA).[24]

## Sec. 304. Education and Outreach Campaign Regarding Preventive Benefits

This section would require the Secretary, in consultation with the IOM, to plan and implement a national public-private partnership for a prevention and health promotion outreach and education

[24] For information about the Federal Advisory Committee Act, see CRS Report R40520, *Federal Advisory Committees: An Overview*, by Wendy R. Ginsberg.

campaign. The purpose of the campaign would be to raise public awareness of health improvement across the life span. The campaign would disseminate information that, among other things, describes the benefits of preventive services and healthy lifestyles, and describes the preventive services covered under health plans offered through a Gateway.[25] There would be authorized to be appropriated SSAN to carry out this section.

## Access to Clinical Preventive Services

### Sec. 311. Right Choices Program

This section would require the Secretary to provide annual grants to each state to establish a "Right Choices" program, which the state could administer through Medicaid or a comparable program. States would be required to conduct outreach to the uninsured and provide a "Right Choices" card to eligible individuals. Eligible individuals would be those who are citizens or nationals of the United States, or aliens lawfully admitted for permanent residence or otherwise legally residing in the United States; who are without private insurance coverage for the six months prior to the date of determination of eligibility; who have a family income at or below 350% of the federal poverty level; and who are not eligible for Medicare, Medicaid, CHIP, armed services, or veterans health benefits.

An eligible individual would receive a one-time health risk appraisal and a risk-stratified care plan from a primary care physician participating in Medicare or Medicaid, or with a state or federal safety net provider. To the extent feasible, care plans would also include referrals to appropriate federal and state programs. A participant with a chronic illness would be referred for treatment to existing state or federal safety net providers/facilities. Providers would be paid by the states, with reimbursement based on Medicaid rates, and not to exceed Medicare rates. States would have to require individuals with family incomes above 200% of the federal poverty level to contribute a portion of the cost of their care, on a sliding scale determined by the Secretary.

Grants would be distributed according to the state's percentage of uninsured adults and children and the prevalence of the most common costly chronic diseases, as determined by the Secretary. The Secretary would be required to determine the amount of the grant that could be used for state administration of the program, and would be allowed to set aside not more than 20% of the funds appropriated to the program to fund the treatment of participants who need it. The Secretary would be required to determine how payments would be made to states on a prospective basis, to enable them to provide program participants with access to items and services until federal or state Gateways were available.[26] The Secretary would be prohibited from obligating more than $5 billion per fiscal year to the program.

The Secretary would be required to conduct an annual evaluation of the effectiveness of the pilot program under this section. States could not be required to use state revenues to fund activities under this program. The program would sunset on the date on which federal or state Gateways were available.

[25] See footnote 22.

[26] Ibid.

## Sec. 313. Oral Health Care Prevention Activities

This section would create in Title III a new **PHSA Part S**, "Oral Healthcare Prevention Activities." It would include a new **PHSA Sec. 399GG** requiring the Secretary, through the CDC Director, to establish a five-year national public education campaign focused on oral health care prevention and education, including prevention of oral diseases such as dental carries, 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 would also create a new **PHSA Sec. 399GG-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), including FQHCs, clinics of a state-owned hospital; state or local departments of health; private providers of dental services; certain educational institutions; 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 PHSA Sec. 399GG, as established in this section.

Finally, the section would create a new **PHSA Sec. 399GG-1,** authorizing the appropriation of SSAN to carry out new PHSA Part S.

## Sec. 314. Oral Health Improvement

This 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).

The section would also 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 programs, to include data collection, 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 through FY2014.

The section would also require the Secretary to 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 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.

## Community Preventive Services

### Sec. 321. Community Transformation Grants

This section 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, or an Indian tribe. 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 through FY2014 to carry out this program.

### Sec. 322. Healthy Aging, Living Well

This section would require the Secretary, through the CDC Director, to award grants to state and local health departments and Indian tribes for five-year pilot programs to provide public health community 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 would also 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.

For individuals found to have chronic disease risk factors, grantees would be required to determine whether such individuals 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 through FY2014 to carry out this section.

