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Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline

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Summary

In March 2010, President Obama signed into law a comprehensive health reform bill, the Patient Protection and Affordable Care Act (ACA; P.L. 111-148), and a package of amendments to ACA, the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152). Health reform was one of President Obama's top domestic policy priorities during his first term, 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 were seen to require changes to both the financing and delivery of health care. This report—one of a series of CRS products on ACA, as amended—focuses on the law's workforce, public health, health care quality, and related provisions. It includes summaries of these provisions, explores some of their implications for health policy, and contains an associated timeline.

This report is primarily for reference purposes. The material in it is intended to provide context to help the reader better understand the intent of ACA's individual provisions at the time of enactment. The report does not track or discuss ongoing ACA-related regulatory and other implementation activities.

ACA includes numerous provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things. It amends and expands many of the existing health workforce programs authorized under Title VII (health professions) and Title VIII (nursing) of the Public Health Service Act (PHSA); creates a Public Health Services Track to train health care professionals emphasizing team-based service, public health, epidemiology, and emergency preparedness and response; and makes a number of changes to the Medicare graduate medical education (GME) payments to teaching hospitals, in part to encourage the training of more primary care physicians. The new law also establishes a national commission to study projected health workforce needs.

In addition, ACA creates an interagency council to promote healthy policies and prepare a national prevention and health promotion strategy. It establishes a Prevention and Public Health Fund to boost funding for prevention and public health; increases access to clinical preventive services under Medicare and Medicaid; promotes healthier communities; and funds research on optimizing the delivery of public health services. Funding also is provided for maternal and child health services, including abstinence education and a new home visitation program. ACA also establishes a national strategy for quality improvement; creates an interagency working group to advance quality efforts at the national level; develops a comprehensive repertoire of quality measures; and formalizes processes for quality measure selection, endorsement, data collection, and public reporting of quality information. It creates and funds a new private, nonprofit comparative effectiveness research institute.

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

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Introduction

On March 23, 2010, President Obama signed into law a comprehensive health reform law, the Patient Protection and Affordable Care Act (ACA).[1] The following week, on March 30, 2010, the President signed the Health Care and Education Reconciliation Act of 2010 (HCERA), which amended numerous health care and revenue provisions in ACA.[2]

Among its many provisions, ACA restructures the private health insurance market, sets minimum standards for health coverage, and, beginning in 2014, will require most U.S. residents to obtain health insurance coverage or pay a penalty. The law provides for the establishment by 2014 of state-based health insurance exchanges for the purchase of private health insurance. Qualifying individuals and families will be able to receive federal subsidies to reduce the cost of purchasing coverage through the exchanges.

In addition to expanding private health insurance coverage, ACA requires state Medicaid programs to expand coverage to all eligible nonelderly, non-pregnant individuals under age 65 with incomes up to 133% of the federal poverty level (FPL). Under ACA, the federal government will initially cover 100% of the expansion costs, phasing down to 90% of the costs by 2020. Medicaid law allows the Secretary of Health and Human Services (HHS) to withhold existing federal Medicaid matching funds if states refuse to comply with the expansion. However, in *National Federation of Independent Business v. Sebelius*, the U.S. Supreme Court found that the Medicaid expansion violated the Constitution by threatening states with the loss of their existing federal Medicaid matching funds.[3] The Court precluded the HHS Secretary from penalizing states that choose not to participate in the Medicaid expansion (see text box).

ACA also amends the Medicare program in an effort to reduce the rate of its projected growth; imposes an excise tax on insurance plans found to have high premiums; and makes many other changes to the tax code, Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP). In addition to changes to private insurance and these federal health programs, ACA includes numerous provisions intended to increase the primary care and public health workforce, promote preventive services, and strengthen quality measurement, among other things.

ACA is projected to have a significant impact on federal direct spending and revenues. The law includes direct spending to subsidize the purchase of health insurance coverage through the exchanges, as well as increased outlays for the expansion of state Medicaid programs. ACA also includes numerous mandatory appropriations that provide billions of dollars to fund temporary programs to increase access and funding for targeted groups, provide funding to states to plan and establish exchanges, and support many other research and demonstration programs and activities.[4] The costs of expanding public and private health insurance coverage and other

[1] P.L. 111-148, 124 Stat. 119. During the year-long legislative debate on health care reform, the House and the Senate passed separate health reform bills. On November 7, 2009, the House voted 220-215 to approve the Affordable Health Care for America Act (H.R. 3962). The Senate passed its own health reform legislation, the Patient Protection and Affordable Care Act (H.R. 3590, as amended), on December 24, 2009, by a vote of 60-39. On March 21, 2010, the House voted 219-212 to approve the Senate-passed bill, clearing it for the President's signature.

[2] P.L. 111-152, 124 Stat. 1029. Note that several other bills that were subsequently enacted during the 111th and 112th Congresses made more targeted changes to specific ACA provisions. All references to ACA in this report refer to the law as amended by HCERA, unless otherwise specified.

[3] *NFIB v. Sebelius*, No. 11-393, slip op. (June 28, 2012), available at http://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf.

[4] For a summary of all ACA's mandatory appropriations, including details of the obligation of these funds, see CRS Report R41301, *Appropriations and Fund Transfers in the Patient Protection and Affordable Care Act (ACA)*, by C. Stephen Redhead.

spending are offset by revenues from new taxes and fees, and by savings from payment and health care delivery system reforms designed to slow the growth in spending on Medicare and other federal health care programs.

U.S. Supreme Court Decision on ACA (June 28, 2012)

In *National Federation of Independent Business v. Sebelius (NFIB)*, the Court ruled on the constitutionality of both the individual mandate, which requires most U.S. residents (beginning in 2014) to carry health insurance or pay a penalty, and the Medicaid expansion. The Court upheld the individual mandate as a constitutional exercise of Congress's authority to levy taxes. The penalty is to be paid by taxpayers when they file their tax returns and enforced by the Internal Revenue Service.

In a separate opinion, the Court found that compelling states to participate in the ACA Medicaid expansion—which the Court determined to be essentially a new program—or risk losing their existing federal Medicaid matching funds was coercive and unconstitutional under the Spending Clause and the Tenth Amendment. The Court's remedy for this constitutional violation was to prohibit HHS from penalizing states that choose not to participate in the expansion by withholding any federal matching funds for their existing Medicaid programs. However, if a state accepts the new ACA expansion funds (initially a 100% federal match), it must abide by all the expansion coverage rules.

Under *NFIB*, all other provisions of ACA remain fully intact and operative. For more information, see CRS Report R42698, *NFIB v. Sebelius: Constitutionality of the Individual Mandate*, by Erika K. Lunder and Jennifer Staman, and CRS Report R42367, *Medicaid and Federal Grant Conditions After NFIB v. Sebelius: Constitutional Issues and Analysis*, by Kenneth R. Thomas.

Implementing ACA also is likely to affect discretionary spending, which is provided in and controlled by annual appropriations acts. The law established numerous new discretionary grant programs and provided for each an authorization of appropriations. It also reauthorized funding for many existing discretionary grant programs. While the authorizations of appropriations for most of these existing programs expired prior to ACA's enactment, typically they continued to receive an annual appropriation. Funding for all these discretionary programs, both new and existing, is subject to action by congressional appropriators.[6]

This report is primarily for reference purposes. The material in it is intended to provide context to help the reader better understand the intent of ACA's individual provisions at the time of enactment. The report does not track or discuss ongoing ACA-related regulatory and other implementation activities. Each section of the report includes a text box listing more recent CRS products on ACA implementation as well as other important publications and reports.[5]

Report Overview

This report—one in a series of CRS products summarizing ACA that were issued after the law's enactment—describes the law's workforce, public health, quality, and related provisions. ACA is composed of 10 titles (see **Table 1**). The provisions summarized in this report are for the most part found in Title II (Medicaid, maternal and child health); Title III (Medicare, quality of care); Title IV (prevention and wellness); Title V (health workforce); Title VI (comparative effectiveness research, elder justice); Title VII (drugs and biologics); and Title IX (revenues). Title X, which was added as a manager's amendment to the underlying bill, amended (and in some cases repealed) numerous existing provisions in Titles I through IX and added several new provisions. As already noted, ACA was further amended by the companion reconciliation

[5] CRS products on ACA and its implementation are available at http://www.crs.gov.

[6] For a summary of all ACA's discretionary spending provisions, including details of annual appropriations since the law's enactment, see CRS Report R41390, *Discretionary Spending in the Patient Protection and Affordable Care Act (ACA)*, coordinated by C. Stephen Redhead.

legislation, HCERA. **Table A-1** in **Appendix A** at the end of the report, shows which of the ACA sections discussed in this report were amended by Title X and/or HCERA.[7]

Table 1. ACA Titles and Relevant CRS Reports

ACA Title	Topic	Relevant CRS Reports
Title I–Quality, Affordable Health Care for All Americans	Private Insurance	CRS Report R42069, *Private Health Insurance Market Reforms in the Patient Protection and Affordable Care Act (ACA)*, by Annie L. Mach and Bernadette Fernandez. CRS Report R42663, *Health Insurance Exchanges Under the Patient Protection and Affordable Care Act (ACA)*, by Bernadette Fernandez and Annie L. Mach; CRS Report R41166, *Grandfathered Health Plans Under the Patient Protection and Affordable Care Act (ACA)*, by Bernadette Fernandez.
Title II–Role of Public Programs	Medicaid and CHIP; Maternal and Child Health	CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al. and this report.
Title III–Improving the Quality and Efficiency of Health Care	Medicare; Quality	Discussed in this report and CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis.
Title IV–Prevention of Chronic Disease and Improving Public Health	Prevention and Wellness	Discussed in this report and CRS Report R40978, *Medicare Coverage of Clinical Preventive Services*, by Sarah A. Lister and Kirsten J. Colello.
Title V–Health Care Workforce	Health Workforce	Discussed in this report.
Title VI–Transparency and Program Integrity	Program integrity provisions including physician ownership of hospitals; nursing homes; Medicare and Medicaid fraud-related provisions; elder justice; and comparative effectiveness research.	Medicare-related provisions discussed in CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis; Medicaid-related provisions discussed in CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al.; nursing home changes; elder justice and comparative effectiveness research are discussed in this report.
Title VII–Improving Access to Innovative Medical Therapies	Prescription drugs and Biologics	Discussed in this report.
Title VIII–CLASS Act[a]	Creation of the Community Living Assistance Services and Supports Program	CRS Report R40842, *Community Living Assistance Services and Supports (CLASS): Overview and Summary of Provisions*, by Kirsten J. Colello and Janemarie Mulvey.
Title IX–Revenue Provisions	Amendments to the tax code and changes in taxes for health care providers and health insurance providers.	CRS Report R41128, *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (ACA)*, by Janemarie Mulvey.

[7] The full text of ACA, as amended by HCERA and other legislation enacted during the 111th and 112th Congresses (see footnote 2), is available at http://www.house.gov/legcoun/Comps/PPAACA_BEL.pdf.

ACA Title	Topic	Relevant CRS Reports
Title X–Strengthening Quality, Affordable Health Care for All Americans	Amendments to Titles I-IX; Indian Health Care Improvement	Amendments are discussed in the reports covering each title. CRS Report R41630, *The Indian Health Care Improvement Act Reauthorization and Extension as Enacted by the ACA: Detailed Summary and Timeline*, by Elayne J. Heisler and CRS Report R41152, *Indian Health Care: Impact of the Affordable Care Act (ACA)*, by Elayne J. Heisler.

Source: CRS Analysis of the ACA.

a. This title was repealed by the American Tax Payer Relief Act of 2010 (P.L. 112-240); see CRS Report R42944, *Medicare, Medicaid, and Other Health Provisions in the American Taxpayer Relief Act of 2012*, coordinated by Jim Hahn.

The summaries of the ACA provisions are grouped and discussed under the following section headings: (1) Health Centers and Clinics; (2) Health Workforce; (3) Prevention and Wellness; (4) Maternal and Child Health; (5) Teen Pregnancy Prevention and Adoption Support; (6) Quality; (7) Nursing Homes and Other Long-Term Care Facilities and Providers; (8) Comparative Effectiveness Research; (9) Health Data Collection; (10) Health Information Technology; (11) Emergency Care; (12) Pain Care Management; (13) Elder Justice; (14) Biomedical Research and Medical Products; (15) Biosimilars; (16) Nutrition Labeling; (17) 340B Drug Pricing; and (18) Medical Malpractice and Liability Reform. Each section of the report begins with a brief overview of the ACA provisions to be summarized and includes some discussion of relevant policies in place at the time of ACA's enactment as well as the intent, and, where available, projected impact, of the law.

ACA specifies numerous dates for new or expiring legal authorities, for the initiation or completion of key administrative and regulatory activities, and for the establishment or termination of commissions and other statutory bodies. **Table A-1**in **Appendix A** provides a detailed timeline of all such dates. Unless otherwise stated, all references in this report to "the Secretary" refer to the Secretary of Health and Human Services (HHS). A list of all the acronyms used in the report is provided in **Appendix B**.

Health Centers and Clinics

Overview and Impact of ACA

PHSA Sec. 330 authorizes the health centers 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 are required to furnish comprehensive and affordable primary care to the community residents they serve. Health centers also often provide case management, health education, and other supportive services to meet the needs of their patients. Health centers must be located in (or serve) medically underserved communities or populations. Approximately half of all health centers serve rural populations. In order to ensure that services are accessible to the entire community, health centers must treat all patients without regard to their ability to pay. Centers offer sliding-scale fee arrangements based on patients' financial circumstances. Prior to the ACA, there were more than 1,100 health centers operating over 7,500 service delivery sites in every U.S. state and territory. According to HRSA, in FY2008 these facilities served more than 17 million unique patients and responded to over 67 million patient visits.[8] A substantial body of evidence shows that health centers increase access to primary health care services. This helps improve the health of the community by lowering infant mortality, reducing racial and ethnic disparities in health and increasing access to health care, and lowering spending by averting more expensive emergency room visits.[9]

Health Centers

CRS Report R42433, *Federal Health Centers*, by Elayne J. Heisler.

U.S. Government Accountability Office, *Health Center Program: Improved Oversight Needed to Ensure Grantee Compliance with Requirements*, 12-546, May 2012, http://www.gao.gov/products/GAO-12-546.

U.S. Government Accountability Office, *Health Center Program: Improved Oversight Needed to Ensure Grantee Compliance with Requirements*, 12-546, May 2012, http://www.gao.gov/products/GAO-12-546.

U.S. Government Accountability Office, *Hospital Emergency Departments: Health Center Strategies that May Help Reduce Their Use*, GAO-11-414R, April 11, 2011, http://www.gao.gov/products/GAO-11-414R.

U.S. Government Accountability Office, *School-Based Health Centers: Available Information on Federal Funding*, 11-18R, October 8, 2010, http://www.gao.gov/products/GAO-11-18R.

U.S. Government Accountability Office, *Medicare Payments to Federally Qualified Health Centers*, GAO-10-576R, July 30, 2010, http://www.gao.gov/products/GAO-10-576R.

At the time of enactment some thought that health centers could provide access to care to those who would become newly insured under the ACA. ACA provides a total of $11 billion in supplemental funding for community health centers over the five-year period FY2011 through FY2015.[10] The law creates a multi-billion Community Health Center Fund, from which the Secretary is required to transfer $9.5 billion for center operations and patient services. A separate appropriation provides the remaining $1.5 billion, which is for health center construction and

[8] For more information on the health center program, including current data on the number of delivery sites, see http://bphc.hrsa.gov.

[9] Research on outcomes associated with health centers is discussed in CRS Report R42433, *Federal Health Centers*, by Elayne J. Heisler.

[10] From FY2011 through FY2013, the Community Health Center Fund has not been used to supplement health center appropriations; rather, annual appropriations for health centers have been reduced and partially supplanted by CHCF funds. See discussion in CRS Report R42433, *Federal Health Centers*, by Elayne J. Heisler.

renovation. These ACA funds add to the $2 billion in FY2009 supplementary funds that were provided for the health centers program in the American Recovery and Reinvestment Act (ARRA; P.L. 111-5). The ARRA funds included $1.5 billion for health center construction and renovation, and $500 million for center operations and patient services.[11] In addition to the supplemental appropriations, ACA increases the amounts authorized to be appropriated for health centers under the regular annual appropriations process and permanently authorizes the health centers program. The program had been authorized through the end of FY2012.

ACA also appropriates funds for a grant program to establish school-based health centers (SBHCs) and authorizes grants for the operation of such centers. SBHCs are not explicitly authorized in the PHSA, but have been established pursuant to the general authority to establish community health centers.[12] Another ACA provision establishes a grant program to fund the operation of nurse-managed health clinics to provide primary health care to vulnerable and underserved populations. Funding for this program is subject to future action in annual appropriations bills.

Two additional ACA provisions are summarized at the end of this section. Neither specifically mentions health centers or clinics, though both address access to care among the medically underserved. The first authorizes state grants to health care providers who treat the medically underserved, and the second creates a state demonstration program to provide the uninsured with access to health care.

Sec. 5601. Health Center Appropriations

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

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

Sec. 10503. Community Health Center Fund

This section, as amended by HCERA Sec. 2303, establishes a Community Health Center Fund and appropriates a total of $11 billion over the five-year period FY2011 through FY2015 to the fund. The following amounts are to be transferred from the fund to increase funding, over the FY2008 level, for health center operations and patient services: $1 billion for FY2011; $1.2 billion for FY2012; $1.5 billion for FY2013; $2.2 billion for FY2014; and $3.6 billion for

[11] For more information on ARRA funding for health centers, see CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by C. Stephen Redhead.

[12] See discussion in U.S. Government Accountability Office, *School-Based Health Centers: Available Information on Federal Funding*, 11-18R, October 8, 2010, http://www.gao.gov/assets/100/97141.pdf.

FY2015. Funds are to remain available until expended. The section also appropriates $1.5 billion for health center construction and renovation for the period FY2011 through FY2015, to remain available until expended.

Sec. 4101. School-Based Health Centers

Subsection 4101(a) requires the Secretary to create a grant program for the establishment of SBHCs. To receive a grant, an SBHC or a sponsoring facility of an SBHC must agree to use grant funds for certain specified purposes including facility construction, expansion, and equipment. SBHCs are prohibited from using funds for personnel or to provide health services. The Secretary is required to give preference to SBHCs that serve a large population of children eligible for the Medicaid and CHIP programs. The section appropriates, out of Treasury funds not otherwise appropriated, $50 million for each of FY2010 through FY2013, to remain available until expended.

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

Sec. 5208. Nurse-Managed Health Clinics

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

Sec. 5606. State Grants to Providers

This section, as added by ACA Sec. 10501(k), authorizes states to award grants to health care providers who treat a high percentage of the medically underserved or other special populations.

Funds allocated to the Medicare, Medicaid, and Tricare programs may not be used to award grants or administer the grant program.

Sec. 10504. Access to Affordable Care Demonstration

This section requires the Secretary, within six months of enactment, to establish a three-year demonstration project in up to 10 states to provide access to comprehensive health care services to the uninsured at reduced fees. Each state may receive up to $2 million. There are authorized to be appropriated SSAN to carry out the demonstration.

Health Workforce

Overview and Impact of ACA

Health workforce policy is an important component of health care reform. Transforming the nation's health care delivery system—from one focused on fragmented specialty care for acute illness to one that places more emphasis on primary care, disease prevention, and the coordination and management of care for chronic illness across settings—will require significant changes in health workforce education and training. Health policy experts are concerned about the current size, specialty mix, and geographic distribution of the healthcare workforce. Certain geographic areas, such as inner cities and rural areas, experience significant healthcare provider shortages. HRSA, which administers most of the federal health workforce programs, estimated that, prior to ACA, an additional 7,000 physicians would be needed in federally designated health professional shortage areas (HPSAs).[13] Existing health care provider shortages are projected to increase based on growing patient demand for services. HRSA estimates that by 2020 there will shortages in a number of physician specialties and nearly 67,000 too few primary care physicians. Additionally, a federal advisory group on the nursing workforce estimates that as of 2000 there was a 6% shortage of nurses and that this shortage is expected to grow to 20% in 2020.[14] Enactment of ACA is likely to further exacerbate health workforce shortages as the newly insured seek health care services.[15]

Health Workforce

[13] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, *Physician Supply and Demand: Projections to 2020*, October 2006. Note that areas designated as health professions shortage areas are eligible for a number of federally supported health workforce programs. Physician shortages and general supply issues are discussed in CRS Report R42029, *Physician Supply and the Affordable Care Act*, by Elayne J. Heisler.

[14] National Advisory Council on Nursing Education and Practice (NACNEP), *Fifth Report to the Secretary of Health and Human Services and Congress*, Meeting Held April 2005, December 2007, ftp://ftp.hrsa.gov/bhpr/nursing/fifth.pdf.

[15] Michael J. Dill and Edward S. Salsberg, *The Complexities of Physician Supply and Demand: Projections Through 2025*, Association of American Medical Colleges, Washington, DC, November 2008.

The federal government has a long-standing role in the education and training of the health workforce. PHSA Title VII supports health professions workforce development—including the education and training of physicians, dentists, physician assistants, and public health workers—through grants, scholarships, and loan repayment. Title VII includes a number of programs to support physician training in primary care, including training in rural or otherwise underserved areas, and student loan repayment programs to encourage medical students to enter primary care. Some researchers have found that Title VII programs increase the number of primary providers and the primary care competency of the physician workforce as a whole.[16] Title VII also includes programs to encourage racial and ethnic diversity in the health care workforce. 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.

CRS Report R42029, *Physician Supply and the Affordable Care Act*, by Elayne J. Heisler.

CRS Report R42880, *Physician Practices: Background, Organization, and Market Consolidation*, by Suzanne M. Kirchhoff.

Council on Graduate Medical Education, Twentieth Report, *Advancing Primary Care*, Rockville, MD, December 2010

Institute of Medicine, *The Future of Nursing: Leading Change, Advancing Health*, Washington, DC, October 5, 2010.

Institute of Medicine, *The Mental Health and Substance abuse Workforce for Older Adults: In Whose Hands?* Washington, DC., July 10, 2012.

Health Resources and Services Administration, *Strategies for Enumerating the U.S. Government Public Health Workforce*, Rockville, MD, February 2012.

Health Resources and Services Administration, *The Registered Nurse Population: Findings from the 2008 National Sample Survey of Registered Nurses*, Rockville, MD, September 2010.

Health Resources and Services Administration, *Negotiated Rulemaking Committee on the Designation of Medically Underserved Populations and Health Professional Shortage Areas: Final Report to the Secretary*, Rockville, MD, October 31, 2011.

National Governors Association, *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care*, Washington, DC, December 20, 2012.

ACA reauthorizes and expands numerous existing PHSA health workforce programs. The law also creates several new PHSA workforce programs to increase training experiences in primary care, in rural areas, and in community-based settings. Research has found that location and experience during residency training is an important factor in determining future practice.[17] ACA includes programs that provide training opportunities and fellowships to increase the supply of other types of providers with identified shortages such as pediatric subspecialists, public health workers, and geriatricians. Finally, ACA modifies Medicare graduate medical education (GME) payment policy. Medicare subsidizes medical residency training through GME payments to teaching hospitals. ACA's changes to GME payments, along with a new health center grant program and a number of other provisions, are intended to promote primary care training in nonhospital settings.

The summaries of the ACA health workforce provisions that follow are grouped as follows: (1) National Health Service Corps; (2) physician workforce; (3) dental workforce; (4) nursing workforce; (5) geriatric and long-term care workforce; (6) public health workforce; (7) U.S.

[16] Robert L. Phillips, Jr. et al., *Specialty and Geographic Distribution of the Physician Workforce: What Influences Medical Student & Resident Choices?* Robert Graham Center, Washington, DC, March 2, 2009.

[17] U.S. Government Accountability Office, *Graduate Medical Education: Trends in Training and Student Debt*, 09-438R, May 4, 2009; Howard K. Rabinowitz, James J. Diamond, Fred W. Markham, et al., "Critical Factors for Designing Programs to Increase the Supply and Retention of Rural Primary Care Physicians," Journal of the American Medical Association, vol. 286, no. 9 (September 5, 2001), pp. 1041-1048; and Carl G. Morris, Brian Johnson, and Sara Kim, et al., "Training Family Physicians in Community Health Centers: A Health Workforce Solution," Health Services Research, vol. 40, no. 4 (April 2008), pp. 271-276.

Public Health Service Commissioned Corps; (8) workforce diversity training; (9) allied health workforce; (10) mental and behavioral health workforce; (11) health workforce evaluation and assessment; and (12) Medicare GME payments. Each of these sections begins with some additional background and discussion of the impact of ACA's provisions.

National Health Service Corps

PHSA Title III authorizes the National Health Service Corp (NHSC) program, which provides scholarships and student loan repayments for medical students, nurse practitioners, physician assistants, and others who agree to a period of service as a primary care provider in full-time clinical practice in a federally designated HPSA—a geographic area, population group, medical facility, or other public facility that the Secretary has designated as having an inadequate supply of qualified health care providers (such as physicians, dentists, mental health providers or other health care providers). 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. The NHSC serves as a major source of providers for health centers. HRSA estimates that more than half of NHSC clinicians fulfill their service commitment in a health center.[18] However, there is far more demand for NHSC clinicians than supply. There are also many more clinicians interested in scholarships or loan repayment opportunities than can be met under the program's budget.[19]

ACA provides a total of $1.5 billion in supplemental funding for the NHSC over the five-year period FY2011 through FY2015.[20] This funding adds to the $300 million in FY2009 supplementary funds that were provided for the NHSC in the American Recovery and Reinvestment Act of 2009 (P.L. 111-5, ARRA).[21] In addition, ACA increases the amounts authorized to be appropriated for the NHSC under the regular annual appropriations process and permanently authorizes the NHSC program. The program had been authorized through the end of FY2012.

ACA modifies the NHSC program by permitting NHSC clinicians to fulfill their service commitments through part-time work. It is believed that this strategy may encourage more younger providers, particularly newly graduated physicians interested in work-life balance, to participate in the program.[22] In addition, female physicians, on average, work fewer hours than do their male counterparts.[23] Thus, part-time service opportunities may also encourage female physicians to participate in the NHSC.

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[18] Department of Health and Human Services, Health Resources and Services Administration, *Justification of Estimations for Appropriations Committees, FY2013, Rockville, MD.*

[19] Ibid.

[20] The ACA funding provided for the NHSC was intended to be supplemental funding. However, from FY2011 through FY2013, annual appropriations for the NHSC program have been eliminated and supplanted by the ACA funding. See discussion in CRS Report R42029, *Physician Supply and the Affordable Care Act*, by Elayne J. Heisler.

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

[22] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, *Physician Supply and Demand: Projections to 2020*, October 2006; and U.S. Government Accountability Office, *Graduate Medical Education: Trends in Training and Student Debt*, 09-438R, May 4, 2009.

[23] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, *Physician Supply and Demand: Projections to 2020*, October 2006.

ACA also includes provisions to encourage medical residency training in community-based sites, called teaching health centers (discussed below under "Physician Workforce"). These sites include health centers and rural health clinics, two settings that frequently use NHSC providers. As a corollary to this provision, ACA amends the NHSC program to permit its providers to count time spent teaching toward fulfillment of their NHSC service commitment.

Finally, ACA requires the Secretary to redefine how HPSAs are designated. The HPSA designation—which is currently based on a service area's physician-to-population ratio—determines where NHSC clinicians are placed. Over time, the HPSA designation has been used for other purposes such as to establish preference for federal grants programs administered by HHS. GAO has raised concerns that the methodology used to designate HPSAs does not effectively identify shortage areas and is not updated often enough.[24] HHS has been working since 1998 to develop alternative methodology to designate HPSAs.[25] ACA sets a timeline for developing and finalizing a new HPSA designation methodology. ACA also amends the Internal Revenue Code (IRC) to clarify that amounts received from state-operated loan repayment programs that aim to bring health professionals to shortage areas are not taxable income. Prior to the ACA, amounts received from the NHSC were excluded from taxable income, but amounts received under state programs were not, which reduced the value of the state loan repayment program awards and made participation less attractive to health professionals.

