Public Health, Workforce, Quality, and Related Provisions in H.R. 3962

C. Stephen Redhead, Coordinator
Specialist in Health Policy

November 5, 2009

Congressional Research Service
7-5700
www.crs.gov
R40892

CRS Report for Congress
Prepared for Members and Committees of Congress
c11173008

Summary

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

The health reform debate has encompassed a number of proposals to address these challenges and improve the delivery of health care services. They include initiatives to encourage individuals to adopt healthier lifestyles, and to change the way that physicians and other providers treat and manage disease. Delivery reform proposals focus on expanding the primary care workforce, encouraging the use of clinical preventive services, and strengthening the role of chronic care management. Health care delivery reform relies on putting mechanisms 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 important, the alignment of payment incentives with high-quality care. In February 2009, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act to promote the widespread adoption of electronic health records for sharing of clinical data among hospitals, physicians, and other health care stakeholders.

On October 29, 2009, Representative Dingell introduced a comprehensive health reform bill, the Affordable Health Care for America Act (H.R. 3962). The legislation is based on an earlier measure, the America's Affordable Health Choices Act of 2009 (H.R. 3200), which was jointly developed and reported by the House Committees on Ways and Means, Energy and Commerce, and Education and Labor. This report, one of a series of CRS products on H.R. 3962, summarizes the bill's workforce, prevention, quality, and related provisions.

H.R. 3962 includes numerous provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things. The legislation would amend and expand on many of the existing health workforce programs authorized under Title VII (health professions) and Title VIII (nursing) of the Public Health Service Act (PHSA). It would create a Public Health Workforce Corps and establish a new loan repayment program, modeled on the National Health Service Corps (NHSC), for individuals who agree to practice in medically underserved areas with unmet health care needs. The bill also would make a number of changes to the Medicare graduate medical education (GME) payments to teaching hospitals, in part to encourage the training of more primary care physicians.

In addition, H.R. 3962 would bolster quality improvement activities, including performance measurement, and broaden Medicare and Medicaid coverage of clinical preventive services. The legislation would establish a multi-billion dollar Public Health Investment Fund to provide additional funding for these and other new programs and activities.

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 are seen to require changes to both the financing and delivery of health care. Experts point to a growing body of evidence of the health care system's failure to consistently provide high-quality care to all Americans.

On October 29, 2009, Representative Dingell introduced a comprehensive health reform bill, the Affordable Health Care for America Act (H.R. 3962).[1] The legislation is based on an earlier measure, the America's Affordable Health Choices Act of 2009 (H.R. 3200), which was jointly developed and reported by the House Committees on Ways and Means, Energy and Commerce, and Education and Labor.[2] This report, one of a series of CRS products on H.R. 3962, summarizes the bill's workforce, prevention, quality, and related provisions, including the changes made by the Dingell manager's amendment.[3] It begins with some background on health care delivery reform, followed by an overview of the report's content and organization.

Health Care Delivery Reform

In a November 2008 report outlining its goals for health reform, the National Priorities Partnership, representing 32 key stakeholder groups in the health sector, identified four major challenges to the delivery of high-quality care.[4] According to the Partnership, the first is to improve patient safety by eliminating medical errors and other adverse events. These errors mostly result from faulty systems, processes, and conditions that lead to mistakes. The second challenge is to eradicate disparities in care. Racial and ethnic minorities and low-income groups face disproportionately higher rates of disease, disability, and mortality, largely because of variations in access to care, and quality of care. The third challenge is to reduce the burden of chronic disease, which affects almost half of all Americans and accounts for three-quarters of health care spending. The final challenge is to eliminate unnecessary and ineffective care that compromises quality, drives up costs, and neglects the needs of patients. According to the Institute of Medicine, an estimated 30%-40% of health care spending is wasted on unnecessary and even unsafe care.[5]

While primarily focused on health care financing issues, the health reform debate has encompassed a number of proposals to address these challenges and improve the delivery of

[1] The full text of the bill is at http://www.congress.gov/cgi-lis/query/z?c111:H.R.3962:/.

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

[3] The manager's amendment is posted on the House Rules Committee website at http://www.rules.house.gov/.

[4] 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/.

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

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

Health workforce policy has emerged as an important component of the health reform debate. Transforming the nation's health care delivery system—from one that is focused on fragmented specialty care for acute illness to one that places a greater emphasis on primary care, disease prevention, and the coordination and management of care for chronic illness across settings—would require significant changes in health professions education and training. While some advisory groups have warned of a future physician shortage, based on the growing patient demand for services, others caution that simply adding more physicians to the current health care system will increase costs and not improve accessibility or quality. Currently, the number of physicians per capita varies significantly across the country. But that variation is largely driven by where physicians like to live and practice, rather than by patient need. Moreover, higher physician supply is not associated with better patient outcomes or satisfaction, or improved quality of care.[6] Instead of focusing on overall physician supply, many 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.[7]

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

[6] 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.

[7] 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.

partnership, disease management programs typically are run by health plans or specialized vendors.

Drivers of Reform

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

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

American Recovery and Reinvestment Act

Congress moved toward reforming the health care delivery system when it enacted the American Recovery and Reinvestment Act (ARRA; P.L. 111-5) in February 2009. ARRA incorporated the Health Information Technology for Economic and Clinical Health (HITECH) Act, which is intended to promote the widespread adoption of health information technology (HIT) for the electronic sharing of clinical data among hospitals, physicians, and other health care stakeholders. It also included $2 billion to fund HIT grant programs authorized by the HITECH Act.[8]

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

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

Overview of Report

H.R. 3962 consists of four divisions. Division A addresses private health insurance. Its provisions would mandate health insurance coverage, establish health insurance exchanges, and create a public health insurance plan. Division B covers the Medicare and Medicaid programs. It would substantially reduce the growth of Medicare's payment rates for most covered services, relative to the growth rates projected in current law, and significantly expand eligibility for Medicaid. Division C, entitled "Public Health and Workforce Development," includes a series of provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things. Finally, Division D incorporates the Indian Health Care Improvement Act Amendments of 2009 (H.R. 2708).

This report summarizes the workforce, prevention, quality, and related provisions in Division C. Several provisions in Division A and B that directly relate to health care quality, prevention, and some of the other topics covered under Division C are also included. Division C, Title V, Subtitle D, which would establish a new national insurance program for purchasing community living assistance services and supports (CLASS), is discussed in a separate CRS product. The report groups the bill's provisions under the following headings: (1) Public Health Investment Fund; (2) health centers; (3) health workforce, including programs authorized under the Public Health Service Act (PHSA) and under other statutes; (4) prevention and wellness; (5) maternal and child health; (6) behavioral health; (7) quality; (8) health information technology; (9) emergency care; (10) pain care and management; (11) Food and Drug Administration, including provisions relating to medical devices, biological drugs, and food labeling; and (12) 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 Health and Human Services (HHS). A list of all the acronyms used in the report is in the **Appendix**.

Public Health Investment Fund

H.R. 3962 would amend numerous PHSA programs. While authorizations of appropriations for many of these programs have expired, in most cases programs continue to receive an annual appropriation. H.R. 3962 includes new authorizations of appropriations to fund most of these programs, typically through FY2015. It also would create a multi-billion dollar Public Health Investment Fund to provide additional funds for the programs. As described below, the legislation includes several provisions authorizing the appropriation of amounts from the Fund for specified PHSA programs. These amounts would be in addition to any amounts provided in annual appropriations acts under regular procedures. To ensure that the Fund is used to supplement and not supplant such annual appropriations, the authority to appropriate amounts from the Fund would be contingent on maintaining a certain level of annual appropriations for the programs.

Sec. 2002. Establishment, Authorization of Appropriations

This section would establish a Public Health Investment Fund, into which the following amounts would be deposited from general revenues of the Treasury: $4.6 billion for FY2011, $5.6 billion for FY2012, $6.9 billion for FY2013, $7.8 billion for FY2014, and $9.0 billion for FY2015.

Amounts in the Fund would be authorized to be appropriated for carrying out various designated provisions in Division C, as described below, and would be in addition to any other amounts authorized to be appropriated for such purposes. Amounts in the Fund would be authorized to be appropriated only if the funding provided in annual appropriations for a given fiscal year are no less than the funds appropriated in FY2008 for the following PHSA agencies and programs: (1) Agency for Healthcare Research and Quality; (2) National Center for Health Statistics; (3) National Health Service Corps, including the scholarship and loan repayment programs; (4) community health centers; and (5) various designated workforce programs under PHSA Titles VII and VIII.

Sec. 2003. Deficit Neutrality

Spending from the Fund would occur through subsequent enactment of annual appropriations acts. Pursuant to a directed-scorekeeping provision in this section, the authorization of appropriation levels in Sec. 2002 would be scored as direct spending and would be incorporated by the Congressional Budget Office (CBO) into future budget baseline projections as appropriated entitlements. In this way, the anticipated spending from the Fund for all covered fiscal years is accounted for as part of the direct spending provided by H.R. 3962 and not as discretionary spending in subsequent annual appropriations acts.[9]

Health Centers

Background and Issues

PHSA Sec. 330 authorizes the health center program, administered by the Health Resources and Services Administration (HRSA), which provides grants to community health centers, migrant health centers, health centers for the homeless, and health centers for residents of public housing. Health centers are a key component of the nation's health care safety net and provide primary care and preventive services to many uninsured and underinsured. These centers are required to accept all patients regardless of ability to pay and must offer sliding scale fee arrangements for patients. Health centers are located in areas that are medically underserved and target populations with insufficient health care access. PHSA Sec. 224 provides health centers that receive Sec. 330 funding with liability protection from medical malpractice claims under the Federal Tort Claims Act (FTCA). FTCA coverage for health centers also applies to its employees, board members, and certain contactors. However, it does not extend to health care providers who volunteer their services at health centers. GAO found that the lack of medical malpractice coverage is a barrier to such volunteerism, though not the only one. Other barriers to provider volunteerism include lack of time to volunteer, licensure costs, misperceptions about litigiousness, and the limited capacity of health centers to recruit, retain, and effectively use volunteers.[10]

[9] In its preliminary assessment of the impact of H.R. 3962 on the federal budget deficit, CBO included as direct spending the anticipated appropriations from the Public Health Investment Fund. CBO's analysis, which scores the budgetary impact of several other provisions discussed in this report, is at http://www.cbo.gov/ftpdocs/106xx/doc10688/hr3962Rangel.pdf.

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

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.[11] The program was reauthorized by the Health Care Safety Net Act of 2008 (P.L. 110-355).[12] The Act also included the requirement that GAO study the economic costs and benefits of school-based health clinics (SBHCs) and their impact on student health. SBHCs are not are not explicitly authorized in the PHSA, but have been established pursuant to the general authority to establish community health centers. Studies show that health centers increase access to primary health care services, which helps reduce disparities and reduce costs by averting more expensive emergency room visits.[13]

Sec. 2101. Increased Funding for Community Health Centers

This section would amend **PHSA Sec. 330** by authorizing to be appropriated for the health center program such sums as may be necessary (SSAN) for each of FY2013 through FY2015. The section also would authorize to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for the program, the following amounts: $1 billion for FY2011, $1.5 billion for FY2012, $2.5 billion for FY2013, $3 billion for FY2014, and $4 billion for FY2015.

Sec. 2586. Liability Protection For Health Center Volunteers

This section would amend **PHSA Sec. 224** by extending the FTCA liability protections against medical malpractice to volunteer practitioners at Sec. 330-funded health centers.

Sec. 2511. School-Based Health Clinics

This section would create a new **PHSA Sec. 399Z-1** requiring the Secretary to establish an SBHC grant program. To receive a grant, an SBHC would have to meet certain specified criteria, match 20% of the grant amount from nonfederal sources, agree to use grant funds to supplement and not supplant funds received from other sources, and demonstrate that grant funds will not be used until funds from all payers, including private insurance, Medicaid, and CHIP, are used. Additionally, SBHCs would not be permitted to use funds to provide abortions. The Secretary would be required to give priority to qualified applicants based on their record of providing care to at least one of the following: medically underserved children and adolescents, and of providing care in communities where a high percentage of children and adolescents are uninsured, underinsured, or eligible for Medicaid or CHIP. The section would authorize the appropriation of $50 million for FY2011, and SSAN for FY2012 through FY2015.

The section also would amend P.L. 110-355 to strike language requiring GAO to conduct a study on SBHCs.

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

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

[13] 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.

Sec. 2512. Nurse-Managed Health Centers

This section would add a new **PHSA Part S, Sec. 399FF**, requiring the Secretary, acting through the HRSA Administrator, to establish a program to award grants to entities to plan and develop nurse-managed health centers (NMHCs) or to operate NMHCs. To receive a grant, eligible entities would have to match 20% of the grant amount from nonfederal sources, agree to use grant funds to supplement and not supplant federal and nonfederal funds received from other sources, maintain expenditures of nonfederal amounts at levels not less than those expended in the fiscal year prior to the entity's receipt of the grant, and demonstrate that grant funds will not be used until funds from all payers, including private insurance, Medicaid, and CHIP, are used.

The Secretary would be authorized to award NMHC planning grants only if the entity agrees to assess the needs of the medically underserved population that the NMHC proposed to serve and then design the services and operation of the NMHC based on the assessment. Further, the Secretary would be authorized to award NMHC operating grants only if the entity assured that it would provide primary care and other health care services deemed appropriate by the Secretary; care to all patients regardless of insurance status or ability to pay; and services by advanced practices nurses, other types of nurses and other specified providers. The section would authorize to be appropriated SSAN for FY2011 through FY2015.

Sec. 2534. Community-based Collaborative Care Networks

This section would add a new **PHSA Sec. 340H**, authorizing HRSA to award grants to public and nonprofit private entities, including federally qualified health centers (FQHCs) and public health departments, to establish community-based collaborative care networks. The objectives of these networks include (1) developing or strengthening the coordination of services, especially for uninsured and low-income individuals, to improve the quality of care; (2) developing an infrastructure for efficient and sustainable health care delivery; (3) developing or strengthening chronic care coordination activities; and (4) reducing unnecessary use of emergency departments, inpatient care, and other expensive resources where primary care provider services are appropriate. Eligible collaborative care networks (CCNs) must be comprised of a consortium of health care providers with a joint governance structure capable of delivering integrated health care services to low-income populations or medically underserved individuals, irrespective of health insurance status. Generally, a CCN would be expected to include all FQHCs located in the geographic area served by the network and to have at least one safety net hospital that provides services to a high volume of low-income patients. Other kinds of entities, such as critical access hospitals, county departments of health, and community clinics, may be included in CCNs. One single entity, such as an existing integrated health system may itself qualify as a CCN provided it meets all of the criteria enumerated in the section.

The Secretary would be required to give priority to applicants that demonstrate the capacity to provide the broadest array of health care services to low-income, vulnerable populations, including providers that currently serve a high volume of low-income individuals. Permissible uses of CCN funding would include assisting uninsured, underinsured, and low-income individuals to: (1) access and appropriately use health services; (2) enroll in applicable public or private health insurance programs; (3) obtain referrals to a primary care provider; and (4) get appropriate care for chronic conditions. Permissible uses of funds also would include providing case management, application assistance, and appropriate referrals through the use of HIT networks and community outreach, and expanding the capacity to provide care at any provider participating in the CCN through the use of telehealth, and by hiring additional staff and

providing access to services after hours and on weekends. In order to comply with HRSA requirements, the percentage of CCN funds that may be spent on direct care services may be limited for members of networks who are also grantees of programs administered by HRSA.

No more than 7% of funds appropriated to carry out the section may be used by the Secretary for providing technical assistance to grantees, obtaining the assistance of experts and consultants, holding meetings, developing of tools, disseminating of information, and conducting evaluations. Participation in a CCN would not alter an FQHC's obligation to comply with the governance requirements of PHSA Sec. 330. Conversely, participating FQHCs would only be required to provide services that were required by their federal health center scope of project, as approved by HRSA.

The Secretary would be permitted to conduct periodic audits and request periodic spending reports from community-based CCNs. The Secretary would have the authority to terminate funding for any CCN for good cause. Three years following an initial grant, each CCN would be required to submit to the Secretary an evaluation of its activities detailing (at a minimum): the number of patients served; the most common health problems treated; any reductions in emergency department use; any improvements in access to primary care; an accounting of how amounts received were used; and any quality measures or other performance measures as specified by the Secretary. Beginning no later than six months after the first evaluations are submitted, the Secretary would have to submit to Congress an annual evaluation including information on the degree to which CCNs reduced emergency department utilization; the prevalence of certain chronic conditions in various populations; and the health conditions of persons presenting at the emergency departments of participating hospitals. There would be authorized to be appropriated SSN for each of FY2011 through FY2015 to carry out the grant program.