### Sec. 323. 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 to issue standards for minimal technical criteria for

medical diagnostic equipment (as specified) used in medical settings.[27] The standards must ensure that individuals with disabilities can use, enter, and 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. 324. 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 would also add a new **subsection 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 Task Force on Community Preventive Services (administered by CDC) 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 regarding the effectiveness of the demonstration program, and recommendations regarding whether it should be extended or expanded. There would be authorized to be appropriated SSAN through FY2014 to carry out this subsection.

The section would also amend **PHSA Sec. 317(j)** to permanently reauthorize the program of immunization grants to states.

Finally, the section provides that nothing in the section or any other provision of the bill should be construed to decrease children's access to immunizations.

## Sec. 327. Demonstration Project Concerning Individualized Wellness Plan

This section would create a new **PHSA Sec. 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.

[27] Section 502 of the Rehabilitation Act established the Architectural and Transportation Barriers Compliance Board to 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.

### Sec. 328. Reasonable Break Time for Nursing Mothers

This section would amend **Sec. 7 of the Fair Labor Standards Act of 1938**[28] by adding a new **subsection (r)**, requiring 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, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public, which may be used by an employee to express breast milk. 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 it 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.

## Research, Information Management, and Education

### Sec. 188. Report on Preventable Diseases in New Medicare Enrollees

This section would require GAO to conduct a study of the health status of new Medicare enrollees, to determine whether the health insurance coverage they received for preventive services prior to enrollment affects their rates of preventable illness at enrollment.

### Sec. 331. Research on Optimizing the Delivery of Public Health Services

This section would require the Secretary, through the CDC Director, to fund research in the area of public health services and systems. Such research must 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 Community Preventive Services Task Force.

### Sec. 332. Understanding Health Disparities: Data Collection and Analysis

This section would establish a **new PHSA Title XXXIII**, "Data Collection, Analysis, and Quality," consisting of new **Sec. 3301**. It would require the Secretary to ensure that any ongoing or federally conducted or supported health care or public health program, activity, or survey meets certain standards regarding the collection and reporting of data. All such activities would be required to collect and report the following data for applicants, recipients, or beneficiaries: (1) race and ethnicity; (2) gender, geographic location, socioeconomic status (including education, employment, or income), primary language, and disability status; (3) data at the smallest geographic level, if such data can be aggregated; (4) if practicable, racial and ethnic subgroups,

[28] 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.

using statistical oversamples if needed; and (5) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

The Secretary (or designee) would be required to develop data standards for the above requirements. In so doing, the Secretary would be required to (1) use the Office of Management and Budget (OMB) standards, at a minimum, for race and ethnicity measures; (2) develop standards for measures of gender, geographic location, socioeconomic status, primary language, and disability; and (3) develop standards regarding data that are self-reported by the applicant, recipient, or beneficiary; and from a parent or legal guardian if such person is a minor or legally incapacitated. The Secretary would also be required, acting through the National Coordinator for Health Information Technology, to develop national standards for the management of data collected, and interoperability and security systems for data management.

The Secretary would also be required to analyze the data collected as above to detect and monitor trends in health disparities (as defined) at the federal and state levels; make such analyses available to specified agencies in HHS and other agencies and entities as the Secretary determines; report such data and analyses through public Internet sites and other appropriate mechanisms; and make such data available for research, analysis, and dissemination to other federal agencies, non-governmental entities, and the public.

The section states that nothing in it should be construed to permit the use of information collected under it in a manner that would adversely affect any individual. The Secretary would be required to ensure, through regulation or otherwise, that all data collected as above would be (1) covered by privacy safeguards that are at least as protective as the HIPAA privacy rule and (2) protected from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary. In addition, the Secretary would be required to ensure that any data collected in accordance with this section regarding racial and ethnic minority groups is also collected regarding underserved rural and frontier populations.

There would be authorized to be appropriated to carry out this section SSAN through 2014. Notwithstanding any other provision of this section, data could not be collected under this section unless funds were directly appropriated for such purpose in an appropriations act.