Sec. 5207. NHSC Appropriations

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

Sec. 10503. Community Health Center Fund

This section, as amended by HCERA Sec. 2303, establishes a Community Health Center Fund and appropriates a total of $11 billion over the five-year period FY2011 through FY2015 to the fund. In addition to the transfers for community health centers (described above), the following amounts are to be transferred from the fund to increase funding, over the FY2008 level, for the NHSC: $290 million for FY2011; $295 million for FY2012; $300 million for FY2013; $305 million for FY2014; and $310 million for FY2015. Funds are to remain available until expended.

[24] U.S. Government Accountability Office: (1) *Health Care Shortage Areas: Designation Not A Useful Tool for Directing Resources to the Underserved*, GAO/HEHS-95-200, Washington, DC, September 8, 1995; (2) *Health Workforce: Ensuring Adequate Supply and Distribution Remains Challenging*, GAO-01-1042T, Washington, DC, August 1, 2001; and (3) *Health Professional Shortage Areas*, GAO-07-84 Washington, DC, October 2006.

[25] In 1998, the Secretary published a proposal to revise the HPSA methodology (Department of Health and Human Services, "Designation of Medically Underserved Populations and Health Professional Shortage Areas; Proposed Rule," 63 *Federal Register* 46583-46555, September 1, 1998). The proposal was subsequently withdrawn. In February 2008, HHS proposed a new rule (Department of Health and Human Services, "Designation of Medically Underserved Populations and Health Professional Shortage Areas; Proposed Rule," 73 *Federal Register* 11232-11281, February 29, 2008). In July 2008, the Secretary announced that HHS would issue a new notice of public rulemaking for further review and public comment prior to issuing a final rule.

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

This section amends **PHSA Sec. 331(i)**, allowing the Secretary to waive the requirement that NHSC service be provided in full-time clinical practice so that the service obligation may 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 are required to agree to double the period of obligated service that would otherwise be required, or, if receiving loan repayment, accept a minimum of two years of obligated service and 50% of the amount that would otherwise be provided. The section also amends **PHSA Sec. 337** by deleting language that prohibits the reappointment of members to the NHSC National Advisory Council. It amends **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 further amends **PHSA Sec. 338C(a)** by striking the requirement added by ACA Sec. 5508(b) and instead permitting the Secretary to treat teaching as clinical practice for up to 20% of the period of obligated NHSC service.[26] However, for NHSC clinicians participating in the teaching health centers GME program under new **PHSA Sec. 340H** (established by Sec. 5508(c) of ACA), up to 50% of time spent teaching may be counted towards the NHSC service obligation.

Sec. 5602. Designating Medically Underserved Populations and HPSAs

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

Sec. 10908. Loan Repayment Tax Exclusion

This section amends **IRC Sec. 108(f)** to exclude from an individual's gross income for tax purposes any amount received under any state loan repayment or loan forgiveness programs that are intended to increase the availability of health care services in HPSAs or other underserved areas as determined by a state. The tax exclusion applies to amounts received by individuals in taxable years beginning after December 31, 2008.[27]

Physician Workforce

ACA reauthorizes and expands the Title VII primary care education and training programs and adds new programs to encourage pediatric subspecialists. Research has shown that there are shortages of pediatric subspecialists and suggests that pediatricians may not subspecialize for financial reasons. The salary difference between a general pediatrician and the pediatric subspecialist is small; in contrast, the salary difference between a primary care physician caring

[26] ACA Sec. 5508(b) would have allowed up to 50% of the time spent teaching by an NHSC member to be counted towards his or her service obligation.

[27] The America's Job Creation Act of 2004 (P.L. 108-357) amended the IRC to exclude from an individual's gross income for tax purposes any amount received from NHSC loan repayment programs, beginning after December 31, 2003.

for adults and a specialist can be significant.[28] As noted earlier, ACA establishes a new grant program to promote community-based residency training. Despite evidence that such programs may be an effective way of increasing the primary care workforce caring for the underserved, some have suggested that these community-based settings may not have the staffing or other resources to provide training.[29] This grant program, which provides funding for faculty and other resources, may facilitate the health centers establishing residency programs. ACA also includes a new program to provide training to medical students interested in rural practice. A number of medical schools have implemented specialized rural training during medical school and evidence suggests that such programs can encourage medical students to practice in rural areas.[30]

Sec. 5201. Federally Supported Student Loan Funds

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

Sec. 5301. Primary Care Training and Enhancement

This section strikes the existing provisions in **PHSA Sec. 747** and replaces them with new language authorizing the Secretary to award five-year grants or contracts to accredited public or nonprofit hospitals, schools of medicine or osteopathic medicine, academically affiliated physician assistant training programs, or other public or private nonprofit entities for the purpose of supporting primary care training programs. Funds are to be used to plan, develop, or operate accredited training programs in family medicine, general internal medicine, or general pediatrics and to provide financial assistance in the form of traineeships and fellowships, among other things. The Secretary is also authorized to award five-year grants or contracts to schools of medicine or osteopathic medicine for the purpose of capacity building in primary care. Funds are to be used to establish, improve, or integrate academic units or programs in the various primary care fields. Priority is to be given to entities proposing innovative approaches to clinical teaching in primary care and who have a record of training primary care practitioners, among other things. The section authorizes to be appropriated $125 million for FY2010, and SSAN for each of FY2011 through FY2014, and requires that 15% of the amount appropriated in each fiscal year be allocated to physician assistant training programs that prepare students for practice in primary care. For purposes of carrying out programs that integrate academic administrative units in the

[28] Kevin O'Leary, Gerald Katz, and Fred Hollander, "The Shortage of Pediatric Subspecialists," *Children's Hospitals Today*, Winter 2003; and Scott A. Shipman, Jon D. Lurie, and David C. Goodman, "The General Pediatrician: Predicting Future Workforce Supply and Requirements," Pediatrics, vol. 113, no. 3 (March 2004), pp. 435-442. See, also, American Medical Group Association, *2008 Medical Group Compensation and Financial Survey: 2008 Report Based on 2007 Data,* ed. RSM McGladrey, Inc. Consulting (Alexandria, VA: American Medical Group Association, 2008).

[29] Fitzhugh Mullan, Candice Chen, and Elizabeth Wiley, *The Case for Teaching Health Centers,* Medical Education Futures Study, Policy Brief, Washington, DC, July 14, 2009, http://www.medicaleducationfutures.org.

[30] Howard K. Rabinowitz, James J. Diamond, Fred W. Markham, et al., "Critical Factors for Designing Programs to Increase the Supply and Retention of Rural Primary Care Physicians," Journal of the American Medical Association, vol. 286, no. 9 (September 5, 2001), pp. 1041-1048.

various fields of primary care, the section authorizes to be appropriated $750,000 for each of FY2010 through FY2014.

Sec. 5203. Pediatric Specialist Loan Repayment Program

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

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

Subsection 5508(a) adds at the end of PHSA Title VII, Part C a new **PHSA Sec. 749A**, *Teaching Health Centers Development Grants*, authorizing the Secretary to award grants to teaching health centers (THC) to establish newly accredited or expanded primary care residency training programs. The section defines a THC as a community-based, ambulatory patient care center that operates a primary care residency program, including the following entities: FQHCs, community mental health centers, Rural Health Clinics (RHCs), Indian health centers,[31] and entities receiving funds under PHSA Title X (family planning program). It requires that grants be awarded for not more than three years with a maximum award of $500,000. Grant funds must be used for activities associated with establishing or expanding a primary care residency training program including curriculum development; faculty and trainee recruitment, training, and retention; accreditation; and other specified purposes. The Secretary is required to give preference to applications that document an existing affiliation agreement with an Area Health Education Center (AHEC) that sponsors projects to increase and improve health personnel services in medically underserved communities. In addition, there are authorized to be appropriated $25 million for FY2010, $50 million for FY2011 and for FY2012, and SSAN for each fiscal year thereafter. No more than $5 million annually may be used for technical assistance program grants.

Subsection 5508(c) amends **PHSA Title III, Part D** by adding a new Subpart XI, *Support of Graduate Medical Education in Qualified Teaching Health Centers*, and, within this subpart, creates a new **PHSA Sec. 340H,** *Program of Payments to Teaching Health Centers that Operate*

[31] Indian health centers refer to health centers that are operated by the Indian Health Service, an Indian Tribe, a Tribal Organization, or an Urban Indian Organization as these terms are defined in Sec. 4 of the Indian Health Care Improvement Act (25 U.S.C. § 1604).

Graduate Medical Education Programs. The new section requires the Secretary to make payments for direct and indirect costs to qualified THCs for the expansion of existing or the establishment of new approved graduate medical residency training programs. It specifies how the direct and indirect graduate medical education payments to THCs and the annual updates for payments are calculated. It also requires the Secretary to limit the funding of full-time equivalent residents to ensure that these payments do not exceed the annual appropriation under this section. The section specifies that THC graduate medical education payments are in addition to any indirect or direct payments made to teaching hospitals and do not count against the limit on the number of full-time equivalent residents paid for by Medicare or by Children's Hospital Graduate Medical Education Programs. The section also requires the Secretary to determine any changes to the resident reporting requirements to determine whether hospitals have received overpayments. It specifies annual reporting requirements and authorizes the Secretary to audit THCs. The section requires the Secretary to reduce the amount of payments made to a THC by 25% if a THC fails to report certain information, and specifies a THC's opportunity to remediate the failure to report. The section also requires the Secretary to promulgate regulations to carry out this section, and appropriates SSAN, not to exceed $230 million, for the period of FY2011 through FY2015.

Sec. 10501(l). Rural Physician Training Grants

This section adds a new **PHSA Sec. 749B**, *Rural Physician Training Grants*, requiring the Secretary, acting through HRSA, to award grants to medical schools to recruit and provide focused training and experiences to students likely to practice medicine in underserved rural communities. Priority is to be given to medical schools with a demonstrated record of training students to practice in such communities, that have established rural community institutional partnerships, or who submit a long-term plan for tracking program graduates. Entities receiving grants would be required to use funds to establish, improve or expand a rural-focused training program that meets certain specified requirements. The section requires the Secretary to define, by regulation, the term "underserved rural community" for the purpose of this section within 60 days of enactment. Grantees would have to use the funds to supplement and not supplant federal and non-federal funds received from other sources, and maintain expenditures of non-federal amounts at levels not less than those expended in the fiscal year prior to the entity's receipt of the grant. The section authorizes to be appropriated $4 million for each of FY2010 through FY2013.

Sec. 10502. Hospital Construction Grants

This section authorizes to be appropriated and appropriates $100 million for FY2010, to remain available through FY2011, for debt service on, or construction or renovation of, a hospital affiliated with a state's sole public medical and dental school. The section specifies that the Secretary may only make appropriated amounts available upon receipt of an application from a state governor that meets certain specified requirements.

Dental Workforce

ACA also addresses training in dentistry. Researchers have expressed concerns about the availability of dental services, especially for disadvantaged populations.[32] GAO found that children enrolled in Medicaid lack access to dental care because dentists do not accept Medicaid,

[32] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Financing Dental Education: Public Policy Interests, Issues and Strategic Considerations*, Rockville, MD, 2005; and Cynthia Shirk, *Oral Health Checkup: Progress in Tough Fiscal Times?* National Healthy Policy Forum, Washington, DC, March 29, 2010.

or because there are few providers in a geographic area.[33] In a 2005 report examining dental training, HRSA recommended that federal programs that support the dental workforce, particularly those that provide support for dental faculty and address student indebtedness, be expanded. Increasing specialization may exacerbate concerns about the adequacy of the general dental workforce. Dental school debt has increased by 55% from 1996 to 2006, controlling for inflation.[34] Due in part to increased amounts of student debt, more dental school graduates are choosing dental specialties because they can often earn more than general dentists.[35]

ACA implements a number of changes to encourage training in primary care dentistry. Some of these changes are in response to the 2005 HRSA report as they support efforts to expand dental faculty, and provide loan repayment for dental students and faculty.[36] In addition, these programs seek to expand the dental workforce available for the underserved through programs that support alternative dental care providers.

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

This section redesignates **PHSA Sec. 748**, as amended by ACA Sec. 5103, as **PHSA Sec. 749** and inserts a new **PHSA Sec. 748,** authorizing the Secretary to make grants or enter into contracts with specified entities to support training, provide financial assistance, and fund projects for dental students, dental residents, dental hygienists, practicing dentists, or dental faculty in the fields of general dentistry, pediatric dentistry, or public health dentistry. The section also establishes a faculty loan repayment program under which individuals agree to serve full-time as faculty members in one of the specified dental fields, and the program agrees to pay specified percentages of the principal and interest on their outstanding student loans based on the number of years served as a full-time faculty member. Entities eligible for the programs under this section include dental and dental hygiene schools and approved residency or advanced educational programs in the specified fields. Eligible entities also may partner with schools of public health so that dental residents or dental hygiene students may receive master's-level training in public health. When making training awards, the Secretary is required to give priority to certain qualified applicants. When making awards for both the training and faculty loan repayment programs, the Secretary is required to give preference to applicants based on their record of providing care in underserved areas or to populations experiencing health disparities, entities that have established a formal relationships with certain specified types of providers, or to entities that in the two fiscal years prior to receiving the award had an increased rate of placing their graduates in settings that serve health disparity populations. The section authorizes an appropriation of $30 million for FY2010, and SSAN for each of FY2011 through FY2015 and permits entities to carry over funds across fiscal years.

Sec. 5304. Alternative Dental Health Care Provider Demonstration

This section adds a **new PHSA Sec. 340G-1** that authorizes the Secretary to establish a demonstration program to train or employ alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

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[33] U.S. Government Accountability Office, *Medicaid: State and Federal Action Have Been Taken to Improve Children's Access to Dental Services, But More Can Be Done*, 10-112T, October 7, 2009.

[34] U.S. Government Accountability Office, *Graduate Medical Education: Trends in Training and Student Debt*, 09-438R, May 4, 2009.

[35] Ibid.

[36] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Financing Dental Education: Public Policy Interests, Issues and Strategic Considerations*, Rockville, MD, 2005.

Alternative dental health care providers include community dental health coordinators, advance practice dental hygienists, independent dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professionals the Secretary determines appropriate. Entities eligible for this grant program include qualified institutions of higher education; public-private partnerships; FQHCs; health facilities operated by the Indian Health Service (IHS), an Indian Tribe, a Tribal Organization or an Urban Indian Organization, as specified; state or county public health clinics; public hospitals or health systems; or other entities as specified. The Secretary is authorized to award 15 grants of not less than $4 million over a five-year period. The section also specifies the funding disbursement formula for grants and requires that demonstration projects begin within two years after enactment and conclude not later than seven years after enactment. Additionally, this section requires the Secretary to contract with the Institute of Medicine (IOM) to conduct a study of the demonstration program regarding access to dental health care. Nothing in the section prohibits an IHS-approved dental health aide training program from being eligible for a grant under this section. There are authorized to be appropriated SSAN to carry out this section.

Nursing Workforce

The National Advisory Council on Nurse Education and Practice (NACNEP) reports that there will be 10,000 too few nurses in 2020 to meet the nation's health care needs.[37] Furthermore, this group expressed concerns that the existing and future nursing workforce may not be adequate, or sufficiently skilled, because the health care work environment has become increasingly complex.[38] Nursing workforce development programs authorized under PHSA Title VIII fund grants and scholarships 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. ACA expands these programs and addresses a number of the concerns raised by NACNEP and other experts. In particular, ACA seeks to increase the skill level of the nursing workforce by authorizing programs to train advanced practice nurses and family nurse practitioners.

Sec. 5202. Nursing Student Loan Program

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

Sec. 5308. Advanced Nursing Education Grants

This section amends **PHSA Sec. 811** to establish separate authorizations for the support of nurse practitioner and nurse midwifery programs. It also inserts new language establishing expanded

[37] NACNEP, HRSA, Bureau of Health Professionals, Division of Nursing, *First Report to the Secretary and to the Congress*, Rockville, MD, November 2001.

[38] NACNEP, HRSA, Bureau of Health Professionals, Division of Nursing, *Meeting the Challenges of the New Millennium: Challenges Facing the Nurse Workforce in a Changing Health Care Environment*, Sixth Report to the Secretary of Health and Human Services and the Congress, Rockville, MD, January 2008.

grant eligibility criteria for nurse midwifery programs. The section deletes the prohibition on obligating more than 10% of the traineeships for individuals in doctoral programs.

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

This section amends **PHSA Sec. 831** by renaming the grant program, *Nurse Education, Practice, and Quality Grants*, and deleting from the program's listed priority areas support for internship and residency programs to encourage mentoring and the development of specialties within nursing. The section restates certain specified grant priority activities, and redefines nursing schools to have the same meaning as the term in Sec. 801(2). The section authorizes to be appropriated SSAN for each of FY2010 through FY2014. (See also ACA Sec. 5312, below.)

Also, the section adds a new **PHSA Sec. 831A**, *Nurse Retention Grants*, authorizing the Secretary to provide funding to eligible entities for nurse retention and promotion ("career ladder") programs, and for the enhancement of patient care that is directly related to nursing activities. The Secretary is required to give preference to entities that have not received a grant under this subsection, to entities that have not received a grant under the earlier nursing "career ladder" grant program, and to entities that address other high-priority areas as determined by the Secretary. The section authorizes to be appropriated SSAN to carry out grant programs in this section for each of FY2010 through FY2012. (See also ACA Sec. 5312, below.)

Sec. 5310. Student Loan Repayment and Scholarship Program

This section amends **PHSA Sec. 846** by expanding eligibility for the nursing student loan repayment and scholarship program to individuals who agree to serve as nurse faculty at an accredited school of nursing for two years or more. The section also contains several technical and conforming amendments for PHSA Title VIII, including redesignating **Sec. 841** (Funding) as **Sec. 871**, and **Sec. 855** (Geriatric Education and Training, discussed below) as **Sec. 865**.

Sec. 5311. Nurse Faculty Loan Program

This section amends **PHSA Sec. 846A** by renaming the nurse faculty loan program *School of Nursing Student Loan Fund*. It adds the requirement that loan fund agreements must be made with accredited schools of nursing. Priority is given to support for doctoral nursing students. The section also increases the annual loan limit from $30,000 to $35,500 for FY2010 and FY2011 and provides for cost-of-attendance adjustments in subsequent years. ACA authorizes to be appropriated SSAN for each of FY2010 through FY2014.

Additionally, the section creates a new **PHSA Sec. 847** authorizing the Secretary, acting through HRSA, to enter into an agreement with eligible individuals for the repayment of qualified education loans for the purpose of increasing the number of qualified nursing faculty. Award recipients are required to serve as a faculty member at an accredited school of nursing for at least four of the six years after (1) the individual receives a qualifying degree; or (2) the date the individual entered the agreement. Priority is given to support for doctoral nursing students. The section also sets the annual loan limit at $10,000 for individuals with a master's or equivalent degree in nursing ($20,000 for those with a doctorate or equivalent degree in nursing), and an aggregate loan limit of $40,000 for individuals with a master's or equivalent degree in nursing ($80,000 for those with a doctorate or equivalent degree in nursing) for FY2010 and FY2011. Thereafter, the annual and aggregate loan limits would be adjusted to provide for a cost-of-attendance increase. The section authorizes to be appropriated SSAN for each of FY2010 through FY2014.

Sec. 5312. Authorization of Appropriations

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

Sec. 5509. Medicare Graduate Nurse Education Demonstration Program

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

Sec. 5316. Family Nurse Practitioner Demonstration

This section, as added by ACA Sec. 10501(e), requires the Secretary to establish a demonstration program to provide recently qualified nurse practitioners with 12 months of training for careers as primary care providers in FQHCs and NMHCs (see Sec. 5208 of ACA). Eligible FQHCs and NMHCs will receive three-year grants to create a training model that may be replicated nationwide. Grant amounts may not exceed $600,000 per year. To be eligible for acceptance into a training program, a nurse practitioner has to demonstrate a commitment to a career as a primary care provider in an FQHC or NMHC. Preference will be given to bilingual candidates. The Secretary is authorized to award grants to one or more FQHCs or NMHCs with expertise in establishing nurse practitioner residency training programs to provide technical assistance to other grantees. There are authorized to be appropriated SSAN for each of FY2011 through FY2014 to carry out the demonstration program.

Geriatric and Long-Term Care Workforce

The IOM, among others, has raised concerns about whether the geriatric workforce is sufficiently skilled to provide care to an aging population.[39] The IOM also has raised concerns about the training of direct care workers, noting that these workers are the primary source of care for older adults, but have little training in geriatric medicine. PHSA Titles VII and VIII include programs to augment the geriatric workforce by training physicians, dentists, mental health professionals, and nurses in geriatric care. ACA creates new, and amends existing, programs for geriatric training.

[39] Institute of Medicine, *Retooling for an Aging America: Building the Health Care Workforce* (Washington, DC: The National Academies Press, 2008).

These new programs draw from the IOM recommendations in that they establish programs to increase training for the direct care workforce, provide training in geriatrics for the health care workforce, and provide incentives for other types of providers to enter the field of geriatrics.

Sec. 5302. Training Opportunities for Direct Care Workers

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

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

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

The second subsection creates incentive grants or contracts for certain qualified health professionals entering the field of geriatrics, long-term care, and chronic care management. Health professionals receiving this award are required to teach or practice in one of the above fields for a minimum of five years. There are authorized to be appropriated $10 million for this program for the period FY2011 through FY2013.

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

Sec. 5305(c). Geriatric Education and Training

This subsection amends **PHSA Sec. 855** to include new language establishing traineeships for individuals preparing for advanced degrees in geriatric nursing or other nursing areas that specialize in elder care. It authorizes to be appropriated SSAN for each of FY2010 through FY2014. [Note: ACA Sec. 5310 redesignated PHSA Sec. 855 as **Sec. 865**.]

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

Subsection 5507(a) amends Title XX of the Social Security Act (SSA) by adding a new **Sec. 2008**, *Demonstration Projects to Address Health Professions Workforce Needs*, establishing two separate demonstration projects. The first project requires the Secretary, in consultation with the

Secretary of Labor, to award grants that provide individuals receiving assistance under the State Temporary Assistance for Needy Families (TANF) program and other low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand. Funds may be used to provide individuals with financial aid, child care, case management, and other supportive services, and are not be considered income for the purposes of determining eligibility for benefits under any means-tested program. The second project requires the Secretary to award grants to states to conduct demonstrations for the purpose of developing core training competencies and certification programs for personal or home care aides. The section appropriates $85 million to carry out both demonstration projects for each of FY2010 through FY2014. The Secretary is required to use $5 million of the amount appropriated for each of FY2010 through FY2012 to carry out the second demonstration project. After FY2012, no appropriated funds may be used to carry out this project.

Subsection 5507(b) amends SSA Sec. 501(c), which appropriated $5 million for FY2009 for the Secretary (through grants, contracts, or otherwise) to provide funding for special projects of regional and national significance for the development and support of family-to-family health information centers. ACA appropriates $5 million for each of FY2009 through FY2012 to provide for the development and support of these centers.

Sec. 8002(c). Personal Care Attendants

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

Public Health Workforce

The PHSA 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, re-training, and placement programs.[40] 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. ACA reauthorizes these programs and creates some new ones, including a U.S. Public Health Sciences Track for graduate training in public health disciplines.

Health Workforce Loan Repayment Program

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

[40] PHSA Title VII, Part E, Subpart 2, comprising Secs. 765-770.

Sec. 5206. Public Health Workforce Grants for State and Local Programs

This section amends **PHSA Sec. 765** to add public health workforce loan repayment programs to the list of allowable activities for public health workforce development grants. It also creates a new **PHSA Sec. 777** authorizing the Secretary to make grants to eligible educational entities to award scholarships for the training of mid-career professionals in public health and allied health. There are no stated scholarship amounts or service obligations. The section authorizes the appropriation of $60 million for FY2010, and SSAN for each of FY2011 through FY2015.

Sec. 5313. Grants for Community Health Worker Programs

This section, as amended by ACA Sec. 10501(c), creates a new **PHSA Sec. 399V**, requiring the CDC Director to award grants to eligible entities to promote healthy behaviors and outcomes for populations in medically underserved communities through the use of community health workers (CHWs). The Secretary is required, among other things, to establish guidelines for the training and supervision of CHWs. The section authorizes to be appropriated SSAN for each of FY2010 through FY2014.

Sec. 5314. Public Health Fellowships

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

Sec. 5315. United States Public Health Sciences Track

This section adds a new **PHSA Title II, Part D**, "United States Public Health Sciences Track," consisting of four new PHSA sections. New **PHSA Sec. 271** establishes a science track at academic sites selected by the Secretary, to award degrees that emphasize team-based service, public health, epidemiology, and emergency preparedness and response. The track is to be organized so as to graduate, annually, specified minimum numbers of students of medicine, dentistry, nursing (including advanced nursing), public health, behavioral and mental health, physician assistance, and pharmacy. New **PHSA Sec. 272** delegates administration of the science track to the U.S. Surgeon General (SG), according to specified requirements.

New **PHSA Sec. 273** establishes requirements for selection of students for the science track, and their service obligations, under the administration of the SG. The SG may provide students with funding for tuition and a stipend for up to four years, subject to specified contractual obligations, among them a requirement to serve in the United States Public Health Service (USPHS) Commissioned Corps for a specified time period. Among other things, the SG is required to develop criteria for the appointment of promising science track faculty, students, and graduates to elite federal disaster preparedness teams to train and respond to public health emergencies. New **PHSA Sec. 274** requires the Secretary, beginning in FY2010, to transfer from the Public Health and Social Services Emergency Fund SSAN to carry out this new Part.[41]

[41] The Public Health and Social Services Emergency Fund (PHSSEF) is an HHS account administered by the Secretary,

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

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

Sec. 10501(m)(2). Reauthorization of Public Health Workforce Programs

This subsection reauthorizes public health workforce programs in PHSA Secs. 765-769 (as amended by ACA) by amending **PHSA Sec. 770(a)**, authorizing to be appropriated $43 million for FY2011, and SSAN for each of FY2012 through FY2015.

U.S. Public Health Service (USPHS) Commissioned Corps

The USPHS Commissioned Corps is a branch of the U.S. uniformed services, but is not one of the armed services.[42] The Corps is based in HHS under the authority of the U.S. Surgeon General (SG). USPHS commissioned officers are physicians, nurses, pharmacists, engineers, and other public health professionals who serve in federal agencies, or as detailees to state or international agencies, to support a variety of public health activities. Corps officers serve in regular or reserve status. Due to a statutory cap on the number of Regular Corps officers, many officers were placed when on active-duty status in the Reserve Corps instead. ACA eliminates the cap and places active-duty reserve officers into regular status. Also, ACA establishes a Ready Reserve Corps of officers who are subject to intermittent involuntary deployment to bolster the available workforce for both routine and emergency public health missions, such as serious natural disasters and infectious disease outbreaks. It is expected that Ready Reserve Corps officers will be drawn mainly from professionals who work in the private sector, not in the federal workforce, between deployments.

Sec. 5209. Elimination of Cap on USPHS Regular Corps

Sec. 202 of P.L. 102-394, FY1993 appropriations for Labor/HHS/Education, capped the number of commissioned officers in the USPHS Regular Corps (versus the Reserve Corps) at 2,800 and prohibited the use of appropriations from that act, or any subsequent appropriations act, to fund additional positions.[43] This section amends Sec. 202 of P.L. 102-394 to eliminate the cap.

Sec. 5210. USPHS Ready Reserve Corps

This section replaces **PHSA Sec. 203** with new language designating active-duty officers in the USPHS Reserve Corps as members of the Regular Corps, effective upon enactment. The section also establishes a Ready Reserve Corps of officers who are subject to involuntary call to active duty (including for training) by the SG, in order to bolster public health workforce capacity. The section authorizes the appropriation, for each of FY2010 through FY2014, of $5 million for recruitment and training, and $12.5 million for the Ready Reserve Corps.

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which Congress has historically used to provide one-time funding for non-routine activities. Congress appropriates amounts to the PHSSEF for specified purposes. ACA does not authorize or appropriate funds to the PHSSEF.

[42] 10 U.S.C. § 101. The USPHS Commissioned Corps is authorized in PHSA Secs. 201-224 (42 U.S.C. §§ 202-233). For more information see HHS, USPHS Commissioned Corps, http://www.usphs.gov/default.aspx.