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.[14]

Medicare pays the costs of graduate medical education (GME) by making two types of payments to teaching hospitals. First, direct graduate medical education (DGME) payments help cover the costs of the residency training program, including resident salaries and benefits, supervisory physician salaries, and administrative overhead expenses. DGME payments are calculated based on the product of three factors: a hospital-specific per resident amount, a weighted count of full-time equivalent (FTE) residents supported by the hospital, and the hospital's Medicare patient share. Second, indirect medical education (IME) payments, which vary with the intensity of a hospital's residency program, are intended to compensate hospitals for the higher costs of patient care in teaching hospitals. Those costs are the result of such factors as having sicker patients and the fact that inexperienced residents may order more tests. The IME adjustment is a percentage add-on to a hospital's Medicare payments for inpatient care and is based, in part, on the hospital's resident-to-bed ratio. Medicare includes the time that residents spend in both patient care and non-patient care activities, including didactic activities, when calculating DGME payments. When calculating IME payments, however, only the time spent in patient care activities is included. In 2008, Medicare DGME and IME payments totaling an estimated $9 billion were paid to more than 1,100 teaching hospitals to educate and train about 90,000 residents, equivalent to approximately $100,000 per resident. Health policy analysts view Medicare GME payments as a potentially important instrument for shaping future health workforce policy; for example, by linking the subsidies to delivery system reform and by structuring them to encourage the training of more generalists and to increase the amount of time residents spend in nonhospital settings such as community health centers and rural health clinics.[15]

National Health Service Corps

Sec. 2201. National Health Service Corps

This section would amend **PHSA Sec. 331**, allowing the Secretary to waive certain requirements of NHSC service so that the service obligation could be fulfilled on a half-time basis (i.e., a minimum of 20 hours per week in clinical practice). Individuals fulfilling their service obligation in this manner would have to agree to double the period of obligated service that would otherwise be required, or, if receiving loan repayment, accept a minimum of two years of obligated service and 50% of the amount that would otherwise be provided. It also would amend **PHSA Sec. 337**, repealing the prohibition on reappointment of members to the NHSC National Advisory Council. It would amend **PHSA Sec. 338B**, increasing the maximum annual NHSC loan repayment amount from $35,000 to $50,000, adjusted annually for inflation beginning in FY2012. Finally, the section would amend **PHSA Sec. 338C**, permitting teaching to be counted for up to 20% of the NHSC service obligation.

[14] For more information on the NHSC program, see CRS Report R40533, *Health Care Workforce: National Health Service Corps*, by Bernice Reyes-Akinbileje.

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

Sec. 2202. Authorization of Appropriations

This section would amend **PHSA Sec. 338** by (1) authorizing to be appropriated for NHSC program operations SSAN through FY2015; and (2) authorizing to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for NHSC program operations, the following amounts: $63 million for FY2011, $66 million for FY2012, $70 million for FY2013, $73 million for FY2014, and $77 million for FY2015.

In addition, the section would amend **PHSA Sec. 338H,** by authorizing to be appropriated for the NHSC scholarship and loan repayment programs SSAN for each of FY2013 through FY2015. The section would add a new **PHSA Sec. 338H-1** authorizing to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for NHSC scholarships and loan repayments, the following amounts: $254 million for FY2011, $266 million for FY2012, $278 million for FY2013, $292 million for FY2014, and $306 million for FY2015.

Promotion of Primary Care and Dentistry

PHSA Title VII, Part A, comprising Secs. 701-735, authorizes student loan programs for health professions students. Sec. 735 establishes general provisions for the administration of the student loan fund. Title VII, Part C, Sec.747, 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. Title VII, Part D, Sec. 751 authorizes the Area Health Education Centers (AHEC) grant program. Among other activities, AHEC funds may be used to support community-based primary care residency programs. There is no connection between AHEC-supported community-based residency training and the Medicare GME program (described later in this report).

The House legislation includes the following seven sections that would establish or amend existing programs to increase the supply of primary care providers. The first such provision would create a new loan repayment program, analogous to the NHSC program, for individuals who agree to practice in medically underserved areas whose health care needs are not being met by the NHSC.

Sec. 2211. Frontline Health Providers

This section would amend the **PHSA Title III,** by adding at the end a new Subpart XI–Health Professional Needs Areas, and creating in that subtitle four new sections as described below.

PHSA Sec. 340H would require the Secretary, acting through the HRSA Administrator, to establish the Frontline Health Professional Loan Repayment Program. It would require the Secretary to designate “health professional needs areas” (as defined), establish eligibility requirements for loan repayors, and define “primary health services” as family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, and mental health.

PHSA Sec. 340I would require the Secretary, acting through the HRSA Administrator, to contract with individuals who agree to serve in a health professional needs area as either a full-time primary health services provider, or as a part-time or full-time provider of other health services,

for a period of two or more years. The Secretary would be required to pay, for each year of service, an amount on the principal and interest of the educational loan of the individual that is not more than 50% of the average award made under the NHSC Loan Repayment Program in that year. Individuals would be allowed to satisfy the service requirement through employment at specified practice settings. Statutory provisions for the NHSC Loan Repayment Program would apply to the Frontline Health Professional Loan Repayment Program, where appropriate. Finally, the section would require the Secretary to transfer all unobligated funds from this program to the NHSC for the purpose of recruiting participants for the following year.

PHSA Sec. 340J would require the Secretary to submit an annual report to Congress on the Frontline Health Professional Loan Repayment Program.

PHSA Sec. 340K would require the following allocation of funds obligated for each fiscal year for loan repayments: (1) 90% must be allocated for physicians and other health professionals providing primary health services, and (2) 10% must be allocated for non-physicians and non-primary health professionals.

Sec. 2212. Primary Care Student Loans

PHSA Sec. 735 establishes general provisions for the administration of the student loan fund for medical students and health professions students. Health professions schools are required to take into account the expected financial contribution from parents or other family members when considering student loan applications, regardless of the tax status of the student.

This section would amend **PHSA Sec. 735**, permitting the Secretary to require that loan applicants submit information on their financial resources in order to determine the financial resources available to them. It also would require the Secretary to take into account the extent to which the applicant is financially independent in determining whether to require the submission of financial information about an applicant's family members.

Sec. 2213. Primary Care Training and Enhancement

This section would amend **PHSA Sec. 747** to require 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, general pediatrics, or geriatrics—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, public or private nonprofit entities, or a consortium of two or more of these entities. However, only schools of medicine or osteopathic medicine would be eligible for capacity building grants. The Secretary would be required to give preference to qualified applicants based on an applicant's record of (1) training primary care providers and individuals from minority groups or disadvantaged backgrounds; (2) training individuals who provide care in underserved areas or to populations experiencing health disparities including those eligible for Medicaid and CHIP; and/or (3) supporting teaching programs targeting vulnerable populations.

Sec. 2214. Training of Medical Residents in Community-Based Settings

This section would redesignate current PHSA Sec. 748–Advisory Committee on Training in Primary Care Medicine and Dentistry as Sec. 749A, and create a new **PHSA Sec. 748,** requiring

the Secretary to award grants or contracts for planning and/or operating primary care residency training programs in community-based settings. Eligible entities would be (1) Medicare GME-eligible non-hospital providers; (2) teaching health centers as defined in Sec.1502(d) of this bill;[16] or (3) an applicant for the designation described in (1) or (2) that meets certain specified criteria. The Secretary would be required to give preference to qualified applicants that are an FQHC or a rural health clinic, and to programs that would address the health care needs of vulnerable populations, or that have a demonstrated record of training individuals from disadvantaged backgrounds including those who are underrepresented in primary care, or who practice in underserved areas or in areas experiencing health disparities.

Sec. 2215. Training in Dentistry

This section would amend PHSA Title VII, Part C by adding at the end a new **PHSA Sec. 749**, described below. It also would add the newly created section to the list of programs—currently Secs. 747 and 750—that are subject to the granting preference and other requirements under Sec. 791. That section specifies that the Secretary is required give preference to programs that have a high or recently improved rate of placing graduates in settings that provide care to medically underserved communities.

The new PHSA Sec. 749 would require the Secretary to award grants or contracts for a variety of activities to support and develop oral health training programs for general, pediatric, and public health dentists, and dental hygienists. Eligible entities would include accredited schools of dentistry, training programs in dental hygiene, public or nonprofit private hospitals, or consortia of these entities and a school of public health. The Secretary would have to give preference to entities meeting similar criteria as for the grant program established in Sec. 2213 of this bill.

Sec. 2216. Authorization of Appropriations

This section would add a new **PHSA Sec. 799C,** authorizing to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for such purposes, the following amounts to carry out PHSA Title III, Part D, Subpart XI (as established in Sec. 2211 of this bill, regarding frontline health providers) and PHSA Secs. 747, 748, and 749, as added or amended by this bill: $240 million for FY2011, $253 million for FY2012, $265 million for FY2013, $278 million for FY2014, and $292 million for FY2015. The section also would amend **PHSA Sec. 747** by authorizing to be appropriated SSAN through FY2015.

Sec. 2217. Study on Effectiveness of Scholarships and Loan Repayments

This section would require GAO, within 12 months of enactment, to conduct and report the findings of a study on the effectiveness of the NHSC and Frontline Health Provider programs, as amended by this bill. The study must include an evaluation of whether scholarships or loan repayments are more effective in (1) incentivizing physicians and other providers to pursue

[16] Among other things, Sec. 1502(d) would amend the SSA to allow for Medicare GME payments to qualified teaching health centers, such as federally qualified health centers and rural health centers that develop and operate an accredited primary care residency program for which GME funding would be available if such program were operated by a hospital. It also would establish a demonstration project to facilitate affiliations between teaching health centers and teaching hospitals to encourage residency training in community-based settings. See the discussion of the bill's GME provisions.

careers in primary care; (2) retaining primary care providers; and (3) encouraging them to practice in underserved areas.

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 House legislation would modify and reauthorize several of these existing programs, and delete the cultural and linguistic competency grant program. In addition, it would authorize two new programs: a nursing training and retention program administered by the Department of Labor, and a program administered by the Department of Education to help reduce the student-to-nurse ratio in schools.

Sec. 2221. Amendments to the Public Health Service Act

This section would amend **PHSA Sec. 801** to include "nurse-managed health centers" as eligible entities for purposes of Title VIII's nursing workforce development programs, and would insert a definition for the term "nurse-managed health centers" into the section. It also would delete **PHSA Sec. 807**, a grant program for cultural and linguistic competence training for nurses.

The section would add a new **PHSA Sec. 809**, requiring the Secretary to submit annual reports to Congress on each of the loan and grant programs in Title VIII that do not already require an annual report (i.e., **Secs. 811, 821, 836, 846A,** and **861,** as redesignated). It would delete the 10% limit on Advanced Education Nursing Grant awards to doctoral program traineeships in **PHSA Sec. 811**. It also would add to the list of eligible entities meriting special consideration those that agree to expend the award to increase diversity among advanced education nurses.

The section would amend **PHSA Sec. 831,** regarding Nurse Education, Practice, and Retention Grants, to restate grant activity priorities from managed care and quality improvement to coordinated care, quality care, and other skills needed to practice nursing. It would delete a subsection regarding preference for these grants.

The section would amend **PHSA Sec. 836** to increase the maximum amount of loan funds a recipient can receive per year from $2,500 to $3,300; increase the annual limit for the last two academic years from $4,000 to $5,200; and increase the total loan amount that may be provided to a student from $13,000 to $17,000. These limits would be annually adjusted for inflation beginning in FY2012. **PHSA Sec. 846** would be amended to include individuals in the Loan Repayment and Scholarship Program who agree to serve for not less than two years as a faculty member at an accredited nursing school. **PHSA Sec. 846A** would be amended to raise the Nurse Faculty Loan Program limit from $30,000 to $35,000. These limits would be annually adjusted for inflation beginning in FY2012.

The section would delete the current **PHSA Title VIII, Part H**, related to federal, state, and local public service announcements to promote careers in nursing.

The section would redesignate PHSA Sec. 841 as **PHSA Sec. 871** and amend it to authorize the appropriation of SSAN for each fiscal year through FY2015 for PHSA Title VIII Parts B, C, and

D (i.e., Sec. 811, Advanced Education Nursing Grants; Sec. 821, Workforce Diversity Grants; and Sec. 831, Nurse Education, Practice, and Retention Grants). It also would authorize to be appropriated SSAN through FY2015 for the following programs: Sec. 831 (Nurse Education and Retention Grants); Sec. 846 (Student Loan Repayment and Scholarships); Sec. 846A (Nursing Faculty Loans); and Sec. 861, as redesignated (Geriatric Education). Finally, the section would add a new **PHSA Sec. 872**, authorizing to be appropriated out of monies in the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for such purposes, the following amounts for Title VIII programs: $115 million for FY2011; $122 million for FY2012; $127 million for FY2013; $134 million for FY2014; and $140 million for FY2015.

Sec. 2521. Grants for Nursing Training and Pipeline Programs

This section would require the Secretary of Labor to establish a new partnership grant program to support nurse education, practice, and retention. The program would provide matching grants to eligible entities for qualified nursing training programs, including nurse "career ladder" programs and nurse faculty development programs. Eligible entities would include partnerships of health care providers and labor unions, trade associations, or groups that represent direct health workers. In making awards, the Secretary of Labor would be required to give preference to programs that improve nurse retention; increase the diversity of the nursing workforce; improve the quality of nursing education; have demonstrated success for transitioning health care workers into nursing; have established pilot programs to increase nurse faculty; or are modeled after or affiliated with established transitioning and pilot programs mentioned above. Any awards made would require a dollar-for-dollar match by the recipient. There would be authorized to be appropriated SSAN to carry out this partnership grant program.

Sec. 2536. Reducing Student-to-School Nurse Ratios

This section would authorize the Secretary of Education (in consultation with HHS) to establish a demonstration grant program for local education agencies to reduce the student-to-school nurse ratio in public elementary and secondary schools. In making awards, the Secretary of Education would be required to give special consideration to applicants that demonstrate high need, in part by providing information about current student-to-school nurse ratios. Eligible local educational agencies would be defined as those in which the student-to-school nurse ratio in the public elementary and secondary schools they serve is 750 or more students to every school nurse. High-need local educational agencies would mean those that serve at least 10,000 children from families with incomes below the poverty line, or for which at least 20% of the children are from families with incomes below the poverty line. The Secretary of Education could require non-federal matching contributions from grant recipients. To carry out this section, there would be authorized to be appropriated SSAN for each of FY2011 through FY2015.

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. 2231. Public Health Workforce Corps

This section would add three new **PHSA sections (340L, 340M, and 340N)**, requiring the Secretary to establish within the U.S. Public Health Service a Public Health Workforce Corps (PHWC), similar to the National Health Service Corps. The Secretary would be required to use the PHWC to address critical public health workforce shortages and may designate as shortage areas state, local, and tribal health departments, and FQHCs. In exchange for a postgraduate period of service in a designated shortage area, members of the PHWC would be eligible for scholarships while in training, and loan repayment while in service.

Sec. 2232. Enhancing the Public Health Workforce

This section would replace **PHSA Sec. 765** with new language requiring the Secretary to establish a grant program for certain health professions schools, state, local, or tribal health departments, public or private nonprofit entities, or consortia of these entities, to develop public health training programs and provide assistance to students. The Secretary would be required to award grants preferentially to entities that train: (1) professionals who serve in underserved communities; (2) individuals from minority groups or disadvantaged backgrounds; (3) individuals in public health specialties experiencing shortages of public health professionals (as determined by the Secretary); [and/or] (4) professionals serving in governmental public health.

Sec. 2233. Public Health Training Centers

This section would amend **PHSA Sec. 766**, which authorizes the Secretary to award grants for Public Health Training Centers. Current law (1) defines these centers as accredited schools of public health, or other public or nonprofit private accredited institutions, that provide graduate or specialized training in public health and (2) authorizes grants for training activities that further the decennial "Healthy People" national health goals developed and published by the Secretary. This section would amend PHSA Sec. 766 to refer, instead of the Healthy People goals, to the National Prevention and Wellness Strategy that would be required under Sec. 2301 of this bill.

Sec. 2234. Preventive Medicine and Public Health Training Grant Program

This section would replace the current **PHSA Sec. 768**, regarding preventive medicine residency training, with new language requiring the Secretary to award grants or contracts for residency training programs in preventive medicine and public health. Eligible applicants would include schools of public health; state, local, or tribal health departments; schools of medicine or osteopathic medicine; public or private hospitals; or consortia of the above entities.