## Sec. 333. Health Impact Assessments

The stated purpose of this section is to facilitate the use of health impact assessments as a means to assess the effect of the built environment on health outcomes. “Built environment” and “health impact assessment” would be defined. The section would require the Secretary, in coordination with the Administrator of the Environmental Protection Agency, to establish a program at the National Center for Environmental Health at CDC to foster advances and provide technical support in the field of health impact assessment. The Secretary would be required to collect and disseminate evidence-based practices, provide grants for technical assistance and training, and provide guidance for implementation and program evaluation.

## Sec. 334. CDC and Employer-Based Wellness Programs

This section would add a new **PHSA Part T**, "Employer-Based Wellness Program," including several new PHSA sections. A new **PHSA Sec. 399HH** would require the CDC Director, subject to appropriations and in consultation with others, to conduct targeted educational campaigns to (1) make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs; (2) establish a culture of health by emphasizing health promotion and disease prevention; (3) emphasize an integrated and coordinated approach to workplace wellness; and (4) ensure informed decisions through high quality information to organizational leaders.

A new **PHSA Sec. 399HH-1** 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 would also be required to build evaluation capacity among workplace staff by providing resources, technical assistance, and consultation.

A new **PHSA Sec. 399HH-2** would require the CDC Director, within two years of enactment and at regular intervals thereafter (as determined by the Director), to conduct a national survey to assess employer-based health policies and programs, and to report to Congress on survey findings and recommendations for the implementation of effective employer-based health policies and programs.

A new **PHSA Sec. 399HH-3** would require the CDC Director, in collaboration with academic institutions and employers, to institute workplace demonstration projects across small, medium, and large employers. Projects should be designed to determine best practices for achieving effective and sustainable workplace wellness interventions. The Director would be required to report to Congress on findings of the demonstrations, including recommendations for the implementation of effective policies and programs.

A new **PHSA Sec. 399HH-4** would require the Secretary to evaluate, in accordance with this Part, 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.

A new **PHSA Sec. 399HH-5** 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. 335. 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 health departments,

local health departments or tribal jurisdictions that meet CDC-specified criteria, or a partnership of one or more of the above with an academic center.

Grantees would be required to use funds for several specified activities, including expanding surveillance and laboratory capacity, responding to and investigating outbreaks, staffing, and training. In addition, grantees would be required to carry out a number of information-gathering and reporting activities in accordance with guidelines, which CDC would be required to develop and issue within 180 days of enactment, in consultation with National Coordinator for Health Information Technology, consistent with national standards for health information technology. Specifically, grantees would be required to establish *secure web-based information systems* to receive electronic case reports from health care facilities and public health entities; to analyze and report appropriate de-identified data to CDC within 24 hours; to conduct specified analyses of such data, including geographic analyses; to share information and alerts with other jurisdictions, and with public health and health care partners, as specified; to appropriately secure and protect information and information systems, including providing for backups and continuity in the event of disasters; and to provide for other capabilities as the Secretary determines appropriate. In allocating funds for these activities, the Secretary would be required to give priority to eligible entities that demonstrate need.[29]

In addition, grantees would be required to ensure that public health *laboratories* in their jurisdiction were fully integrated with respect to these requirements. Grantees would also be permitted to use funds for systems development and maintenance, and hiring and training staff, and could develop their own systems or use federally developed systems to carry out required activities.

The Secretary would be required to annually report to Congress regarding activities under this section. There would be authorized to be appropriated $190 million for each of FY2011 through FY2013, of which at least $95 million per fiscal year must be used to award grants for general capacity-building activities, at least $60 million per fiscal year for grants for secure information systems, and at least $32 million per fiscal year for expansion of laboratory systems.

## Sec. 336. Federal Messaging on Health Promotion and Disease Prevention

This section would require the Secretary to carry out five 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, through the CDC Director, the Secretary must develop and implement a science-based media campaign according to several specified conditions. Second, in consultation with private-sector experts, the Secretary must develop a website containing information for health providers and consumer regarding specified chronic diseases and conditions. Third, through the CDC Director, the Secretary must develop a program to disseminate information about health promotion to health care providers who participate in federal health care programs. Fourth, through the CDC Director, the Secretary must develop a Web-based tool that individuals can use to develop personalized prevention plans. Finally, the Secretary must establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities. The section states that funding for these activities shall take priority over funding provided through the CDC grants for similar purposes and goals

[29] "Need" is not defined.

as provided for in this section, and that no more than $500 million may be spent on the activities required under this section.