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

Workforce Diversity Training

The IOM has raised concerns about the racial and ethnic diversity of the health care workforce.[44] A more diverse healthcare workforce—including a more diverse group of providers in training—is important because (1) minority groups disproportionately live in areas with provider shortages,[45] (2) patients who receive care from members of their own racial and ethnic background tend to have better outcomes,[46] and (3) members of racial and ethnic minority groups are more likely to enter primary care and practice in shortage areas.[47] In addition, research has found that all students benefit from a more diverse student body. Specifically, non-minority students who attend more diverse medical schools feel more prepared to provide care to a diverse racial and ethnic population.[48] PHSA Title VII authorizes programs to increase the diversity of the health care workforce and to create interdisciplinary community-based training. ACA reauthorizes and amends a number of these programs and creates a new program to increase the diversity of the nursing workforce. ACA also expands the role of the AHEC program—centers that sponsor projects to increase and improve health personnel services in medically underserved communities—by requiring coordination with ACA-established teaching health centers and primary care extension programs.

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

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

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

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[44] Institute of Medicine, *In the Nation's Compelling Interest: Ensuring Diversity in the Health Care Workforce* (Washington, DC: National Academy Press, 2004).

[45] CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje.

[46] Institute of Medicine, *In the Nation's Compelling Interest: Ensuring Diversity in the Health Care Workforce* (Washington, DC: National Academy Press, 2004).

[47] U.S. Government Accountability Office, *Graduate Medical Education: Trends in Training and Student Debt*, 09-438R, May 4, 2009.

[48] Institute of Medicine, *In the Nation's Compelling Interest: Ensuring Diversity in the Health Care Workforce* (Washington, DC: National Academy Press, 2004).

Sec. 5401. Centers of Excellence

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

Sec. 5402. Health Care Professionals Training for Diversity

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

Sec. 10501(d). Increasing Diversity in Physician Assistant Education

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

Sec. 5403. Interdisciplinary, Community-Based Linkages

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

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

Sec. 5404. Workforce Diversity Grants

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

Allied Health Workforce

ACA amends eligibility for an existing education loan forgiveness program to include allied health professionals. Allied health providers, such as audiologists, nutritionists, dieticians, and occupational, physical or rehabilitation therapists, share in the responsibility for delivering health care services.

Sec. 5205. Allied Health Workforce Recruitment and Retention Programs

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

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

Mental and Behavioral Health Workforce

ACA creates a new PHSA Title VII grant program for training mental and behavioral health providers. According to the President Bush's New Freedom Commission on Mental Health, there is a shortage of behavioral health care providers, and this shortage is notably severe in rural areas.[49] Due to the lack of specialty behavioral health providers in rural areas, primary care providers who practice in nonmetropolitan areas play a large role in behavioral health care.

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

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

The section requires at least four of the grant recipients to be historically black colleges or universities, or other minority-serving institutions. For grants for education and training in social work, priority must be given to applicants that are accredited by the Council on Social Work Education, have a graduation rate of at least 80% for social work students, and are able to recruit from and place social workers into areas with a high-need and high-demand population. For grants in graduate psychology, priority must be given to institutions that focus on the needs of specified vulnerable groups. For grants to train professional and paraprofessional child and adolescent mental health workers, priority must be given to applicants that, among other things, (1) have demonstrated the ability to collect data on the number of child and adolescent mental

[49] The President's New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America*, July 2003, http://www.mentalhealthcommission.gov/reports/reports.htm.

health workers trained and the populations they serve upon completion of the training; (2) are familiar with evidence-based methods; (3) have programs designed to increase the number of child and adolescent mental health workers serving high-priority populations; and (4) provide services through a community mental health program described in PHSA Sec. 1913(b)(1).

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

Health Workforce Evaluation and Assessment

ACA establishes a National Health Care Workforce Commission to undertake comprehensive workforce planning. At the time of the ACA's enactment experts believed that existing groups—such as the Advisory Council on Graduate Medical Education, the Advisory Committee on Training in Primary Care Medicine and Dentistry, the Advisory Committee on Interdisciplinary, Community-based Linkages, and the NACNEP—were not coordinated and that comprehensive workforce planning was needed to better synchronize federal workforce investments.[50] Some have argued that the lack of a comprehensive workforce policy has contributed to concerns about the size, geographic, and specialty distribution of the current health professions workforce.[51] In addition, GAO has noted that data challenges hamper efforts to evaluate programs funded under PHSA Title VII, and such data may be necessary inputs for comprehensive workforce planning.[52]

ACA establishes a grant program to enable states to undertake state-level health workforce planning and includes provisions intended to increase the data collected and analyzed under ACA Title V (Health Workforce) programs. It also creates a National Center for Health Care Workforce Analysis (NCHWA) to centralize data collection and analysis,[53] and establishes a federal task force on Alaska health care delivery.

Sec. 5101. National Health Care Workforce Commission

This section, as amended by Sec. 10501(a) of ACA, establishes a National Health Care Workforce Commission (Commission) to serve as a national resource focused on evaluating and meeting the need for health care workers. Composed of 15 members appointed by the U.S. Comptroller General, the Commission is required to recognize partnerships that develop and offer effective health care career pathways; disseminate information on promising practices; and communicate important policies and practices regarding recruitment, retention, and training of the health care workforce. The Commission is required to review health care workforce supply and demand and make recommendations on national priorities and policies as well as review and make recommendations on one or more additional specified high priority topics and, beginning in 2011, submit annual reports on both activities to Congress and the Administration. The Commission is required to (1) review implementation progress reports and report on the state health care

[50] David C. Goodman, "Improving Accountability for the Public Investment in Health Profession Education: It's Time to Try Health Workforce Planning," Journal of the American Medical Association, vol. 300, no. 10 (September 10, 2008), pp. 1205-1207.

[51] Ibid. See, also, Association of Academic Health Centers, *Out of Order Out of Time: The State of the Nation's Health Workforce*, Washington, DC, 2008, http://www.aahcdc.org.

[52] U.S. Government Accountability Office, *Health Professions Education Programs: Action Still Needed to Measure Impact*, 06-55, February 28, 2006.

[53] Prior to the ACA, HRSA had an entity that conducted similar activities, called the National Center for Health Workforce Analysis.

workforce development grants program (established by Sec. 5102 of ACA); (2) study effective mechanisms for financing education and training for careers in health care; (3) make recommendations about improving health care workers' safety, health, and protections in the workplace; and (4) assess reports from the NCHWA (established under PHSA Sec. 761(b), as amended by Sec. 5103 of ACA). There are authorized to be appropriated SSAN to carry out this section.

Sec. 5102. State Health Care Workforce Development Grants

This section establishes a competitive health care workforce development grants program for the purpose of enabling state partnerships to plan and implement activities leading to coherent and comprehensive health care workforce development strategies at the state and local levels. HRSA is responsible for (1) administering the program, in consultation with the Commission (established by Sec. 5101 of ACA); (2) providing technical assistance to grantees; and (3) reporting performance information to the Commission. For planning grants, the section authorizes to be appropriated $8 million for FY2010, and SSAN for each subsequent fiscal year. For implementation grants, it authorizes to be appropriated $150 million for FY2010, and SSAN for each subsequent fiscal year.

Sec. 5103. Health Care Workforce Program Assessment

This section amends **PHSA Sec. 761** by requiring the Secretary to (1) establish a National Center for Health Care Workforce Analysis (NCHWA); (2) establish State and Regional Centers for Health Workforce Analysis; and (3) increase grant amounts for longitudinal evaluations of specified individuals who have received education, training, or financial assistance from programs under PHSA Title VII. The section authorizes the following appropriations for each of FY2010 through FY2014: (1) $7.5 million for the NCHWA; (2) $4.5 million for State and Regional Centers; and (3) SSAN for grants for longitudinal evaluations. No later than 180 days after enactment, all responsibilities of HRSA's existing National Center for Health Workforce Analysis must be transferred to the new NCHWA.

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

Sec. 5104. Task Force on Alaska Health Care

This section, as added by ACA Sec. 10501(b), establishes the Interagency Access to Health Care in Alaska Task Force to develop a strategy to improve delivery of care to beneficiaries of federal health care systems in Alaska. Composed of nine federal officials appointed by specified Secretaries, the task force is required, within 180 days of enactment, to submit a report to Congress with recommendations, policies, and initiatives. The task force will be terminated upon submission of the report.[54]

[54] For report, see Interagency Access to Health Care in Alaska Task Force, *Report to Congress*, Washington, DC, September 17, 2010, http://www.healthcare.gov/news/reports/alaskataskforce.html.

Sec. 5701. Reports

This section requires the Secretary to submit to Congress an annual report on the activities carried out under the amendments made by Title V (Health Care Workforce) of ACA, and the effectiveness of such activities. In addition, the Secretary may require, as a condition of receiving funds under these amendments, that recipients of such awards report on the activities carried out with the awards, and the effectiveness of such activities.

Medicare GME Payments[55]

Medicare subsidizes the costs of medical residency training 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 may be 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. While health policy analysts view Medicare GME payments as a potentially important instrument for influencing health workforce policy, to date they have largely not been used to shape the physician workforce.

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.[56] The cap was implemented because of concerns that there would be an oversupply of physicians. Now with experts concerned that physician supply may be insufficient to meet demand, a number of physician and hospital groups have called for additional Medicare-supported residency slots.[57]

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[55] For a 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; and Medicare Payment Advisory Commission, Graduate Medical Education Financing: Focusing on Educational Priorities, Report to the Congress: Aligning Incentives in Medicare, Washington, DC, June 2010, http://www.medpac.gov/documents/Jun10_EntireReport.pdf.

[56] The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 permitted a one-time redistribution of up to 75% of a certain teaching hospital's unused resident positions to hospitals seeking to increase their medical residency programs, according to specific priorities.

[57] See, for example, an editorial arguing to lift the cap by the president of the Association of American Medical Colleges (AAMC), published in the Wall Street Journal on January 4, 2010, at http://online.wsj.com/article/SB10001424052748703483604574630321885059520.html; or the AAMC's policy brief, *Physician Shortages to Worsen Without Increases in Residency Training*, Washington, DC, accessed January 31, 2013, https://www.aamc.org/download/153160/data/physician_shortages_to_worsen_without_increases_in_residency_tr.pdf.

ACA increases the number of residents that Medicare supports through provisions that would redistribute unused residency slots and preserve residency positions from closed hospitals, but does not remove the limit on Medicare-supported residency slots. Although Medicare does not set targets for the type or mix of resident physicians that a hospital trains, under ACA the redistributed slots must largely be used for training in primary care or general surgery.

Medicare allows teaching hospitals to receive DGME and IME payments for the time residents rotate in nonhospital 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 nonhospital site, costs which include the resident stipends and fringe benefits and those associated with supervising physicians.[58] Time spent in non-patient care activities in the nonhospital 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 nonhospital 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 nonhospital 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. Some have argued that this may make residents less likely and less prepared to be a community-based provider.[59] Research has found that residents who train in health centers are more likely to provide care to the underserved, including by working at a health center.[60]

Sec. 5503. Distribution of Additional Residency Positions

This section establishes criteria to be used to reduce the otherwise applicable resident limit for a hospital that has unused residency positions, as defined, and directs the Secretary to redistribute 65% of those unused positions and assign them to other qualifying hospitals. Hospitals that meet certain specified criteria are exempt from the redistribution of any of their unfilled positions. No more than 75 FTE additional residents can be made available to a qualifying hospital.

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

Sec. 5504. Counting Resident Time in Other Settings

This section requires that all time spent by a resident in patient care activities be counted towards the DGME payment, regardless of the setting, provided the hospital incurs the costs of the

[58] Medicare GME payments are summarized in MedPAC's June 2009 Report to Congress: Improving Incentives in the Medicare Program, Chapter 1, at http://www.medpac.gov/chapters/Jun09_Ch01.pdf.

[59] Ibid.

[60] Carl G. Morris, Brian Johnson, and Sara Kim, et al., "Training Family Physicians in Community Health Centers: A Health Workforce Solution," Health Services Research, vol. 40, no. 4 (April 2008), pp. 271-276.

stipends and the fringe benefits of the resident during the time spent in that setting. If more than one hospital incurs those costs, then each hospital counts a proportional share of the time that the resident spends training in that setting. Further, all the time spent by a resident in patient care activities in a nonhospital setting counts towards the IME payment, provided the hospital continues to incur those same costs. Again, if more than one hospital incurs the costs, then each hospital counts a proportional share of the time that the resident spends training in that setting.

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

This section, as amended by Sec. 10501(j) of ACA, requires 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 nonhospital setting that is primarily engaged in furnishing patient care be counted towards the DGME payment. In addition, Medicare must 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.

Similarly, when calculating IME payments, 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—counts towards the IME payment.

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

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

Prevention and Wellness

Overview and Impact of ACA

ACA substantially expands federal disease prevention and health promotion efforts through several approaches. Subsequent subsections of this section discuss how the law: (1) expands coverage of clinical preventive services under Medicare, Medicaid, and private health insurance; (2) encourages the development and expansion of wellness programs by employers and insurers; (3) calls for a national strategy for disease prevention and health promotion; and (4) expands federal research, grantmaking, and other public health activities aimed at the prevention of disease risk factors such as obesity and tobacco use, providing a permanent annual appropriation to support this expansion. These provisions are found primarily in ACA Title IV, "Prevention of Chronic Disease and Improving Public Health," and in Title X, Subtitle D.

Coverage of Clinical Preventive Services

ACA expands requirements for coverage of clinical preventive services under Medicare, Medicaid, and private insurance. Although the approach is different for each of these, two key elements are incorporated in all three: (1) linking coverage requirements to recommendations of

the U.S. Preventive Services Task Force (USPSTF)[61] and, in some cases, additional advisory bodies; and (2) eliminating most or all cost-sharing for use of clinical preventive services.[62]

Prevention and Wellness

CRS Report R40661, *Wellness Programs: Selected Legal Issues*, by Jody Feder et al..

CRS Report R41166, *Grandfathered Health Plans Under the Patient Protection and Affordable Care Act (ACA)*, by Bernadette Fernandez.

GAO, *Preventive Health Activities: Available Information on Federal Spending, Cost Savings, and International Comparisons Has Limitations*, GAO-13-49, December 6, 2012, http://www.gao.gov/products/GAO-13-49.

GAO, *Prevention and Public Health Fund Activities Funded in Fiscal Years 2010 and 2011,* GAO-12-788, September 13, 2012, http://www.gao.gov/products/GAO-12-788.

GAO, *Medicare: Use of Preventive Services Could Be Better Aligned with Clinical Recommendations*, GAO-12-81, January 18, 2012, http://www.gao.gov/products/GAO-12-81.

GAO, *Medicare: Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations,* GAO-12-61, December 15, 2011, http://www.gao.gov/products/GAO-12-61.

HHS, Office of the Surgeon General, *National Prevention Strategy*, 2011, and *National Prevention Council Action Plan*, 2012, http://www.surgeongeneral.gov/initiatives/prevention/index.html.

Medicare Part B covered a number of clinical preventive services prior to ACA, including a one-time initial preventive physical examination (IPPE), certain cancer screenings and immunizations, and other services. Cost-sharing was waived for some, but not all, preventive services. ACA now requires that Part B also cover an annual wellness visit and health assessment, and waive any cost-sharing for almost all previously covered preventive services. In addition, ACA allows the Secretary to modify coverage of preventive services to comport with USPSTF recommendations, including by withholding payment for services that the USPSTF recommends against using. Finally, ACA provides that FQHCs may be reimbursed for providing Medicare-covered preventive services. The Congressional Budget Office (CBO) and the Centers for Medicare and Medicaid Services (CMS) Actuary projected that, in aggregate, these expansions of covered benefits will incur a net cost for the Medicare program (although the provision that authorizes the withholding of payments for ineffective services was projected to be cost-saving).[63] These provisions are summarized below in the section "Prevention Under Medicare."[64]

State Medicaid programs must cover a suite of preventive services under the Early and Periodic Screening, Diagnostic, and Treatment Services program (EPSDT) for beneficiaries under 21 years of age.[65] Neither preexisting law nor ACA explicitly require state plans to cover preventive services for adults, although coverage may be required if a service meets another applicable requirement, such as a physician's service. However, ACA requires state Medicaid plans to cover tobacco cessation counseling and drug therapy for pregnant women. In addition, ACA provides

[61] The USPSTF is an independent panel of private-sector experts in primary care and prevention that assesses scientific evidence of the effectiveness of a broad range of clinical preventive services. It is reauthorized by ACA Sec. 4003. See U.S. Preventive Services Task Force, http://www.uspreventiveservicestaskforce.org/.

[62] Beneficiary cost-sharing has been shown to decrease utilization of certain preventive services in some contexts. Elimination of cost-sharing is sometimes recommended to improve utilization.

[63] CBO, "H.R. 3590, Patient Protection and Affordable Care Act," cost estimate for the bill as passed by the Senate on December 24, 2009, March 11, 2010, p. 10 of 16, http://www.cbo.gov/doc.cfm?index=11307&zzz=40511; and Richard S. Foster, Chief Actuary, Centers for Medicare and Medicaid Services, "Estimated Financial Effects of the 'Patient Protection and Affordable Care Act,' as Amended," Letter, April 22, 2010, Table 3, p. 5 of 8.

[64] For general information on Medicare, see CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis and Scott R. Talaga.

[65] For general information on Medicaid, see CRS Report RL33202, *Medicaid: A Primer*, by Elicia J. Herz.

for enhanced federal Medicaid matching funds for states that opt to cover without cost-sharing a complete package of preventive services for eligible adults recommended by the USPSTF, as well as recommended immunizations. The CBO and the CMS Actuary projected a net cost to the Medicaid program for the state option to cover adult preventive services, and net savings for the provision that provides coverage of tobacco cessation services for pregnant women.[66] These and additional provisions are summarized below in the section "Prevention Under Medicaid."

Prior to ACA, federal law did not require private insurers to cover preventive services. Under ACA, group health plans and health insurance issuers in the group and individual markets must now cover specified evidence-based clinical preventive services, including immunizations, without any cost-sharing. Preexisting health plans are "grandfathered" and are exempt from this requirement. In addition, beginning in 2014, qualified health plans that participate in insurance exchanges must cover a package of preventive services that are defined by the Secretary. These provisions are summarized below in the section "Prevention in Private Health Insurance."[67]

An ACA provision clarifies requirements for coverage of breast cancer screening services under Medicaid and private insurance. The provision says that "for the purposes of this Act, *and for the purposes of any other provisions of law*, the current recommendations of the [USPSTF] regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009."[68] (Emphasis added.) In November 2009, the USPSTF updated its recommendation regarding the use of mammography for breast cancer screening. Previously, the panel recommended that routine screening for women begin at age 40; it now recommends that routine screening begin at age 50 and continue through age 74.[69] The ACA provision negates the November 2009 recommendations and directly affects the expansions of benefits covered under Medicaid and private insurance. Although the Secretary has more discretion with respect to the application of this provision under Medicare, Secretary Sebelius signaled when the revised USPSTF recommendations were announced that she did not intend to change federal coverage policies in response, and Medicare policy continues to provide coverage for annual screening mammography for women beginning at age 40.[70]

Wellness Programs Provided by Employers and Insurers

Employers and insurers, faced with rising health care costs, have adopted various strategies to reduce these costs including incentivizing healthy behaviors through wellness programs. Such programs offered by employers may be subject to a number of federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which amended the Employee Retirement Income Security Act (ERISA), the PHSA, and the IRC to improve portability and

[66] See supra note 63. In the CMS Actuary's letter, Medicaid preventive service provisions are presented in Table 4 on p. 2 of 4.

[67] For more information, see CRS Report R42069, *Private Health Insurance Market Reforms in the Patient Protection and Affordable Care Act (ACA)*, by Annie L. Mach and Bernadette Fernandez.

[68] ACA § 1001, creating a new PHSA § 2713. This provision is PHSA §2713(a)(5); 42 U.S.C. § 300gg–13(a)(5).

[69] USPSTF, "Screening for Breast Cancer," released November 2009, updated December 2009, http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrca.htm. For women between age 40 and 49, the USPSTF recommends patient/provider consultation regarding the risks and benefits of breast cancer screening in women of that age. The USPSTF does not recommend against screening of women that age, but that screening be considered pursuant to consultation, rather than provided routinely.

[70] HHS, "Secretary Sebelius Statement on New Breast Cancer Recommendations," press release, November 18, 2009, http://www.hhs.gov/news; and CMS, "Medicare Quick Reference Information: Preventive Services," May 2012, http://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/downloads/MPS_QuickReferenceChart_1.pdf.

continuity of health coverage. Prior to ACA, HIPAA created certain nondiscrimination requirements, which prohibit a group health plan or a group health insurance issuer from basing coverage eligibility rules on health-related factors including health status (physical or mental), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability.[71] In addition, a group health plan or health insurance issuer may not require that an individual pay a higher premium or contribution than another "similarly situated" participant, based on these health-related factors. However, HIPAA clarifies that this requirement "do[es] not prevent a group health plan and a health insurance issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention [i.e., wellness programs]."[72]

The HIPAA wellness program regulations issued prior to ACA divide wellness programs into two categories.[73] First, if a wellness program provides a reward[74] based solely on participation in a wellness program (or if the wellness program does not provide a reward), the program complies with the HIPAA nondiscrimination requirements without having to satisfy any additional standards, as long as the program is made available to all similarly situated individuals. Second, if the conditions for obtaining a reward under a wellness program are based on an individual meeting a certain standard relating to a health factor, then the program must meet additional requirements. Under one of these additional requirements, a reward offered by this type of wellness program must not exceed 20% of the cost of employee coverage under the plan.[75]

ACA essentially codifies the HIPAA wellness program regulations, but for applicable rewards, it raises the cap on the allowed value of the reward to 30% of the cost of employee coverage, and gives discretion to the Secretaries of HHS, Labor, and the Treasury to increase the reward value up to 50%. ACA also establishes reporting requirements for certain plans and insurers that implement wellness and health promotion activities; establishes grant programs to assist employers in establishing and evaluating workplace wellness programs; requires the Secretary to evaluate wellness initiatives for the federal workforce; and bars wellness programs from collecting information about the lawful possession of firearms. These ACA provisions are summarized below in the section "Wellness Programs."

Community-Based Prevention Programs

ACA establishes a framework for federal community-based (i.e., public health) prevention activities, including a coordinating council, a national strategy, and a national education and

[71] 29 U.S.C. § 1182(a); 42 U.S.C. § 300gg-1(a); 26 U.S.C. § 9802(a). It should be noted that the Internal Revenue Code does not apply to health insurance issuers.

[72] 29 U.S.C. § 1182(b)(2)(B); 42 U.S.C. § 300gg-1(b)(2)(B); 26 U.S.C. § 9802(b)(2)(B).

[73] "Nondiscrimination and Wellness Programs in Health Coverage in the Group Market," 71 *Fed. Reg.* 75014 (December 13, 2006).

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

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

outreach campaign. In addition, ACA supports a new approach to federal grantmaking, based on preventing risky behaviors such as physical inactivity and tobacco use.

A key element of this approach is the Prevention and Public Health Fund (PPHF). ACA provided a total appropriation of $5 billion to this new fund for the period from FY2010 through FY2014, and a permanent annual appropriation of $2 billion for each year thereafter, with the stated purpose "to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs."[76]

The PPHF and several new grantmaking authorities in ACA (such as the Community Transformation Grants) mark a shift in focus in federal prevention activities, away from disease-specific or "categorical" programs (e.g., those for heart disease, cancer, etc.) and toward preventable or modifiable risk-factors for disease, such as poor nutrition, sedentary behavior, and tobacco use. Regular appropriations to CDC have generally been provided for disease-specific activities.[77] However, the agency asserts that this approach is limiting, and has asked Congress for authority to give state grantees greater flexibility in their use of appropriated funds, saying "The existing resources dedicated to preventing and reducing chronic diseases, conditions and risk factors do not reflect with (sic) the burden of chronic diseases and the risk factors that cause them. Limited resources could be more effectively and efficiently managed if CDC and states were provided with flexibility to use resources to enhance collaborations among key chronic disease and risk factor prevention programs."[78] In order to assure the effective application of funding to risk-based rather than disease-based programs, ACA requires reviews, evaluations, and reports for specific prevention programs, as well as a comprehensive review by GAO, at least every five years, of every federal disease prevention and health promotion initiative, program, and agency. In addition, many of the community-based prevention activities authorized in ACA must comport with recommendations of the Task Force on Community Preventive Services (TFCPS). The TFCPS, administered by CDC, conducts evidence reviews to determine the effectiveness of community (i.e., population-based) interventions, using a process similar to that of the USPSTF, discussed earlier.[79] ACA codifies authority for the TFCPS.

Applicable ACA provisions are summarized below in the section "Community-Based Prevention Programs."

Prevention in Private Health Insurance

Sec. 1001. Regarding Coverage of Preventive Services

Among other things, this section creates a new **PHSA Sec. 2713** requiring a group health plan or a health insurance issuer in the group or individual health insurance market, for plan years beginning six months after the date of enactment of ACA, to cover the following preventive services, without cost-sharing requirements: (1) items or services recommended (i.e., with a grade of A or B) by the USPSTF; (2) immunizations recommended by the ACIP; (3) for infants,

[76] ACA Sec. 4002; 42 U.S.C. § 300u-11.

[77] CRS Report R41737, *Public Health Service (PHS) Agencies: Overview and Funding, FY2010-FY2012*, coordinated by C. Stephen Redhead and Pamela W. Smith.

[78] For example, see the program activities table for Chronic Disease Prevention, Health Promotion, and Genomics in CDC, *FY2011 Justification of Estimates for Congressional Committees*, pp. 117-118, http://www.cdc.gov/fmo/topic/Budget%20Information/index.html.

[79] Task Force on Community Preventive Services, http://www.thecommunityguide.org/index.html.

children and adolescents, preventive care and screenings provided for in comprehensive guidelines supported by HRSA; and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA. A plan or issuer may either cover or decline to cover additional services not recommended by the USPSTF. For the purposes of this section, the current USPSTF recommendations regarding breast cancer screening, mammography, and prevention are considered the most current other than those issued in or around November 2009.[80] The Secretary is permitted to develop guidelines to allow a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance design.[81]

Sec. 1302. Essential Health Benefits Requirements

This section defines the elements of an "essential health benefits package," those benefits that must be provided by plans offered by qualified health plans that participate in insurance exchanges.[82] Plans must cover, among other required benefits, preventive and wellness services, which are not defined in the law. Plans may not apply the deductible to any preventive services specified in PHSA Sec. 2713, as established in Sec. 1001 of ACA (above). The Secretary is required to determine the specific elements of such coverage, which must be provided for plan years beginning on or after January 1, 2014.

Prevention Under Medicare

In addition to the provisions summarized below, see the following sections later in this report, which also address certain aspects of Medicare coverage and prevention: "Sec. 4202. Community Wellness Pilot; Medicare Wellness Evaluation"; and "Sec. 4204. Immunizations."

Sec. 4103. Medicare Annual Visit and Personalized Prevention Plan

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

All beneficiaries enrolled in Part B are eligible for personalized prevention plan services once every year, without any cost-sharing. During the first year of enrollment, beneficiaries may receive only the initial preventive physical examination (IPPE). Beneficiaries may receive

[80] See discussion in the earlier section, "Coverage of Clinical Preventive Services."

[81] Value-based insurance design refers to coverage that encourages the use of services that have clinical benefits exceeding the costs, while discouraging the use of services when the expected clinical benefits do not justify the costs. See, for example, statement of Peter R. Orszag, "Health Care and the Budget: Issues and Challenges for Reform," before the Committee on the Budget, United States Senate, June 21, 2007.

[82] Note that under PHSA Sec. 2707, coverage provided by health insurance issuers in the individual or small group market must include coverage of the essential health benefits package as described in section 1302(b) of ACA. See also CRS Report R42663, *Health Insurance Exchanges Under the Patient Protection and Affordable Care Act (ACA)*, by Bernadette Fernandez and Annie L. Mach.

personalized prevention plan services each year thereafter provided that they have not received either an IPPE or personalized prevention plan services within the preceding 12 months. The Secretary is required to develop appropriate guidance, and to conduct outreach and related activities, with respect to personalized prevention plan services and health risk assessments.