Sec. 2235. Authorization of Appropriations

This section would amend new **PHSA Sec. 799C** (as established by Sec. 2216 of this bill) to authorize appropriations through the Public Health Investment Fund for all of the public health workforce provisions summarized above (i.e., new PHSA Secs. 340L, 340M, and 340N, and amended PHSA Secs. 765, 766, and 768). For all of these activities, in addition to any other amounts authorized to be appropriated for such purposes, there would be authorized to be appropriated from the Fund the following amounts: $51 million for FY2011; $54 million for FY2012; $57 million for FY2013; $59 million for FY2014; and $62 million for FY2015. In

addition, this section would authorize or reauthorize the appropriation of SSAN for the following PHSA sections through FY2015: Sec. 765 (public health workforce training grants), Sec. 766 (Public Health Training Centers), Sec. 767 (public health traineeships), Sec. 768 (preventive medicine and public health training), and Sec. 769 (health administration traineeships and special projects).

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. They include grants to establish Centers of Excellence at health professions schools that recruit and train significant numbers of underrepresented minority students, scholarships and other educational assistance for students from disadvantaged backgrounds, and loan repayments and fellowships for individuals from disadvantaged background who agree to serve as faculty members in health professions schools. 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.

The House legislation includes the following five sections that would amend several of the existing workforce diversity and interdisciplinary, community-based training programs.

Sec. 2241. Faculty Loan Repayments

This section would amend **PHSA Sec. 738(a)**, increasing the annual limit on the loan repayment amount from $20,000 to $35,000. Beginning in FY2012, that amount would be subject to an annual adjustment for inflation.

Sec. 2242. Nursing Workforce Diversity Grants

This section would amend **PHSA Sec. 821**, eliminating the requirement that the Secretary, in awarding nursing workforce diversity grants, take into account the recommendations of the three Invitational Congresses for Minority Nurse Leaders that were convened in the 1990s.

Sec. 2243. Coordination of Diversity and Cultural Competency Programs

This section would add a new **PHSA Sec. 739A**, requiring the Secretary to coordinate the health workforce diversity programs under Title VII, Part B and Title VIII (Sec. 821). It also would amend **PHSA Sec. 736**, directing the Secretary to submit an annual report on the Centers of Excellence program.

Sec. 2251. Cultural and Linguistic Competency Training

This section would amend **PHSA Sec. 741,** by replacing the existing grant program for training health care professionals how to reduce disparities in outcomes and provide culturally competent care with a new cultural and linguistic competency training grant program. The Secretary would be required to award grants to health professions schools, academic health centers, and other

entities to develop, test, and implement such training programs. Grantees would have to agree to test and evaluate models of cultural and linguistic competence training.

Sec. 2252. Innovations in Interdisciplinary Care Training

This section would add a new **PHSA Sec. 759**, requiring the Secretary to award grants to health professions schools, academic health centers, and other entities to develop, test, and implement training programs that promote the delivery of health care services through interdisciplinary and team-based models (e.g., patient-centered medical homes) of care.

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.

The House legislation includes the following two sections that would replace existing PHSA provisions with new language establishing an Advisory Committee on Health Workforce Evaluation and Assessment and requiring certain health workforce data collection activities.

Sec. 2261 and Sec. 2271. Health Workforce Evaluation and Assessment

Sec. 2261 would add a new **PHSA Sec. 764** requiring the Secretary, acting through the Assistant Secretary for Health, to establish a permanent Advisory Committee on Health Workforce Evaluation and Assessment. The Advisory Committee would be required to recommend classifications, standardized methodologies, and procedures to enumerate the health workforce. In addition, the Advisory Committee would have to submit recommendations regarding health workforce supply, diversity, geographic distribution, retention, and expansion and to suggest policies to carry out these recommendations. The Secretary would be required to consult with the Secretary of Education and the Secretary of Labor in carrying out these activities.

Sec. 2271 would replace **PHSA Sec. 761(a) and (b)** with new language requiring the Secretary to collect data on the health workforce, based on the work developed by the Advisory Committee, and data on individuals participating in specified programs authorized by the bill. The Secretary would be authorized to enter into grants or contracts with specified entities and collaborate with federal agencies and other specified organizations for the purpose of carrying out these data collection activities. Pending completion, the Secretary would be authorized to make a judgment about the classifications, methodologies, and procedures developed by the Advisory Committee with respect to their use for data collection under **PHSA Sec. 761(a)**, as amended. Secs. 2261 and 2271 each require the Secretary to submit an annual report to Congress on activities of the Advisory Committee and activities related to data collection, respectively.

Authorization of Appropriations

Sec. 2281. Authorization of Appropriations

This section would amend new **PHSA Sec. 799C** (as established by Sec. 2216 of this bill) to authorize to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for such purposes, the following amounts for activities in specified PHSA sections: (1) health professions training and diversity (**PHSA Secs. 736, 737, 738, 739, and 739A**): $90 million for FY2011; $97 million for FY2012; $100 million for FY2013; $104 million for FY2014; $110 million for FY2015; and (2) interdisciplinary training programs, the Advisory Committee on Health Workforce Evaluation and Assessment, and health workforce assessment (**PHSA Secs. 741, 759, 761, and 764**): $87 million for FY2011; $97 million for FY2012; $103 million for FY2013; $105 million for FY2014; $113 million for FY2015.

The section also would authorize to be appropriated SSAN through FY2015 for the following PHSA health workforce programs: **Sec. 736** regarding Centers of Excellence; **Sec. 737** regarding scholarships for disadvantaged students; **Sec. 738** regarding faculty loan repayments and fellowships; **Sec. 739** regarding educational assistance for individuals from disadvantaged backgrounds; **Sec. 741** regarding grants for cultural and linguistic competency training for health professionals; and **Sec. 761** regarding health professions workforce information and analysis.

Medicare Graduate Medical Education Payments

With certain exceptions, Medicare caps the number of residents used to calculate GME payments for individual teaching hospitals at the level reported at the end of 1996. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permitted a one-time redistribution of up to 75% of a teaching hospital's unused resident position to hospitals seeking to increase their medical residency programs, according to specific priorities. Medicare does not set targets for the type or mix of resident physicians that a hospital trains, nor are Medicare GME payments linked to promoting or fostering specific goals in medical education.

Medicare allows teaching hospitals to receive DGME and IME payments for the time residents rotate in non-hospital settings provided (1) they are performing patient care, and (2) the hospital pays all or substantially all (i.e., 90%) of the costs of the training at the non-hospital site, which include the resident stipends and fringe benefits and the costs associated with supervising physicians. Time spent in non-patient care activities in the non-hospital setting is not counted when calculating either type of payment. A hospital that jointly operates a residency program with another hospital cannot include the time spent by residents working at a non-hospital site if it incurs all or substantially all of the costs for only a portion of the residents in that program at the non-hospital site. Additional regulatory requirements discourage rotations in non-hospital settings. Moreover, hospitals have a financial incentive to retain the often lower-cost clinical labor that residents provide. While experts see value in having residents gain experience in nonhospital settings such as community health centers and nursing facilities, residency programs today are largely based in inpatient, acute-care teaching hospitals. H.R. 3962 includes the following five sections, which collectively would make a number of changes to Medicare to address these and related issues.

Sec. 1501. Distribution of Unused Residency Positions

This section would, among other things, establish criteria to be used to reduce the otherwise applicable resident limit for hospitals with unused residency positions, as defined, and direct the Secretary to redistribute those unused positions and assign them to other qualifying facilities. A facility that qualifies for an increase in residency positions would have to maintain its base level of primary care residents and use the additional slots for training primary care residents. Preference would be given to (1) hospitals that have demonstrated that they will fill the additional positions in a timely manner; (2) hospitals that had a reduction in residency training slots under this section; (3) hospitals that have a three-year primary care training program; (4) hospitals that have a formal arrangement to train residents in health centers, other non-hospital settings, and other specified settings; and (5) hospitals located in states with a low resident-to-population ratio, among other criteria.

The section also would establish the criteria used to calculate DGME and IME payments for hospitals that receive redistributed residency positions.

Sec. 1502. Increasing Training in Non-Provider Settings

This section would require that all time spent by a resident be counted towards the DGME payment, regardless of the setting, provided the hospital continues to incur the costs of the stipends and the fringe benefits of the resident during the time spent in that setting. In addition, all time spent by a resident in patient care activities in a non-hospital setting would be counted towards the IME payment, provided the hospital continues to incur those same costs. The HHS Inspector General would be required to assess the extent to which there is an increase in time spent by medical residents training in non-hospital settings.

The section also would establish a demonstration project, under which a teaching health center—such as an FQHC or a rural health center that develops and operates an accredited primary care residency program for which funding would be available if it were operated by a hospital—would contract with a teaching hospital to provide primary care residency training. The center would be responsible for payment of the hospital's costs of the residents' salary and benefits, and would be eligible for DGME payments to cover those costs. Residents training at the center would not be counted as the contracting hospital's residents and thus would not count toward that hospital's cap on residents. In addition, the contracting hospital would not be permitted to reduce its number of primary care residents.

Sec. 1503. Rules for Counting Resident Time for Non-Patient Care Activities

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

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

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

Sec. 1504. Preservation of Resident Cap Positions from Closed Hospitals

This section would direct the Secretary, by rulemaking, to establish a process to redistribute medical residency slots from recently closed hospitals. Such residency slots would be redistributed to other hospitals in the same state in a manner specified by the Secretary, taking into account recommendations by the senior health official in the state.

Sec. 1505. Improving Accountability for Approved Medical Residency Training

This section would establish certain goals for medical residency training programs. Specifically, programs would have to train residents to (1) work in non-acute traditional settings; (2) coordinate patient care within and across settings; (3) understand the relevant cost and value of various diagnostic and treatment options; (4) work in multi-disciplinary teams; (5) identify systematic errors in health care delivery and implement solutions for such errors; and (6) be meaningful users of electronic health records.

GAO would be required to evaluate and, within 18 months of enactment, report on the extent to which medical residency training programs are meeting the above workforce goals in a range of residency programs, including primary care and specialties, and have the appropriate faculty expertise to teach the topics required to achieve those goals. The study would include recommendations on the development of curriculum requirements and an assessment of the accreditation processes of the Accreditation Council for Graduate Medical Education and the American Osteopathic Association.

Other Workforce Provisions

The following describes four workforce provisions that would address health sciences training in secondary schools, the direct care workforce and family caregivers, and grants to establish online health workforce information and training programs.

Sec. 2533. Secondary School Health Sciences Training Program

This section would permit the Secretary, acting through the HRSA Administrator, and in consultation with the Secretary of Education, to establish a grants program for developing health sciences curricula at the secondary school level. Grants would be awarded to local educational agencies that are in partnerships with specified entities for the purpose of planning, developing or implementing secondary school health sciences curricula to prepare students for health professions or health professions-related degree programs and increase interest in applying to these programs. The section would require the Secretary to submit an annual report on the program to Congress. It would authorize to be appropriated SSAN for each of FY2011 through FY2015.

Sec. 2589. Long-Term Care and Family Caregiver Support

Title II, Sec. 202 of the Older Americans Act (OAA) authorizes various functions of the Administration on Aging (AoA) and the Assistant Secretary for Aging. This section would amend **OAA Sec. 202(b)(1)** to require the Assistant Secretary to make recommendations to other federal entities regarding appropriate and effective means of identifying and implementing investments in the direct care workforce and assisting states in developing state workforce development plans with respect to such workforce. **OAA Sec. 202** would be amended to include a new **subsection (g)(1)** requiring the Assistant Secretary to establish a Personal Care Attendant Workforce Advisory Panel and pilot program to improve working conditions and training for long-term care workers.

OAA Title III, Part E, the National Family Caregiver Support Program (NFCSP), provides direct support to family caregivers primarily caring for the elderly through information and referral assistance, respite care, and training and support. Sec. 303(e) authorizes funding to be appropriated to the NFSCP for FY2007 through FY2011. **OAA Sec. 303(e)(2)** would be amended to increase amounts authorized to be appropriated for the NFCSP to $250 million for each of FY2011 through FY2013.

Sec. 2590. Web-Site on Health Care Labor Market

This section would require the Secretary of Labor, in consultation with HRSA's Bureau of Health Professions, National Center for Health Workforce Analysis (NCHWA), to establish and maintain a website to serve as a comprehensive source of information on the health care labor market and related educational and training opportunities.

Sec. 2591. Online Health Workforce Training Programs

The Workforce Investment Act (WIA) provides, in general, job training and related services to unemployed and underemployed individuals. WIA programs are administered by the Department of Labor (DOL), primarily through DOL's Employment and Training Administration (ETA). WIA Title I, Sec. 171 establishes pilot and demonstration programs to develop and evaluate innovative approaches to providing employment and training services.[17]

This section would amend **WIA Sec. 171** to add a **new subsection (f)** requiring the Secretary of Labor, in consultation with the HHS Secretary, to award National Health Workforce Training Grants to eligible entities who would carry out online workforce training for individuals to attain or advance in health care occupations. The section also would require the Secretary of Labor to award Online Health Professions Training Program Clearinghouse grants to eligible postsecondary educational institutions to provide technical assistance and collect and disseminate data to entities that receive National Health Workforce Training Grants, as well as disseminate best practices identified by grantees. To carry out the National Health Workforce Training Grants, the section would authorize to be appropriated $50 million for FY2011 through FY2020. To carry out the Online Health Professions Training Program Clearinghouse, it would authorize to be appropriated $1 million for FY2011 through FY2020.

[17] For further information, see CRS Report RL33687, *The Workforce Investment Act (WIA): Program-by-Program Overview and Funding of Title I Training Programs*, by David H. Bradley.

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.[18] 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.

Beneficiary cost-sharing has been shown to decrease utilization of certain preventive services, in some contexts. Based on an evidence review, the Task Force on Community Preventive Services (which is administered by CDC) 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]

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;[20] 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.[21]

Coverage of Clinical Preventive Services

While federal law does not mandate coverage of preventive services for state and local government and private health insurance plans, Medicare Part B covers a number of clinical preventive services, including a one-time comprehensive examination, certain periodic cancer screenings, and other services. Medicare Part B also covers vaccines against influenza,

---

[18] 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.

[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] See the U.S. Preventive Services Task Force, established in Section 915(a) of the PHSA, http://www.ahrq.gov/clinic/uspstfix.htm; and the Task Force on Community Preventive Services, not explicitly authorized but conducted under general authorities in Title III of the PHSA, http://www.thecommunityguide.org/index.html.

[21] CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones.

pneumococcus, and, for individuals at increased risk, hepatitis B. Medicare Part D covers any FDA-licensed vaccine, when prescribed by a recognized provider. Congress has waived cost-sharing for some, but not all, Medicare covered preventive services in Part B. Medicare Advantage (Part C) is an alternative way for Medicare beneficiaries to receive covered benefits through private health plans. Medicare Advantage plans must cover benefits covered under Part B,[22] but have considerable flexibility in how they apply or waive cost-sharing. Many of these plans waive cost-sharing for preventive services.

State Medicaid plans must cover a package of preventive services under the Early and Periodic Screening, Diagnostic, and Treatment Services program (EPSDT), for beneficiaries under 21 years of age. Current law does not explicitly require that Medicaid state plans cover preventive services for adults, although coverage may be required if a service meets another applicable requirement, such as a physician's service.

Sec. 222. Essential Benefits Package Defined

Title II of Division A of this bill would establish requirements for "qualified health benefits plans" (QHBPs), which are plans that provide private health insurance, as well as the public insurance option, that meet new federal requirements regarding consumer protections and other matters. QHBPs would be required to cover, at a minimum, a specified list of services constituting an "essential benefits package." This section would define the required elements of this package to include preventive services, among others. Covered preventive services would include services recommended (i.e., given a grade of A or B) by the Task Force on Clinical Preventive Services (established by this bill) and vaccines recommended by the CDC. Cost-sharing would be waived for these covered preventive services, as well as for required well-baby and well-child care. Cost-sharing would apply, with certain stipulations, to other services in the essential benefits package.

Sec. 1305. Medicare Coverage and Waiver of Cost-Sharing

This section would amend **SSA Sec. 1861** to define "Medicare covered preventive services" as a specified list of currently covered services, and any services subsequently covered under the Secretary's administrative authority. Coverage would be subject to conditions and limitations that currently apply to each listed service, except that any cost-sharing (deductible and/or coinsurance) that currently applies would be waived.