## Environmental Public Health Network

### Sec. 351. Coordinated Environmental Public Health Network

This section would create a new **PHSA Title XXXIV**, "Coordinated Environmental Public Health Network," including five new PHSA sections.[30] New **PHSA Sec. 3400** would provide definitions. New **PHSA Sec. 3401** would require the Secretary, through the CDC Director, to establish and operate a Coordinated Environmental Public Health Network, by identifying and expanding existing data sources, and providing for a publicly accessible database of information. In addition, the Secretary would be required to provide for state networks, including providing technical assistance, and developing specified information management standards. The Secretary would also be required to provide grants to states to establish such networks. Grantees would be required to use the funds to meet a number of stated requirements. States may also apply to use funds for pilot projects. The Secretary would be required to ensure that all activities associated with the network, including those of state grantees, protect health information consistent with the HIPAA privacy rule. To carry out new Sec. 3401, there would be authorized SSAN through FY2014.

New **PHSA Sec. 3402** would require the Secretary, through the CDC Director, to enter into a cooperative agreement with the Council of State and Territorial Epidemiologists to train and place epidemiology fellows in state and local health departments, to expand public health capacity for environmental health and chronic diseases. There would be authorized to carry out this new section SSAN through FY2014.

New **PHSA Sec. 3403** would require the Secretary to integrate activities under this title with existing environmental health tracking activities, and to assist in developing state programs that address local and regional concerns.

New **PHSA Sec. 3404** states its purpose as the expansion of federal and state biomonitoring capability.[31] The Secretary would be required to enter into cooperative agreements with states or consortia of states to provide laboratory training and quality assurance for biomonitoring. The Secretary would be required to ensure that all applicable activities, including those of state grantees, ensure protections of health information consistent with the HIPAA privacy rule. There would be authorized to carry out this new section SSAN through FY2014.

[30] According to CDC, environmental public health tracking is the ongoing collection, integration, analysis, and interpretation of data about environmental hazards, exposure to them, and possible health effects potentially related to such exposure. See CDC, background on National Environmental Public Health Tracking, http://www.cdc.gov/nceh/tracking/background.htm.

[31] According to CDC, biomonitoring is the direct measurement of people's exposure to toxic substances in the environment by measuring the substances or their metabolites in human specimens, such as blood or urine. See CDC, National Biomonitoring Program, http://www.cdc.gov/biomonitoring/.

# Other Public Health Provisions

## Sec. 221. 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 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 (new **PHSA Sec. 927**), HRSA (new **PHSA Sec. 713**), and the Food and Drug Administration (FDA, new **Federal Food, Drug, and Cosmetic Act, FFDCA Sec. 1011**). For each of these offices there would be authorized to be appropriated SSAN through FY2014. The section would also amend current authority for offices of women's health in the National Institutes of Health (NIH) and Substance Abuse and Mental Health Services Administration (SAMHSA), to establish that the director of each office would report to the senior official of the respective agency.

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. 361. Sense of the Senate Concerning CBO Scoring

This section 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 results may occur outside the 5- and 10-year budget windows currently considered by the Congressional Budget Office (CBO). The section 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.

## Sec. 362. 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 of such programs as they relate to 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 Employee Health Benefits Program. The Secretary would be required to report to Congress regarding the evaluation and conclusions concerning program effectiveness.

# 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.[32] 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.[33] The products' effectiveness, which FDA 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.

The HELP bill contains four FDA-related provisions that would affect the agency's regulation of two 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. For foods, a second provision would require nutrition labeling at certain restaurants and vending machines. For biologics, a third and fourth provision would create a licensure pathway for biosimilars (generic biologics) and authorize the agency to collect associated fees. Both of these are 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 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.[34]

[32] For further information about FDA, see CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*, by (name redacted).

[33] 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.

[34] For further information see 21 CFR 201 (regarding labeling), and 21 CFR 202 (regarding prescription drug advertising).