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

This section, as amended by ACA Sec. 10406, amends **SSA Sec. 1861** to define preventive services covered by Medicare as a specified list of currently covered services, including colorectal cancer screening services even if diagnostic or treatment services are furnished in connection with the screening. The list also includes the IPPE, as well as the personalized prevention plan services that are covered pursuant to ACA Sec. 4103. Coverage remains subject to all criteria that previously applied to each covered preventive service.

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

Amendments made by this section became effective on January 1, 2011.

Sec. 4105. Evidence-Based Coverage of Medicare Preventive Services

This section authorizes the Secretary to modify the coverage of any currently covered preventive service (including services included in the IPPE, but not the IPPE itself), to the extent that the modification is consistent with USPSTF recommendations. The section also allows the Secretary to withhold payment for any covered preventive service graded D (i.e., not recommended) by the USPSTF. The enhanced authorities do not apply to services furnished for the purposes of diagnosis or treatment (rather than as preventive services furnished to asymptomatic patients). The provision states that these authorities were effective January 1, 2010. For practical purposes, these provisions were effective upon enactment.

Sec. 10501(i)(2). Preventive Services Furnished at FQHCs

This section amends **SSA Sec. 1861(aa)(3)(A)** to provide that FQHCs may receive reimbursement for Medicare covered preventive services, as defined in ACA Sec. 4104, furnished on or after January 1, 2011.

Prevention Under Medicaid[83]

Sec. 4106. Medicaid Preventive Services for Adults

This section amends **SSA Sec. 1905(a)(13)** to, among other things, expand the current Medicaid state option to provide other diagnostic, screening, preventive, and rehabilitation services to include (1) any clinical preventive services recommended (i.e., with a grade of A or B) by the USPSTF; and (2) immunizations recommended for adults by the ACIP, and the cost of their administration. Effective in 2013, states that elect to cover these additional services and prohibit cost-sharing for them receive an increased federal medical assistance percentage (FMAP), which varies depending on whether the beneficiary is "newly eligible."[84] The law makes the regular FMAP (which generally ranges between 50% and 76% in any given fiscal year, depending on the state) explicitly available for adult preventive services and immunizations.

For newly eligible individuals who receive adult preventive services (including immunizations) for which cost-sharing is prohibited, states receive a one percentage point increase in their FMAP, in addition to the increased FMAP applicable to services provided to newly eligible mandatory individuals.[85] For most formerly eligible individuals who receive adult preventive services (including immunizations) for which cost-sharing is prohibited, states receive the regular FMAP plus an additional one percentage point.[86]

Sec. 4107. Medicaid Tobacco Cessation Services for Pregnant Women

This section requires states, effective October 1, 2010, to provide Medicaid coverage to pregnant women for counseling and drug therapy for tobacco cessation. Such services include diagnostic, therapeutic, and counseling services, prescription and non-prescription tobacco cessation products approved by the FDA, and other services that the Secretary recognizes to be effective. These services exclude coverage for drugs or biologics that are not otherwise covered under Medicaid. Cost-sharing for these services is prohibited, as is true for other pregnancy-related services under Medicaid. Beginning January 1, 2013, states receive a one percentage point increase in their regular FMAP for these smoking cessation services for pregnant women if they elect to cover the new optional adult preventive care benefit (described above, ACA Sec. 4106).[87]

States may continue to exclude coverage of smoking cessation services for Medicaid beneficiaries other than pregnant women. However, beginning on January 1, 2014, ACA requires state Medicaid programs that offer prescription drug coverage to cover smoking cessation drugs (including FDA-approved over-the-counter products) for most beneficiaries.[88]

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[83] For more information about these and other Medicaid provisions in ACA, see CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al.

[84] The definition of "newly eligible" is discussed in CRS Report RL32950, *Medicaid's Federal Medical Assistance Percentage (FMAP), FY2013*, by Alison Mitchell and Evelyne P. Baumrucker.

[85] Ibid.

[86] The CBO and the CMS Actuary projected a net cost to the Medicaid program for the state option to cover adult preventive services. See supra note 63.

[87] The CBO and CMS Actuary projected a net savings for the provision that provides coverage of tobacco cessation services for pregnant women. See supra note 63.

[88] ACA Sec. 2502.

Sec. 4108. Incentives for Chronic Disease Prevention Under Medicaid

This section requires the Secretary to award grants to states to provide incentives for Medicaid beneficiaries to participate in healthy lifestyle programs. Such programs must be comprehensive and targeted to the needs of Medicaid beneficiaries; must address criteria developed by the Secretary according to evidence-based guidelines from the USPSTF, TFCPS, and the National Registry of Evidence-based Programs and Practices;[89] and must have demonstrated effectiveness for managing cholesterol and/or blood pressure, losing weight, quitting smoking, and/or preventing or managing diabetes. This section appropriates $100 million for the program for the five-year period beginning on January 1, 2011. The Secretary may waive specified administrative requirements, and must ensure that participating states make the program widely available. Incentives received by a beneficiary cannot be taken into account for the purpose of determining eligibility for, or the amount of, benefits under any federally funded program.

Wellness Programs

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

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

Also, the new PHSA Sec. 2717, as established by Sec. 1001 and amended by Sec. 10101(e) of ACA, contains provisions relating to gun rights. Among them, a wellness or health promotion activity (as referenced above) cannot require disclosure or collection of any information relating to the presence or storage of a lawfully possessed firearm or ammunition in the residence or on the property of an individual; or to the lawful use, possession, or storage of a firearm or ammunition by an individual.[90]

Sec. 1201. Regarding Prohibiting Discrimination Based on Health Status

New **PHSA Sec. 2705**, created by ACA Sec. 1201, amends HIPAA's nondiscrimination requirements. Among other things, this new section largely codifies an amended version of the HIPAA wellness program regulations. Wellness programs that do not require an individual to

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

[90] ACA neither requires nor prohibits physicians asking their patients about gun ownership. See CRS Legal Sidebar, *Physicians' Freedom to Ask Patients About Gun Ownership*, posted Dec. 18, 2012, by Kathleen Swendiman.

satisfy a standard related to a health factor as a condition for obtaining a reward (or that do not offer a reward) do not violate HIPAA, so long as participation in the programs is made available to all similarly situated individuals. Wellness programs that impose conditions for obtaining a reward, based on an individual meeting a certain standard relating to a health factor, must meet additional requirements. Among them, the reward must be capped at 30% of the cost of the employee-only coverage under the plan (instead of 20% under regulations issued prior to ACA), but the Secretaries of HHS, Labor, and the Treasury may increase the reward up to 50%. The HHS Secretary, in consultation with the Secretaries of the Treasury and Labor, must establish a 10-state pilot program in which participating states are required to apply the wellness program provisions to health insurers in the individual market.

Also, although ACA Sec. 1201 only modifies the PHSA, ACA Sec. 1562, as amended by Sec. 10107, also makes these provisions applicable to group health plans and health insurance issuers regulated under ERISA and the IRC.

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

This section, as amended by Sec. 10404, adds a new **Part U** in PHSA Title III, "Employer-Based Wellness Program," including several new sections. A new **PHSA Sec. 399MM** requires the CDC Director to provide employers with technical assistance and other resources to evaluate workplace wellness programs. The Director also is required to build evaluation capacity among workplace staff and to provide resources, technical assistance, and consultation. A new **PHSA Sec. 399MM-1** requires the Director to conduct a national survey of employer-based health policies and programs, and to report to Congress with findings and recommendations. In addition, a new **PHSA Sec. 399MM-2** requires the Secretary to evaluate all programs funded through the CDC before conducting such an evaluation of privately funded programs, unless an entity with a privately funded wellness program requests such an evaluation. Finally, a new **PHSA Sec. 399MM-3** prohibits the use of any recommendations, data, or assessments carried out under this Part to mandate requirements for workplace wellness programs.

Sec. 4402. Effectiveness of Federal Health and Wellness Initiatives

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

Sec. 10408. Workplace Wellness Program Grants

This section requires the Secretary to award grants to eligible employers to provide employees with access to comprehensive workplace wellness programs. Eligible employers employ fewer than 100 employees who work 25 or more hours per week, and do not provide a wellness program as of the date of enactment. The Secretary must develop program criteria consistent with evidence-based research and best practices, considering the Guide to Clinical Preventive

Services,[91] the Guide to Community Preventive Services,[92] and the National Registry for Effective Programs.[93] Programs must be made available to all employees and must include specified components, including education, efforts to encourage participation, initiatives to change unhealthy behaviors, and supportive work environments. There are authorized to be appropriated $200 million in total, to be available until expended, for FY2011 through FY2015.

Community-Based Prevention Programs

Secs. 3509 and 3511. Offices on Women's Health

ACA creates 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 is required to establish a National Women's Health Information Center and an HHS Coordinating Committee on Women's Health. The Secretary may provide funding and make interagency agreements as necessary to carry out these duties, and must conduct evaluations of such activities and provide periodic reports to Congress. There are authorized to be appropriated SSAN for FY2010 through FY2014. The section transfers to this new office all functions of the existing Office on Women's Health of the Public Health Service.

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

This section does not alter existing regulatory authority; terminate, reorganize, or transfer authority away from women's health offices in existence as of enactment, unless approved by Congress; or change existing administrative activities at HHS regarding women's health.

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

This section, as amended by Sec. 10401, requires the President to establish a National Prevention, Health Promotion and Public Health Council, composed of secretaries, chairmen, and directors of federal departments, boards and agencies (as specified), and to appoint the U.S. Surgeon General as chairperson. The Council is required to provide federal coordination and leadership with respect to prevention, wellness, and health promotion practices; to develop a national prevention, health promotion, and public health strategy; and to report annually to the President and Congress on activities under the strategy and progress toward identified goals, among other specified activities. The President also must establish an Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, composed of 25 nonfederal members, to advise the Council and report to the Surgeon General on lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion.

[91] This guide is published by the U.S. Preventive Services Task Force (USPSTF).

[92] This guide is published by the Task Force on Community Preventive Services (TFCPS).

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

Sec. 4002. Prevention and Public Health Fund

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

Sec. 4003. Clinical and Community Preventive Services Task Forces

Subsection 4003(a) reauthorizes and extends the authority for the U.S. Preventive Services Task Force (USPSTF). It strikes and replaces **PHSA Sec. 915(a)**, the previous authority for the USPSTF, with language requiring the AHRQ Director to convene and administer a Preventive Services Task Force, composed of individuals with appropriate expertise. This task force is required to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services in order to develop recommendations for the health care community, and to update previous clinical preventive recommendations, for publication in the *Guide to Clinical Preventive Services*. The task force has specified duties, including development of topic areas for review, review and revision of existing recommendations at least once every five years, and improved integration with federal government health objectives and related targets for health improvement, among others. All members of the task force convened under this subsection, and any recommendations made by such members, are to be independent and, to the extent practicable, not subject to political pressure. There are authorized to be appropriated SSAN for each fiscal year to carry out task force activities.

Subsection 4003(b) provides explicit authority for the existing Task Force on Community Preventive Services (TFCPS). It creates a new **PHSA Sec. 399U** requiring the CDC Director to convene and administer a Community Preventive Services Task Force ("Community Task Force"), composed of individuals with appropriate expertise, to review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations for publication in the *Guide to Community Preventive Services*. The Community Task Force has specified duties similar to those of the Preventive Services Task Force above, except applied to policies, programs, processes, or activities designed to affect or otherwise affecting health at the population level. There are authorized to be appropriated SSAN for each fiscal year to carry out these activities.

Each task force must coordinate its activities with the other and with the ACIP. In addition, neither task force is subject to requirements of the Federal Advisory Committee Act (FACA).[94]

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

Sec. 4004. Education and Outreach Campaign Regarding Preventive Benefits

This section requires the Secretary to carry out seven communications activities regarding health promotion and disease prevention, generally oriented toward common and serious chronic health problems, including poor nutrition, tobacco use, and obesity. First, the Secretary, in consultation with the IOM, must plan and implement a national public-private partnership for a prevention and health promotion outreach and education campaign. Second, through the CDC Director, the Secretary must develop and implement a science-based media campaign, according to several specified conditions. Third, in consultation with private-sector experts, the Secretary must develop a website containing information for health providers and consumers regarding specified chronic diseases and conditions. Fourth, through the CDC Director, the Secretary must develop a program to disseminate information about health promotion to health care providers who participate in federal health care programs. Fifth, through the CDC Director, the Secretary must develop a Web-based tool that individuals can use to develop personalized prevention plans. Sixth, the Secretary must establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities. Finally, the Secretary must provide guidance and relevant information to states and health care providers regarding preventive and obesity-related services that are available to Medicaid enrollees, including obesity screening and counseling for children and adults. In addition, each state must design a public awareness campaign to educate Medicaid enrollees regarding the availability and coverage of such services.

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

Sec. 4102. Oral Health Activities

This section creates a new **PHSA Title III, Part T**, and "Oral Healthcare Prevention Activities." It includes a new **Sec. 399LL** that requires the Secretary, through the CDC, to establish a five-year national public education campaign on oral health, including prevention of oral diseases such as dental carries, periodontal disease, and oral cancer. In addition, a new **PHSA Sec. 399LL-1** requires the Secretary, through the CDC, to award grants to demonstrate the effectiveness of research-based dental caries disease management activities. A new **PHSA Sec. 399LL-2** authorizes the appropriation of SSAN to carry out this new PHSA Part. Additionally, the section amends **PHSA Sec. 317M** to mandate a school-based dental sealant program that was previously discretionary, and to require the Secretary to award program grants to each of the 50 states and territories, and to Indians, Indian tribes, tribal organizations, and urban Indian organizations.

The section also adds a new **PHSA subsection 317M(d)** (redesignating existing subsections), requiring the Secretary, through the CDC, to enter into cooperative agreements with states, territories, and tribal entities to establish oral health leadership and programs to improve oral health. There are authorized to be appropriated SSAN for FY2010 through FY2014 for this activity. Finally, the section requires the Secretary to update, improve, and implement oral health components in several specified national health surveys and surveillance systems, including the National Oral Health Surveillance System (NOHSS), administered by CDC. For NOHSS, there are authorized to be appropriated SSAN for each of FY2010 through FY2014 to increase participation from the current 16 states to all 50 states, the territories, and the District of Columbia. Also, the Secretary is required to ensure that NOHSS measures early childhood caries.

Sec. 4201. Community Transformation Grants

This section, as amended by ACA Sec. 10403, requires the Secretary, through the CDC Director, to award competitive grants for the implementation, evaluation, and dissemination of evidence-based community preventive health activities, in order to reduce chronic disease rates, address health disparities, and develop a stronger evidence base of effective prevention programming. Eligible entities are state or local government agency, a national network of community-based organizations, a state or local non-profit organization, or an Indian tribe. Grantees are required to develop community transformation plans that include the policy, environmental, programmatic, and infrastructure changes needed to promote healthy living and reduce health disparities; and to conduct health promotion activities and evaluations and disseminate findings. The CDC Director is required to provide appropriate training and technical assistance. There are authorized to be appropriated SSAN for FY2010 through FY2014 to carry out this program.

Sec. 4202. Community Wellness Pilot; Medicare Wellness Evaluation

Subsection 4202(a) requires the Secretary, through the CDC, to award grants to state or local health departments or Indian tribes for pilot programs to provide community prevention interventions, screenings, and clinical referrals for individuals between 55 and 64 years of age. Grantees are to use funds to deliver interventions to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population; to identify risk factors for cardiovascular disease, stroke, and diabetes; and to ensure that individuals with these risk factors receive follow-up services to reduce such risk. Grantees must refer insured individuals with risk factors to participating providers, and must work with community partners to assist uninsured individuals in finding public coverage options or other sources of care. The Secretary must conduct annual program evaluations by examining changes in the prevalence of uncontrolled chronic disease risk factors among new Medicare enrollees (or individuals nearing enrollment) who reside in states or localities receiving grants under this section as compared with national and historical data. There are authorized to be appropriated SSAN for FY2010 through FY2014 to carry out this subsection.

Subsection 4202(b) requires the Secretary to conduct an evaluation of community-based prevention and wellness programs, and, based on findings, develop a plan to promote healthy lifestyles and chronic disease self-management among Medicare beneficiaries. To fund the evaluation, the Secretary is required to transfer to CMS $50 million in total from the Medicare Part A and Part B trust funds, in whatever proportion the Secretary determines.

Sec. 4203. Wellness for Individuals with Disabilities

This section adds a new **Sec. 510 of the Rehabilitation Act** requiring the Architectural and Transportation Barriers Compliance Board, in consultation with FDA, to issue regulatory standards for minimal technical criteria for medical diagnostic equipment (as specified) used in medical settings.[95] The standards must ensure that individuals with disabilities can use, enter, and exit such equipment independently, to the maximum extent possible. The board is required periodically to review the standards and amend them as necessary.

[95] 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. 4204. Immunizations

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

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

Finally, the section requires a GAO study of the impact of vaccine coverage under Medicare Part D on access to those vaccines by beneficiaries who are 65 years of age or older. It appropriates $1 million for FY2010 for this study. (The GAO study is listed in the text box at the beginning of this section of the report.)

Nothing in the section or any other provision of ACA is to be construed to decrease children's access to immunizations.

Sec. 4206. Demonstration Project Concerning Individualized Wellness Plan

This section creates a new **PHSA subsection 330(s)**, requiring the Secretary to establish a pilot program in not more than 10 community health centers (CHCs) to test the impact of providing at-risk individuals who use the centers with individualized wellness plans, designed to reduce risk factors for preventable conditions as identified by a comprehensive assessment. A wellness plan could include one or more of the following: (1) nutritional counseling; (2) a physical activity plan; (3) alcohol and smoking cessation counseling and services; (4) stress management; (5) dietary supplements that have health claims approved by the Secretary; and (6) compliance assistance provided by a CHC employee. Risk factors must include weight, tobacco and alcohol use, exercise rates, nutritional status, and blood pressure. Wellness plans must make comparisons between the individuals involved and a control group of individuals with respect to these risk factors. There are authorized to be appropriated SSAN to carry out these activities.

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

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

Sec. 4304. Epidemiology and Laboratory Capacity Grants

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

Sec. 4306. CHIPRA Childhood Obesity Demonstration Project

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA; P.L. 111-3) contains several quality of care provisions, including one requiring the Secretary to conduct a demonstration project to develop a model for reducing childhood obesity. CHIPRA authorized the appropriation of $25 million for the period FY2009 through FY2013 for this demonstration. This ACA section amends **SSA Sec. 1139A(e)**, replacing the authorization of appropriations with a total appropriation of $25 million for the period of FY2010 through FY2014.

Sec. 10334. Offices of Minority Health

This section amends **PHSA Sec. 1707**, elevating the existing Office of Minority Health ("the Office") in the Office of Public Health and Science at HHS by placing it within the Office of the Secretary. The Office is to be headed by a Deputy Assistant Director for Minority Health (DAD) who reports directly to the Secretary. The Secretary, through the DAD, is required to award grants and contracts, and to enter into agreements with certain types of entities to assure improved health status of racial and ethnic minorities, and to develop measures to evaluate the effectiveness of activities aimed at reducing health disparities and supporting the local community, as specified. The Secretary must report to Congress biennially regarding the program. A similar requirement is placed on HHS agency heads regarding their respective Offices of Minority Health, which must be established as described below. The section authorizes the appropriation of SSAN for each of FY2011 through FY2016 for the Office.

The section also adds a new **PHSA Sec. 1707A**, requiring the heads of CDC, HRSA, SAMHSA, AHRQ, FDA, and CMS to establish offices of minority health within the respective agencies. Each office's director is appointed by and reports directly to the agency head. The Secretary is required to designate as specified, for carrying out the activities of the section, an appropriate amount of funds appropriated for each agency for a fiscal year.

Finally, the section amends **PHSA Title IV**, redesignating the NIH National Center on Minority Health and Health Disparities as an Institute. It expands the Institute Director's authority to make research endowments to include those made to certain centers of excellence for research education and training. It also changes eligibility requirements for centers to receive certain endowments, making the calculation based upon the national median of endowment funds. The section requires the Institute Director, as the primary federal official responsible for coordinating

all NIH research and activities on minority health and health disparities, to plan, coordinate, review and evaluate research and other activities conducted or supported by NIH.

Sec. 10407. Better Diabetes Care

This section requires the Secretary, in collaboration with CDC, to prepare and publish a biennial national diabetes report card, and, to the extent possible, a report card for each state. In addition, the Secretary is required, through the CDC, 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 Secretary is also required, in collaboration with IOM, to study and report on the impact of diabetes on medical practice, and the appropriateness of medical education regarding diabetes. Finally, the Secretary is allowed to promote improvements to the collection of diabetes mortality data. There are authorized to be appropriated SSAN to carry out this section.

Sec. 10411. Congenital Heart Disease Programs

This section amends Part P of Title III of the PHSA adding a new **PHSA Sec. 399V-2**. This new section authorizes the Secretary, through the CDC, to enhance and expand infrastructure to track the epidemiology of congenital heart disease; to organize such information into a nationally representative surveillance system; or to award a grant to one eligible entity to undertake these activities. This surveillance system must be made available to the public and must comply with the HIPAA Privacy Rule.[96]

This section also amends Subpart 2 of Part C of Title IV of the PHSA by adding at the end a new **PHSA Sec. 425**. This new section authorizes the Director of the NIH National Heart, Lung, and Blood Institute (the Director) to expand, intensify and coordinate research with respect to congenital heart disease. The Director must consider the application of this research to minority and medically underserved populations. There are authorized to be appropriated SSAN for each of FY2011 through FY2015 for both the surveillance system and the expanded research program.

Sec. 10412. Public Access Defibrillation Programs

This section amends and reauthorizes **PHSA Sec. 312**, which requires the Secretary to award grants for public access defibrillation programs. Specifically, ACA requires that information clearinghouses established to increase access to defibrillation in schools be administered by an organization with expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death. Also, the section authorizes the appropriation of $25 million for each of FY2003 through FY2014.

Sec. 10413. Young Women's Breast Health Awareness

This section adds a new Part V to PHSA Title III, "Programs Relating to Breast Health and Cancer," consisting of a new **PHSA Sec. 399NN**. This new section requires the Secretary, through the CDC, to conduct a national evidence-based education campaign, with several specified elements, to increase breast cancer awareness among young women between the ages of 15 and

[96] 45 CFR Part 160 and Part 164, Subparts A and E. For more information, see HHS, Office of Civil Rights, "Health Information Privacy," http://www.hhs.gov/ocr/privacy/index.html.

44. Among other things, the Secretary is required, within 60 days of enactment, to establish an advisory committee to assist in conducting the campaign. The section also requires the Secretary, through the CDC, to conduct prevention research on breast cancer in younger women. In addition, the NIH is required to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women. The section authorizes the appropriation of $9 million for each of FY2010 through FY2014 for these activities.

Sec. 10501(g). National Diabetes Prevention Program

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

Maternal and Child Health

Overview and Impact of ACA

Infant mortality, low birth weight, and complications of pregnancy and childbirth disproportionately affect low-income and minority populations. Access to health care coverage and related psychological, educational, and material support has been shown to positively influence these outcomes.

The federal government funds health care coverage and services to increase access to maternity care for low-income women, improve the quality of the care pregnant women receive, and improve pregnancy outcomes. Several federal programs support access to health care for low-income pregnant women and their families. Specifically, Medicaid coverage is the largest single source of federal support for maternal and child health care. Other major sources of maternal and child health funding are the Maternal and Child Health Services Block Grant Program and Healthy Start, both of which support state-level initiatives. In addition to health care services, these programs provide links to other support systems, including housing, nutrition, and education assistance.

Maternal and Child Health

CRS Report R42428, *The Maternal and Child Health Services Block Grant: Background and Funding*, by Amalia K. Corby-Edwards.

CRS Report RS20301, *Teenage Pregnancy Prevention: Statistics and Programs*, by Carmen Solomon-Fears.

CRS Report RS20873, *Reducing Teen Pregnancy: Adolescent Family Life and Abstinence Education Programs*, by Carmen Solomon-Fears.

As noted elsewhere in this report, the ACA expands eligibility and coverage requirements for Medicaid and increases funding for community health centers, which are both important providers of maternal and child health care. The ACA also promotes other policies that may improve access to prenatal care for low-income women and that are associated with improved outcomes for mothers and infants, such as home visiting and school-based support for pregnant and parenting teens and women. Additionally, the ACA funds programs that encourage breastfeeding for those who are able, and promotes screening and treatment of post-partum depression.

The ACA appropriates $1.5 billion over five years (FY2010-FY2014) to support evidence-based early childhood home visiting programs. Home visitation is used to deliver support and services to families or individuals in their homes. Early childhood home visitation programs typically seek to improve maternal and child health; early childhood social, emotional, and cognitive development; and family/parent functioning. Depending on the particular model of early home visitation being used, the visitors may be specially trained nurses, other professionals, or paraprofessionals. Participation of families is voluntary. Early childhood home visitation programs are in operation in all 50 states and the District of Columbia. In addition to private and state and local public funds provided for early childhood home visitation, a number of federal programs have been used to support early childhood home visiting programs. Sources include, among others, Medicaid, the Temporary Assistance for Needy Families (TANF) block grant, Community-Based Grants to Prevent Child Abuse and Neglect, the Maternal and Child Health (MCH) Services Block Grant, Healthy Start, and Early Head Start. Prior to the enactment of the ACA there was no dedicated federal support for early childhood home visitation and the Obama Administration, as part of its "Zero to Five Initiative," (discussed in its FY2010 budget request), sought mandatory federal funding for this purpose.[97]

The ACA also appropriates $250 million over 10 years ($25 million for each of FY2010 through FY2019) to establish a new competitive grant program to enable states to provide services for pregnant and parenting teens and women. With regard to postpartum depression, the ACA authorizes funding for support, education, and research, and requires HHS to conduct a study on the benefits of screening for that condition. The ACA requires employers to provide certain nursing mothers of infants both time and a place to express breast milk while at work.

Maternal and Early Childhood Home Visitation

Sec. 2951. Maternal, Infant, and Early Childhood Home Visiting Programs

This section amends Title V to add a new **SSA Sec. 511**, *Maternal, Infant, and Early Childhood Home Visiting Programs*. This section requires states to conduct a unique statewide needs assessment as a condition of receiving their FY2011 MCH Services Block Grant funds. This section also appropriates $1.5 billion over five years (FY2010-FY2014) to support evidence-based early childhood home visiting programs.

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

Support for Pregnant and Parenting Teens and Women

Secs. 10211-10214. Pregnancy Assistance Fund

These sections create and fund a new competitive grant program administered by the HHS Secretary to help pregnant and parenting teens and women. Sec. 10211 defines terms associated

[97] For more information, see CRS Report R40705, *Home Visitation for Families with Young Children*, by Emilie Stoltzfus and Karen E. Lynch.

with the new pregnancy assistance fund. Sec. 10212 creates a new Pregnancy Assistance Fund that requires the HHS Secretary (in collaboration and coordination with the Secretary of Education) to establish a competitive grant program to states to help pregnant and parenting teens and women. Sec. 10213 allows states to make pregnancy assistance grant funds available to (1) institutions of higher education, (2) high schools and community service centers, (3) a state's attorney general, and/or (4) to increase public awareness and education.

Sec. 10214 authorizes and appropriates $25 million annually for each of the 10 fiscal years FY2010 through FY2019 for the new pregnancy assistance fund.

Postpartum Depression

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

This section of the ACA encourages the Secretary to expand and intensify specified types of research—including epidemiology, improved screening and diagnosis, clinical research, and public education—to expand understanding of the causes and treatments for postpartum depression and related conditions. Further, this section creates a new **SSA Sec. 512** that requires the HHS Secretary to study the benefits of screening for postpartum conditions (including postpartum depression and postpartum psychosis) and, within two years of enactment (i.e., no later than March 23, 2012), to submit a report to Congress on the results.