Sec. 1306. Waiver of Medicare Deductible for Colorectal Cancer Screening

This section would amend **SSA Sec. 1833** to clarify that coinsurance and the deductible would be waived for colorectal cancer screening services regardless of the code applied, of the establishment of a diagnosis, or of the removal of tissue or other matter or other procedure that is performed in connection with and as a result of the screening test.

[22] Medicare Advantage plans must also cover all Part A services, except hospice care. CRS Report R40374, *Medicare Advantage*, by Paulette C. Morgan.

Sec. 1310. Expanding Access to Vaccines Under Medicare

This section would provide Medicare Part B coverage for all federally recommended vaccines, defined as any approved vaccine that is recommended by the CDC upon advice from the Advisory Committee on Immunization Practices.

Sec. 1311. Expansion of Medicare Covered Preventive Services at FQHCs

This section would amend **SSA Sec. 1861** to provide that FQHCs may receive Medicare reimbursement for Medicare covered preventive services, as defined in Sec. 1305 of this bill.

Sec. 1313. Certified Diabetes Educators as Certified Medicare Providers

This section would amend **SSA Sec. 1861** to designate certain certified diabetes educators as Medicare-certified providers of covered diabetes self-management training (DSMT) services. A "certified diabetes educator" would be defined as an individual who meets specified criteria, including certification by a "recognized certifying body," which also would be defined.

Sec. 1711. Medicaid Coverage of Preventive Services

This section would amend **SSA Sec. 1905** to require Medicaid state plans to cover, for all beneficiaries, preventive services that the Secretary determines are (1) services recommended by the Task Force on Clinical Preventive Services (established by this bill), or vaccines recommended by the CDC; and (2) appropriate for Medicaid beneficiaries.[23] Beneficiary cost-sharing would not be required.[24]

Sec. 1712. Medicaid Coverage of Tobacco Cessation Products

Federal Medicaid law requires states that cover outpatient drugs (which all states do) to cover all drugs for which manufacturers have rebate agreements in place with the federal Medicaid program. SSA Sec. 1927 lists 11 drug categories, including smoking cessation products, that states are permitted to exclude from their coverage of outpatient drugs. This section would remove smoking cessation products from the list of excluded drugs, thereby requiring state Medicaid plans to cover prescription and non-prescription FDA-approved smoking cessation products for which rebate agreements are in effect.

[23] In addition, this section would clarify that vaccines covered under the Vaccines for Children (VFC) program are those recommended by the CDC Director, rather than an advisory committee to the Director. Under the VFC program, Medicaid assumes the costs for certain low-income children who receive recommended vaccinations. SSA Sec. 1928(g) provides that Sec. 1928 (and, therefore, the VFC program) would cease to be in effect if federal law were to provide for immunization services for all children as part of a broad-based reform of the national health care system. This section of the bill would also strike SSA Sec. 1928(g).

[24] For more information about cost-sharing in Medicaid, see CRS Report RS22578, *Medicaid Cost-Sharing Under the Deficit Reduction Act of 2005 (DRA)*, by Elicia J. Herz.

Sec. 1725. Including Public Health Clinics in the Vaccines for Children Program

This section would amend **SSA Sec. 1928** to add public health clinics to the list of providers that may administer vaccines to eligible children under the Vaccines for Children (VFC) program.[25] SSA Sec. 1928 authorizes the VFC program, under which Medicaid assumes the costs for providing certain low-income children with recommended vaccinations. Medicaid law currently defines VFC-eligible children as those who are eligible for Medicaid; who are uninsured; who do not have health insurance coverage for vaccines and receive vaccines purchased through VFC and administered at a FQHC or rural health clinic; or who are Indians.

Provisions in the Public Health Service Act

Sec. 2301. Prevention and Wellness

This provision would create a new **PHSA Title XXXI**–Prevention and Wellness, consisting of several new PHSA subtitles and sections, as described below.

Subtitle A, Sec. 3111–Prevention and Wellness Trust would establish a Prevention and Wellness Trust and authorize the appropriation to the Trust of funds from the Public Health Investment Fund as established in Sec. 2002 of this bill, as follows: $2.400 billion for FY2011; $2.845 billion for FY2012; $3.100 billion for FY2013; $3.455 billion for FY2014; and $3.600 billion for FY2015. Amounts in the Trust would be available for carrying out this title as provided in advance in appropriation acts. The provision would authorize the appropriation from the Trust of specified amounts for specified subtitles or sections in this title for each of FY2011 through FY2015. (These amounts are provided with the summaries of each provision, below.)

Subtitle B, Sec. 3121–National Prevention and Wellness Strategy would require the Secretary to submit to Congress, and update biennially, a National Prevention and Wellness Strategy ("the Strategy") to improve the nation's health through evidence-based clinical and community-based prevention and wellness activities, including public health infrastructure improvements. The strategy would include goals and priorities, and identify health disparities in prevention, among other things.

Subtitle C, Secs. 3131 and 3132–Prevention Task Forces would require the Secretary to establish two task forces: a Task Force on Clinical Preventive Services, to be administered by the Agency for Healthcare Research and Quality (AHRQ), and a Task Force on Community Preventive Services, to be administered by CDC.[26] Each task force would be required, among other things, to review evidence regarding the benefits, effectiveness, appropriateness, and costs of clinical or community preventive services, respectively, and to develop and disseminate recommendations for the use of such services. Each task force would also be required to convene an advisory stakeholders board and would, in general, be subject to the Federal Advisory

[25] "Public health clinic" is not defined in the SSA or in this bill.

[26] In effect, this section would reauthorize or codify two existing task forces: the U.S. Preventive Services Task Force, authorized in PHSA Sec. 915 (see http://www.ahrq.gov/clinic/uspstfix.htm for more information), and the Task Force on Community Preventive Services, which is not explicitly authorized (see http://www.thecommunityguide.org for more information).

Committee Act (FACA). For carrying out this section, Sec. 3111 would authorize the appropriation from the Trust of $30 million for each of FY2011 through FY2015. (See also new Subtitle G below, regarding the transition of functions from the existing task forces to the task forces established under this section.)

Subtitle D, Secs. 3141, 3142, and 3143–Prevention and Wellness Research. Sec. 3141 would require the Directors of the CDC and NIH, in conducting or supporting research on prevention and wellness, to take into consideration the Strategy and the recommendations of the Task Forces on Clinical and Community Preventive Services.

Sec. 3142 would require the Secretary, through the CDC Director, to conduct, or award grants for, research in prevention and wellness priority areas identified in the Strategy, or by the Task Forces.

Sec. 3143 would require the Secretary to fund research and demonstration projects on the use of incentives to encourage individuals and communities to promote wellness, adopt healthy behaviors, and use evidence-based preventive services. Projects would focus on tobacco use, obesity, and other priorities identified in the Strategy under PHSA Sec. 3121, as established by this bill. If, on the basis of project findings, the Task Force on Clinical Preventive Services determines that an incentive is effective and should be recommended, the Secretary would be required to ensure that it is included in the essential benefits package under Sec. 222 of this bill. Similarly, if the Task Force on Community Preventive Services determines that an incentive is effective, the Secretary would be required to ensure that it is an allowable use of grant funds under PHSA Sec. 3151, as established by this bill. The Secretary would also be required to ensure that any incentive does not have a discriminatory effect on the basis of any personal characteristic extraneous to the provision of health care or related services, and is not tied to premiums or cost-sharing under any qualified health benefits plan, as defined in Sec. 100 of this bill.

For carrying out this subtitle, Sec. 3111 would authorize the appropriation from the Trust of the following amounts: $155 million for FY2011; $205 million for FY2012; $255 million for FY2013; $305 million for FY2014; and $355 million for FY2015.

Subtitle E, Sec. 3151–Delivery of Community Prevention and Wellness Services would require the Secretary, through the CDC Director, to award grants for programs to deliver prevention and wellness services that address priority areas identified in the Strategy. Program requirements would emphasize services intended to reduce health disparities. Funds could not be used for construction, or to fund services that would otherwise be covered by public or private health care programs. For carrying out this section, Sec. 3111 would authorize the appropriation from the Trust of the following amounts: $1.065 billion for FY2011; $1.260 billion for FY2012; $1.365 billion for FY2013; $1.570 billion for FY2014; and $1.600 billion for FY2015.

Subtitle F, Secs. 3161 and 3162–Core Public Health Infrastructure. Sec. 3161 would require the Secretary to award grants to each state health department, and authorize the Secretary to award competitive grants to state, local, and tribal health departments, to address core public health infrastructure needs. A specified funding formula would apply to the mandatory grant program; specified maintenance of effort requirements would apply to both grant programs. In addition, the Secretary, acting through the CDC Director, would be required to develop and implement a program of voluntary accreditation of state or local health departments and public health laboratories. For carrying out this section, Sec. 3111 would authorize the appropriation from the Trust of the following amounts: $800 million for FY2011; $1.000 billion for FY2012; $1.100 billion for FY2013; $1.200 billion for FY2014; and $1.265 billion for FY2015.

Sec. 3162 would require the Secretary to expand and improve the core public health infrastructure and activities of the CDC to address unmet and emerging public health needs. For carrying out this section, Sec. 3111 would authorize the appropriation from the Trust of $350 million for each of FY2011 through FY2015.

Subtitle G, Sec. 3171–General Provisions would provide certain definitions applicable to this new title, and procedures for the transition of the functions of the existing U.S. Preventive Services Task Force and Task Force on Community Preventive Services to the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, established under Secs. 3131 and 3132 of this bill.

Sec. 2525. WISEWOMAN Program

This section would amend **PHSA Sec. 1509** to reauthorize the WISEWOMAN program. This CDC grant program funds demonstration programs to provide preventive services (such as blood pressure and cholesterol screening) and appropriate follow-up to low-income women. Only states that receive funding to provide breast and cervical cancer screening services to low-income women (authorized under PHSA Sec. 1501) are eligible for these grants. Appropriations authority for the WISEWOMAN program expired at the end of FY2003, but the program has continued to receive funding. Although PHSA Sec. 1509 authorizes grants to no more than 3 states, currently 19 states and 2 tribal organizations receive funding, under the Secretary's general authority to award grants for public health and disease prevention programs in PHSA Title III.

This section would remove the 3-state limit and authorize the appropriation of the following amounts for the WISEWOMAN program: $70.0 million for FY2011, $73.5 million for FY2012, $77.0 million for FY2013, $81.0 million for FY2014, and $85.0 million for FY2015.

Sec. 2530. Grants to Promote Positive Health Behaviors and Outcomes

This section would amend PHSA Title III, Part P by adding a new **Sec. 399V** authorizing the Secretary, in collaboration with CDC and other federal officials as appropriate, to award grants to public and nonprofit private entities (including FQHCs and public health departments) to promote positive health behaviors for populations in medically underserved communities through the use of community health workers. Grants would be used to provide training support to community health workers, subject to federal guidelines. Those workers, in turn, would provide education, guidance, and outreach to communities regarding: health problems that are prevalent in the medically underserved; effective strategies to promote positive health behaviors; enrollment in health insurance programs, including CHIP and Medicaid; referral to appropriate health care agencies and community-based programs and organizations; and access to home visitation services to promote maternal health and prenatal care.

The Secretary would be required to give priority to grant applicants that propose to target geographic areas with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured, a high percentage of residents who suffer from chronic diseases, and a high infant mortality rate. The Secretary also would be required to prioritize applicants with experience in providing health and social services to underserved individuals and engaging community health workers.

The Secretary would be required to encourage funded programs to implement an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate and timely services. Finally, the Secretary would have to report to Congress regarding specified aspects of the program not later than four years after grants are first awarded. There would be authorized to be appropriated $30 million to carry out the grant program for each of FY2011 through FY2015.

Sec. 2535. Community-Based Overweight and Obesity Prevention Program

This section would amend PHSA Title III, Part Q by adding a new **Sec. 399W-1,** requiring the Secretary to award grants and contracts for an evidence-based, community-based overweight and obesity prevention program. Funds would be awarded for five year periods (renewable for demonstrated performance) to community partnerships that demonstrate broad stakeholder involvement. Awardees would be required to match $1 for every $9 of federal funds, and meet specified maintenance of effort requirements. Funds could not be used to provide health care services that could be covered through existing public or private programs. Preference would be given to entities that serve communities with high levels of overweight and obesity and related chronic diseases, or that plan to implement programs in school or workplace settings. There would be authorized to be appropriated $10 million for FY2011 and SSAN for each of FY2012 through FY2015.

Employer-Provided Wellness Programs

Increasingly, employers are offering incentives to encourage their employees to participate in worksite health and wellness programs. Employer-sponsored wellness programs are subject to Health Insurance Portability and Accountability Act's (HIPAA's) nondiscrimination rules and, depending on their design, may also be affected by other statutes such as the Americans with Disabilities Act (ADA).[27] Generally, HIPAA prohibits an employer-sponsored health plan from denying enrollment or increasing an individual's premium contribution based on the individual's health status. However, the law provides an exception for plans that offer financial incentives (e.g., premium rebates, lower deductibles) to join a wellness program. A program that provides an incentive simply to encourage participation is considered nondiscriminatory under HIPAA (e.g., reimbursing the cost of a gym membership, or offering an incentive to participate in a smoking cessation clinic, regardless of outcome). But a wellness program that provides an incentive based on achieving a specified health-related outcome, such as giving up smoking or reaching a stated weight loss goal, must meet certain requirements in order to be considered nondiscriminatory. Those requirements include having a program that is reasonably designed to promote health or prevent disease, offering the program to all eligible employees, and providing a reasonable alternative to individuals for whom it would be unreasonably difficult or medically inadvisable to attempt to satisfy the goal.[28]

[27] 42 U.S.C. §§ 12101 et seq.

[28] Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006). See also CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones; and CRS Report R40791, *Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act*, by Amanda K. Sarata.

The ADA, which in part prohibits an employer from discriminating against an individual with a disability with regard to employment and benefits, specifically exempts health programs from its requirements if (1) participation in the program is voluntary and (2) the health information is treated confidentially, kept separate from other employment records, and not used to limit health insurance coverage. However, according to Equal Employment Opportunity Commission (EEOC) guidance on ADA enforcement, offering an incentive may render a wellness program involuntary if it is required in order to participate in an employer's insurance program.[29]

Employer-sponsored wellness programs also are subject to federal health privacy laws. Generally, individually identifiable health information acquired through a wellness program is protected under the HIPAA privacy rule if (1) the program is considered a part of the health plan, (2) the program provides and bills for health care services, or (3) the program is operated outside of the health plan by an entity that has a HIPAA-compliant business associate contract with the plan. ARRA strengthened the privacy rule's business associate requirements, making such entities criminally liable if they violate the HIPAA privacy protections. The HIPAA privacy rule allows health plans to disclose health information to employers, subject to certain conditions that include prohibiting the use of such information for employment-related actions.

Sec. 112. Wellness Program Grants

This section would require the Secretaries of HHS and Labor jointly to establish a grant program to help small employers (to be defined) cover 50% of the costs of providing employee wellness programs. Allowable costs would be those attributable to the wellness program (excluding the cost of food), and not to the health plan or health insurance coverage offered in connection with such a plan. Grants for a given plan year would be capped at $150 per employee. Grants could be provided for up to three years and would be capped at $50,000, in total, for an employer.

A qualified wellness program would be jointly certified by the Secretaries of HHS and Labor as meeting several criteria, including (1) being consistent with current evidence-based research and best practices; (2) being culturally appropriate, and accessible for individuals with disabilities and with limited English proficiency, among others; (3) having a number of required components, including health awareness, health education, periodic screenings, employee engagement, and listed behavioral change activities (including smoking cessation and weight reduction); and (4) having supportive work policies regarding tobacco use, food choices, stress management, and physical activity. A program could not be certified unless each required program component were available to all employees. Employee participation could not be mandated. Qualified programs could provide incentives for participation provided such incentives are not tied to the premium or cost-sharing of the individual under the health benefits plan. Any employee health information collected through the wellness program would be confidential and could not be used for purposes other than administration of the program.

There would be authorized to be appropriated SSAN to carry out this section.

[29] http://www.eeoc.gov/foia/letters/2009/ada_disability_medexam_healthrisk.html. For a more detailed discussion see CRS Report R40661, *Wellness Programs: Selected Legal Issues*, coordinated by Nancy Lee Jones.

Other Provisions

Sec. 2524. School Influenza Vaccination Centers

This section would require the Secretary to award grants for demonstration programs to study the feasibility of using elementary and secondary schools as influenza vaccination centers. The Secretary would be required to coordinate with the Secretaries of Labor and Education, state Medicaid agencies, state insurance agencies, and private insurers, to ensure that children have coverage for the costs of influenza vaccinations, including purchasing and administering the vaccine outside of the physician's office in a school or other related setting. The participation of any school or individual would be voluntary.