### Sec. 218. 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.

## 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. 325. 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.[35]

Congress has indicated interest 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. 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. 602. Approval Pathway for Biosimilar Biological Products

This section would amend **PHSA Sec. 351** by opening a pathway for the FDA approval of biosimilars. A biosimilar would be 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

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

biological product and the reference product. A biological product would be 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 would also allow for a period of exclusive marketing for the biological product that is the first to be established as interchangeable with the reference product.[36]

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 require that all biological product applications must 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 be required to develop recommendations regarding goals for the review of biosimilar product applications for FY2013 through the end of FY2017 and present them to Congress. It would require that the recommendations 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 these recommendations, it is the sense of the Senate that Congress should authorize a user fee program effective October 1, 2012. Through October 1, 2010, the Secretary would be required to 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

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

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.

The section would require the Treasury Secretary, in consultation with the Secretary of HHS, to determine for each fiscal year the amount saved to the federal government and transfer that amount to the Biological Product Savings Fund. Amounts in the fund would be spent by the Secretary of HHS on activities authorized under the PHSA.

The section would require that the GAO conduct a study within three years of enactment to determine the extent to which pediatric studies of biological products are being required under the FFDCA as part of risk evaluation and mitigation strategies, whether any pediatric needs are not being met under existing authority, and recommendations for ensuring pediatric testing, including consideration of incentives.

### Sec. 603. Savings

This section would require that the Treasury Secretary, in consultation with the Secretary of HHS, 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 in the biosimilars approval pathway, the savings to the federal government as a result of enactment of this pathway would be required to be used for deficit reduction.

# 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.[37]

## Sec. 175. 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.

## Sec. 214. 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**, authorizing the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award competitive grants for pilot projects to improve regional coordination of emergency services. Funding would be awarded to entities that propose a pilot project to design, implement, and evaluate certain emergency medical and trauma systems. Applications must, among other things, include a plan to address pediatric patient coordination. 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 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. 215. Trauma Care Centers

This section would amend **PHSA Secs. 1241-1245** by replacing the existing language with the following new provisions. The Secretary would be required to establish three programs to award grants to qualified trauma centers to (1) help defray substantial uncompensated care costs, (2) further the core missions of such centers, and (3) provide emergency relief to ensure the

[37] 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.

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.

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.

# Behavioral Health Care

## Background and Issues

Existing behavioral health programs authorized under PHSA 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.[38] Schools and training programs in social work are generally not eligible for funding under PHSA 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. PHSA 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[39] users of illicit drugs.[40] The behavioral health care system has numerous issues including access to and availability of services, quality of care, insurance coverage and payment, and coordination of care.[41]

The Senate HELP bill 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, and mental health parity.

## Sec. 142. Applicability of Mental Health Parity to Qualified Plans

This section would require qualified health benefits plans[42] to comply with existing mental health parity rules in **PHSA Sec.2716**, in the same manner and to the same extent as health insurance issuers and group health plans.

## Sec. 176. Co-locating Care in Community-Based Mental Health Settings

This section would create a new **PHSA Section 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 disease through the co-location of primary and specialty care 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. The Secretary would be required to ensure equitable geographic distribution of grant awards. Within three months 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. Within five years of enactment, the Secretary would be required to submit to Congress a report on the impact of co-locating primary and specialty care in community mental health

[38] For more information on SAMHSA, see CRS Report RL33997, *Substance Abuse and Mental Health Services Administration (SAMHSA): Reauthorization Issues*, by (name redacted).

[39] A "current user" is defined as someone who used an illicit drug during the month prior to the survey interview.

[40] 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.

[41] 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 (name redacted).

[42] A qualified health benefits plan is one that meets the requirements set forth in PHSA Sec. 3101(m), as added by Sec. 142 of S. 1679.

settings, and include recommendations on whether the demonstration program should be made permanent. 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. 436. 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. 413 of this 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 programs in 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.

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; and (4) 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.

# Pain Care and Management

Under general authorities in PHSA 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, PHSA 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. Sec. 799(f) requires each applicant for a health professions education grant under Title VII (except any scholarship or loan program) to submit to a peer review group for an evaluation of the merits of the proposals made in the application.