In addition, under the new **SSA Sec. 512**, *Services to Individuals with a Postpartum Condition and their Families*, the HHS Secretary is authorized to award grants to eligible entities to establish, operate and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with, or at risk of, postpartum depression (including postpartum psychosis) and their families. The law authorizes funding of $3 million for these grants for FY2010, and such sums as may be necessary for each of FY2011 and FY2012. The section stipulates that the HHS Secretary may, to the extent practicable and appropriate, integrate this program with other grant programs administered by HHS, including grants related to health centers for medically underserved populations (authorized under Sec. 330 of the PHSA). Eligible grantees include public or nonprofit private entities, state or local government public-private partnerships, recipients of Healthy Start grants, public or nonprofit private hospitals, community-based organizations, hospices, ambulatory care facilities, community health centers, migrant health centers, public housing, primary care centers, and homeless health centers.

Finally, ACA Sec. 2952 states that it is the sense of Congress that the Director of the National Institute of Mental Health (NIMH) may conduct a nationally representative longitudinal study (during the period FY2010-FY2019) on the relative mental health consequences for women of resolving a pregnancy, intended and unintended, in various ways (e.g., carrying the pregnancy to term and parenting the child, carrying the baby to term and placing the child for adoption, miscarriage, and abortion). Subject to the completion of such a study, beginning within five years after enactment (i.e., March 23, 2015), and periodically thereafter for the duration of the study, the NIMH Director may submit to Congress reports on the study's findings.

Break Time for Nursing Mothers to Express Breast Milk

Sec. 4207. Reasonable Break Time for Nursing Mothers

This section amends **Sec. 7 of the Fair Labor Standards Act (FLSA)**,[98] to require employers to provide a reasonable break time for an employee to express breast milk for her nursing child (for one year after the child's birth). The break time must be made available each time such an employee needs to express milk. Further the employer must provide a space for the employee to express milk that is not a bathroom, is shielded from view, and is free from intrusion from coworkers and the public. The section stipulates that an employer is not required to compensate an employee for this break time. Further, because it amends the part of FLSA related to maximum work hours, this section's requirement does not apply to employees who are exempt from federal overtime pay provisions of that law (e.g., executive, administrative, and professional employees). In addition, the ACA explicitly states that employers of fewer than 50 employees are not subject to these requirements if they would impose an undue hardship by causing the employer significant difficulty or expense when considered in relation to the size, financial resources, nature, or structure of the employer's business. Finally, these provisions do not preempt any state law that provides greater protections to employees.

Teen Pregnancy Prevention and Adoption Support

Overview and Impact of PPACA

Prior to enactment of the ACA, several laws addressed the subject of teen pregnancy prevention. PHSA Title XX (Adolescent Family Life (AFL) Demonstration Projects) authorizes a number of voluntary teen pregnancy prevention, counseling, and related programs. PHSA Title X (Population Research and Voluntary Family Planning Programs) authorizes grants for comprehensive voluntary family planning services, education, and research, including such activities for adolescents. PHSA Sections 318 and 318A authorize grants for technical assistance and voluntary services (including screening, treatment, counseling, and education) to address sexually transmitted diseases in women (these provisions do not explicitly address adolescents).

P.L. 111-117, the Consolidated Appropriations for FY2010, included a new discretionary Teen Pregnancy Prevention (TPP) program, identical to one proposed in the President's FY2010 budget, that provides grants and contracts, on a competitive basis, to public and private entities to fund "medically accurate and age appropriate" programs that reduce teen pregnancy. The TPP program is administered by the new Office of Adolescent Health within HHS. P.L. 111-117 also provided a separate appropriation (within the Public Health Service Act program evaluation funding) to carry out evaluations of teenage pregnancy prevention approaches.[99] There are also several other federally funded programs that provide pregnancy prevention information and/or services to teens.[100]

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[98] The Fair Labor Standards Act is the primary federal statute dealing with maximum hours and minimum wages for employees.

[99] For more information on the discretionary Teen Pregnancy Prevention (TPP) program, see CRS Report R40618, *Teen Pregnancy Prevention: Background and Proposals in the 111th Congress*, by Carmen Solomon-Fears.

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

SSA Sec. 510 authorizes a separate state formula grant program to support abstinence-only education programs. Funds are awarded to states based on the proportion of low-income children in each state compared to the national total, and may only be used for teaching abstinence. To receive funding, a state must match every $4 in federal funds with $3 in state funds. Sec. 510 provided $50 million for each of the six fiscal years (FY1998-FY2003). Prior to the ACA, the program had not been reauthorized, although appropriations were extended through 2009.[101]

The ACA restores funding for the abstinence-only approach to teen pregnancy prevention. Congress had let the funding for the SSA Sec. 510 abstinence education program expire on June 30, 2009. The ACA resumes that funding, appropriating $250 million for the program at $50 million per year for five years. Concurrently, the ACA also establishes a new state formula grant program and appropriates $375 million at $75 million per year for five years (FY2010-FY2014) to enable states to operate a new Personal Responsibility Education program, which is a comprehensive approach to teen pregnancy prevention that educates adolescents on both abstinence and contraception to prevent pregnancy and sexually transmitted diseases, and also provides youth with information on several adulthood preparation subjects (i.e., healthy relationships, adolescent development, financial literacy, parent-child communication, educational and career success, and healthy life skills). The ACA also amends the adoption tax credit.

Personal Responsibility Education and Abstinence Education

Sec. 2953. Personal Responsibility Education

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

The section also specifies that each state's Personal Responsibility Education program must include at least three of the six stipulated adulthood preparation subjects, which are (1) healthy relationships, including marriage and family interactions; (2) adolescent development, including the development of healthy attitudes and values about adolescent growth and development, body image, racial and ethnic diversity, and other related subjects; (3) financial literacy; (4) parent-child communication; (5) educational and career success, including developing skills for employment preparation, job seeking, independent living, financial self-sufficiency, and workplace productivity; and (6) healthy life skills, including goal-setting, decision making, negotiation, communication and interpersonal skills, and stress management.

The Secretary is required to annually reserve $10 million (out of the $75 million annual appropriation) for grants to entities to implement innovative youth pregnancy prevention strategies and target services to high-risk, vulnerable, and culturally under-represented youth populations. An entity that is awarded a grant is required to participate in a rigorous federal evaluation of the activities funded by the grant. The Secretary is required to reserve 5% of

[101] For more information, see CRS Report RS20873, *Reducing Teen Pregnancy: Adolescent Family Life and Abstinence Education Programs*, by Carmen Solomon-Fears.

remaining funds for allotments to Indian tribes and tribal organizations and 10% of remaining funds for technical assistance and evaluation expenditures by the Secretary.

Sec. 2954. Restoration of Funding for Abstinence Education

This section amends **SSA Sec. 510** by appropriating $50 million for each of FY2010 through FY2014 for the abstinence-only education block grant program to states.

Adoption Support

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

This section amends **IRC Sec. 23b,** which had, prior to the enactment of the ACA, provided both an adoption tax credit and income tax exclusion for taxpayers with qualified expenses related to a domestic or international adoption of a child.[102] The ACA increased the qualified expense limitation for the adoption tax credit and the income exclusion for qualified employer-provided adoption assistance programs to $13,170 for tax year 2010 (a $1,000 increase over prior law) and it indexes this new amount to inflation for tax year 2011. In addition, for tax years 2010 and 2011, the ACA made the adoption tax credit refundable. Finally, the elimination of the exclusion for employer-provided adoption assistance and the changes in the adoption tax credit scheduled to go into effect with tax year 2011 were delayed by one year. Under the ACA, those changes took effect in tax year 2012 (i.e., the tax year beginning after December 31, 2011). The Joint Committee on Taxation estimated tax expenditures resulting from ACA amendments to these adoption-related tax benefits will total $1.2 billion.[103]

Quality

Overview and Impact of ACA

Prior to the ACA, numerous stakeholders, including policymakers, had engaged in a wide range of efforts to improve health care quality. These efforts generally focused on developing, improving and refining metrics for measuring the quality of care delivered in a number of settings; publicly reporting comparative information on quality performance; and aligning payment policies with performance on metrics as a mechanism to incentivize and encourage provider accountability (e.g., value-based purchasing). In addition, a number of approaches that seek to improve the delivery of health care services, and thus both quality and efficiency, had gained attention, including efforts focused on improved coordination of care; the development of new patient-centered care models, for example, medical homes; and the enhancement of patient safety. However, these efforts had not generally been guided by a single federal strategy, entity, or set of priorities or goals, nor had they benefitted from a coordinated infrastructure specifically devoted to improving health care quality.

Quality

[102] For more information see CRS Report RL33633, *Tax Benefits for Families: Adoption*, by Christine Scott.

[103] See JCX-17-10, p. 3, at http://www.jct.gov/publications.html?func=startdown&id=3672.

ACA employs a multi-faceted approach to improving the quality of health care, which relies for the most part on a collection of incremental steps that together aim to make progress toward addressing the key issues outlined above. ACA specifically leverages three broad mechanisms to improve the quality of health care:

1. Codifying a series of provisions which together comprise a national-level approach to the improvement of health care quality, quality measurement, and the use of quality data;
2. Supporting quality improvement and patient safety activities through research support, grants to implement research findings, and educational efforts; and
3. Incentivizing the development or implementation of, or facilitating, a number of health service delivery reforms (such as care coordination through medical homes or other approaches) including those that target quality improvement reforms across the spectrum of payers, including private health insurers, Medicare, and Medicaid.

CRS Report R42347, *Health Care Quality: Enhancing Provider Accountability Through Payment Incentives and Public Reporting*, by Amanda K. Sarata.

CRS Report R40749, *Measuring Health Care Quality: Measure Development, Endorsement, and Implementation*, by Amanda K. Sarata.

Agency for Healthcare Research and Quality. "National Healthcare Quality Report," 2010. http://www.ahrq.gov/qual/nhqr10/Key.htm.

National Quality Forum, "Measure Development and Endorsement Agenda." January 2011, Washington, DC, http://www.qualityforum.org/MeasureDevelopmentandEndorsementAgenda.aspx.

National Quality Forum, "Measurement Application Partnership: MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS," Final Report, February 2013. http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

RAND Health, "Technical Report: An Evaluation of the Use of Performance Measures in Health Care." Washington, DC, 2011, http://www.rand.org/content/dam/rand/pubs/technical_reports/2011/RAND_TR1148.pdf.

The Joint Commission, "Improving America's Hospitals: The Joint Commission' Annual Report on Quality and Safety," Santa Monica, CA, 2011, http://www.jointcommission.org/assets/1/6/tjc_annual_report_2011_9_13_11_.pdf.

United States Government Accountability Office. "Health Care Quality Measurement: HHS Should Address Contractor Performance and Plan for Needed Measures." January 2012, http://www.gao.gov/assets/590/587658.pdf.

Regarding the first of these mechanisms, the ACA seeks to create a coordinated strategy for quality measurement. Prior to ACA's enactment, health care quality improvement efforts were largely uncoordinated, although in some cases efforts were led by AHRQ and CMS. These efforts—spanning quality improvement activities at the delivery level, measure development, measure endorsement, measure selection and implementation, public reporting of quality data, and inter-agency coordination of health care quality activities—were often linked, but were not systematically coordinated. In addition, progress in these areas was not necessarily being assessed for comprehensiveness. ACA aimed to take steps to address these issues by including a series of five provisions focusing on the development of a national strategy, priorities, and strategic plan to improve health care quality; coordination of health care quality activity at the federal level; measure development and endorsement; public reporting of quality data; and the coordinated selection of measures for use in federal quality programs through a pre-rulemaking process.

Regarding the second mechanism, ACA includes provisions that aim to support both quality improvement and patient safety activities. Specifically, ACA includes a provision tasking an existing center at AHRQ with carrying out research on best practices in a number of areas and establishing a grant program to assist entities with implementation and adoption of the research

findings of this center. The ACA also includes patient safety related provisions that aim to enhance the education of health care providers in this area and that establish an effort to publicly report on measures for hospital acquired conditions (HACs) that are currently utilized by CMS for the adjustment of payment to hospitals based on rates of hospital-acquired infections;[104] and through provisions that aim to improve the quality and safety of care delivered to nursing home residents. For more information on these provisions, see the section "Nursing Homes and Other Long-Term Care Facilities and Providers."

Regarding the third mechanism, health care delivery reforms have often sought to improve the efficiency of the delivery of services, as well as improving the quality or value of service delivery. ACA includes a number of provisions that aim to improve the coordination of the delivery of health care across settings. Many of these provisions specifically focus on patient-centered models of care, such as medical homes, and on improving care for chronic conditions. Specifically, the ACA authorizes funding for several types of programs aimed at enhancing the coordination of care. Some programs seek to improve the delivery of health care services by supporting medical homes, medication management services, primary care extension programs, the co-location of mental and other health services, or community-based collaborative care networks. Others aim to empower patients by facilitating shared decisionmaking among patients, caregivers and providers, or modifying requirements for patient navigator services. The ACA care coordination-related provisions incentivize the improvement of the coordination of care by broadly encouraging reforms in various settings, with different patient populations, with different payer sources, and by attempting to educate and empower patients to improve coordination of their care. Specifically, ACA includes numerous provisions that expand value-based purchasing in the Medicare program;[105] that target improvements in the quality of care provided through the Medicaid program;[106] and which extend to private insurers' quality reporting requirements relating to both covered benefits and reimbursement structures that improve health outcomes and patient safety.[107] The application of health care quality requirements to private health plans governed by the PHSA, ERISA and the IRC, and not as a condition of participation in a public program, is a noteworthy departure from law prior to ACA.

The following sections provide an overview of the specific provisions related to developing and coordinating health care quality activities at the national level, quality improvement/patient safety related reforms, and health care service delivery reforms related to care coordination.[108]

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[104] Hospital-acquired infections are a type of a hospital-acquired condition.

[105] ACA, Title III, Subpart A, Part I, Secs. 3001-3008.

[106] ACA, Title II, Subtitle I, Secs. 2701-2707.

[107] The private market reforms added by ACA directly amend the PHSA, and thus apply to all health insurance issuers offering coverage in the individual and group markets, and to nonfederal government plans (ACA Sec. 1001). In addition, through conforming amendments, ACA extends the application of these reforms to all employer-sponsored group health plans regulated by ERISA and the IRC (Sec. 1563(e) and (f), respectively).

[108] For more information about value-based purchasing provisions under Medicare and new patient care models, see CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis. For more information about Medicaid quality provisions, see CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al. Finally, for more information about private health insurance reform provisions, see CRS Report R42069, *Private Health Insurance Market Reforms in the Patient Protection and Affordable Care Act (ACA)*, by Annie L. Mach and Bernadette Fernandez.

National Strategy to Improve Health Care Quality and Quality Measurement

Sec. 3011. National Strategy

Sec. 3011, as amended by ACA Sec. 10302, creates in Title III a new **PHSA Part S,** *Health Care Quality Programs*, **Subpart I**, *National Strategy for Quality Improvement in Health Care*. It includes a new **Sec. 399HH**, *National Strategy for Quality Improvement in Health Care*, which required the Secretary to establish a national strategy for healthcare quality improvement to improve the delivery of health care services, outcomes, and population health, and to identify national priorities for quality improvement by January 1, 2011. This section requires the Secretary to ensure that the national priorities would address health care provided to patients with high-cost chronic diseases; improve federal payment policy to emphasize quality and efficiency; have the greatest potential for improving health outcomes, efficiency, and patient-centeredness of care; reduce health disparities; and address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggregation techniques, among others. The national strategy must include a comprehensive strategic plan to achieve the national priorities for quality improvement and will be required to address a number of issues, including coordination among agencies within the Department and strategies to align public and private payers with regard to quality and patient safety efforts, among others. The Secretary is also required to create a health care quality website to make public the national priorities and other information the Secretary deems appropriate.

Sec. 3012. Interagency Working Group on Health Care Quality

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

Sec. 3013. Quality Measure Development

Subsection 3013(a) creates in **PHSA Title IX Part D**, *Health Care Quality Improvement*, **Subpart I**, *Quality Measure Development*. It includes a new **PHSA Sec. 931**, *Quality Measure Development,* which requires the Secretary, in consultation with AHRQ and CMS, to identify gaps where no quality measures exist or where existing measures need improvement, updating or expansion consistent with the national strategy under Sec. 399HH. In identifying these gaps, the Secretary is to consider the gaps identified by the entity with a contract under SSA Sec. 1890(a) and other stakeholders. The Secretary must make a report on any gaps identified, and the process used to identify the gaps, available to the public. The section further requires the Secretary to fund or enter into agreements with eligible entities to develop, improve, update, or expand quality measures in areas identified as gap areas. The Secretary is to give priority to the development of quality measures that allow for the assessment of health outcomes and functional status of patients; the management and coordination of health care across episodes of care and care

transitions; the meaningful use of health information technology; the safety, effectiveness, efficiency, patient-centeredness, and timeliness of care; and health disparities, among other things. An entity receiving funds under this section is required to use the funds to develop quality measures that allow, to the extent practicable, data on measures to be collected using health information technology, that are free of charge to users, and that are publicly available, among other things. The Secretary may use funds under this section to update and test quality measures endorsed by the entity with a contract under SSA Sec. 1890(a). As amended by ACA Sec. 10303(a), the section requires the Secretary to develop, and periodically update, provider-level outcome measures for hospitals and physicians, and other providers as determined appropriate. The measures must include outcome measurement for acute and chronic disease and primary and preventive care. In developing the outcome measures, the Secretary is required to seek to address risk adjustment, accountability, and sample size issues; and include the full scope of services that comprise a cycle of care.

Subsection 3013(b) amends new **SSA Sec. 1890A**, as added by ACA Sec. 3014(b), discussed below, by requiring CMS, in consultation with AHRQ, through contracts, to develop quality and efficiency measures as determined appropriate for use under the SSA. The subsection also requires the Secretary to publicly report on measures for hospital-acquired conditions (see ACA Sec. 10303(b), discussed below).

Subsection 3013(c) authorizes to be appropriated $75 million for each of FY2010 through FY2014, to remain available until expended, to carry out the provisions in this section. At least 50% of the amounts appropriated must be used for the activities authorized under subsection (b).

Sec. 3014. Quality Measurement

Subsection 3014(a), as amended by ACA Sec. 10304, amends **SSA Sec. 1890(b)** by expanding the duties of the consensus-based entity under contract with CMS pursuant to this section (currently the National Quality Forum). The entity is required to convene multi-stakeholder groups to provide input on the national priorities for health care quality improvement developed under ACA. In addition, the multi-stakeholder groups are required to provide input on the selection of quality measures for use in various specified Medicare payment systems for hospitals and other providers, as well as in other health care programs, and for use in reporting performance information to the public. The entity is required to transmit to the Secretary the input of multi-stakeholder groups no later than February 1 of each year, beginning in 2012. The subsection amends **SSA Sec. 1890(b)(5)(A)** to require the consensus-based entity to submit a report to Congress and the Secretary describing gaps in endorsed measures and areas where evidence is insufficient to support endorsement of quality measures in priority areas identified under the national strategy.

Subsection 3014(b), as amended by ACA Sec. 10304, adds a new **SSA Sec. 1890A**, *Quality and Efficiency Measurement.* This section requires the Secretary to establish a multi-step pre-rulemaking process and timeline for the adoption, dissemination, and review of measures by the Secretary. The steps include gathering multi-stakeholder input; making measures under consideration available to the public; transmission to, and consideration by the Secretary of, the input of multi-stakeholder groups; and the publication of the rationale for the use of any quality measure in the Federal Register. The subsection also requires the Secretary to establish a process for disseminating quality measures used by the Secretary and to periodically review quality measures and determine whether to maintain the use of the measure or to phase it out.

To carry out the provisions above, the Secretary must provide for the transfer of $20 million from the Medicare Part A and Part B trust funds to the CMS Program Management Account for each of FY2010 through FY2014.

Sec. 3015. Data Collection; Public Reporting

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

The section also adds a new **PHSA Sec. 399JJ**, *Public Reporting of Performance Information*, which requires the Secretary to make available to the public, through standardized websites, performance information summarizing data on quality measures. This performance information is required to include information regarding clinical conditions to the extent such information is available, and the information would, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions. The Secretary is required to consult with the entity with a contract under SSA Sec. 1890(a) and other entities as appropriate to determine the type of information that is useful to stakeholders. In addition this section requires the entity with a contract under Sec. 1890(a) to convene multi-stakeholder groups to review the design and format of each website and to transmit the views of these groups to the Secretary. There are authorized to be appropriated SSAN for FY2010 through FY2014.

Quality Improvement and Patient Safety

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

This section creates a new **Subpart II**, *Health Care Quality Improvement Programs*, and includes a new **PHSA Sec. 933**, *Health Care Delivery System Research,* to enable the Director of AHRQ to identify, develop, evaluate, and disseminate innovative strategies for quality improvement practices in the delivery of health care services that represent best practices, and to require The Center for Quality Improvement and Patient Safety of AHRQ (hereinafter referred to as the "Center"), or another relevant agency or department designated by the Director, to carry out several specified functions. The general functions of this Center include, among others (1) identifying providers that deliver consistently high-quality, efficient health care services and employ best practices that are adaptable and scalable to diverse health care settings; (2) assessing research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery; (3) finding ways to translate such information rapidly and effectively; (4) creating strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variation in the delivery of health care; and (5) building capacity at the state and community level to lead quality and safety efforts

through education, training and mentoring programs. The center is required to support research on health care delivery system improvement and the development of tools to facilitate the adoption of best practices. This section requires the Director to make the research findings of the center available to the public, ensures that research findings and results generated by the center are shared with the Office of the National Coordinator of Health Information Technology, and requires the center to coordinate its activities with the Center for Medicare and Medicaid Innovation established by ACA. The Director is required to identify a list of processes or systems on which to focus research and dissemination activities, and is required to take into account a number of factors, including the cost to federal health programs and provider assessment of such processes or systems, among others. This section authorizes to be appropriated $20 million for FY2010 through FY2014.

This section also adds a new **PHSA Sec. 934**, *Quality Improvement Technical Assistance and Implementation,* which requires the Director, through the center, to award technical assistance funding to specified eligible entities. Funds provide technical support to institutions that deliver health care so that such institutions understand, adapt, and implement the models and practices identified by the research conducted by the center. Funds also support implementation awards to eligible entities to implement these models and practices. Sec. 3511 of ACA authorizes the appropriation of SSAN to carry out the activities in this section.

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

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

Sec. 10303(b). Hospital-Acquired Conditions

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

Sec. 10303(b) amends **SSA Sec. 1890A**, as added by Sec. 3014(b), and as amended by Sec. 3013(b), to require the Secretary, to the extent practicable, to publicly report on measures for

HACs that are currently utilized by CMS for the adjustment of payment to hospitals based on rates of hospital-acquired infections.[109]

Sec. 10303(c). Clinical Practice Guidelines

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Sec. 304(b)) required the Secretary to enter into a contract with the IOM to conduct a study on the best methods used in developing clinical practice guidelines in order to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent. The IOM is required to submit to the Secretary, and the appropriate committees of jurisdiction of Congress, a report containing the results of this study and recommendations for legislation and administrative action. Finally, stakeholders with expertise in making clinical recommendations are required to participate on the panel responsible for conducting this study and preparing the report.

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

Care Coordination

Sec. 3502. Community Health Teams to Support Medical Homes

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

[109] Hospital-acquired infections are a type of a hospital-acquired condition.

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

This section adds a new **PHSA Sec. 935,** *Grants or Contracts to Implement Medication Management Services in Treatment of Chronic Diseases*, which requires the Secretary, acting through the Patient Safety Research Center established in PHSA Sec. 933 (as added by Sec. 3501 of ACA), to provide grants to support medication therapy management (MTM) services provided by licensed pharmacists. Grantees are required 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 are 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 is required to assess and evaluate specified aspects of the program and report to Congress. Sec. 3511 of ACA authorizes the appropriation of SSAN to carry out the activities in this section.

Sec. 3506. Program to Facilitate Shared Decisionmaking

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

Sec. 3510. Patient Navigator Program

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

Sec. 5405. Primary Care Extension Program

This section, as amended by Sec. 10501(f) of ACA, adds a new **PHSA Sec. 399V-1**, *Primary Care Extension Program*, requiring the Secretary to establish a Primary Care Extension Program. The program is to provide support and assistance to primary care providers (as defined) to educate providers about preventive medicine, health promotion, chronic disease management, mental health services, and evidence-based therapies in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as "Health Extension Agents"). A Health Extension Agent is any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

The Secretary is required to award competitive grants to states to establish Primary Care Extension Program State Hubs, consisting of the state health department and other specified entities. Hubs established under a grant must contract with and provide grant funds to county or local entities to serve as Primary Care Extension Agencies and organize statewide or multistate networks of such agencies to share information. Primary Care Extension Agencies established by a Hub are required to (1) assist primary care providers to implement a patient-centered medical home; (2) develop and support primary care learning communities; (3) participate in a national network of hubs and proposed how best practices can be shared; and (4) develop a plan for financial sustainability after the initial six-year period of funding under this section is completed.

The section authorizes six-year program grants for entities that submit a fully developed Hub implementation plan, and two-year planning grants for entities to develop such a plan. Recipients of program grants are to be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary, and may receive additional support if their program and sustainability plan receive a satisfactory evaluation. There are authorized to be appropriated $120 million for each of FY2011 and FY2012, and SSAN for FY2013 and FY2014.

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

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

Sec. 10333. Community-Based Collaborative Care Networks

This section adds a **new PHSA Sec. 340H**,[110] *Community-Based Collaborative Care Networks*, authorizing the Secretary to award grants to eligible entities to support community-based collaborative care networks (CCNs). An eligible CCN is a consortium of health care providers with a joint governance structure that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations. CCNs must include (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation) a safety net hospital and all FQHCs in the community. Grant funds may be used to assist low-income individuals, as described; provide case management and care management; perform health outreach; provide transportation; expand capacity; and provide direct patient care services. The Secretary is authorized to limit the percent of grant funding that may be spent on direct care services provided by HRSA grantees or to impose other requirements on such grantees deemed necessary. There is authorized to be appropriated SSAN for each of FY2011 through FY2015.

Sec. 10410. Centers of Excellence for Depression

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

[110] Note that ACA created two new PHSA Sec. 340H. This summary refers to 42 U.S.C. § 256i. The other new PHSA Sec. 340H (42 U.S.C. § 256h) is described in "Sec. 5508(a) and (c). Teaching Health Centers."

Nursing Homes and Other Long-Term Care Facilities and Providers

Overview and Impact of ACA

Federal and state governments share responsibility to ensure that nursing homes provide quality care in a safe environment for the nation's 1.5 million skilled nursing facilities (SNF) and nursing facilities (NF) residents. Prior to ACA, Congress established most quality requirements for Medicare-certified SNFs and Medicaid-certified NFs under the Omnibus Budget Reconciliation Act of 1987 (OBRA87; P.L. 100-203). OBRA87 defined standards that nursing homes must meet in order to receive Medicare and Medicaid payment (called conditions of participation). OBRA87 also contained a range of sanctions that state and federal officials could impose on facilities that failed to meet the federal standards—including civil money penalties (CMPs), payment denial for new admissions, termination from federal health programs, installation of temporary management, and directed plans of action. For example, as a condition for participation, certification, or re-certification, SSA Sec. 1124 requires Medicare and Medicaid entities to disclose full and complete information for each person with ownership or control interest.[111]

As part of the shared federal and state responsibility for enforcing SNF and NF quality requirements, CMS contracts with state survey agencies to conduct periodic inspections and investigate complaints, both of which contribute to whether or not SNFs and NFs meet federal standards. Generally, state agencies follow federal regulations for surveying facilities; however, some survey activities and policies are determined by state survey agencies, including hiring and retaining a surveyor workforce, training surveyors, reviewing deficiency citations, and managing regulatory interactions with the industry and public . State surveyors generally first propose sanctions based on deficiencies identified during inspections. CMS regional office officials will then review and implement the state surveyor recommendations.