The grant program would cover the costs of influenza vaccine and its administration for children who are not otherwise covered by an existing federal program or private insurance. Children eligible to receive influenza vaccines under existing federal programs would not be covered under this program. The Secretary would be required to ensure that this program adheres to the HIPAA privacy rule, which addresses the use and disclosure of personal health information, and Sec. 444 of the Family Educational Rights and Privacy Act of 1974 (FERPA), which addresses the use and disclosure of information in students' education records. The Secretary would be required to award: (1) a minimum of 10 grants in 10 different states to eligible partnerships that each include one or more public schools serving primarily low-income students (as defined); and (2) a minimum of 5 grants in 5 different states to eligible partnerships that each include one or more public schools located in a rural local education agency.

Within 90 days of its completion, the Secretary would be required to report to Congress on the effect of the program on influenza vaccination rates, including an assessment of the utility of using elementary and secondary school vaccination programs to respond to seasonal influenza and an influenza pandemic. There would be authorized to be appropriated SSAN to carry out the program for each of FY2011 through FY2015.

Sec. 2594. Diabetes Screening Collaboration and Outreach Program

This section would require the Secretary, in consultation with specified government agencies and private groups, to review and report to Congress regarding the utilization of benefits for recommended diabetes screening and any problems with utilization or associated data collection, and to establish an outreach program to increase awareness among seniors and providers of diabetes screening benefits.

Maternal and Child Health

Maternal and Early Childhood Home Visitation

Home visiting is used to deliver support and services to families or individuals in their homes. Early childhood home visitation programs typically seek to improve maternal and child health; early childhood social, emotional, and cognitive development; and family/parent functioning. Depending on the particular model of early home visitation being used, the visitors may be specially trained nurses, other professionals, or paraprofessionals. Visits may occur on a weekly

basis, may begin during a woman's pregnancy or some time after the birth of a child, and may continue until the child reaches his/her second birthday (in some cases) or enters kindergarten. Participation of families is voluntary. Early childhood home visitation programs are in operation in all 50 states and the District of Columbia. No federal program provides funds exclusively for early childhood home visitation programs. However, in addition to private and state and local public funds, several federal programs have been tapped to support home visitation. Among others, these include Medicaid, the Temporary Assistance for Needy Families block grant, the Social Services Block Grant, Community-Based Grants to Prevent Child Abuse and Neglect, the Promoting Safe and Stable Families Program, the Maternal and Child Health (MCH) block grant, Healthy Start, and Early Head Start. For more information, see CRS Report R40705, *Home Visitation for Families with Young Children.*

Title IV-B of the Social Security Act (SSA) authorizes formula grants to states, territories and tribes for the provision of a range of child and family services. Those services are generally intended to ensure the safety of children and the well-being of children and their families, and to enable and ensure that children have a permanent family to call their own. Subpart 1 authorizes the Stephanie Tubbs Jones Child Welfare Services program. Subpart 2 authorizes the Promoting Safe and Stable Families program. Both programs are administered at the federal level by the Administration for Children and Families, (ACF) within HHS. There is no current law provision for formula grants to states to support home visitation programs for families with young children and those expecting children.

Sec. 1904. Home Visitation State Grant Program

This section would add a new **SSA Title IV-B, Subpart 3** to provide funds to states, territories and tribes for the establishment and expansion of voluntary home visitation programs for families with young children (under school age) and families expecting children and is intended to improve the well-being, health, and development of children. States would need to conduct a statewide needs assessment to determine current services and capacity of home visitation programs; sources of and amounts of funding for these programs; families and individuals served and gaps in the services; and training and technical assistance offered to support the goals of current programs. The results of the assessment would need to be submitted in the state's grant application. That application would further need to describe the home visitation programs the state plans to support, outcomes intended to be achieved, and evidence to support the effectiveness of those programs. It would further need to provide assurances, including the state's commitment to identifying and prioritizing support to home visitation programs serving high-need communities; reserving 5% of the grant fund for training and technical assistance; and providing annual reports to the Secretary on the programs funded with the grant, including characteristics of programs funded and families served as well as outcomes achieved and other information.

The Secretary would be required to make an allotment of funds to each state that successfully applied and met the maintenance of effort requirement. Beginning with FY2011, a state would not be eligible for these funds unless the Secretary determined its combined spending from state and local sources for early childhood home visitation programs was no less in the immediately preceding fiscal year than in the fiscal year prior to that. Each state's allotment amount would be based on its relative share of children living in families with incomes at or below 200% of the federal poverty level. To receive its full allotment a state would need to provide non-federal funding of no less than 15% of the total dollars spent under the early childhood home visitation

program in FY2010; no less than 20% of that spending in FY2011; and no less than 25% in FY2012 and succeeding fiscal years.

To be counted as spending under this program, services would need to be provided on a voluntary basis to families expecting children or those with children under the age of entry to school, and they must delivered under a home visitation program that adheres to a clear, evidence-based service delivery model with demonstrated positive effects on child and parent outcomes (such as reducing child abuse and neglect and improving child health and development) and meet other criteria that would be specified in law. States would be permitted to use part of the program funding, declining over time, on home visitation programs that do not meet the "strongest evidence of effectiveness." The Secretary would be required to provide an interim report on an independent evaluation of the home visitation program within three years of enactment and a final report on the evaluation within five years. Further, HHS would be required to submit a report to Congress, annually, on activities carried out with funds provided under the home visitation program.

The section would appropriate a total of $750 million for the early childhood home visitation program over five years, as follows: $50 million for FY2010; $100 million for FY2011; $150 million for FY2012; $200 million for FY2013; and $250 million for FY2014. Of these amounts, 5% must be reserved for federal evaluation, training and technical assistance related to the program and, after that reservation, 3% of the remaining funds must be used to support tribal home visitation programs.

Postpartum Depression

Sec. 2529. Research and Screening

This section would encourage the Secretary to expand and intensify research on the causes of, and treatments for, postpartum depression and other conditions, including conducting basis research and epidemiological studies, improving screening and diagnostic techniques, and developing information and education programs. The Secretary would be required to study and, within two years of enactment, report to Congress on the benefits of screening for postpartum conditions. It would be the sense of Congress that the Director of the National Institute of Mental Health may conduct a nationally representative longitudinal study, between FY2011 and FY2020, on the relative mental health consequences for women of resolving a pregnancy (intended and unintended) in various ways. There would be authorized to be appropriated to carry out this section, in addition to any other amounts authorized to be appropriated for such purpose, SSAN for FY2011 through FY2013.

Teen Pregnancy

PHSA Title XX, Adolescent Family Life Demonstration Projects, authorizes a number of voluntary teen pregnancy prevention, counseling, and related programs. The Secretary may award demonstration grants to public or nonprofit private entities to provide care and/or prevention services (including educational services) according to specified requirements. Grantees are required to evaluate program results and report to the Secretary, and the Secretary is authorized to support research on teen pregnancy prevention. **PHSA Title X**, Population Research and Voluntary Family Planning Programs, authorizes grants for comprehensive voluntary family

planning services, education, and research, including such activities regarding adolescents. There are several other federal programs that provide information about contraceptives, provide contraceptive services to teens, and provide referral and counseling services related to reproductive health. They include Medicaid family planning, the MCH block grant, the Title XX Social Services block grant, and the Temporary Assistance for Needy Families (TANF) block grant.

In addition, **SSA Sec. 510** authorizes a state formula grant program to support abstinence education programs for adolescents. Funds are awarded to states based on the proportion of low-income children in each state compared to the national total, and may only be used for teaching abstinence. Funds must be requested by states when they solicit MCH block grant funds. To receive funding, a state must match every $4 in federal funds with $3 in state funds. Sec. 510 provided $50 million for each of the fiscal years FY1998 through FY2003. Although the program has not been reauthorized, the latest of several extensions, included in the Medicare Improvements for Patients and Providers Act of 2008, continued funding through June 30, 2009. For more information, see CRS Report RS20873, *Reducing Teen Pregnancy: Adolescent Family Life and Abstinence Education Programs.*

Sec. 2526. Healthy Teen Initiative To Prevent Teen Pregnancy

This section would add a new **PHSA Sec. 317U**, creating a state grant program for evidence-based education programs to reduce teen pregnancy or sexually transmitted diseases. The amount of funding provided to each state would be based on the proportion of the nation's low-income children residing in that state. States would be required to provide $1 in matching funds or in-kind contributions for each $4 of grants funds, and use no more than 10% of the grant funds for an independent evaluation of the program.

The Secretary would be required, within 180 days of enactment, to develop and periodically update a registry of evidence-based, medically and scientifically accurate, age-appropriate programs, from which the states would choose the programs they intend to use. The section would authorize an appropriation of $50 million for each of FY2011 through FY2015.

Infant Mortality

Sec. 2532. Pilot Program to Support Social, Education, and Clinical Services

This section would require the Secretary, acting through the CDC Director, to award five-year grants to state, county, city, territorial, or tribal health departments to create, implement and oversee infant mortality programs that the Secretary deems likely to reduce infant mortality rates. The pilot program would allow grantees to use the funds for a range of activities including community need identification and strategy planning; outreach to at-risk mothers, including those in rural areas; development and implementation of standardized systems to improve access, utilization, and quality of social, education, and clinical services to promote healthy pregnancies, full-term births, and healthy infancies; establishment of regional public education campaigns; and provision of other activities, programs, or strategies as identified by the community plan. Each pilot program would be allowed to use not more than 10% of the grant for program evaluation. The Secretary would be required to give preference to applications regarding areas in the United States with the highest rates of infant mortality. The section would authorize to be appropriated $10 million for each of FY2011 through FY2015.

Behavioral Health

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. These programs are administered by the 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.[30] 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 (i.e., 23.7 million individuals) 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 (i.e., 19.9 million individuals) were current users of illicit drugs.[31] 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.[32]

The House legislation includes the following four sections that address behavioral health issues. They focus on mental health parity, federally qualified behavioral health centers, training programs, and postpartum depression.

Sec. 214 and Sec. 222. Parity for Mental Health and Substance Abuse Benefits

Under Sec. 214, QHBPs (including the public health insurance option) would be required to comply with the existing parity rules regarding the amount, duration, and scope of mental health and substance abuse benefits. Those rules do not mandate that plans provide behavioral health coverage. However, Sec. 222 requires the essential benefits package, offered as part of the public health insurance option, to include behavioral health services. Thus, the public health insurance option would be required to offer full parity mental health and substance abuse treatment benefits.

Sec. 2513. Federally Qualified Behavioral Health Centers

This section would amend **PHSA Sec. 1913** to establish federally qualified behavioral health centers as part of SAMHSA's Community Mental Health Services block grant. It would modify the Secretary's authority to waive the statutory requirement for states to maintain their efforts to provide services to children with serious emotional disturbance at a certain level. The section

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

[31] Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *National Survey on Drug Use and Health*, 2007, at http://www.oas.samhsa.gov/NSDUHlatest.htm. A "current user" is defined as someone who used an illicit drug during the month prior to the survey interview.

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

would delete the term "community mental health services" and insert the term "behavioral health services." In addition, it would replace the term "community mental health centers" with "federally qualified behavioral health centers" in existing requirements for the venue where these health services are provided. The section would require that services be provided through either appropriate, qualified community programs or federally qualified behavioral health centers. The section also would require an entity to be certified as a federally qualified behavioral health center by the SAMHSA Administrator at least every five years, based on certain specified criteria. The Administrator would be required to issue regulations for certifying these centers within 18 months of enactment.

Sec. 2522. Mental and Behavioral Health Training

This section would amend PHSA Title VII, Part E by adding at the end a new **PHSA Sec. 775**, requiring HRSA to, among other things, establish a grant program to support interdisciplinary mental and behavioral health training programs. Eligible entities would include (1) accredited schools or programs of psychology, psychiatry, social work and other disciplines as specified; (2) an accredited public or nonprofit private hospital; (3) a public or private nonprofit entity; or (4) a consortium of two or more such entities. The Secretary would give preference to applicants who have a demonstrated record of (1) training health professionals who serve in underserved communities; (2) supporting teaching programs that address the health care needs of vulnerable populations; (3) training individuals who are from underserved areas, minority groups or disadvantaged backgrounds; (4) training individuals who serve geriatric populations; and (5) training individuals who serve pediatric populations.

The Secretary would be required to submit an annual report to Congress on this program. There would be authorized to be appropriated for this program $60 million for each of FY2011 through FY2015. Of the amounts appropriated for each fiscal year, at least 15% would be required to be used for psychology training programs.

Sec. 2538. Behavioral Health Services in Primary Care Settings

This section would add a new **PHSA Sec. 544**, requiring the Secretary to establish a program to fund mental health and substance abuse screening, brief intervention, referral, and recovery services in primary care settings. Eligible entities would include those that (1) provide primary care services, (2) seek to integrate behavioral health into their services, (3) have working relationships with behavioral health providers, (4) demonstrate the need to integrate behavioral health into their services, and (5) agree to certain reporting requirements. The Secretary would give preference to applicants who provide services in rural or frontier settings; school, college, or university-based settings; or those who provide services to certain special needs populations. The funding period would not exceed five years.

The Secretary would be required to submit an annual report to Congress on evaluation results and performance measures of this program within four years of when funds are first appropriated for it. There would be authorized to be appropriated for this program $30 million for FY2011 and SSAN for FY2012 through FY2015. Of the amounts appropriated for each fiscal year, no more than 5% would be used for program management.

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 strategy, entity, or set of priorities or goals, nor have they benefitted from a coordinated infrastructure specifically devoted to improving health care quality.

Quality Measurements

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

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

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

H.R. 3962 includes the following sections, which together would require the development of an explicit national effort to prioritize quality improvement activities; develop a comprehensive repertoire of quality measures; formalize the role of multi-stakeholder input into the selection of quality measures for use in health care programs; create a mechanism for evaluating the processes used to collect quality data by the Secretary; and harmonize requirements across settings for the use of endorsed measures (and instances in which non-endorsed measures may be selected).

Sec. 1441. Establishment of National Priorities for Quality Improvement

This section would amend **SSA Title XI** by adding a new Part E–Quality Improvement: Establishment of National Priorities for Performance Improvement, and by creating a new **SSA Sec. 1191**. It would require the Secretary to establish national priorities for performance improvement and to solicit and consider recommendations from multiple outside stakeholders

when establishing and updating these national priorities. When establishing the national priorities, the Secretary would be required to give priority to care delivery areas that contribute to a large burden of disease, have the greatest potential to decrease morbidity and mortality, and will address health disparities, among others. For the purposes of carrying out this section, the Secretary would be required to provide for the transfer, from the Medicare Part A and Part B trust funds, of $2 million for each of FY2010 through FY2014. The section also would authorize the appropriation of $2 million, for each of FY2010 through FY2014, from any funds in the Treasury not otherwise appropriated.

Sec. 1442. Development of New Quality Measures

This provision would add two new sections to SSA Title XI, Part E (as established by Sec. 1441 of this bill). **SSA Sec. 1192** would require the Secretary to enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States. The Secretary would be required, as specified, to determine areas in which quality measures for assessing health care services in the United States are needed. The section would require the Secretary to make proposed quality measures available to the public and it would authorize the Secretary to fund the testing of proposed quality measures by qualified entities and the updating, by consensus-based entities, of quality measures that have been previously endorsed by such an entity as new evidence is developed. For purposes of carrying out this section, the Secretary would be required to provide for the transfer, from the Medicare Part A and Part B trust funds, of $25 million for each of FY2010 through FY2014. In addition, the section would authorize the appropriation of $25 million, for each of the FY2010 through FY2014, from any funds in the Treasury not otherwise appropriated.

SSA Sec. 1193 would require GAO to periodically evaluate the implementation of the data collection processes for quality measures used by the Secretary and to report to Congress and to the Secretary on the findings and conclusions of the results of each such evaluation.

Sec. 1443. Selection of Quality Measures

This section would amend **SSA Sec. 1808** to establish a process whereby multi-stakeholder groups would formally provide input into the selection of Medicare quality measures. Specifically, it would require the Secretary to make public quality measures being considered for selection in rulemaking, and require the consensus-based entity that has entered into a contract with the Secretary under SSA Sec. 1890 (i.e., National Quality Forum, NQF) to convene multi-stakeholder groups to provide recommendations on the selection of individual or composite quality measures for use in public reporting of performance information or in public health care programs. The consensus-based entity, in convening multi-stakeholder groups, would be required to provide for an open and transparent process for the activities conducted pursuant to such convening. The section would further require the proposed rule to contain a summary of the recommendations made by the multi-stakeholder groups, as well as other comments received regarding the proposed measures, and the extent to which the proposed rule follows such recommendations and the rationale for not following such recommendations.