The Senate HELP bill includes the following four sections that would address pain research, education, and awareness for the purposes of recognizing pain as a national public health problem.

### Sec. 341. Institute of Medicine Conference on Pain

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 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 $500,000 for each of FY2010 and FY2011.

### Sec. 342. Pain Research at National Institutes of Health

This section would amend PHSA Title IV, Part B to add a new **Sec. 409J**, 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, 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.

### Sec. 343. Pain Care Education and Training

This section would amend PHSA Title VII, Part D to add a new **Sec. 759** authorizing the Secretary to establish a program to train health professionals in pain care. The Secretary could fund specified entities for the development and implementation of education and training programs at certain specified program sites. The Secretary would be required to give priority to awards for implementation programs. 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. With respect to peer review groups established under PHSA Sec. 799(f), the Secretary would be required to ensure that these groups include individuals with expertise and experience in pain care. For the purposes of carrying out this section, there would be authorized to be appropriated $5 million for each of FY2010 through FY2012 and would require amounts appropriated to remain available until expended.

### Sec. 344. Public Awareness Campaign on Pain Management

This section would amend PHSA Title II, Part B to add a new **Sec. 249** requiring the Secretary to establish and implement a national pain care education outreach and awareness campaign to educate consumers, patients, their families, and other caregivers about various issues with respect to pain as a national public health problem. The Secretary would be authorized to make awards to public agencies and private nonprofit organizations to assist with the development and implementation of the public awareness campaign. For the purposes of carrying out this section, there would be authorized to be appropriated $2 million for FY2010 and $4 million for each of FY2011 and FY2012.

# PHSA 340B Drug Pricing Program

## Background and Issues

Under PHSA Sec. 340B, pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program are required to enter into pharmaceutical pricing agreements (PPA) 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 14,000 covered entities and 800 pharmaceutical manufacturers participate in the program.[43] 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 Federally Qualified Health Centers (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 based on the average manufacturer price (AMP) reduced by the Medicaid rebate percentage of 15.1% for single source and innovator multiple source drugs, and 11% for non-innovator multiple source drugs. AMP is defined in Medicaid statute as the average price paid to the manufacturer 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. Proposed rules to implement the expansion of covered entities to children's hospitals were issued by HRSA on July 9, 2007. A final rule for participation of children's hospitals in the 340B program was issued September 1, 2009.

[43] 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.

## Sec. 611. 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 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. 612. 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.

It would authorize 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. 613. GAO Study on Improving the 340B Program

This section would require GAO to submit to Congress a report 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.

# Miscellaneous

## Sec. 174. Equity for Certain Eligible Survivors

Section 411(c)(4) of the Black Lung Benefits Act provides for a rebuttable presumption of eligibility for Black Lung Benefits for a miner and his or her survivors in the case of a miner who had worked in underground coal mines for at least 15 years, had a negative chest roentgenogram, and had other evidence of a totally disabling respiratory or pulmonary impairment. Section 422(l) of the Black Lung Benefits Act provides that the survivors of a miner who was eligible for Part C Black Lung Benefits at the time of his or her death are not required to submit a new claim in order to receive survivors benefits. Neither of these provisions applies to claims filed on or after January 1, 1982. Sec. 174 of the bill would apply these provisions to claims under Part B or C of the Black Lung Benefits Act filed after January 1, 2005 and that are pending on or after the date of enactment of the proposed law.

## Sec. 189. Transparency in Government

This section would require the Secretary to publish, on the HHS website, a list of all the authorities provided to the Secretary under the proposed law no later than 30 days after enactment.

## Sec. 189A. Preserving the Solvency of Medicare and Social Security

This section would prohibit any provisions in the proposed law (or an amendment made by this proposed law) from being carried out in a manner that threatens the solvency of either the Medicare or Social Security programs.