Prior to ACA enactment, there were no provisions in law requiring use of a standardized complaint form. However, there were mechanisms to ensure nursing facilities met certain minimum patient safety and quality standards—standard surveys and complaint investigations. Every SNF or NF undergoes a standard survey at least every 15 months, and the statewide average interval for these surveys must not exceed 12 months. During a standard survey, surveyor teams assess how well SNFs and NFs meet comprehensive federal quality-of-care and fire safety requirements. In contrast, complaint investigations generally focus on specific allegations of substandard resident care or safety violations. Complaint investigations provide an opportunity for state surveyors to intervene promptly if problems arise between standard surveys. Complaints may be filed against a home by a resident, the resident's family, or a nursing home employee verbally, via a complaint hotline, or in writing, but there were not standard reporting forms that helped document the complaint for investigators or helped in collecting comparable data. Surveyors generally follow state procedures when investigating complaints, but must comply with certain federal guidelines and time frames. In resident abuse cases, such as pushing, slapping, beating, or otherwise assaulting residents by individuals to whom their care has been entrusted, state survey agencies may notify state or local law enforcement agencies that can initiate criminal investigations. States must maintain a registry of qualified nurse aides, the

[111] Individuals are considered to have ownership or control interests when directly or indirectly (1) they own 5% or more of an entity; or they hold a whole or part of any mortgage, deed of trust, note or other obligation secured by the entity or any property or assets that equal 5% of the total property; (2) they are officers or directors of the entity, if the entity is organized as a corporation; or (3) they are partners in the entity if it is organized as a partnership.

primary caregivers in nursing homes. The registry contains any findings where aides were responsible for abuse, neglect, or theft of residents' property, which constitutes a ban from further nursing home employment ban.

Overall, ACA's nursing home transparency, enforcement, and staff training provisions expand federal quality and accountability requirements for SNFs and NFs. These provisions require SNFs and NFs to disclose ownership and organizational relationships, implement ethics and compliance programs, and report direct care staff expenditures. ACA also requires the Secretary, among other activities, to develop and disseminate a standardized complaint form, refine and update Medicare's Nursing Home Compare website, and implement a national independent monitor demonstration program. In addition, GAO is required to conduct a study and report to Congress on CMS's Five-Star Quality Rating System. ACA authorizes the Secretary and states to impose CMPs on SNFs and NFs found to provide deficient care that jeopardizes residents' safety and health.

Further, ACA's nursing home transparency and accountability changes establish new requirements for SNF and NF administrators to inform residents, their representatives, the Secretary, states, and other stakeholders of planned facility closures. ACA requires the Secretary to conduct demonstration projects on best practices for culture change and use of information technology in SNFs and NFs. Moreover, ACA requires the Secretary to expand initial nurse aide training, competency, and evaluation requirements to include dementia and abuse prevention.

Sec. 6101. Disclosure of Owners and Other Parties

ACA Sec. 6101 amended SSA Sec. 1124 to require the Secretary, within two years of enactment (by March 23, 2012), to issue regulations or amend contracts mandating SNFs and NFs supply the Secretary or state agency complete information on ownership or control interests (owner, governance, management, officer, etc.) for each SNF or NF where there was least a 5% ownership interest. ACA Sec. 6101 also required facilities to disclose each facility's organizational structure as well as relationships where subcontractors have at least a 5% control interest in the facility. In implementing these requirements, the Secretary was to ensure SNF and NFs reported disclosable party and other accountability information in standard formats.

Sec. 6102. Compliance and Ethics Requirements for Nursing Facilities

Prior to ACA, Medicare and Medicaid law did not require SNFs and NFs to develop and implement compliance and ethics training programs. ACA Sec. 6102 required the Secretary, by March 23, 2012, and in collaboration with the HHS Office of Inspector General (OIG), to issue regulations specifying requirements for SNFs and NFs to follow in developing and implementing compliance and ethics programs. Within three years after date by which facilities had to comply with ethics program regulations are issued (by March 23, 2015), the Secretary is to submit a report to Congress on whether these requirements reduced deficiency citations, increased quality performance, or affected other patient quality-of-care metrics.

Sec. 6103. Nursing Home Compare Medicare Website

CMS developed the Nursing Home Compare (NH Compare) website to improve SNF and NF quality of care and to improve access to nursing home quality information for long-term care (LTC) consumers and their families. Since its launch in November 2002, CMS has enhanced the website by adding or improving quality measures and website navigation. Medicare's NH Compare website includes national data on all nursing facilities that participate in Medicare and

Medicaid. The data include facility ratings, selected results from survey and certification inspections, and staffing information on Medicare SNFs and Medicaid NFs.

Sec. 6103 requires the Secretary to enhance the information on SNFs and NFs available on the NH Compare website, and to ensure that the information is prominent, easily accessible, searchable, and readily understandable to LTC consumers.

Sec. 6104. Reporting of Expenditures

This section requires SNFs to report expenditures for wages and benefits for direct care staff on facility cost reports. The reports must be broken out into categories including registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff. Within one year of enactment (by March 23, 2011) the Secretary was required to consult with private sector accountants experienced with cost reports to assist in redesigning those reports to separately capture direct care staff wage and benefit expenditures. In addition, the Secretary was required to consult with the Medicare Payment Advisory Commission (MedPAC), the HHS OIG, the Medicaid and CHIP Payment Access Commission (MACPAC), and other experts in categorizing direct care wages and benefits into functional areas. SNFs were required to report expenditures for direct care staff on cost reports submitted two years after ACA's enactment date (by March 23, 2012). The Secretary was required to categorize the first year's expenditure data within 30 months of enactment (by September 23, 2012) and on an annual basis thereafter. The Secretary is further required to establish procedures for making expenditure reports readily available to interested parties upon request.

Sec. 6105. Standardized Complaint Form

ACA Sec. 6105 requires the Secretary to develop a standardized form to be used by SNF and NF residents and their representatives in submitting quality-of-care complaints. The new standard complaint form is not to prevent SNF and NF residents from submitting complaints in other ways, including orally. States are required to establish a complaint resolution process that includes (1) procedures to ensure accurate tracking of received complaints, including notifications to the complainant (or his/her representative) that the complaint was received; (2) procedures to determine the complaint's likely severity, and for the investigation of the complaint; and (3) deadlines for responding to the complaint and for notifying the complainant of the outcome of the investigation. Such processes are required to ensure that legal representatives or other responsible parties are not denied access to a resident or otherwise retaliated against if they complain about the facility's quality of care or safety issues. The changes in this section became effective on March 23, 2011.

Sec. 6106. Ensuring Staffing Accountability

This section amends SSA Sec. 1128I requiring the Secretary, in consultation with stakeholders, to establish specifications for SNFs and NFs to electronically report direct staffing information to the Secretary. These regularly reported staffing data are to include agency and contract staff, by staff position categories (based on payroll and other verifiable and auditable data). The reporting requirements are to include the category of work employees perform, resident census data, information on employee turnover and tenure, and the hours of care provided per resident per day. The reporting process is required to be electronic and data are to be reported in a uniform format. Facilities were required to begin submitting uniform staffing information electronically within two years of enactment (by March 23, 2012).

Sec. 6107. GAO Study and Report on Five-Star Quality Rating System

The Medicare NH Compare website includes data from the quality rating system that gives facilities a rating of between one and five stars. Nursing homes with five stars are considered to provide superior quality and nursing homes with one star are considered to provide lower quality care. NH Compare gives each nursing home an overall rating as well as separate ratings for the following three areas: health inspections, staffing, and quality measures. ACA Sec. 6107 required GAO to conduct a study and submit a report to Congress on the CMS nursing home Five-Star Quality Rating System. GAO's report was due by March 23, 2012, and was to include the following analyses: (1) how the Five-Star Quality Rating System was being implemented; (2) any problems associated with implementation of the system; and (3) how the Five-Star Quality Rating System can be improved. GAO's report also was to offer recommendations for legislative and administrative action.

Sec. 6111. Civil Money Penalties

ACA Sec. 6111 authorizes the Secretary and states to impose additional CMPs on SNFs and NFs with deficiencies and quality-of-care issues that jeopardize residents' safety and health. This section also requires the Secretary to issue regulations establishing an independent, informal dispute resolution process that produces a written record. The dispute hearing is to occur within 30 days of the penalty citation. In instances where deficiencies are cited at the level of actual harm and immediate jeopardy, the Secretary may place CMPs in an escrow account following completion of the informal dispute resolution process, or up to 90 days after the date of the CMP, whichever is earlier. Monetary amounts collected and placed in escrow are to be kept in interest bearing escrow accounts pending the resolution of appeals. The Secretary and states may reduce CMPs if deficiencies were self-reported and corrected within 10 calendar days after imposition. Reductions are to be made for self-reported deficiencies cited at the immediate jeopardy level, at the actual harm level if the harm were found to be a "pattern" or "widespread," or for deficiencies that result in a resident's death. Facilities cited for repeat deficiencies during the past year are ineligible for reductions, even if the deficiencies were self-reported.

The Secretary also is required to issue regulations that, in the case where such appeals are unsuccessful, authorize a portion of CMPs to fund activities that benefit residents. These activities include projects that strengthen and support resident and family councils, offset the costs of relocating residents to home and community-based settings or another facility, and support and protect residents in situations where a facility closes or is decertified. CMP funds used to benefit patients also may be used for facility improvement initiatives approved by the Secretary, including joint training of facility staff and surveyors; technical assistance for facilities implementing quality assurance programs; and appointment of temporary management firms. The changes in this section became effective March 23, 2011.

Sec. 6112. National Independent Monitor Demonstration Program

This section required the Secretary within one year of enactment (by March 23, 2011) to develop, test, and implement a two-year national independent monitoring demonstration program to oversee interstate and large intrastate chains of SNFs and NFs. The Secretary is required to select chains for participation in the demonstration and evaluate them for evidence of serious safety and quality-of-care deficiencies. The facilities in those chains are subject to review, oversight, and root-cause quality and deficiency analyses by an independent monitor under contract to the Secretary.

Chains that receive a report containing findings and recommendations from the independent monitor are required, within 10 days, to submit a report outlining corrective actions that will be taken. If a chain declines to implement the independent monitor's recommendations, the chain is required to submit reasons why it will not do so. After receiving the chain's response, the independent monitor is required to finalize recommendations and to submit a report to the chain and the facilities of the chain, the Secretary, and relevant state or states, as appropriate. Chains are responsible for a portion of the costs associated with appointment of independent monitors. The Secretary has authority to waive Medicare and Medicaid laws to carry out the independent monitor pilot program. Within six months of the end of the independent monitor demonstration, (by September 23, 2013) the HHS OIG will evaluate the independent monitor program to determine the feasibility of establishing a permanent program, as well as appropriate procedures and mechanisms to implement the program permanently and to submit the evaluation report to Congress and the Secretary. There are authorized to be appropriated SSAN to carry the section.

Sec. 6113. Notification of Facility Closure

This section requires the administrator of a SNF or NF that is preparing to close to provide written notification to residents, legal representatives of residents or other responsible parties, the state, the Secretary, and the LTC ombudsman program. This notification is to be made at least 60 days before closure. Facilities are required to prepare a plan for closing the facility by a specified date and submit the plan to the state where the facility is located. States are required to approve the plan and ensure the safe transfer of residents to another facility or alternative setting that the state finds appropriate in terms of quality, services and location, and takes into consideration the needs and best interests of each resident. In cases where the Secretary terminates a facility's participation, the Secretary is required to provide written notification to stakeholders by the date that the Secretary determines appropriate. Facilities are not permitted to admit new residents on or after the date on which written notification is submitted. The Secretary is to continue making payments to a facility to support residents until they are relocated, as the Secretary determines appropriate. SNF and NF administrators who fail to comply with the closure notice requirements could be subject to sanctions of up to $100,000 and exclusion from federal health program participation. The requirements for SNF and NF administrators to notify stakeholders of pending facility closures take effect one year after enactment.

Sec. 6114. Culture Change and Information Technology Demonstrations

This section requires the Secretary to conduct the following two demonstration projects for SNFs and NFs: (1) to develop best practices for facilities involved in culture change (developing patient-centric models of care); and (2) to develop SNF and NF best practices for the use of information technology to improve resident care. The demonstration projects are required to take into consideration the special needs of facility residents with cognitive impairments. The Secretary was to award one or more grants three-year duration under each demonstration project by March 23, 2011. The Secretary is required to submit a report to Congress within nine months of the completion of the demonstration projects that evaluates the projects and makes recommendations for legislation and administrative actions. There are authorized to be appropriated SSAN to carry out the projects.

Sec. 6121. Dementia and Abuse Prevention Training

This section amends SSA Secs. 1819 (Medicare) and 1919 (Medicaid) by requiring SNFs and NFs, respectively, to include dementia and abuse prevention training as part of pre-employment initial training for permanent and contract or agency staff and, if the Secretary determines

appropriate, as part of ongoing in-service nurse aide training. These new training requirements took effect on March 23, 2011.

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

This section requires the Secretary to establish a nationwide program for background checks on direct patient access employees of long-term care (LTC) facilities or providers (as defined), and to provide federal matching funds to states to conduct these activities. The Secretary is required to carry out the nationwide program under terms and conditions similar to those used for the Background Check Pilot program, authorized by Sec. 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173). From January 2005 through September 2007, CMS administered the Background Check Pilot program, in consultation with the Department of Justice (DOJ), in seven states (Alaska, Idaho, Illinois, Michigan, Nevada, New Mexico, and Wisconsin) selected to participate.

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

Comparative Effectiveness Research

Overview and Impact of ACA

ACA builds on provisions included in ARRA that expanded the federal government's role in the oversight and funding of comparative effectiveness research. ARRA provided a total of $1.1 billion for comparative effectiveness research, instructed the Secretary to contract with the IOM to produce a report with recommendations on national comparative effectiveness research priorities, and created the Federal Coordinating Council for Comparative Effectiveness Research (FCCCER), an interagency advisory group. FCCCER was required to report to the President and the Congress annually on federal comparative effectiveness research activities.[112]

Comparative Effectiveness Research

U.S. Government Accountability Office, Patient-Centered Outcomes Research Institute: Review of the Audit of Financial Statements for 2012 and 2011, 13-390, March 29, 2013, http://www.gao.gov/products/GAO-13-390R.

U.S. Government Accountability Office, Patient-Centered Outcomes Research Institute: Review of the Audit of Financial Statements for 2011 and 2010,12-663R, May 10, 2012, http://www.gao.gov/products/GAO-12-663R.

U.S. Government Accountability Office, *Agency for Healthcare Research and Quality's Process for Awarding Recovery Act Funds and Disseminating Results*, 12-332, February 29, 2012, http://www.gao.gov/products/GAO-12-332.

U.S. Government Accountability Office, *Use of Recovery Act and Patient Protection and Affordable Care Act Funds for Comparative Effectiveness Research*, 11-712m R, June 14, 2011, http://www.gao.gov/products/GAO-11-712R.

[112] For more information on ARRA's comparative effectiveness research provisions, see CRS Report R40181, *Selected*

The IOM released its report on June 30, 2009.[113] Reflecting broad stakeholder input, the report identified 100 health topics as high-priority areas for comparative effectiveness research. FCCCER also released its initial report in June 2009. The report's recommendations focused on (1) the importance of disseminating comparative effectiveness research findings to doctors and patients; (2) targeting comparative effectiveness research to the needs of priority populations such as racial and ethnic minorities, and persons with multiple chronic conditions; (3) researching high-impact health arenas such as medical and assistive devices, surgical procedures, and behavioral interventions and prevention; and (4) electronic data networks and exchange.[114]

In ACA, Congress terminates FCCCER and replaces it with a new private, non-profit corporation called the Patient-Centered Outcomes Research Institute (PCORI). PCORI is responsible for coordinating and supporting comparative clinical effectiveness research, which is broadly defined in the law to mean "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more ... health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals ... integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury."[115] ACA creates a 10-year, multi-billion dollar trust fund to support such research.

Secs. 6301 and 10602. Patient-Centered Outcomes Research

This section adds a new **SSA Title XI Part D**, *Comparative Clinical Effectiveness Research*, comprising new **SSA Secs. 1181-1183**. New **SSA Sec. *1181***,*Comparative Clinical Effectiveness Research*, authorizes the establishment of a private, nonprofit, tax-exempt (by amending IRC Sec. 501(l)) corporation called the Patient-Centered Outcomes Research Institute (the Institute). The Institute is to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of [clinical] evidence ... through research and evidence synthesis." The Institute is to identify national priorities for research, including attention to chronic conditions, gaps in evidence, quality of care, patient health and well-being, and the effect on national expenditures associated with interventions or conditions, among other concerns. The section requires the Institute to enter into contracts with federal agencies as well as with appropriate academic, private sector research, or study-conducting entities for the management of funding and conduct of research.

The Institute's 19-member board includes the directors (or their designees) of AHRQ and NIH, along with others appointed by the U.S. Comptroller General to include representation of a broad range of groups, including patients and health care consumers; physicians and providers; private payers; pharmaceutical, device, and diagnostic manufacturers; quality improvement or independent health services researchers; and government representatives. The Institute is to, as appropriate, appoint expert advisory panels to assist in identifying research priorities and establishing the research project agenda. The section directs the appointment of panels for clinical trials and rare diseases.

Health Funding in the American Recovery and Reinvestment Act of 2009, coordinated by C. Stephen Redhead.

[113] Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research*, (Washington, DC: The National Academies Press, 2009), http://www.iom.edu/Reports/2009/ ComparativeEffectivenessResearchPriorities.aspx.

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

[115] New SSA Sec. 1181(a)(2), as added by ACA Sec. 6301(a).

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

The section also includes extensive procedures regarding conflict-of-interest, data privacy, peer-review, and the public availability of information.

A new **PHSA Sec. 937**, *Dissemination and Building Capacity for Research*, requires AHRQ to broadly disseminate research findings that are published by the Institute and other government-funded comparative effectiveness research entities; create information tools; and develop a publicly available database of government-funded evidence. Dissemination materials are to identify researchers; describe research methodology, limitations, and subpopulation-specific considerations; and must not include practice guidelines, or recommendations for payment, coverage, or treatment. This section also requires training of researchers and building of data capacity in coordination with other federal health programs, and authorizes federal agencies to contract with the Institute for the conduct and support of relevant research.

New **SSA Sec. 1182***, Limitations on Certain Uses of Comparative Clinical Effectiveness Research,* limits certain uses of evidence and findings from comparative effectiveness research. The Secretary may only use the findings to make coverage determinations if the use is through an iterative and transparent process that includes public comment and considers the effect on subpopulations. The Secretary is prohibited from using these research findings in determining Medicare coverage in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill; or that would preclude or discourage an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability. Also, the Institute is prohibited from using values that discount the value of life because of an individual's disability or to use such measures in determining coverage.

New **IRC Sec. 9511,** *Patient-Centered Outcomes Research Trust Fund,* establishes a new Patient-Centered Outcomes Research Trust Fund (PCORTF) in the U.S. Treasury to fund the Institute and its activities. The fund will receive the following amounts: (1) specified annual appropriations over the period FY2010-FY2019 totaling $1.26 billion (new **IRC Sec. 9511**); (2) additional annual appropriations over the period FY2013-FY2019 equal to the net revenues from a new fee levied on health insurance policies (new **IRC Sec. 4375**) and self-insured health plans (new **IRC Sec. 4376**) through FY2019; and (3) transfers from the Medicare trust funds through FY2019 (new **SSA Sec. 1183,** *Trust Fund Transfers to Patient-Centered Outcomes Research Trust Fund*). The new health insurance fee is to equal $2 multiplied by the average number of covered lives in a policy/plan year ($1 in the case of policy/plan years ending during FY2013), updated annually by the rate of medical inflation. Similarly, the transfers from the Medicare trust funds are to equal $2 multiplied by the average number of Part A and Part B beneficiaries in a given fiscal year ($1 in FY2013), updated annually by the rate of medical inflation.

Sec. 6302. Federal Coordinating Council for Comparative Effectiveness Research

This section terminates the FCCCER upon enactment. This is in keeping with the assignment of coordinating activities to the new Patient-Centered Outcomes Research Institute.

Health Data Collection

Overview and Impact of ACA

Prior to the ACA, the federal government collected data on health disparities through a number of systems administered by various agencies within HHS,[116] but much of this effort was not coordinated. For example, since 1999, HHS-funded and sponsored surveys and data collection systems have been required to collect health disparities data in accordance with the department's Inclusion Policy.[117] The policy mandates the inclusion of information on race and ethnicity and encourages (but does not require) the collection of socioeconomic or cultural background characteristics. It specifies that OMB's standards for racial and ethnic data collection are to be used; however, the requirement for collecting race and ethnicity data may be waived under certain circumstances.[118]

Health Data Collection

Centers for Disease Control and Prevention, *Health Disparities: CDC Health Disparities and Inequalities Report–United States, 2011*, Morbidity and Mortality Weekly Report, Supplement Vol. 60, Atlanta, GA, January 14, 2011, http://www.cdc.gov/mmwr/pdf/other/su6001.pdf.

U.S. Government Accountability Office, *Key Indicators Systems: Experience of Other National and Subnational System Offer Insights for the United States*, GAO-11-396, March 31, 2011, http://www.gao.gov/assets/320/317346.pdf.

Medicare for many years has obtained race and ethnicity information about its beneficiaries from the Social Security Administration (SSA). The SSA provides CMS with copies of the SS-5 ("Application for a Social Security Card") form, which includes information about race and ethnicity. While the SS-5 information is supposed to be OMB-compliant, there are deficiencies in the accuracy and completeness of the data.[119] Section 185 of MIPPA instructed the Secretary to evaluate approaches for collecting disparities data on Medicare beneficiaries and to provide a report to Congress, within 18 months of enactment, including recommendations for reporting nationally recognized quality measures, such as Healthcare Effectiveness Data and Information Set (HEDIS) measures, on the

[116] For example, the National Center for Health Statistics, part of the CDC, collects and reports data on the health and nutrition status of the U.S. population through the National Health and Nutrition Examination Survey (NHANES).

[117] The Inclusion Policy may be found at http://aspe.hhs.gov/datacncl/inclusn.htm.

[118] The OMB standards are officially OMB Directive 15, revised in 1997, and are available at http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html. The OMB standards require a minimum of five racial categories (White, Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander). When ethnicity information is gathered, a dichotomous identification question with the choices—Hispanic or Latino, or not Hispanic or Latino—must be used. Data collection instruments may include additional categories such as Mexican-American, Chicano, Puerto Rican, Cuban, or Filipino, as long as these categories can be aggregated to the standard categories. When individuals are asked to self-identify (which is OMB's preferred method), respondents must be given the opportunity to report multiple races in response to a single question. Including "multiracial" as an option is not acceptable.

[119] See, for example, "Medicare Race and Ethnicity Data," by Marshall McBean, prepared for the National Academy of Social Insurance, 2004, available at http://www.nasi.org/sites/default/files/research/McBean.pdf.

basis of race, ethnicity, and sex. MIPPA further instructed the Secretary to implement the approaches identified in the initial report and, four years after enactment and every four years thereafter, report back to Congress with recommendations for improving the identification of health care disparities among Medicare beneficiaries based on an analysis of those efforts.

The Medicaid Statistical Information System (MSIS) is the primary source of state-reported data on Medicaid enrollees and expenditures. The MSIS required data set includes information on eligibility, including racial and ethnic data. States have the discretion to choose whether or how to collect racial and ethnic information; if they do collect this information CMS requires that it be reported in a standardized format. There is considerable variation in the quantity and quality of the data that is reported.[120]

Regarding the collection of data on key national indicators, there are a number of current efforts, some mandated in the PHSA, to collect and disseminate health statistics on the U.S. population. The National Center for Health Statistics (NCHS), part of the CDC, 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.

NCHS also has responsibility, under PHSA Sec. 306, for compiling national vital statistics from records of births, deaths, marriages, and divorces. That section also establishes the National Committee on Vital and Health Statistics (NCVHS) to assist and advise the Secretary on issues related to the collection of vital and health statistics in the United States. In addition, it directs the Secretary to ensure comparability and reliability of health statistics, requiring the Secretary to provide adequate technical assistance to assist state and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

The ACA includes three sets of provisions that aim to enhance the completeness, accuracy, and uniformity of health data. First, in the area of health disparities, the law mandates the collection and reporting of data on race, ethnicity, sex, primary language, and disability status by all federally conducted and supported health care and public health programs (e.g., Medicare, Medicaid), activities, and surveys (including surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census). It specifies that the existing Office of Management and Budget (OMB) standards must be used, at a minimum, for recording race and ethnicity, and instructs the Secretary to issue new standards for measuring the other three factors (i.e., sex, primary language, and disability status). Second, the law requires the development of a system to collect data on key national indicators, to be determined by the Secretary (notably, the nature of the data to be collected under this system is not addressed by the statutory language, with the term "health" never appearing in the provision). Finally, the ACA seeks to improve states' collection of vital statistics by educating providers about the importance of standardized birth and death certificate data, among other things. Additional background on each of these topics is provided below.

Sec. 4302. Health Disparities Data Collection and Analysis

Subsection 4302(a) creates a new **PHSA Title XXXI—Data Collection, Analysis, and Quality.** It requires the Secretary to ensure that, by no later than two years after enactment, all federally conducted or supported health care and public health programs, activities, and surveys collect and report, to the extent practicable, data on race, ethnicity, sex, primary language, and disability

[120] See, for example, "A Brief Overview of Medicaid Data Sources," Kaiser Commission, Medicaid Facts, 2004, available at http://www.kff.org/kaiserpolls/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=32735.

status. Such data must be aggregated at the smallest practicable geographic level. The collected data must be sufficient to generate statistically reliable estimates of racial, ethnic, sex, primary language, and disability status subgroups. The Secretary may require the collection of other demographic data regarding health disparities.

The subsection establishes uniform standards for the measurement and collection of health disparities data, requiring that OMB's standards must be used, at a minimum, for recording race and ethnicity. The Secretary is instructed to develop standards for the measurement of sex, primary language, and disability status. In addition, the Secretary must develop standards for collecting health disparities data, whether by self-report or from a parent or legal guardian. The Secretary is also required to ensure that federal health care programs that report quality measures include data on individuals receiving health care items and services by race, ethnicity, sex, primary language, and disability status. Finally, the Secretary is instructed to develop data management, interoperability, and security standards for the collected information on health disparities.

The subsection requires the Secretary to analyze the data collected on health disparities; provide for the public reporting and dissemination of the data and analyses; and safeguard the privacy of the information. The subsection authorizes the appropriation of SSAN for each of FY2010 through FY2014 for the above data collection, analysis, and reporting activities. However, data may not be collected unless funds are directly appropriated for such purpose.

Subsection 4302(b)(1) amends the Medicaid statute (i.e., SSA Sec. 1902) to require that any health disparities data collected under a Medicaid state plan meet all the requirements established above. The subsection also amends the CHIP statute (i.e., SSA Sec. 2108) to require states to include in their annual report health disparities data collected and reported in accordance with the same requirements.

Subsection 4302(b)(2) amends the Medicaid statute by adding the language in MIPPA Sec. 185 (discussed in the preamble above) as a new **SSA Sec. 1946**, with the following two revisions. First, all references to Medicare are replaced by referencing both Medicaid and CHIP. Second, whereas the original MIPPA language addressed the collection of data on race, ethnicity, and gender, the new provision in the Medicaid statute addresses data collection on the basis of race, ethnicity, sex, primary language, and disability status (in accordance with the subsection 4302(a) above). Thus, this subsection requires the Secretary to evaluate approaches for collecting disparities data on Medicaid and CHIP beneficiaries and report to Congress on improving the identification of health care disparities among those beneficiaries.

Sec. 5605. Key National Indicators

This section establishes the Commission on Key National Indicators ("Commission") composed of eight members appointed equally by the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives. The Commission has the following responsibilities: (1) conduct comprehensive oversight of the newly established key national indicator system; (2) make recommendations on how to improve the key national indicator system; (3) coordinate with federal government users and information providers to assure access to relevant and quality data; and (4) enter into contracts with the National Academy of Sciences ("Academy").

The Commission is required to enter into an arrangement with the Academy to review available public and private sector research on key national indicator set selection and determine how to best establish a key national indicator system. The Academy must establish the key national indicator system by either creating its own institutional capability, or partnering with an

independent, private, non-profit organization as an Institute. The Academy is required to identify and select all criterion and methodologies to establish and operate the key national indicator system. The Academy is further required to design, publish, and maintain a website for public access to key national indicators. Also, the Academy is to develop a quality assurance framework to ensure rigorous and independent processes and quality data selection, and is required to submit a report not later than 270 days after enactment, and annually thereafter, to the Commission outlining the findings and recommendations of the Academy. The U.S. Comptroller General is required to conduct a study of previous work conducted by a range of entities with respect to best practices for a key national indicator system, and is required to submit this study to the appropriate authorizing committees of Congress.