For purposes of carrying out this section, the Secretary would be required to provide for the transfer, from the Medicare Part A and Part B trust funds, of $1 million for each of FY2010 through FY2014. In addition, the section would authorize the appropriation of $1 million for each of FY2010 through FY2014 from any funds in the Treasury not otherwise appropriated.

Sec. 1444. Application of Quality Measures

Generally, this section would place requirements on the Secretary when selecting quality measures for use in existing quality programs for inpatient hospital, outpatient hospital, physician and renal dialysis services. These requirements relate to the endorsement of quality measures and specifically amend relevant sections of the SSA[33] to (1) require the Secretary to select endorsed quality measures for the purposes of reporting quality data; (2) authorize the Secretary to select a non-endorsed measure, if feasible and practical measures are not available, providing the Secretary gives due consideration to endorsed or adopted measures; and (3) require the Secretary to submit non-endorsed measures to NQF for consideration for endorsement, and if NQF were not to endorse the measure, and the Secretary were to continue to use the measure, require the Secretary to include the rationale for its continued use in rulemaking.

The section would, by amending **SSA Sec. 1890(b)(2)**, require NQF to explain the reasons underlying non-endorsement of a given measure, and to provide suggestions about changes to such measure that might make such a measure potentially endorsable.

Sec. 1445. Consensus-Based Entity Funding

This section would amend **SSA Sec. 1890(d)** to provide for the transfer from the Medicare Part A and Part B trust funds of $10 million for FY2009, and $12 million for each of FY2010 through FY2012 to fund the activities of the consensus-based entity under contract in this section.

Sec. 1446. Quality Indicators for Care of People with Alzheimer's Disease

This section would require the Secretary to develop quality indicators for the provision of medical services to people with Alzheimer's disease and other dementias and develop a plan for implementing the indicators to measure the quality of care provided to individuals with these conditions. Within 24 months of enactment, the Secretary would be required to report to Congress on the status of the implementation of the requirements of this section.

Best Practices and Key Health Indicators

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.

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,

[33] Specifically, this section would amend: (1) SSA Sec. 1886(b)(3)(B) for hospital inpatient services; (2) SSA Sec. 1833(t)(17) for outpatient hospital services; (3) SSA Sec. 1848(k)(2)(C)(ii) for physician services; and (4) SSA Sec. 1881(h)(2)(B)(ii) for renal dialysis services.

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. 2401. Implementation of Best Practices in the Delivery of Health Care

This section would amend **PHSA Title IX** by adding a new Part D–Implementation of Best Practices in the Delivery of Health Care, which would establish within AHRQ a Center for Quality Improvement. The Center would be required to prioritize areas for the identification, development, evaluation, and implementation of best practices for quality improvement activities in the delivery of health care services. In prioritizing these areas, the Center would have to consider the national priorities for performance improvement established pursuant to SSA Sec. 1191 (as added by this bill) and key health indicators identified by the HHS Assistant Secretary for Health Information (discussed below).

The section would require the Center to provide for the public dissemination of information with respect to best practices and activities, and to submit an annual report to the Congress and the Secretary on the activities conducted under this section. Until such time as initial national priorities have been established, priority in initial quality improvement activities and initiatives would have to be given to the following five areas: health care-associated infections, surgery, emergency room, obstetrics, and pediatrics.

Sec. 2402. Assistant Secretary for Health Information

This section would amend **PHSA Title XVII** by adding a new **PHSA Sec. 1709** to create an HHS Assistant Secretary for Health Information. The Assistant Secretary would have a number of responsibilities, mostly related to the collection, reporting, and publishing of information on key health indicators; ensuring the sharing of relevant health data between federal departments; and developing standards for the collection of health data; among others.

This section would require the Assistant Secretary to identify key health indicators and publish statistics on such indicators not less than annually. The review, release, and dissemination of key health indicators would be subject to the same OMB regulations, rules, processes, and procedures that govern the review, release, and dissemination of Principal Federal Economic Indicators by the Bureau of Labor Statistics. This section would require the Assistant Secretary to coordinate with public and private entities that collect and disseminate information on health care and with the National Coordinator for Health Information Technology (ONCHIT). The Assistant Secretary would be required to submit an annual report to the Secretary and to Congress with an analysis of and recommendations based on the health indicator data collected pursuant to this section, as specified.

Sec. 2403. Authorization of Appropriations

This section would amend new **PHSA Sec. 799C** (as established by Sec. 2216 of this bill), authorizing to be appropriated from the Public Health Investment Fund, in addition to any other amounts authorized to be appropriated for such purposes, $300 million for each of FY2011 through FY2015 to carry out PHSA Title IX, Part D and Sec. 1709.

Public Reporting of Health Care-Associated Infections

Current federal law does not, in general, require the reporting of health care-associated infections (HAIs), although such reporting is required in a number of states. Provisions in current federal law attempt to incentivize the reduction of some specific types of health-care acquired catheter-associated infections (which are only one type of HAI) in two ways: through withholding of Medicare reimbursement under certain circumstances, and through incentives for voluntary physician and hospital reporting.

Sec. 1461. Public Reporting of Health Care-Associated Infection

This section would add a new **SSA Sec. 1138A** requiring the Secretary to provide, by regulation, that in order to participate in Medicare and Medicaid, hospitals (including critical access hospitals) and ambulatory surgical centers would have to report certain HAIs that develop in the facility. The Secretary would be required to establish procedures regarding the validity of reported data to ensure appropriate comparisons between facilities, and to post information online in a manner that permits comparisons by facility and by patient demographic characteristics. The section also would provide that it should not be construed as preempting or otherwise affecting applicable state reporting laws.

Comparative Effectiveness Research

ARRA provided $1.1 billion for comparative effectiveness research and created the Federal Coordinating Council for Comparative Effectiveness Research, an interagency advisory group that is required to report to the President and Congress annually.[34]

Sec. 1401. Center for Comparative Effectiveness Research

This section would add a new **SSA Sec. 1181**, establishing a Center for Comparative Effectiveness Research within the AHRQ, as well as an independent Comparative Effectiveness Research Commission, to oversee and evaluate the activities carried out by the Center. The Commission would represent broad constituencies of stakeholders, including clinicians, patients, researchers, third-party payers, and consumers of federal and state beneficiary programs. Nothing in the section would be construed to permit the Commission or the Center to mandate coverage, reimbursement or other policies for any public or private payer. In no case could any research conducted, supported, or developed by the Center, the Commission, or the Federal Coordinating Council for Comparative Effectiveness Research be used by the federal government to deny or

[34] For more information, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by C. Stephen Redhead.

ration care. In addition, CMS could not use federally funded clinical comparative effectiveness research data to make coverage determinations for medical treatments, services, or items under the Medicare program on the basis of cost.

Sec. 1802. Comparative Effectiveness Research Trust Fund

This section would amend the Internal Revenue Code (IRC) by adding a new **IRC Sec. 9511**, establishing the Health Care Comparative Effectiveness Research Trust Fund (CERTF) to fund comparative effectiveness research activities. While activities in the initial years (2010-2012) would be funded entirely from transfers from the Medicare trust funds, the CERTF would eventually receive both public funds (from the Medicare trust funds) as well as monies from the private sector through a fee imposed on health insurance and self-insured plans.

Medicare and Medicaid Nursing Homes

Secs. 1411-1432. Improving Transparency, Enforcement, and Staff Training

H.R. 3962 includes a number of provisions that would enhance a range of accountability requirements for Medicare certified skilled nursing (SNF) and Medicaid certified nursing facilities (NF). These provisions would require SNFs and NFs to maintain and make available additional information on ownership and organizational structure, as well as to establish new staff compliance and ethics training programs. GAO would be required to conduct a study and report to Congress on SNF and NF undercapitalization.

The Secretary would be required to enhance the information available on the Medicare Nursing Home Compare website for SNFs and NFs, and to make that information more easily accessible to long-term care (LTC) consumers. SNFs would be required to report expenditures for wages and benefits for direct care staff on facility cost reports. The Secretary would be required to consult with government and private sector cost report experts to assist in categorizing by functional area SNF expenditure data, as well as in making it publicly available. A new standardized complaint form would be developed, and facilities and states would be required to make this form available to all stakeholders and consumers. The new complaint form would be accompanied by whistle-blower protections for SNF and NF staff who reported quality of care problems.

The Secretary would have to establish a process to require SNFs and NFs regularly to report staffing data, including agency and contract staff, by staff position categories (based on payroll and other verifiable and auditable data). The Secretary also would be required to submit a report to Congress on staff accountability and would be required to establish a nationwide program for national and state background checks on direct patient access employees of certain LTC facilities or providers and provide federal matching funds to states to conduct these activities.

Additional civil money penalties would be established that both the Secretary and states could impose on nursing facilities found to have quality of care and other deficiencies that jeopardized residents' safety. The Secretary would be required to develop, test, and implement a national independent monitoring program for large interstate and intrastate SNF and NF chains. Further, new requirements would be established for SNF and NF administrators to inform residents and their representatives, as well as the Secretary, states, and other stakeholders of planned facility closures. In addition, SNFs and NFs would be required to add additional staff training in the areas of dementia and abuse prevention, and the Secretary would be required to study and report to

Congress on the content of additional staff training for certified nurse aides and supervisors. Finally, Medicare and Medicaid law would be amended to require the full-time director of food services of a nursing facility, if not a qualified dietician, to be a Certified Dietary Manager or a Registered Dietetic Technician or have equivalent military, academic, or other qualifications (as specified by the Secretary).

Patient Navigators

PHSA Sec. 340A 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. 2537. Medical-Legal Partnerships

This section would require the Secretary to establish a nationwide demonstration project that would award grants to medical-legal partnerships to assist patients in the navigation of health-related programs and for the evaluation of the effectiveness of these partnerships. The partnerships awarded funds under this section would be required to enhance access, improve health outcomes, reduce disparities and prevent chronic conditions. The Secretary would be required to submit a report to Congress on the results of this demonstration project. A medical-legal partnership is defined as an entity that is a collaboration between a provider of health services to a significant number of low-income beneficiaries and one or more attorneys, and whose primary mission is the assistance of patients and their families with the navigation of health care-related programs and activities. The section would authorize the appropriation of SSAN for each of FY2011 through FY2015.

Health Disparities

Federal civil rights policy requires most health care providers to make interpretation services available to patients with limited English proficiency (LEP). HHS regulations promulgated under the Civil Rights Act require recipients of HHS financial assistance to provide meaningful access by LEP persons. Recipients of HHS assistance include hospitals; nursing homes; home health agencies; managed care organizations; universities; state, county, and local health agencies; Medicaid agencies; public and private contractors; vendors; physicians; and other providers. Providers who only receive Medicare Part B payments are not considered recipients of HHS assistance.

Research has demonstrated that Medicare beneficiaries with LEP have a harder time accessing health care than LEP seniors covered by Medicaid. Some authors have argued that this difference may be attributed to the fact that federal civil rights policies require Medicaid health care providers to offer language assistance, while physicians serving only Medicare patients are not subject to the same requirements. Although all providers are bound by the Civil Rights Act, which obligates health care professionals to make interpreters available to LEP patients, studies suggest

that a lack of reimbursement for language services and poor enforcement of the Act has sometimes made it difficult for LEP Medicare beneficiaries to access translation services.

Secs. 1221-1224. Medicare Beneficiaries with Limited English Proficiency

These sections would require the Secretary to conduct a study to examine the extent to which Medicare providers utilize, offer, or make available language services for LEP, and the ways that Medicare should develop payment systems for language services. The study would include an analysis of ways to develop and structure appropriate payment systems for language services for Medicare providers; the feasibility of adopting a payment methodology for on-site interpreters; the feasibility of Medicare contracting directly with agencies that provide off-site interpretation, including telephonic and video interpretation; the feasibility of modifying the existing Medicare resource-based relative value scale (RBRVS) by using adjustments for LEP patients; and how each of these options would be funded. It also would examine the nature and type of language services provided to Medicaid beneficiaries, and whether these services could be used by Medicare beneficiaries and providers. The potential payment systems included in the analysis could allow variations based on types of service providers, available delivery methods, and costs for providing language services. The Secretary would be authorized to apply sanctions, such as civil money penalties, suspension of enrollment, and suspension of payments, to Medicare Advantage organizations that fail to provide required language services to LEP beneficiaries enrolled in their plans.

Within six months of the completion of the study, the Secretary would be required to carry out a demonstration program under which the Secretary would award no fewer than 24 three-year grants to eligible Medicare providers to improve effective communication between providers and Medicare beneficiaries living in communities where racial and ethnic minorities, including populations that face language barriers, are underserved with respect to such services. Grantees would be required to provide the Secretary with annual reports, which would include (1) the number of Medicare beneficiaries to whom language services are provided, (2) the languages of those Medicare beneficiaries, (3) the types of language services provided, (4) the type of interpretation, (5) the methods of providing language services, (6) the length of time for each interpretation encounter, and (7) the costs of providing language services. No grant under this program could exceed $500,000 for the three-year period.

The Secretary would be required to conduct an evaluation of the demonstration program and submit a report to Congress not later than one year after the completion of the program. An amount of $16 million would be authorized to be appropriated for each fiscal year of the demonstration program.

The Secretary would be required to contract a study on the impact of language access services on the health and health care of LEP populations and report the findings within three years of enactment. The Secretary would be authorized to use $2 million from the Medicare Trust Fund to pay for the study and report. Based on the study's findings, the Secretary, in consultation with patients, providers, and organizations representing the interests of LEP individuals, may opt to designate one or more training or accreditation organizations to oversee translation services being provided to Medicare beneficiaries.

Health Information Technology

HIPAA Administrative Simplification

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

The health care payment and remittance advice transaction is a communication from a health plan to a provider that includes an explanation of the claim and payment for that claim. The HIPAA standard for this transaction can accommodate an electronic funds transfer (EFT), in which payment is electronically deposited into a designated bank account. EFT is common in the health care sector—health plan contracts often require it—but there is no EFT mandate in federal law for Medicare, Medicaid, or private health insurance. In September 2005, CMS proposed a standard for health care claims attachments, one of the two remaining transactions standards that must be adopted. A claims attachment transaction is used to request and provide additional clinical data necessary to adjudicate a claim.

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

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

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

HIPAA's Administrative Simplification provisions also instructed the Secretary to develop security standards to safeguard electronic health information from unauthorized access, use, and disclosure, and to issue standards to protect the privacy of patient information. The HIPAA privacy rule, which took effect in 2003, established a set of patient rights, including the right of access to one's medical information, and placed certain limitations of when and how health plans

and health care providers may use and disclose patient information. The HITECH Act included a series of privacy and security provisions that amended and expanded the current HIPAA requirements. The HIPAA Administrative Simplification standards do not apply to the use and disclosure of information by financial institutions that are responsible for authorizing, processing, clearing, billing, transferring or collecting payments for premiums or health care.

Sec. 115. Administrative Simplification

This section would amend the HIPAA Administrative Simplification provisions by adding a new **SSA Sec. 1173A**, requiring the Secretary, within two years of enactment, to adopt an additional set of financial and administrative transactions standards to help clarify, complete, and expand the existing standards. The goal would be for the standards to be unique (with no conflicting or redundant standards), authoritative, and comprehensive, requiring minimal augmentation by paper transactions. In addition, the standards would describe all data elements in unambiguous terms and not permit optional fields. They would enable real-time (or near real-time) determination of a patient's financial responsibility at the point of service and adjudication of claims, and harmonize all common data elements across transactions standards. Finally, the standards would have to support electronic funds transfers as well as timely and transparent claim and denial management processes, enable providers to quickly and efficiently enroll with a health plan so as to conduct other electronic transactions, and provide for other requirements related to administrative simplification as identified by the Secretary.

In developing the standards, the Secretary would be required to build upon existing and planned standards and regularly update the new standards. Within six months of enactment, the Secretary would be required to submit to Congress a plan for implementing and enforcing the new standards within five years of enactment. The plan would have to include a timetable for developing and regularly updating the new standards, implementation programs to help rural and other providers, an estimate of the funding needed to ensure timely completion of the implementation plan, and an enforcement process including timely investigation of complaints, random audits, and a fair and reasonable appeals process. The Secretary would have to ensure that all data collected pursuant to the new standards meets the HIPAA privacy and security requirements, as modified by the HITECH Act.