## Sec. 189B. Prohibition Against Discrimination on Assisted Suicide

This section would prohibit the federal government, and any state or local government or health care provider that receives federal financial assistance under this proposed law (or under an amendment made by this proposed law) or any health plan created under this proposed law (or under an amendment made by this proposed law), from subjecting an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individuals, such as by assisted suicide, euthanasia, or mercy killing. Nothing in the above would be construed to apply or to affect any limitation relating to (1) the withholding or withdrawing of medical treatment or medical care; (2) the withholding or withdrawing of nutrition or hydration; (3) abortion; or (4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or assisting in causing, death. The HHS Office of Civil Rights would be designated to receive complaints of discrimination based on this section.

## Sec. 189C. Access to Therapies

Notwithstanding any other provision of the proposed law, the Secretary would be prohibited from promulgating any federal regulation that (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

## Sec. 189D. Freedom Not to Participate in Federal Health Insurance Programs

This section would prohibit requiring any individual, company, business, nonprofit entity or health insurer offering group or individual health insurance from participating in any federal health insurance program created or expanded under this proposed law (or any such amendments made by this proposed law). It would also prohibit penalties or fines from being imposed upon any such insurer for choosing not to participate in such programs.

# Appendix. Acronyms Used in the Report

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|---|---|
| **ACIP** | Advisory Committee on Immunization Practices |
| **AHEC** | Area Health Education Center |
| **AHRQ** | Agency for Healthcare Research and Quality |
| **AMP** | average manufacturer price |
| **ARRA** | American Recovery and Reinvestment Act |
| **CBO** | Congressional Budget Office |
| **CDC** | Centers for Disease Control and Prevention |
| **CHC** | Community Health Center |
| **CHIP** | Children's Health Insurance Program |
| **CHW** | community health worker |
| **CMS** | Centers for Medicare and Medicaid Services |
| **COE** | Center of Excellence |
| **EIS** | Epidemic Intelligence Service |
| **EHR** | electronic health record |
| **ERISA** | Employee Retirement Income Security Act |
| **FACA** | Federal Advisory Committee Act |
| **FCCCER** | Federal Coordinating Council for Comparative Effectiveness Research |
| **FDA** | Food and Drug Administration |
| **FFDCA** | Federal Food, Drug, and Cosmetic Act |
| **FQHC** | Federally Qualified Health Center |
| **GAO** | Government Accountability Office |
| **GEC** | Geriatric Education Center |
| **HELP** | Senate Committee on Health, Education, Labor, and Pensions |
| **HHS** | Health and Human Services |
| **HIT** | Health Information Technology |
| **HIPAA** | Health Insurance Portability and Accountability Act |
| **HITECH** | Health Information Technology for Economic and Clinical Health Act |
| **HRSA** | Health Resources and Services Administration |
| **HPSA** | Health Professional Shortage Area |
| **IHS** | Indian Health Service |
| **IOM** | Institute of Medicine |
| **MA** | Medicare Advantage |
| **MEPS** | Medical Expenditures Panel Survey |
| **MTM** | medication therapy management |
| **NCHS** | National Center for Health Statistics |
| **NCHWA** | National Center for Health Workforce Analysis |
| **NHSC** | National Health Service Corps |
| **NIH** | National Institutes of Health |

| | |
|---|---|
| **NHANES** | National Health and Nutrition Examination Survey |
| **NMHC** | Nurse-Managed Health Clinic |
| **NOHSS** | National Oral Health Surveillance System |
| **OMB** | Office of Management and Budget |
| **ONCHIT** | Office of the National Coordinator for Health Information Technology |
| **PPA** | pharmaceutical pricing agreements |
| **PDP** | prescription drug plan |
| **PHSA** | Public Health Service Act |
| **PQRI** | Physician Quality Reporting Initiative |
| **PRAMS** | Pregnancy Risk Assessment Monitoring System |
| **QHBP** | Qualified Health Benefits Plan |
| **RHQDAPU** | Reporting Hospital Quality Data for Annual Payment Update |
| **SAMHSA** | Substance Abuse and Mental Health Services Administration |
| **SBHC** | School-Based Health Clinic |
| **SG** | U.S. Surgeon General |
| **SSA** | Social Security Act |
| **SSAN** | such sums as may be necessary |
| **TFCPS** | Task Force on Community Preventive Services |
| **USPSTF** | U.S. Preventive Services Task Force |

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