This section authorizes to be appropriated $10 million for FY2010, and $7.5 million for each of FY2011 through FY2018, with amounts appropriated to remain available until expended.

Sec. 10407(c). Vital Statistics

This subsection requires 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 (including the collection of such data for diabetes and other chronic diseases), and work with states to re-engineer their vital statistics systems. (Note: Sec. 10407 in its entirety is discussed earlier in this report under "Prevention and Wellness")

Health Information Technology

Overview and Impact of ACA

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, among others. In addition, HIPAA directed the Secretary to adopt a standard for transferring standard data elements among health plans to improve 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, and listed the codes sets that must be used in the transactions to identify specific diagnoses and clinical procedures.[121] The code sets include the International Classification of Diseases, 9th

Administrative Simplification

Center for American Progress, *Paper Cuts: Reducing Health Care Administrative Costs*, June 2012, http://www.americanprogress.org/wp-content/uploads/issues/2012/06/pdf/papercuts_final.pdf.

HHS, National Committee on Vital and Health Statistics, *Update on Health Care Administrative Transactions: Findings from June 2012 NCVHS Hearings*, September 21, 2012, http://www.ncvhs.hhs.gov/120921lt.pdf.

[121] Electronic standards were adopted for the following seven HIPAA-specified administrative and financial transactions: health care claim submission; patient eligibility inquiry and response; prior authorization and patient referral; health care claim status inquiry and response; plan enrollment and disenrollment; claim payment and remittance advice; and premium payments. Electronic standards have not yet been adopted for the following two transactions: health care claims attachments; and first report of injury.

Revision, Clinical Modification (ICD-9-CM) codes that are used for diagnoses and inpatient procedures. As required under HIPAA, the Secretary published updated standards in early 2009 to replace the existing versions. The compliance deadline for the updated standards was January 1, 2012. CMS also set a deadline of October 1, 2013, for providers to switch from using the ICD-9-CM codes to report diagnoses and clinical procedures to using the greatly expanded ICD, 10th Revision (ICD-10) code set. CMS has since extended the ICD-10 deadline by one year to October 1, 2014, in response to providers' concerns.[122]

The HIPAA standard for the payment and remittance advice transaction, which is a communication from a health plan to a provider that includes an explanation of the claim and payment for that claim, 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 at the time of ACA's enactment there was no EFT mandate in federal law for Medicare, Medicaid, or private health insurance.

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. ACA seeks to address this variability by requiring the adoption of operating rules for each HIPAA transaction for which there is an existing standard, with the goal of creating as much uniformity in the implementation and use of the transactions standards as possible.

HIPAA does not mandate that providers conduct the transactions electronically, though health plans typically 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. In September 2005, CMS proposed a standard for health care claims attachments, one of the two remaining HIPAA-specified transactions for which a standard must be adopted. A claims attachment transaction is used to request and provide additional clinical data necessary to adjudicate a claim.

HIPAA also 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 were adopted prior to ACA, while the health plan identifier was still under review at the time of the law's enactment. Congress has blocked the development of a unique individual identifier through language added to the annual Labor-HHS appropriations bill.

Sec. 1104. Administrative Simplification: Operating Rules

This ACA section[123] amends **SSA Sec. 1173** to establish a timeline for the development, adoption and implementation of a single set of operating rules for each HIPAA transaction for which there is an existing standard. The standards and associated operating rules must meet certain requirements. They have to (1) enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care; (2) be comprehensive, requiring minimal augmentation with paper; and (3) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process. Operating

[122] For more information, see http://www.cms.gov/icd10.

[123] HCERA also includes a section 1104, which addresses Medicare Disproportionate Share Hospital (DSH) payments. That provision is discussed in CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis.

rules are defined as the necessary business rules and guidelines for the electronic exchange of information that are not defined by the electronic standards themselves. In adopting the operating rules, the Secretary is required to consider the recommendations of a qualified nonprofit entity that uses a multi-stakeholder, consensus-based process for developing such rules. Also, the section adds EFT for the payment of health claims as a HIPAA transaction and requires the Secretary to adopt an EFT standard no later than January 1, 2012, to take effect by January 1, 2014.

Operating rules for eligibility and health claims status transactions had to be adopted by July 1, 2011, and were to take effect by January 1, 2013. Operating rules for claims payment/remittance and EFT had to be adopted by July 1, 2012, and are to take effect by January 1, 2014. The Secretary must adopt operating rules for the remaining HIPAA transactions (i.e., health claims, plan enrollment and disenrollment, health plan premium payments, and prior authorization and referral) by July 1, 2014, to take effect by January 1, 2016.

By January 1, 2014, the Secretary must establish a committee to review and provide recommendations for updating and improving the HIPAA standards and operating rules. By April 1, 2014, and biennially thereafter, the committee must conduct hearings to evaluate the adopted standards and operating rules, and by July 1, 2014, and biennially thereafter, the committee must submit its recommendations to the Secretary. The Secretary must adopt the recommendations through promulgation of an interim final rule within 90 days of receipt of the committee's report.

By December 31, 2013, health plans are required to file a certification statement with the Secretary that their data and information systems comply with the most current published standards and associated operating rules, for the following transactions: eligibility, health claims status, claims payment/remittance and EFT. By December 31, 2015, health plans are required to certify to the Secretary that their data and information systems comply with the most current published standards and operating rules for the remaining completed HIPAA transactions. The Secretary is permitted to designate an outside entity to verify that health plans have met the certification requirements and must conduct periodic audits of plans to ensure that they maintain compliance with the standards and operating rules.

The section requires the Secretary, no later than April 1, 2014, and annually thereafter, to assess a penalty fee against health plans that fail to meet the certification requirements. By May 1, 2014, and annually thereafter, the Secretary must provide the Treasury Secretary with a list of health plans that have been assessed a penalty fee for noncompliance, and by August 1, 2014, and annually thereafter, the Treasury Secretary must provide notice to all such plans. The deadline for health plans to pay the penalty fees is November 1, 2014, and annually thereafter. The Secretary of the Treasury, acting through the Financial Management Service, is responsible for the collection of penalty fees. Unpaid penalty fees are to be increased by an interest payment determined in a manner similar to underpayment of income taxes and considered debts owed to federal agencies, which may offset and reduce the amount of tax refunds otherwise payable to a health plan.

The section requires the Secretary to issue a rule to establish a unique health plan identifier. The rule was to take effect no later than October 1, 2012. In addition, the Secretary is required to adopt a transaction standard and single set of associated operating rules for health claims attachments no later than January 1, 2014, to take effect by January 1, 2016.

In addition to the above provisions, the section amends **SSA Sec. 1862(a)** to require that as of January 1, 2014, no Medicare payment may be made for benefits delivered under Part A or Part B other than by EFT or an electronic remittance in a form specified in the HIPAA payment/remittance advice standard.

Sec. 10109. Administrative Simplification: Additional Standards; ICD-10

This section further amends **SSA Sec. 1173** to require the Secretary, by January 1, 2012, and not less than every three years thereafter, to solicit input from the NCVHS, the Health Information Technology Policy and Standards Committees and other stakeholders on whether standards and operating rules should be developed for other administrative and financial transactions. The Secretary was to solicit input on the following specified areas by January 1, 2012: (1) whether enrollment of health care providers by health plans could be made electronic and standardized; (2) whether the HIPAA standards and operating rules should apply to the health care transactions of automobile insurance, worker's compensation, and other programs not covered under HIPAA; (3) whether standardized forms could apply to financial audits required by health plans and government agencies; (4) whether there could be greater transparency and consistency in the methods used to establish claim edits used by health plans; and (5) whether health plans should be required to publish their timeliness of payment rules.

The section also required the Secretary to convene a meeting of the ICD-9-CM Coordination and Maintenance Committee by January 1, 2011, to receive stakeholder input and make recommendations about revisions to the crosswalk between the ICD-9 and ICD-10 codes. The Secretary must make appropriate revisions and post the revised crosswalk on the CMS website. For subsequent versions of the ICD codes, the Secretary is required, after consultation with appropriate stakeholders, to post on the CMS website a crosswalk between the previous and subsequent versions of the codes no later than the date on which the subsequent version is implemented.

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

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

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

Emergency Care

Overview and Impact of ACA

Amid concerns of an overburdened emergency care system, the IOM in 2006 issued three reports examining the state of the U.S. emergency medical system. The reports focused on the hospital-based emergency system (i.e., emergency departments); the emergency medical system including trauma care, ambulances, and other forms of transport; and emergency care for children.[124] Each report discussed deficiencies with the current emergency care system, including overcrowded hospital emergency departments, local and regional variation in the availability of services, an insufficient workforce to provide necessary care, limited financial or personnel resources, and other deficiencies that may strain the systems' ability to handle a disaster. The IOM reports made a number of recommendations to address those deficiencies.

ACA amends existing and creates new emergency and trauma care provisions in Title XII of the PHSA. These provisions address a number of the IOM recommendations to improve the U.S. emergency and trauma care system. They include designating the Assistant Secretary for Preparedness and Response as the lead office within HHS for emergency and trauma care; authorizing grants to create regionalized systems for trauma care; allocating additional funds to facilities with large uncompensated care burdens; and improving the emergency care workforce, among other provisions.

In addition to these specific provisions, ACA may impact the emergency medical system through its changes to the private health insurance system and the expansion of Medicaid that are intended to reduce the number of uninsured. Some of the challenges that the emergency care system—and hospital emergency departments in particular—face are associated with, or exacerbated by, having to provide care to the uninsured. Under the Emergency Medical Treatment and Labor Act (EMTALA), hospital emergency departments must examine and treat any individual who comes to the hospital with an emergency medical condition, and any woman who is in labor. EMTALA 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. The act prohibits discrimination and delay in examining or treating emergency patients, and provides protections to whistleblowers who report violations of its provisions.[125] Uncompensated care provided to the uninsured in emergency departments can place a financial burden on hospitals, which can hinder access to emergency care overall.[126]

Sec. 3504. Regionalized Systems for Emergency Care

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

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[124] Institute of Medicine, *Emergency Medical Services at the Crossroads* (Washington, DC: The National Academies Press, 2006); Institute of Medicine, *Hospital-Based Emergency Care At the Breaking Point,* (Washington, DC: The National Academies Press, 2006); and Institute of Medicine, *Emergency Care for Children: Growing Pains,* (Washington, DC: The National Academies Press, 2006).

[125] For more information, see CRS Report RS22738, *EMTALA: Access to Emergency Medical Care*, by Edward C. Liu.

[126] Institute of Medicine, *Hospital-Based Emergency Care At the Breaking Point,* (Washington, DC: The National Academies Press, 2006).

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

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

Sec. 3505. Trauma Care Centers

This section amends **PHSA Secs. 1241-1245** by replacing the existing provisions with new language requiring the Secretary to establish three programs to award grants to qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers to (1) help defray substantial uncompensated care costs, (2) further the core missions of such centers, and (3) provide emergency relief to ensure the continued availability of trauma services. In states with a trauma care system, a trauma center is not eligible for a grant unless it is part of the trauma care component of the state plan for the provision of emergency care services. The maximum grant amount is $2 million per fiscal year.

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

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

The section authorizes $100 million to be appropriated for FY2009, and SSAN for each of FY2010 through FY2015 to carry out the three grant programs. Seventy percent of the total amount appropriated for a fiscal year is for substantial uncompensated care awards unless the appropriation is less than $25 million, in which case all the funding will be used for such awards.

The Secretary is required to submit a biennial report to Congress on the status of the grant programs. The section also adds a new **PHSA Sec. 1246** that defines the term "uncompensated care costs."

Additionally, this section adds a new **PHSA Sec. 1281**, requiring the Secretary to award grants to states for the purpose of supporting trauma-related physician specialties and broadening access to and availability of trauma care services. Distribution of grant funds among the states is based on the program's annual appropriation level. The lower the appropriation amount, the more the distribution of funds is restricted to those states with trauma centers that provide a substantial amount of uncompensated care. If the appropriation is less than $10 million, the lowest amount specified, then the funds are distributed among only those states with one or more category A centers. The section adds a new **PHSA Sec. 1282** that authorizes $100 million to be appropriated for each of FY2010 through FY2015 to provide for the state grants.

Sec. 5603. Emergency Medical Services for Children

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

Pain Care Management

Overview and Impact of ACA

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.

ACA addresses several issues with the goal of advancing research and treatment for pain care management. For the purpose of recognizing pain as a national public health problem, the Secretary is required to convene an IOM Conference on Pain. The act also encourages the NIH Director to continue and expand pain research through the Pain Consortium and establishes a health professionals training program in pain care. The following describes these provisions in greater detail.

Pain Care Management

Institute of Medicine: *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, June 29, 2011, http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx. See, also, http://www.iom.edu/Activities/PublicHealth/PainResearch.aspx (IOM's web-site about this activity).

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

This section requires the Secretary to seek an agreement with the IOM (or another appropriate entity if the IOM declines) to convene a Conference on Pain, no later than one year after the appropriation of funds, for the purposes of increasing the recognition of pain as a significant

public health problem in the United States, among other purposes. It also requires a report summarizing the Conference's findings to be submitted to Congress. For the purpose of carrying out this section, ACA authorizes to be appropriated SSAN for each of FY2010 and FY2011.

The section adds a new **PHSA Sec. 409J**, which encourages 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, develops and submits to the NIH Director recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under the NIH Common Fund or otherwise available for such initiatives. The Secretary also is required to establish, no later than one year after enactment, and as necessary maintain, the Interagency Pain Research Coordinating Committee to coordinate all efforts within HHS and other federal agencies that relate to pain research, among other duties.

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

Elder Justice

Overview and Impact of ACA

ACA represents Congress's first attempt at comprehensive legislation to address abuse, neglect, and exploitation of the elderly at the federal level by incorporating the Elder Justice Act into health reform legislation. The enactment of elder justice provisions not only brings greater national attention to the issue, but emphasizes various public health and social service approaches to the prevention, detection, and treatment of elder abuse. At the federal level, the enactment of the Elder Justice Act places the issue of elder abuse on par with similar legislation Congress has enacted with respect to child abuse and neglect, under the Child Abuse Prevention and Treatment Act (CAPTA), and domestic violence, under the Violence Against Women's Act (VAWA).

Elder Justice

U.S. Government Accountability Office, *Stronger Federal Leadership Could Enhance National Response to Elder Abuse*, GAO-11-208, Mar 2, 2011, http://www.gao.gov/assets/320/316224.pdf

U.S. Government Accountability Office, *National Strategy Needed to Effectively Combat Elder Financial Exploitation*, GAO-13-110, Nov 15, 2012, http://www.gao.gov/products/GAO-13-110

U.S. Government Accountability Office, *Strengthening Efforts to Combat Elder Financial Exploitation*, GAO-13-140T, Nov 15, 2012, http://www.gao.gov/products/GAO-13-140T

U.S. Government Accountability Office, *Survey of Adult Protective Services Program Administrators* (GAO-11-129SP, March 2011), an E-supplement to GAO-11-208, GAO-11-129SP, Mar 2, 2011, http://www.gao.gov/products/GAO-11-129SP.

Abuse, neglect, and exploitation of older individuals in domestic and institutional settings, such as nursing homes, affects hundreds of thousands of older Americans every year according to national experts.[127] Precisely how many older individuals are mistreated by someone on whom they depend for care or protection is unknown. Efforts to collect data on elder abuse, neglect, and exploitation at the national level are hampered by variation in state statutory definitions of elder abuse that make it difficult to identify actions that constitute abuse and neglect, and by the absence of a uniform reporting system across states. In 2003, a National Research Council Study estimated that between 1 and 2 million Americans age 65 and older had been injured, exploited, or mistreated.[128] Other evidence and anecdotal reports indicate that the problem is serious and that many incidents are never reported.[129]

Congressional interest in the issue of elder abuse, neglect, and exploitation spans more than a quarter of a century with numerous hearings and reports concerning the need for a federal response to abuse, neglect, and exploitation of the elderly. Prior to enactment of ACA, Congress took a number of modest steps towards addressing elder abuse, including federal assistance to state Adult Protective Services programs through the Social Security Block Grant (SSBG) program and amendments to the Older Americans Act (OAA) to provide separate funding for elder abuse prevention and vulnerable elder rights protection activities, including establishment of the Long-Term Care Ombudsman Program (LTCOP). Provisions regarding elder justice were also incorporated in the OAA reauthorization of 2006 (P.L. 109-365).

The Elder Justice Act, first introduced in 2002 and periodically re-introduced since that time, represents an effort to produce a coordinated federal effort with a multidisciplinary approach that combines law enforcement, public health, and social services to combat abuse, neglect, and exploitation of the elderly.[130] The following summarizes the Elder Justice Act provisions enacted under ACA.

Sec. 6703. Elder Justice

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

Elder Justice

Subsection (a) of Sec. 6703 renames SSA Title XX as *Block Grants to States for Social Services and Elder Justice*, places the existing sections (i.e., Secs. 2001-2007) under a new Subtitle A, *Block Grants to States for Social Services*, and adds a new Subtitle B, *Elder Justice*, composed of the following two parts.

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[127] U.S. Government Accountability Office, *Stronger Federal Leadership Could Enhance National Response to Elder Abuse*, GAO-11-208, Mar 2, 2011, http://www.gao.gov/assets/320/316224.pdf. Reissued on March 22, 2011.

[128] Richard J. Bonnie and Robert B. Wallace, eds., *Elder Mistreatment: Abuse, Neglect and Exploitation in an Aging America*, National Research Council (Washington, DC: National Academy Press, 2003).

[129] Ibid.

[130] Congress first introduced the Elder Justice Act of 2002 in the 107th Congress (S. 2933). The Elder Justice Act has been introduced subsequently in the 108th Congress (S. 333; H.R. 2490), 109th Congress (S. 2010; H.R. 4993), and 110th Congress (S. 1070; H.R. 1783). In the 111th Congress, Senator Orrin Hatch introduced the Elder Justice Act of 2009 (S. 795). A companion bill (H.R. 2006) was introduced in the House by Representative Peter T. King. S. 795 was incorporated into the Senate Finance Committee's health reform bill (S. 1796) and subsequently adopted in the Senate health reform bill, ACA (H.R. 3590).

Part I—National Coordination of Elder Justice Activities and Research

Title XX, Subtitle B, Part I is divided into two subparts—**Subpart A** establishes an Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation comprised of new **SSA Secs. 2021-2024**; **Subpart B** adds a new **Sec. 2031** awarding grants to establish and operate stationary and mobile forensic centers. These sections and activities are described in further detail below.[131]

Subpart A—Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation. Subpart A adds a new **Sec. 2021,** *Elder Justice Coordinating Council*, establishing such a Council in the Office of the Secretary. The Council includes the Secretary as chair and the U.S. Attorney General, as well as the head of each federal department or agency, identified by the chair, as having administrative responsibility or administering programs related to elder abuse, neglect, and exploitation. The council is required to submit a report to the appropriate committees of Congress within two years of enactment and every two years thereafter that describes its activities and challenges; and make recommendations for legislation, model laws, and other actions deemed appropriate. There are authorized to be appropriated SSAN to carry out the Council's functions.

Subpart A also adds a new **Sec. 2022**, *Advisory Board on Elder Abuse, Neglect, and Exploitation*, establishing an Advisory Board to create a short- and long-term multidisciplinary plan for development of the field of elder justice and make recommendations to the Elder Justice Coordinating Council. The Advisory Board must be composed of 27 members from the general public appointed by the Secretary and must have experience and expertise in prevention of elder abuse, neglect, and exploitation. The Advisory Board is required to submit a report to the Elder Justice Coordinating Council and the appropriate committees of Congress within 18 months of enactment and annually thereafter that contains information on the status of federal, state, and local elder justice activities; and make specified recommendations. There are authorized to be appropriated SSAN to carry out the functions of the Advisory Board.

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

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

Subpart B—Elder Abuse, Neglect, Exploitation Forensic Centers. Subpart B adds a new **Sec. 2031**, *Establishment and Support of Elder Abuse, Neglect, and Exploitation Forensic Centers*, requiring the Secretary, in consultation with the U.S. Attorney General, to award grants to eligible entities to establish and operate both stationary and mobile forensic centers and to develop forensic expertise pertaining to elder abuse, neglect, and exploitation. It authorizes to be appropriated $4 million for FY2011, $6 million for FY2012, and $8 million for each of FY2013 and FY2014 to carry out these activities.

[131] Prior to Part I, new Subtitle B begins with Secs. 2011 (Definitions) and 2012 (General Provisions), which are not discussed here.

Part II—Programs to Promote Elder Justice

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

Sec. 2041. Enhancement of Long-Term Care. This section requires the Secretary, in coordination with the Secretary of Labor, to carry out activities that provide incentives for individuals to train for, seek, and maintain employment providing direct care in LTC. The Secretary is required to award grants to eligible entities to conduct programs that offer direct care employees continuing training and varying levels of certification. It also authorizes the Secretary to make grants to LTC facilities for specified activities that would assist such entities in offsetting costs related to purchasing, leasing, developing, and implementing certified EHR technology designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors. This section also requires the Secretary to adopt electronic standards for the exchange of clinical data by LTC facilities and, within 10 years of enactment, to have in place procedures to accept the optional electronic submission of clinical data by LTC facilities pursuant to such standards. The standards adopted must be compatible with standards established under current law, as specified, and with general HIT standards. The section authorizes to be appropriated $20 million for FY2011, $17.5 million for FY2012, and $15 million for each of FY2013 and FY2014 to carry out the activities under this section.

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

The section also requires the Secretary to establish two grant programs. The first it to enhance APS programs provided by states and local governments. The second is grants to states for APS demonstration programs. Annual grants awarded to states to enhance APS programs are to be distributed to states based on a formula. For each of FY2011 through FY2014, the section authorizes to be appropriated $100 million for annual grants to enhance APS programs and $25 million for the APS demonstration grants.

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

Sec. 2044. Provision of Information Regarding, and Evaluation of, Elder Justice Programs. To be eligible to receive a grant under Part II, this section requires an applicant to (1) agree to provide the required information to eligible entities conducting an evaluation of the activities

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

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

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

Protecting Residents of Long-Term Care Facilities

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

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

This subsection amends **SSA Title XI, Part A** (as amended by ACA Sec. 6005) by adding a new **Sec. 1150B**, *Reporting to Law Enforcement of Crimes Occurring in Federally Funded Long-Term Care Facilities*, requiring the reporting of crimes occurring in federally funded LTC facilities that receive at least $10,000 during the preceding year. It requires the owner or operator of these facilities to annually notify covered individuals that they are required to report any reasonable suspicion of a crime against a resident or individual receiving care from the facility. Failure to report suspicion of a crime would result in a civil money penalty and the Secretary may make a determination to exclude the covered individual from participation in any federal health care program. If an individual is classified as an "excluded individual," a LTC facility that employs that person is not eligible to receive federal funds under the SSA. It prohibits a LTC facility from retaliating against an employee for making a report. If retaliation occurs, the LTC facility may be subject to a civil money penalty or the Secretary may exclude them from participation in any federal health care program for a period of two years, or both. In addition, each LTC facility is

required to post conspicuously, in an appropriate location, a sign specifying the rights of employees under this section.

National Nurse Aide Registry

Subsection (c) of Sec. 6703 requires the Secretary, in consultation with appropriate government agencies and private sector organizations, to conduct a study on establishing a national nurse aide registry. No later than 18 months after the date of enactment, the Secretary is required to submit a report to the Elder Justice Coordinating Council and appropriate congressional committees containing the findings and recommendations of the study. It authorizes to be appropriated SSAN to carry these activities, with funding for the study not to exceed $500,000.

Biomedical Research and Medical Products

Overview and Impact of ACA

ACA contains provisions that impact various stages of the medical product development pipeline, including basic biomedical research, premarket and postmarket review of medical products by the Food and Drug Administration (FDA), and revenue generation via products already on the market.

Biomedical Research and Medical Products

CRS Report R42130, *FDA Regulation of Medical Devices*, by Judith A. Johnson.

CRS Report R42680, *The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144)*, coordinated by Susan Thaul.

Basic biomedical research supported by the National Institutes of Health (NIH) and other federal agencies can sometimes result in the development of medical products. ACA contains two provisions designed to facilitate biomedical research and help translate promising research findings into new medical products. One creates a two-year temporary tax credit equal to 50% of investment in certain types of therapeutic research. Another authorizes NIH funding for the Cures Acceleration Network (CAN) to speed treatment development not likely to occur through market incentives.

FDA is responsible for ensuring medical product safety and effectiveness; it derives most of its authorities from the Federal Food, Drug, and Cosmetic Act (FFDCA).[132] Adding FDA requirements may increase the quality of medical products but may also raise the cost or delay consumer access to those products. Three ACA provisions affect FDA regulation of medical products. One requires that, if certain conditions are met, additional health benefit and risk information about a prescription drug must be included in its labeling and in advertisements. A second makes it easier for a generic drug to continue to seek FDA approval if the associated brand-name drug changes its labeling within 60 days of the generic's approval. A third provision will enable biosimilar biological products to reach the marketplace for the first time. Because of its significance, the biosimilar provision is discussed in its own section below.

Medical products comprise 14% of health care expenditures.[133] The implementation of ACA may increase the demand for medical products as more individuals obtain health insurance. ACA

[132] 21 USC §§ 301 et seq.

[133] This percentage is based upon CMS data from 2011. It was generated by dividing $349 billion (Retail Outlet Sales of Medical Products) by $2,547 billion (Health Consumption Expenditures). The number does not reflect all of the costs of FDA regulated medical products associated with health care spending, because it does not include those

contains provisions designed to generate tax revenue from the sale of prescription drugs and medical devices. It also contains a provision that taxes (and may deter) the use of another product regulated under the FFDCA: ultraviolet lamps used for indoor tanning. (Note that ACA provisions that affect Medicare and Medicaid reimbursement for medical products are discussed in separate CRS reports, which are listed at the beginning of this report.)

Biomedical Research

Sec. 9023. Qualifying Therapeutic Discovery Project Credit

This section inserts a new **Sec. 48D**, *Qualifying Therapeutic Discovery Project Credit*, into the IRC, Chapter 1, subchapter A, part IV, Subpart E and makes other conforming and clerical amendments. The new provision creates a two-year temporary tax credit program for small companies with 250 or fewer employees that invest in qualifying therapeutic discovery projects. Companies may apply for one or more tax credits, each covering 50% of the cost of qualifying research investments made in 2009 or 2010. However, the total amount of tax credits any one company receives may not exceed $5 million. Overall, the tax credit program is capped at $1 billion.

There are three types of qualifying therapeutic discovery projects for which investments may be eligible for the new tax credit. The first consists of studies designed to treat or prevent diseases or conditions for the purpose of securing FDA approval of a new drug (under FFDCA Sec. 505(b)) or licensure of a new biological product (under PHSA Sec. 351(a)). The second includes projects to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions. The third includes projects to develop a product, process, or technology to further the delivery or administration of therapeutics.

In addition, when determining which investments to certify as qualified for the tax credit (as described below), the Secretary of the Treasury, in consultation with the Secretary is directed to consider:

- only projects that have both a reasonable potential to (1) result in new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions; (2) reduce long-term health care costs in the United States, or (3) significantly advance the goal of curing cancer within the 30-year period; and
- projects that have the greatest potential to create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States, and to advance U.S. competitiveness in the fields of life, biological, and medical sciences.

Within 60 days of enactment, the Treasury Secretary, in consultation with the Secretary, must establish a qualifying therapeutic discovery project program to consider and award certifications for qualified investments eligible for the new credit to qualifying therapeutic discovery project sponsors. Those wishing to obtain the required certification for the new tax credit will have to make an application to the Secretary of the Treasury, who must respond with a determination within 30 days of receipt.

purchased by hospitals (such as pacemakers and other implantable devices), dentists offices (such as fillings), or other health care facilities. "Table 4 - National Health Expenditures by Source of Funds and Type of Expenditures: Calendar Years 2005-2011," CMS website, at http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf.

In lieu of the tax credit for investments in 2009 or 2010, companies may elect to receive one or more grants, subject to the same restrictions (i.e., grants may cover up to 50% of the amount of qualifying investments made in 2009 and 2010, and the total amount of grants any one company receives for the two years may not exceed $5 million). The section appropriates SSAN to carry out the grant program. An application for certification for the new tax credit is also considered by the Secretary of the Treasury to be an application for the new grant program.