In addition, the section would add a new **SSA Sec. 1173B**, requiring the Secretary to adopt an interim companion guide (including operating rules) for each HIPAA electronic transaction to be effective until the new standards, pursuant to Sec. 1173A, are adopted. In adopting the companion guides the Secretary would be required to comply with the existing HIPAA requirements for standards adoption and consult with a nonprofit entity that (1) is focused on administrative simplification; (2) has an established multi-stakeholder, consensus-based process for creating such rules; (3) employs a public set of guiding principles; (4) coordinates its activities with the HIT Policy Committee and the HIT Standards Committee; (5) uses existing market research and proven best practices; (6) employs a set a measures that allow for the evaluation of their market impact and public reporting of aggregate stakeholder impact; (7) supports nondiscrimination and conflict of interest policies; and (9) allows for public reviews and upgrades of the operating rules. Companion guides for eligibility and claims status transactions must be adopted by October 1, 2011, and take effect no later than January 1, 2013. Companion guides for the remaining HIPAA transactions must be adopted by October 1, 2012, and take effect no later than January 1, 2014.

The section would require the Secretary, within one year of enactment, to issue a final rule to establish a standard for health claims attachment transactions and coordination of benefits. It

would clarify that the HIPAA standards do not apply to the use and disclosure of information by financial institutions that process payments unless they are business associates of health plans and health care providers. Also, the Secretary would be required, within two years of enactment, to issue a final rule to establish a unique health plan identifier. The rule could be an interim final rule, effective not later than October 1, 2012. Finally, beginning January 1, 2015, the Secretary would be prohibited from paying Medicare Part A and B claims other than by EFT, provided he Secretary has adopted an EFT standard pursuant to Sec. 1173A. The electronic claims exemption for small providers and in other limited circumstances would remain in effect.

Sec. 237 and Sec. 328. Application of Administrative Simplification Standards

HIPAA's Administrative Simplification standards for electronic transactions, and health information privacy and security would apply to QHBPs (Sec. 237) and to the public health insurance option (Sec. 328).

Electronic Health Records

Congress enacted the HITECH Act to encourage the use of electronic health records (EHRs). Among its provisions, the Act authorized Medicare and Medicaid bonus payments for eligible professionals and hospitals participating in these programs as an incentive to become meaningful users of certified EHR systems. Meaningful use is defined as using certified EHR technology for the purpose of exchanging clinical information to improve the coordination and quality of care, and using such technology to report clinical quality measures. For the Medicare incentives, an eligible professional means a physician, dentist, podiatrist, optometrist, or chiropractor. For the Medicaid incentives, an eligible professional is defined as (1) a non-hospital physician, dentist, certified nurse mid-wife or nurse practitioner with at least a 30% Medicaid patient volume (pediatricians must have at least a 20% Medicaid patient volume); (2) physician assistants that meet certain specified requirements; and (3) FQHCs and rural health clinics with at least a 30% patient volume made up of needy individuals, as defined.

ARRA provided $2 billion to fund activities and grant programs authorized by the HITECH Act. They include the Health Information Technology Extension Program, which will establish a national Health Information Technology Research Center and fund regional extension centers around the country to offer technical and other assistance to health care providers.

Sec. 263. Electronic Health Record Use Among Small Health Care Providers

This section would authorize the Secretary to conduct a study of potential methods to increase the use of EHRs among small health care providers, including providing higher reimbursement rates, promoting low-cost EHR software, and offering training and technical assistance. By December 31, 2013, the Secretary would be required to report to Congress with recommendations for increasing EHR use among small providers.

Telehealth

PHSA Sec. 330I authorizes four-year grants for telehealth networks and for telehealth resource centers. PHSA Sec. 330L authorizes grants to provide incentives to coordinate telemedicine

licensure among states. Appropriations authority for the two programs, which are administered by HRSA's Office for the Advancement of Telehealth (OAT), expired at the end of FY2006.

Sec. 2523. Telehealth Grant Programs

This section would amend **PHSA Sec. 330I** by reauthorizing grants for telehealth networks and telehealth resource centers. The section would permit OAT to award such grants for projects that demonstrate how telehealth technologies may be used to reduce health disparities, and it would add skilled nursing facilities, among others, to the list of facilities that are eligible to participate in a network. It also would expand the list of activities for which funds may be used to include developing projects to use telehealth technology to facilitate collaboration between health care providers, support telenursing services, and promote patient understanding and adherence to national guidelines for personal health care. In addition, the section would establish new criteria for giving funding preference to eligible applicants for both the telehealth network grants and the telehealth recource center grants. Finally, it would amend existing reporting requirements to require an annual report on the progress and accomplishments of the telehealth grant programs.

The section would authorize the appropriation of the following amounts for each of the two Sec. 330I telehealth grant programs: $10 million for FY2011, and SSAN for each of FY2012 through FY2015. It also would amend **PHSA Sec. 330L** by authorizing the appropriation of $10 million for FY2011, and SSAN for each of FY2012 through FY2015 for the telehealth licensure grants.

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 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. PHSA Title XXVIII addresses preparedness for and response to bioterrorism and other public health emergencies.

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 level I or II trauma center within an hour, but access lags in rural areas.[35]

The Emergency Medical Treatment and Labor Act (EMTALA; SSA Sec. 1867) requires hospital emergency departments to examine and treat any individual who comes to the hospital with an

[35] Charles C. Branas, *No Time to Spare: Improving Access to Trauma Care*, University of Pennsylvania, Leonard David Institute of Health Economics, September 2005, at http://www.upenn.edu/ldi/issuebrief11_1.pdf.

emergency medical condition, and any woman who is in labor. EMTALA further requires hospitals to offer treatment, within their capacity and with the individual's consent, to stabilize the emergency condition, or transfer the individual to another medical facility, subject to certain restrictions. EMTALA does not preempt state or local laws unless they directly conflict with its specific requirements. In addition, the Act prohibits discrimination and delay in examining or treating emergency patients, and provides protections to whistleblowers who report violations of its provisions.

Sec. 2551. Trauma Care Centers

This section would amend **PHSA Secs. 1241-1245** by replacing the existing language with the following new provisions.

Sec. 1241–Grants for Certain Trauma Centers would require the Secretary to establish a grant program to fund (1) existing trauma centers to further their core missions or to provide emergency relief to those at risk of closing or in need of financial assistance; and (2) grants to local government and public or private nonprofit entities to establish new trauma centers in urban areas with a substantial degree of trauma due to violent crimes. In states with a trauma care system, a trauma center would not be eligible for such a grant unless it is part of the trauma care component of the state plan for the provision of emergency care. The grantee trauma center would have to be designated as a trauma center by the American College of Surgeons (ACS) or the applicable state health or emergency medical services authority.

Sec. 1242–Preferences in Making Grants would require that when making grants to existing centers the Secretary (1) reserve at least 25% for level III and IV trauma centers in rural and underserved areas, (2) reserve at least 25% for level I and II trauma centers in urban areas, and (3) give preference to areas with unmet needs for trauma services, centers receiving state or political subdivision funding, centers with at least one graduation medical education fellowship program in a specified trauma-related area, and those with a substantial commitment to serving vulnerable populations. The section would require states and local entities to use nonfederal funds to demonstrate financial support for the trauma center. It also would designate trauma center levels for states that do not have trauma centers at designated levels, defining levels I and II as the highest levels of trauma centers. The Secretary would be required to give preference, based on geography and need, to certain applicants for grants made to new and existing trauma centers.

Sec. 1243–Certain Agreements would require grantee trauma centers to participate in a professional trauma care system, where available, and maintain access to trauma services at comparable levels to the prior year during the grant program. Moreover, these trauma centers would be required to agree to provide data to a national and centralized registry of trauma centers, in accordance with guidelines developed by the ACS and other requirements.

Sec. 1244–General Provisions would limit grants to three years (with a specific exception). Receipt of a grant would not preclude a trauma center from being eligible for other grants established by PHSA Sec. 1241(a), as amended. The section also would establish that of the total amount appropriated for these grants in a fiscal year, 90% be used for core mission grants to existing centers, and 10% be used to provide emergency relief to existing centers and to fund new centers. The Secretary would be required to report biennially to Congress on the grant program.

Sec. 1245–Authorization of Appropriations would authorize to be appropriated for the trauma care center grant program, in addition to any other authorization of appropriations for such

purpose, $100 million for FY2011, and SSAN for each of FY2012 through FY2015. The Secretary would be required to reallocate funds not used for providing emergency relief and for establishing new trauma centers to fund the core mission of existing trauma centers.

Sec. 2552. Emergency Care Coordination

This section would amend PHSA Title XXVIII, Subtitle B by adding a new **PHSA Sec. 2816,** establishing an Emergency Care Coordination Center within the Office of the Assistant Secretary for Preparedness and Response (ASPR). The Secretary, acting through the Center Director, would be required to coordinate with the Federal Interagency Committee on Emergency Medical Services to promote and fund research in emergency medicine and trauma care, promote regional partnerships in the emergency medical systems, and promote emergency medical systems' preparedness. The section would establish the Council of Emergency Care, consisting of specified experts, to advise the Director. The Secretary would be required to submit a report to Congress on activities carried out under this section, including the issues of emergency department crowding and delays in care. There would be authorized to be appropriated SSAN to carry out this section for each of FY2010 through FY2014. All functions, personnel, assets, liabilities of, and administrative actions applicable to, the existing Center would be transferred to the new Center established by this section.

Sec. 2553. Regionalized Communication Systems for Emergency Care Response

This section would amend PHSA Title III, Part B by adding a new **PHSA Sec. 315**, requiring the Secretary, acting through the ASPR, to establish at least four multi-year demonstration projects to design, implement and evaluate innovative models of regionalized, comprehensive, and accountable emergency care systems. Entities eligible for funding would be partnerships between one or more states and one or more local governments. The demonstration projects would: (1) coordinate services across certain public agencies and medical facilities; (2) coordinate access to the emergency medical and dispatch system; (3) include a mechanism to ensure that patients are transported to medically appropriate facilities in a timely manner; (4) allow for tracking of resources such as capacity at emergency departments and coordinate this information with regional communications and hospital destination decisions; and (5) include a consistent region-wide data management system, which complies with the National EMS Information System, the National Trauma Data Bank and other specified registries, and can be used for evaluation.

Eligible entities would be required to submit an application, including certain required information on appropriate coordination, systems compatibility, oversight, and surge capacity, and also make nonfederal matching financial contributions to the activities as specified. Grantees would be required to submit an evaluation report to the Secretary within 90 days of completion of the demonstration project. The Secretary would be required to give funding priority to an eligible entity that serves a medically underserved population as defined in PHSA 330(b)(3). The Secretary also would be required to contract with an entity to independently evaluate the demonstration programs and to make publicly available the findings of the evaluation.

There would be authorized to be appropriated to carry out this section $12 million for each of FY2011 through FY2015. Three percent of the appropriated amount would be reserved to conduct the independent evaluation.

Sec. 2554. Emergency Medical Technician Training for Veterans

This section would further amend PHSA Title III by adding a new **PHSA Sec. 315A**, requiring the Secretary to establish a state grant program to assist veterans who have received and completed military emergency medical training during their active duty service in the U.S. Armed Forces to become state licensed or certified emergency medical technicians (EMTs) upon their discharge or release from active duty service. The grants could be used to fund training, reimburse costs associated with training or when applying for EMT licensure, and expedite the licensure process. To be eligible for a grant, a state would be required to demonstrate that the state has a shortage of EMTs. There would be authorized to be appropriated to carry out the grant program SSAN for each of FY2011 through FY2015.

The section would require the Secretary to submit to Congress an annual report on the program. GAO would be required to conduct a study on the barriers experienced by veterans who received medical training while serving on active duty service and, upon their discharge from active duty, sought to become licensed as civilian health professionals. Within two years of enactment, GAO would be required to report on the results of the study, including recommendations on expansion of this EMT training program to other health professions.

Sec. 2555. Dental Emergency Responders: Public Health and Medical Response

This section would amend **PHSA Sec. 2802** to clarify that dental health facilities and assets are to be included in the development of national public health emergency preparedness goals in the National Health Security Strategy, regarding matters of preparedness for and response to public health emergencies. It also would amend **PHSA Sec. 319F** to clarify that emergency curricula and training programs could be carried out at federal dental health facilities.

Sec. 2556. Dental Emergency Responders: Homeland Security

This section would amend Sec. 2 of the Homeland Security Act (HSA) to add emergency dental personnel, agencies, and authorities to the definition of emergency response providers. It also would amend Sec. 653 of the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA, Title VI of P.L. 109-295) to require that federal agency operational plans address the "[t]he preparedness and deployment of public health, medical and dental resources.... " Finally, it would amend Sec. 516 of the HSA to state that the Chief Medical Officer of the Department of Homeland Security serves as the Department's primary point of contact with the medical and dental communities.

Sec. 1908. Application of EMTALA

This section would clarify that nothing in the bill relieves any health care provider from providing emergency services as required by federal and state laws, including EMTALA.

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.

The House legislation includes the following three sections that would address pain research, education, and awareness for the purposes of recognizing pain as a national public health problem.

Sec. 2561. Institute of Medicine Conference on Pain

This section would require the Secretary to seek an agreement with the Institute of Medicine (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 FY2011 and FY2012.

Sec. 2562. Pain Research

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 PHSA 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. 2563. 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 FY2011 and $4 million for each of FY2012 and FY2015.

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.[36]

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.[37] 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 is particularly relevant given links between obesity and chronic diseases that may drive up health care costs.

H.R. 3962 contains seven FDA-related provisions that would affect the agency's regulation of four types of products. For medical devices, one provision would create a national medical device registry, and a second would impose a tax on certain device sales. For foods, a third provision would require nutrition labeling at certain restaurants and vending machines. For drugs, a fourth provision would prohibit activities that can delay FDA's approval of generics. For biologics, a fifth, sixth, and seventh provision would create a licensure pathway for biosimilars (generic biologics) and authorize the agency to collect associated fees. Each of these is described in more detail below.

Medical Devices

Concern about the safety of certain high-risk medical devices has led Congress to consider various tracking and postmarket surveillance mechanisms. Sec. 519(e) of the Federal Food Drug and Cosmetic Act (FFDCA) permits the Secretary to order a medical device manufacturer to adopt a method of tracking for certain devices that may create risks for patients.[38] The FDA Amendments Act of 2007 (P.L. 110-85) added a new Sec. 519(f), yet to be implemented, which

[36] For further information about FDA, see CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*, by Erin D. Williams.

[37] This percentage is based upon 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 product involved in health care spending, because it does not include those purchased by hospitals (such as pacemakers and other implantable devices), dentist's 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.

[38] For background information about the medical device approval system, see CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams

requires medical devices to bear a unique identifier.[39] There are currently no special taxes imposed on the sale of medical devices or on device manufacturers. However since 2002, medical device manufacturers have been subject to certain fees collected by the FDA.[40]

Sec. 2571. National Medical Device Registry

This section would add a new **FFDCA Sec. 519(g)**, requiring the Secretary to establish a public national medical device registry to facilitate analysis of postmarket safety and outcomes data on certain implantable, life-sustaining, and other types of medical devices. The Secretary would be required to establish a procedure to link specified medical device data from manufacturers with patient safety and outcomes data from disparate sources, and integrate the registry activities with certain other postmarket risk and safety activities required by the FFDCA. In addition, acting through ONCHIT, the Secretary would be required to adopt standards for the electronic exchange and use in certified electronic health records of a unique device identifier.

Sec. 552. Excise Tax on Medical Devices

This section would amend **Chapter 31 of the Internal Revenue Code** by adding a new Subchapter D, Medical Devices, imposing a tax of 2.5% of a price determined as specified, on the first taxable sale (including certain leases and uses) of a medical device. The tax would not apply to devices sold to (or of the type and quantity typically sold to) consumers by retail establishments. Certain tax exemptions similar to those in IRC Sec. 4221 and 4222 would apply. These concern devices sold for export, and devices for use by the purchaser for further manufacture. (Other tax exemptions listed under IRC Sec. 4221(a)(3)-(6) would not apply, including those for state and local governments, nonprofit educational entities, and certain others.) Under specified circumstances involving contractually negotiated sales prices, sellers would be entitled to recover the amount of taxes paid from device producers, manufacturers, or importers. The tax would apply to sales made after December 31, 2012.

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). 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. States and localities may petition the Secretary of HHS for an exemption from the preemption clause in FFDCA Sec. 403A.

[39] For information on the implementation status of the unique device identifier, go to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm.

[40] See CRS Report RL34571, *Medical Device User Fees and User Fee Acts*, by Erin D. Williams.

Sec. 2572. 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 which 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.

Generic Drugs

Congressional interest in generic drugs has been piqued by recent reports suggesting that brand name manufacturers have paid generic drug manufacturers to delay the introduction of their generic drugs into the marketplace. Generic drugs may help control health care costs because they typically have lower prices than their brand-name counterparts. This is the case because the research and development costs associated with developing a new drug (the brand name), are greater than those associated with producing a generic copy of an existing drug. While generics provide a cost-saving option for consumers, they also reduce brand name manufacturers' revenue, which may diminish manufacturers' capacity and incentive to develop additional new drugs.[41]

[41] For further information, see CRS Report RL33605, *Authorized Generic Pharmaceuticals: Effects on Innovation,* by John R. Thomas.

Companies seek FDA approval to market generic drugs by filing an Abbreviated New Drug Application (ANDA) under FFDCA Sec. 505(j). The filing of an ANDA may trigger patent infringement litigation between the owner of a relevant patent and the ANDA applicant. The FFDCA currently does not restrict the ability of these parties to resolve their patent dispute through settlement. The MMA of 2003 required that certain of these settlements be filed with the Department of Justice (DOJ) and Federal Trade Commission (FTC).

Requirements for FTC actions (and those by other agencies), such as rulemaking and adjudication, are described in the Administrative Procedure Act (APA). APA Sec. 553 covers informal rulemaking procedures and mandates that all agencies publish a notice of proposed rulemaking in the *Federal Register*, with some exceptions. After an agency publishes such notice, interested persons may then comment on the proposed rule through written submissions with data, views, or arguments, hence the term notice-and-comment rulemaking. Such comments may affect the resulting final rule.

Sec. 2573. Protecting Consumer Access to Generic Drugs

This section would add a new paragraph (w) to **FFDCA Sec. 505,** declaring unlawful any agreement resolving or settling a patent infringement claim in which an ANDA applicant receives anything of value and agrees to limit or forgo research, development, manufacturing, marketing, or sales, for any period of time, of the drug that is the subject of the ANDA and the patent. Agreements under which the ANDA applicant receives no more than the right to sell the drug that is the subject of the ANDA and the patent, along with the waiver of past damages for patent infringement, would remain permissible. The FTC would be authorized to enforce these provisions under Sec. 5 of the FTC Act.

The section also would amend the MMA so that any patent litigation settlement covered by this proposal must also be filed with the DOJ and FTC. The chief executive officer or company official responsible for negotiating the agreement must certify that the filing constitutes the complete, final, and exclusive agreement between the parties. The section would require GAO to conduct a series of studies regarding the practice and impact of pharmaceutical patent litigation. Finally, it would allow the FTC to issue informal rulemakings under APA Sec. 553 to exempt certain agreements from the proposal's requirements if the FTC finds that such agreements are "in furtherance of market competition and for the benefit of consumers." The proposal states that such rules can include interpretive rules and general statements of policy.

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.[42]

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

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

Sec. 2575. Licensure Pathway for Biosimilar Biological Products

This section would amend **PHSA Sec. 351** by opening a pathway for the approval of biosimilars. A biosimilar is defined as a biological product that is highly similar to the reference (brand-name) product such that there is no clinically meaningful difference between the biological product and the reference product. A biological product is defined as a protein (except any chemically synthesized polypeptide).

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

The section would allow for a period of exclusive marketing for the biological product that is the first to be established as interchangeable with the reference product. The provision also would provide a 12-year data exclusivity period (from the date on which the reference product was first approved) for the reference product and would provide an additional six months of exclusivity if pediatric studies show health benefits in that population.[43]

The Secretary may publish proposed guidance as specified for public comment prior to publication of final guidance on the licensure of a biological product. If guidance is to be developed, a process must be established to allow for public input regarding priorities for issuing

[42] For additional information, see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

[43] For more information on exclusivity and patents, see CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

guidance. The issuance or non-issuance of guidance would not preclude the review of, or action on, an application. The provision also would require the Secretary to ensure that the labeling and packaging of each biological product bears a unique name that distinguishes it from the reference product and any other biological products that are evaluated against the reference product.

The 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.

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

Sec. 2576. Fees Relating to Biosimilar Biological Products

This section would amend **FFDCA Sec. 735(1)** to allow for the collection of user fees for the review of applications for approval of biosimilars.

Sec. 2577. Amendments to Certain Patent Provisions

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

PHSA 340B Drug Pricing

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

Under the 340B program, covered entities are prohibited from diverting drugs purchased under the program to other organizations and from obtaining multiple discounts, including participation in outpatient group purchasing arrangements. The 340B discount is 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.

Sec. 2501. 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 hospitals, (3) certain maternal and child health grantees, (4) certain community mental health service grantees, (5) substance abuse prevention and treatment grantees, (6) Medicare-dependent, small rural hospitals, (7) sole community hospitals, and (8) rural referral centers. These new 340B-eligible facilities also would need to meet specified 340B participation requirements. However, the prohibition on hospital participation in outpatient drug group purchasing agreements would remain.

Sec. 2502. 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 systems would include a number of specifications to increase transparency and strengthen the monitoring, oversight, and investigation of the prices manufacturers charge covered entities, as well as additional improvements to ensure

[44] 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.

covered entities are not diverting drugs or obtaining multiple discounts. The Secretary would have new authority to impose monetary penalties on manufactures and covered entities for violations. 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. When supply of a drug was limited, manufacturers would be required to report to the Secretary their plans to ensure that covered entities were not discriminated against in the allocation of available supplies. 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. 2503. Effective Date

Changes made by this section would take effect upon enactment and would apply to drugs dispensed beginning with that date. In addition, the changes in this section would be used as the basis for determining if prescription drug manufacturers' met 340B and Medicaid requirements.

Miscellaneous

Sec. 2527. National Autism Training Initiative

PHSA Title III, Part R, comprising Secs. 399AA-399EE, authorizes several programs related to autism spectrum disorder (ASD) and other developmental disabilities. Sec. 399AA authorizes grants for the collection, analysis, and reporting of state epidemiological data on ASD and other developmental disabilities, and directs the Secretary to establish regional centers of excellence in ASD epidemiology. Sec. 399BB requires the Secretary to establish and evaluate activities to increase public awareness of ASD and other developmental disabilities, research and promote early screening, and support evidence-based interventions. The Secretary is further directed to provide culturally competent information about ASD and other developmental disabilities to meet the needs of individuals with these conditions and their families through federal health, education and welfare programs.

Sec. 399CC requires the Secretary to establish an Interagency Autism Coordinating Committee to track ASD-related research, monitor federal ASD activities, make recommendations to the Secretary, and submit an annual ASD research plan to Congress. Sec. 399DD requires the Secretary to submit to Congress a progress report on activities related to ASD and other developmental disabilities, as outlined in the Combating Autism Act of 2006, no later than four years after its enactment. Sec. 399EE authorizes appropriations for the activities authorized under Secs. 399AA, 399BB, and 399CC through FY2011.

This section would amend Title I of the Developmental Disabilities Assistance and Bill of Rights Act by adding at the end a new Subtitle F, National Training Initiative on Autism Spectrum Disorders. Within that subtitle, a new Sec. 171 would require the Secretary, in consultation with the Interagency Autism Coordinating Committee, to award training grants to qualifying University Centers for Excellence in Developmental Disabilities Education, Research, and Service, or other comparable entities. These grants would be used to (1) expand and develop interdisciplinary training and continuing education initiatives for parents, health, allied health, vocational, educational, and other professionals for the purpose of improving services provided to children and adults with ASD; and (2) develop model services and supports that demonstrate

evidence-based practices, among other activities. The Secretary also would be required to reserve up to 2% of the appropriated funds to make a grant to a qualified national organization for providing training and technical assistance to the University Centers for Excellence. This organization would assist in the national dissemination of evidence-based best practices from the interdisciplinary training programs; compile and disseminate technical assistance materials; assist in the coordination of grantees under this section; and serve as a research-based resource for policymakers, among other activities. There would be authorized to be appropriated $17 million for FY2011, and SSAN for each of FY2012 through FY2015 to carry out the training grant program.

In addition, the section would require the Secretary to award grants to establish up to four new University Centers for Excellence in Developmental Disabilities Education, Research, and Service. Priority would be given to minority institutions and facilities located in a state with one or more underserved populations. The section would authorize to be appropriated $2 million for each of FY2011 through FY2015 for these grants.

Sec. 2528. Medication Management Services for Treating Chronic Disease

This section would require the Secretary, acting through the Director of AHRQ, to provides grants to support medication management (MTM) services provided by licensed pharmacists. Currently, Medicare Part D sponsors are required to establish 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.

The section would require AHRQ to establish an MTM grant program by May 1, 2011. 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. 2531. State Alternative Medical Liability Laws

This section would authorize the Secretary to make incentive payments to states that enact and implement effective alternative medical liability laws that include litigation alternatives such as certificate of merit, early offer, or both, and that do not limit attorneys' fees or impose caps on damages. In determining the effectiveness of such a law, the Secretary must consider whether it (1) makes the medical liability system more reliable through the prevention of, or prompt resolution of, disputes; (2) encourages the disclosure of health care errors; and (3) maintains access to affordable liability insurance. Nothing in the section would preempt or modify existing

state laws that limit attorneys' fees or cap damage awards, impair a state's authority to establish such laws, or restrict the eligibility of a state for an incentive payment on the basis of such laws provided they are not established or implemented as part of an alternative medical liability law that meets the requirements described above. The Secretary would be required to submit to Congress an annual report on the progress states are making in enacting and implementing alternative medical liability laws and the effectiveness of such laws. The section would authorize to be appropriated SSAN for the incentive payments, which would be used to improve health care in the state.

Sec. 2585. States Failing to Adhere to Certain Employment Obligations

This section says that a state would be eligible for federal funds authorized under the PHSA only if it agrees, as an employer, to adhere to the requirements in Division A of this bill, and assures that all political subdivisions in the state do the same.

Sec. 2587. Report on Parasitic and Other Diseases of Poor Americans

This section would require the Secretary to report to Congress, within one year of enactment, on the epidemiology of, impact of, and appropriate funding required to address neglected diseases of poverty, including a number of specified parasitic diseases. The report should provide the information necessary to enhance health policy to accurately evaluate and address the threat of those diseases.

Sec. 2588. 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. 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 the AHRQ office, there would be authorized to be appropriated SSAN for FY2011 through FY2015. The section would also amend current authority for offices of women's health at NIH and 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. 2588A. Offices of Minority Health

This section would amend **PHSA Sec. 1707(a)** to strike language establishing an Office of Minority Health within the Office of Public Health and Science and replace it with new language establishing the office within the Office of the Secretary.

The section also would add a new **PHSA Sec. 1707A** requiring the Secretary to establish an Office of Minority Health in each of the following agencies: CDC, SAMHSA, AHRQ, HRSA, and FDA. Each office would be headed by a director that would be appointed by and report directly to the senior official of the respective agency. The section and amendments made by it would not establish or alter existing regulatory authority; or terminate, reorganize, or transfer authority away from a minority health office or federal appointive position with primary responsibility over minority health issues in HHS in existence as of enactment without the approval of Congress.

Sec. 2592. Access 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 guidelines for minimal technical criteria for new medical diagnostic equipment (as specified) used in medical settings.[45] The guidelines 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 guidelines and amend them as necessary.

Within six months of the issuance of the guidelines, each federal agency authorized to promulgate regulations under the Rehabilitation Act or the ADA would be required to prescribe regulations to carry out the provisions of each Act with respect to accessibility standards that are consistent with the guidelines, and to ensure that health care providers and health care plans covered under this bill meet the requirements of Section 504 of the Rehabilitation Act and the ADA, including ensuring that individuals with disabilities receive equal access to all aspects of the health care delivery system.

Sec. 2593. Duplicative Grant Programs

This section would require the Secretary to conduct a study to determine whether any newly established grant program under Division C of this bill is duplicative of one or more HHS federal grant programs specifically authorized in the PHSA or receiving appropriations. If determined to be duplicative, the Secretary would be required to attempt to integrate the new program with the duplicative programs. And, if integration is not appropriate or not successful, the Secretary would be required to promulgate a rule eliminating the duplication, including terminating one or more programs, if appropriate. Any funds appropriated to carry out a program that is terminated would remain available for obligation for the one or more programs that (1) were determined to be duplicative of such program and (2) remain in effect. The section would require the Secretary to submit a report to Congress and make the results of the study publicly available.

[45] 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. 2595. Improvement of Vital Statistics Collection

This section would require the Secretary, acting through the CDC Director, to promote the education and training of physicians on the importance of birth and death certificate data, encourage state adoption of the latest standard revisions of birth and death certificates, and work with states to re-engineer their vital statistics systems. The section also would allow the Secretary to promote improvements to the collection of diabetes mortality data.

Appendix. Acronyms Used in the Report

ACF	Administration for Children and Families
ACS	American College of Surgeons
ADA	Americans with Disabilities Act
AHEC	Area Health Education Center
AHRQ	Agency for Healthcare Research and Quality
AMP	average manufacturer price
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
ARRA	American Recovery and Reinvestment Act
ASD	Autism Spectrum Disorder
ASPR	Assistance Secretary for Preparedness and Response
CBO	Congressional Budget Office
CCN	Collaborative Care Network
CDC	Centers for Disease Control and Prevention
CERTF	Comparative Effectiveness Research Trust Fund
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
DGME	Direct Graduate Medical Education
DOJ	Department of Justice
DOL	Department of Labor
EEOC	Equal Employment Opportunities Commission
EFT	electronic funds transfer
EHR	electronic health record
EMT	Emergency Medical Technician
EMTALA	Emergency Medical Treatment and Labor Act
EPSDT	Early and Periodic Screening, Diagnostic and Treatment Services
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQHC	Federally Qualified Health Center
FTC	Federal Trade Commission
FTCA	Federal Tort Claims Act
FTE	full-time equivalent
GAO	Government Accountability Office
GME	Graduate Medical Education
HAI	Health Care-Associated Infection
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
HRSA	Health Resources and Services Administration
HPSA	Health Professional Shortage Area
HSA	Homeland Security Act
IME	Indirect Medical Education

IOM	Institute of Medicine
LEP	limited English proficiency
LTC	long term care
MCH	maternal and child health
NCHS	National Center for Health Statistics
NCHWA	National Center for Health Workforce Analysis
NFCSP	National Family Caregiver Support Program
NHSC	National Health Service Corps
NIH	National Institutes of Health
NMHC	Nurse-Managed Health Center
NQF	National Quality Forum
OAA	Older Americans Act
OMB	Office of Management and Budget
ONCHIT	Office of the National Coordinator for Health Information Technology
PHSA	Public Health Service Act
PHWC	Public Health Workforce Corps
PQRI	Physician Quality Reporting Initiative
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
SNF	skilled nursing facilities
SSA	Social Security Act
SSAN	such sums as may be necessary
TANF	Temporary Assistance for Needy Families
VFC	Vaccines for Children
WIA	Workforce Investment Act

Author Contact Information

C. Stephen Redhead, Coordinator
Specialist in Health Policy
credhead@crs.loc.gov, 7-2261

Kirsten J. Colello
Specialist in Health and Aging Policy
kcolello@crs.loc.gov, 7-7839

Elayne J. Heisler
Analyst in Health Services
eheisler@crs.loc.gov, 7-4453

Sarah A. Lister
Specialist in Public Health and Epidemiology
slister@crs.loc.gov, 7-7320

Bernice Reyes-Akinbileje
Analyst in Health Resources and Services
breyes@crs.loc.gov, 7-2260

Amanda K. Sarata
Analyst in Health Policy and Genetics
asarata@crs.loc.gov, 7-7641

Erin D. Williams
Specialist in Public Health and Bioethics
ewilliams@crs.loc.gov, 7-4897

Andrew R. Sommers
Analyst in Public Health and Epidemiology
asommers@crs.loc.gov, 7-4624

Ramya Sundararaman
Analyst in Public Health
rsundararaman@crs.loc.gov, 7-7285

Cliff Binder
Analyst in Health Care Financing
cbinder@crs.loc.gov, 7-7965

Jim Hahn
Analyst in Health Care Financing
jhahn@crs.loc.gov, 7-4914

Judith A. Johnson
Specialist in Biomedical Policy
jajohnson@crs.loc.gov, 7-7077

Amalia K. Corby-Edwards
Analyst in Public Health and Epidemiology
acorbyedwards@crs.loc.gov, 7-0423

Emilie Stoltzfus
Specialist in Social Policy
estoltzfus@crs.loc.gov, 7-2324

Carmen Solomon-Fears
Specialist in Social Policy
csolomonfears@crs.loc.gov, 7-7306