Certain types of expenditures are excluded from the eligibility for the credit and the grant, such as facility maintenance and employee remuneration. Certain other restrictions apply related to the use of tax deductions or other tax credits for project expenses claimed for the new tax credit or grant.

Sec. 10409. Cures Acceleration Network

ACA amends **PHSA Sec. 402(b)** to require the NIH Director (Director) to implement a new Cures Acceleration Network (CAN), to facilitate the development of "high need cures," as described below. It also amends **PHSA Sec. 499(c)(1)** to enable the Foundation for the National Institutes of Health to accept charitable gifts to support the CAN. If funded, CAN will help support the development of treatments for diseases or conditions that are rare, or for which market incentives are inadequate.

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

ACA defines a "high need cure" as a medical product (a drug, device, or biological product) that the NIH Director determines: (1) is a priority to diagnose, prevent, or treat harm from a disease or condition; and (2) that the incentives of the commercial market are unlikely to result in its adequate or timely development. The Director must award, as specified, grants, contracts, or cooperative agreements to accelerate the development of high need cures. Each Cures Acceleration Partnership Award is to, among other things, provide up to $15 million for the first year, payable in a lump sum, with a matching requirement. The Cures Acceleration Grant Awards are similar but have no matching requirement. The Cures Acceleration Flexible Research Awards will be available if the Director determines that the goals of the section could not be met otherwise, and will consist of awards not to exceed 20% of the total funds appropriated under this section (see below).

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

There are authorized to be appropriated $500 million for FY2010, and SSAN for subsequent fiscal years. Other funds appropriated under the PHSA may not be allocated to the CAN.

FDA Requirements for Medical Products

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

This section requires the Secretary, acting through the FDA Commissioner, to determine whether the addition of information about the health benefits and risks of a prescription drug to that drug's labeling and advertising would improve health care decision-making by clinicians, patients, and consumers. Such information would be presented in a standard format such as a "Drug Facts Box." To reach this determination, the Secretary must review all available scientific evidence and research on decision-making and social and cognitive psychology and consult with a wide range of stakeholders. Within one year of enactment, the Secretary must submit to Congress a report that includes the determination and the reasoning behind it. If the determination is that decision-making would be improved, the Secretary must propose implementation regulations not later than three years after the report's submission. Sec. 3511 of ACA authorizes the appropriation of SSAN to carry out the activities in this section.

Sec. 10609. Labeling Changes

To receive FDA approval, a generic drug must, in addition to other requirements in an abbreviated new drug application (ANDA), use the same labeling that FDA had approved for the listed referent (usually brand-name) drug. This provision addresses the situation in which the labeling of the listed referent drug is changed within 60 days of its generic product ANDA approval. ACA amends **FFDCA Sec. 505(j)** to allow the Secretary to approve an otherwise qualified generic application with the existing (unrevised) labeling if (1) the revisions did not involve the "Warning" section, (2) the generic sponsor submits revised labeling (to put it in accord with the listed referent drug's revised labeling) within 60 days, and (3) the Secretary has not determined that sale of the product with the existing (unrevised) labeling adversely impacts the safe use of the drug.

Revenue Provisions Related to FDA-Regulated Products

Sec. 9008. Annual Fee for Brand Name Pharmaceuticals

This section, as amended by HCERA Sec. 1404, imposes an annual fee on covered entities; that is, certain manufacturers and importers of branded prescription drugs (including biological products and excluding orphan drugs).[134] Effective in 2011, a covered entity must pay an annual fee to the Secretary of the Treasury. The total fee amounts authorized per year are as follows: $2.5 billion for 2011; $2.8 billion for each of 2012 and 2013; $3 billion for each of 2014 through 2016; $4 billion for 2017; $4.1 billion for 2018; and $2.8 billion for 2019 and each year thereafter. Fees amounts are to be transferred to the Medicare Part B trust fund.

The annual fee amount that each covered entity must pay is based on its share of the total prescription drug sales to specified government programs. Each entity must pay a proportion of

[134] The FDA designates products (or combinations of products) that are used to treat rare diseases or conditions as orphan drugs. To meet this designation, a manufacturer must request this designation and must meet certain criteria. The orphan drug designation qualifies the manufacturer for a tax credit and certain marketing incentives. For more information, see U.S. Department of Health and Human Services, U.S. Food and Drug Administration, "Designating an Orphan Product: Drugs and Biologics," December 11, 2012, http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm.

the annual fee total equal to the entity's proportion of all such sales for the previous year. However, only specified amounts of such drug sales are taken into account when calculating entities' annual fees; for sales of not more than $5 million, none will be taken into account. For sales of more than $5 million and not more than $125 million, 10% will be taken into account. For sales of more than $125 million and not more than $225 million, 40% will be taken into account. For sales of more than $225 million and not more than $400 million, 75% will be taken into account. For sales of more than $400 million, 100% will be taken into account. In the event that more than one person is liable for a fee with respect to a single covered entity, all such persons are jointly and severally liable for payment.

The Secretary of the Treasury is required to calculate the proportion to be paid by each covered entity based upon annual reports made by the Secretaries of HHS, Veterans Affairs, and Defense. Reports are required to contain the total branded prescription drug sales for each covered entity with respect to Medicare Parts B and D, Medicaid, the Department of Veterans Affairs programs, and the Department of Defense programs and TRICARE. The Secretary of the Treasury is required to publish guidance necessary to carry out the purposes of this section.

HCERA Sec. 1405 (repeals ACA Secs. 9009, 10904). Medical Device Tax

This provision creates a new **IRC Sec. 4191** in new **Subchapter E – Medical Devices**. Beginning in 2013, the law imposes a 2.3% sales tax on the sale of a medical device by a manufacturer, producer, or importer. Taxable devices include those defined in FFDCA Sec. 201(h), excluding eyeglasses, contact lenses, hearing aids, and any other devices determined by the Secretary to be of a type the general public typically buys at retail for individual use. Tax exemptions listed under IRC Sec. 4221(a)(3)-(6) and Sec. 6416(b)(2)(B)-(E) do not apply, including those for state and local governments, nonprofit educational entities, and certain others.

This provision also repeals ACA Sec. 9009, as amended by ACA Sec.10904 (imposition of annual fee on medical device manufacturers and importers).

Sec. 10907 (nullifies Sec. 9017). Excise Tax on Indoor Tanning Services

This section adds a new **IRC Sec. 5000B** (in a new Chapter 49), imposing a 10% tax on amounts paid for indoor tanning services performed on or after July 1, 2010. Phototherapy services performed by licensed medical professionals are not subject to this tax. The person receiving payment for the service must collect the amount of the tax from the individual on whom the procedure is performed, and is responsible for the tax amount if the client does not submit the payment. The provider must submit the tax to the Treasury Secretary on a quarterly basis.

This section also nullifies ACA Sec. 9017 (Excise Tax on Elective Cosmetic Medical Procedures).

Biosimilars

Overview and Impact of ACA

ACA establishes a new FDA regulatory authority by creating a licensure pathway for biosimilars and authorizing the agency to collect associated fees. 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.[135]

Biosimilars

CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

Congressional interest in an expedited pathway for the licensure of biosimilars is the same as it was for generic chemical drugs in 1984; namely, cost savings. The pathway for biosimilars is 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 innovator 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 about $15,000 per year.[136] A pathway enabling the FDA approval of biosimilars may allow for market competition and reduction in prices, though perhaps not to the same extent as occurred with generic chemical drugs under Hatch-Waxman. Based on its analysis of published studies of the impact of follow-on biologics on health care spending, CBO estimates that establishing a regulatory pathway for approving such products would result in a net savings to the federal government of $9.2 billion over a 10-year period.[137]

Sec. 7001. Short Title

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

Sec. 7002. Approval Pathway for Biosimilar Biological Products

This section amends **PHSA Sec. 351** to create a new regulatory pathway for the FDA 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 allows 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

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

[136] Carter, C.T., Chongolkar, A.K., and Scott McKenzie, R., "Adalimumab, Etanercept, and Infliximab Utilization Patterns and Drug Costs Among Rheumatoid Arthritis Patients," *Journal of Medical Economics*, vol. 15, no. 2 (January 6, 2012), pp. 332-339. Enbril is the commercial name for etanercept.

[137] Congressional Budget Office, *Budget Options Volume 1: Health Care*, December 2008, at http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf.

unnecessary. The Secretary will determine if the reference product and a biosimilar biological product are interchangeable according to specified criteria. Interchangeable means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The section provides a 12-year data exclusivity period (from the date on which the reference product was first approved) for the reference product during which time the FDA cannot approve a follow-on version of the innovator biologic drug. If a reference product has been designated an orphan drug, an application for a biosimilar or interchangeable product may not be filed until the later of (1) the seven-year period of orphan drug exclusivity described in the FFDCA, or (2) the 12-year period established by this section. The section also allows for a period of exclusive marketing for the biological product that is the first to be established as interchangeable with the reference product.[138]

The Secretary is authorized to publish proposed guidance as specified for public comment prior to publication of final guidance on the licensure of a biological product. If guidance is to be developed, a process must be established to allow for public input regarding priorities for issuing guidance. The issuance or non-issuance of guidance does not preclude the review of, or action on, an application.

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

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

The section allows for the collection of user fees for the review of applications for approval of biosimilars. The Secretary is required to develop recommendations regarding goals for the review of biosimilar product applications for FY2013 through the end of FY2017 and present them to Congress. The recommendations must be published in the *Federal Register* with a 30-day public comment period, and a public meeting must be held. The revised recommendations must be presented to Congress by January 15, 2012. Based on those recommendations, it is the sense of the Senate that Congress will authorize a user fee program effective October 1, 2012. Through October 1, 2010, the Secretary must collect data on the cost of biosimilar product application review as conducted according to the prescription drug user fee program. Two years after receiving the first user fee for a biosimilar product application, and every two years thereafter until October 1, 2013, the Secretary must perform an audit of the application review costs. An alteration of the user fee will occur depending on results of the audit, as specified in this section.

The section authorizes the appropriation of SSAN for each of FY2010 through FY2012 to cover the costs of developing recommendations for a user fee program and for auditing the costs of reviewing biosimilar product applications.

An extra six months of data (market) exclusivity will be provided for a new biologic drug if pediatric studies are conducted prior to FDA approval of the drug. An extra six months of data (market) exclusivity is provided for a biologic drug already on the market if pediatric studies are conducted and the request for the extension is made not less than nine months before the

[138] 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.

expiration of the original exclusivity period. The section requires an IOM study to be conducted that will review and assess the number and importance of biological products for children that are being tested as a result of amendments made by this ACA title, as well as biological products that are not being tested for pediatric use, and offer recommendations for ensuring pediatric testing of biological products.

Sec. 7003. Savings

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

Nutrition Labeling

Overview and Impact of ACA

Concern about the rising rates of obesity and the resulting effect on individuals' health and health care costs has prompted Congress to consider a number of options in an effort to reduce obesity levels in the U.S. population. ACA includes one such option. The law requires nutrition labeling for foods sold in chain restaurants and vending machines, which were previously exempted from FDA's nutrition labeling regulations.

Nutrition Labeling

CRS Report R42825, *Nutrition Labeling of Restaurant Menus*, by Amalia K. Corby-Edwards.

Sec. 4205. Nutrition Labeling of Restaurant Menus and Food Sold in Vending Machines

This section inserts 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 must disclose on the menu and the menu board, as specified, for standard menu items: (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 must also make available at the premises upon request certain detailed written nutritional information. The establishments must have a reasonable basis for their nutrient content disclosures. The Secretary must establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but that are listed as a single menu item.

The section also requires 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 must 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 amends **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 sold in certain restaurants and similar retail food establishments. The section also prohibits 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, except if the restaurant or retail food establishment is not part of a chain of 20 or more locations but elects to comply with requirements for such restaurants.

340B Drug Pricing

Overview and Impact of ACA

340B Drug Pricing

U.S. Government Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, 11-836, September 23, 2011, http://www.gao.gov/assets/330/323702.pdf.

Under PHSA Sec. 340B, pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program are required to enter into pharmaceutical pricing agreements that provide discounts on covered outpatient drugs purchased by certain public health facilities (covered entities). HRSA, the agency that administers the 340B program, indicates that approximately 14,000 covered entities and 800 pharmaceutical manufacturers participate in the program.[139] 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 do not receive discounts on inpatient drugs under the 340B program.

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

Sec. 6004 of the Deficit Reduction Act of 2005 (DRA, P.L. 109-171) amended SSA Sec. 1927(a) to require prescription drug manufacturers to add certain qualifying children's hospitals (those

[139] 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.

that are exempt from the Medicare prospective payment system) to the entities entitled to receive discounts under the 340B program. DRA Sec. 6004 also required the children's hospitals to meet all other 340B participation requirements. A final rule for participation of children's hospitals in the 340B program was issued on September 1, 2009.[140] The ACA further expanded the types of entities that could participate in the program. It also included two provisions related to improving program integrity and oversight.

Sec. 7101. Expanded Participation in 340B Program

This section, as amended by HCERA Sec. 2302, amends **PHSA Sec. 340B** to add the following to the list of covered entities 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; and (3) certain rural referral centers and sole community hospitals. These new 340B-eligible facilities also must meet other specified 340B participation requirements. In addition, the changes in this section and Sec. 7102 (described below) are to be used to determine whether drug manufacturers meet the pricing requirements under Sec. 340B and SSA Sec. 1927. The provisions in this section and Sec. 7102, as amended by HCERA, became effective on January 1, 2010, and were applicable to drug purchases beginning January 1, 2010.

Sec. 7102. Improvements to 340B Program Integrity

This section further amends **PHSA Sec. 340B** to require the Secretary to develop systems to improve manufacturer and covered entity compliance and program integrity activities, as well as administrative procedures to resolve disputes. The compliance and program integrity systems are to include a number of specifications to increase transparency and strengthen monitoring, oversight, and investigation of the prices that manufacturers charge covered entities, as well as additional improvements to ensure covered entities do not divert drugs or obtain multiple discounts. The Secretary is required to establish a new administrative dispute resolution process to mediate and resolve covered entity overpayment claims and manufacturer claims against covered entities for drug diversion or multiple discounts. Civil money penalty sanctions up to $5,000 per instance for manufacturer overcharges are authorized under this section. The Secretary is required to establish standards and issue regulations for assessing CMPs on drug manufacturers for overcharge violations by September 19, 2010. The Secretary also is required to issue regulations within 180 days of enactment (by September 19, 2010) to implement a dispute resolution process by which covered entities can report instances where they suspect they have been overcharged. The section authorizes the appropriation of SSAN for FY2010 and each succeeding fiscal year to carry out the improvements to the 340B program.

Finally, this section amends the **PHSA Sec. 340B** to require that pricing agreements stipulate that drug makers will report to the Secretary quarterly ceiling prices for each covered drug and to offer these drugs to covered entities at or below these prices. HCERA Sec. 2302 amends ACA Sec. 7102 to exclude orphan drugs, as designated by FFDCA Sec. 526, from 340B discounts for the newly added hospital entities.[141]

[140] 74 *Federal Register*, 45206 (September 1, 2009), available at http://edocket.access.gpo.gov/2009/pdf/E9-21109.pdf.

[141] These entities are certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system, (2) critical access hospitals, and (3) certain rural referral centers and sole community hospitals.

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

This section requires GAO to submit a report to Congress that examines whether individuals receiving services through 340B-covered entities are receiving optimal health care services. The report was due within 18 months of enactment (by September 23, 2011) and is to at least make recommendations on (1) whether the 340B program should be expanded; (2) whether mandatory 340B sales of certain products could hinder patients' access to those therapies through any provider; and (3) whether 340B income is being used by covered entities to further program objectives.

Medical Malpractice and Liability Reform

Overview and Impact of ACA

Although medical malpractice liability reform has attracted congressional attention over the years, ACA is the first law enacted with provisions on the topic. One provision expresses the Sense of the Senate that Congress should consider establishing a state demonstration program to evaluate alternatives to tort litigation. The second establishes such an initiative that will be in effect for five years. Since before ACA was enacted, various states have regulated and implemented tort reform for medical malpractice lawsuits. In states that have done so, tort reform laws include statutes of limitation and caps on non-economic damages or punitive damages, for example. It is unclear whether, or by how much, such reforms have reduced costs on the health care system.[142] ACA does not create a federal medical liability reform law as prior congressional bills have sought to do, but rather gives states a financial incentive to develop their own alternatives to tort litigation aimed at meeting specific goals. Furthermore, ACA extends Federal Tort Claims Act liability protection to members, employees, and contractors of free clinics.

Secs. 6801 and 10607. Medical Malpractice and Liability Reform

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

Sec. 10607 creates a new **PHSA Sec. 933V-4**, that authorizes the appropriation of $50 million for a five-year period beginning in FY2011 for the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or organizations. These grants will exist for no more than five years. States that receive a grant are required to develop an alternative that (1) allows for the resolution of disputes caused by health care providers or organizations; and (2) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to the resolved disputes.

Prior to receiving a grant, a state will have to demonstrate that its alternative: (1) increases the availability of prompt and fair resolutions of disputes; (2) encourages the efficient resolution of disputes; (3) encourages the disclosure of health care errors; (4) enhances patient safety by

[142] For more information, see CRS Report R40862, *Medical Malpractice Insurance and Health Reform*, by Baird Webel, Vivian S. Chu, and Bernadette Fernandez.

reducing medical errors and adverse events, (5) improves access to liability; (6) informs the patient about the differences between the alternative and tort litigation; (7) allows the patient to opt out of the alternative at any time; (8) does not conflict with state law regarding tort litigation; (9) does not abridge a patient's ability to file a medical malpractice claim.

Each state will be required to identify the sources from and methods by which compensation will be paid, which can include public and private funding sources. In addition, each state will be required to establish a scope of jurisdiction to whom the alternative will apply so that it is sufficient to evaluate the effects of the alternative. The Secretary will provide to the states that are applying for the grants technical assistance, including guidance on common definitions, non-economic damages, avoidable injuries, and disclosure to patients of health care errors and adverse events.

When reviewing states' grant applications, the Secretary will consult with a newly established review panel that will be composed of relevant experts appointed by the Comptroller General. There are various reporting requirements that must be completed. First, states that receive a grant must submit a report to the Secretary covering the impact of the activities funded on patient safety and on the availability and price of medical liability insurance. Second, the Secretary must submit an annual compendium to Congress that examines any differences that may result in the areas of quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance. Third, the Secretary, in consultation with the review panel, must contract with a research organization to conduct an overall evaluation of the effectiveness of grants awarded. This evaluation must be submitted to Congress no later than 18 months following the date of implementation of the first funded program. Fourth, MedPAC and the Medicaid and CHIP Payment and Access Commission (MACPAC) must each conduct an independent review of the impact of state-implemented alternatives on their programs and beneficiaries. These reports must be submitted no later than December 31, 2016.

The section would not limit any prior, current, or future efforts of any state to establish any alternative to tort litigation.

Sec. 10608. Liability Protection for Free Clinics

The Federal Tort Claims Act (FTCA) waives sovereign immunity to make the United States liable, in accordance with the law of the state where a tort occurs, for "injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the government while acting within the scope of his office or employment."[143] Congress can choose to immunize a private organization, or its employees or volunteers, from tort liability by enacting a statute that specifically deems them federal employees for purposes of the FTCA. In 1996, Congress granted FTCA liability protection to volunteer health professionals at free clinics.[144] In other words, such individuals have been deemed federal employees such that they are immunized from liability under the FTCA if medical malpractice claims are brought against them.

ACA Sec. 10608 amends **PHSA Sec. 224(o)(1)** to extend FTCA liability protection to officers, governing board members, employees, and contractors of free clinics. Under this, free clinics that

[143] 28 U.S.C. § 1346(b).

[144] 42 U.S.C. § 233(o)(1). It is worth noting that in 1992 Congress deemed federally funded health centers, their officers, members, employees, and contractors employees of the federal government for purposes of the FTCA. 42 U.S.C. § 233(g).

qualify for such protection have the option of not purchasing medical malpractice insurance to cover the organization, members, employees, or contractors.

Appendix A. ACA Provisions Amended or Struck by ACA Title X and/or HCERA

Table A-1. ACA Provisions Amended or Struck by ACA Title X and/or HCERA

Topic	Underlying ACA Section	Amending (*or Striking*) Section	
		ACA Title X	HCERA
National health care quality strategy	3011	10302	
Quality measure development	3013	10303(a)	
Quality measurement selection/dissemination	3014	10304	
Public reporting of performance information	3015	10305	
National Prevention and Health Promotion Council	4001	10401(a)	
School-based health centers	4101	10402(a)	
Medicare personalized prevention plan	4103	10402(b)	
Medicare preventive services cost-sharing	4104	10406	
Community transformation grants	4201	10403	
Employer-sponsored wellness program grants	4303	10404	
CBO scoring of prevention and wellness programs	4401	*10405*	
National Health Care Workforce Commission	5101	10501(a)	
Community health workforce grants	5313	10501(c)	
Primary care extension program	5405	10501(f)	
GME rules for counting resident time	5505	10501(j)	
NHSC rules for counting teaching time	5508(b)	*10501(n)(5)*	
Patient-centered outcomes research	6301	10602	
340B drug program	7101-7103		2302
Prescription drug tax	9008		1404
Medical device tax	9009	10904	*1405(d)*
Elective cosmetic procedure/indoor tanning bed tax	9017	*10907(a)*	
Community health center/NHSC funding	10503		2303[a]

Source: Prepared by the Congressional Research Service based on a review of the Patient Protection and Affordable Care Act (ACA), P.L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152.

a. ACA Sec. 10503 appropriates a total of $8.5 billion for community health centers over the five-year period FY2011 through FY2015; $7.0 billion for center operations and patient services, and $1.5 billion for construction and renovation. HCERA Sec. 2303 increases the amount for center operations and patient services to $9.5 billion. Note that Sec. 10503 also appropriates $1.5 billion for the NHSC.

Appendix B. Timeline of Public Health, Workforce, Quality, and Related ACA Provisions

In some instances, ACA, as amended by HCERA, specifies dates for key administrative or programmatic activities or requirements. The following timeline (see **Table B-1**) lists provisions summarized in this report that include dates for the following:[145]

- final report deadlines, including reports to Congress;
- implementation or termination of new or existing grant programs;
- rulemaking or guidance;
- new or expiring authorities, activities, or requirements; and establishment or termination of entities.

Other activities or requirements that have no date specified in ACA and are implicitly effective upon enactment (March 23, 2010) are not included in this timeline.

Table B-1 lists the ACA dates which are grouped alphabetically under headings that correspond to section headings in the report. Within each heading, table entries are organized alphabetically by title with key dates in chronological order within each title. Effective dates stated in terms of days, months, or years after enactment have been converted to calendar dates (e.g., 180 days is 9/19/2010; six months is 9/23/2010, etc.). Table entries for specific implementation requirements or deadlines that are not tied to a specific calendar date are presented at the end of each title. Each table entry includes the ACA section number (as amended); a descriptive title for each activity or requirement; a brief description of the activity or requirement; and the associated start date, effective date, or deadline. Where applicable, the end date, frequency or duration associated with specific activities or requirements is noted.

For additional information on provisions that appear in the timeline, refer to the more detailed section summaries in the report.[146] For definitions of acronyms used in the timeline, refer to **Appendix C**. Unless otherwise stated, references in the table to "the Secretary" refer to the Secretary of Health and Human Services (HHS).

[145] For a timeline of the ACA provisions regarding Nursing Homes and Other Long-Term Care Facilities and Providers (i.e., Secs. 6101-6107, 6111-6114, and 6121), see CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al.

[146] In the electronic version of this report, ACA section numbers in the timeline are hyperlinked to corresponding sections of this report.

Table B-1. Timeline of Public Health, Workforce, Quality, and Related ACA Provisions

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
340B DRUG PRICING					
7101 (amended by HCERA 2302)	**340B**: Expanded Participation in 340B Program	Adds the following facilities to the list of covered entities eligible to receive discounts through the PHSA Sec. 340B program: (1) children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals.	1/1/2010		
7102[a]	**340B**: Improvements to 340B Program Integrity (Improved compliance)	Requires the Secretary to issue regulations on program integrity, the dispute resolution process, and a methodology for calculating ceiling prices.	9/19/2010		
7103	**340B**: GAO Study to Make Recommendations on Improving the 340B Program	Requires the U.S. Comptroller General and GAO to submit to Congress a report that examines at least the following: (1) whether the 340B program should be expanded; (2) whether mandatory 340B sales of certain products could hinder patients' access to those therapies through any provider; and (3) whether 340B income is being used by covered entities to further program objectives.	9/23/2011		
BIOMEDICAL RESEARCH AND MEDICAL PRODUCTS					
9023(e)[b]	**Biomedical Research**: Qualifying Therapeutic Discovery Project Credit	Requires the Secretary of the Treasury to establish a qualifying therapeutic discovery project program for investments made in taxable years beginning in 2009 and 2010.	5/22/2010		
9023(e)[b]	**Biomedical Research**: Qualifying Therapeutic Discovery Project Credit	Prohibits Secretary of the Treasury from making any grants for Qualified Investments in Therapeutic Discovery Projects unless the application is received before specified date.	1/1/2013		
7002	**Biosimilars**: User fees	Requires the Secretary to collect and evaluate data regarding the costs of reviewing applications for biosimilar biological products.	3/23/2010	10/1/2010	
7002[a]	**Biosimilars**: Approval Pathway for Biosimilar Biological Products	Requires the Secretary to begin to develop recommendations to present to Congress related to the biosimilar biological product application review process for the first 5 FYs after FY2012.	10/1/2010		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
7002[a]	**Biosimilars**: Approval Pathway for Biosimilar Biological Products	Requires the Secretary to transmit to Congress the revised recommendations (developed in consultation with specified parties and following public review) related to the biosimilar biological product application review process and associated material.	1/15/2012		
7002	**Biosimilars**: Approval Pathway for Biosimilar Biological Products	Deems an approved application under FFDCA Sec. 505 for a biological product to be a license under PHSA Sec. 351.	3/23/2020		
7002	**Biosimilars**: Approval Pathway for Biosimilar Biological Products	Allows the submission of an approved application under FFDCA Sec. 505 for a biological product if it belongs to a product class that is already approved under FFDCA Sec. 505.		3/23/2020	
7002	**Biosimilars**: User fees	Requires the Secretary to perform an audit of the costs of reviewing biosimilar applications and alter user fee amounts if appropriate.	Two years after first receiving a user fee for a biosimilar application		Biennially thereafter
6302	**Comparative Effectiveness Research**: Federal Coordinating Council for Comparative Effectiveness Research	Notwithstanding any other provision of law, terminates the FCCCER.	3/23/2010		
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to appoint, as specified, 17 members of the Board of Governors of the PCORI.	9/23/2010		
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	For each policy year between the specified dates, imposes certain fees on specified health insurance policies and applicable self-insured health plans.	10/1/2012	9/30/2019	
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to review the adequacy and use of the funding for the PCORI and the activities conducted under new PHSA Sec. 937, as added by this Act, and to determine whether the funding sources are appropriate.	3/23/2018		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Terminates availability for expenditure amounts in PCORTF and requires that amounts in PCORTF after that date be transferred to the general fund of the U.S. Treasury.	9/30/2019		
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the PCORI methodology committee to, directly or by contract, develop and periodically update methodological standards for research and a translation table for reference.	18 months after establishment of PCORI		
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires PCORI to make research findings available to clinicians, patients, and the general public.	90 days after findings		
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires PCORI to submit to Congress and the President and to make available to the public a report describing activities, research priorities, methodological standards developed, and other specified items.			Annually
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to provide for financial audits by a private entity.			Annually
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to report to Congress on reviews and to recommend legislative and administrative action as appropriate.			Annually
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to review financial audits of PCORI.			Not less frequently than on an annual basis
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires the U.S. Comptroller General to review specified processes and activities of PCORI involving, among other items, research priorities, conduct of research, dissemination, and training.			Not less frequently than every five years

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
6301[b]	**Comparative Effectiveness Research**: Patient-Centered Outcomes Research	Requires PCORI to review and update, as appropriate, evidence from research it carries out.			On a periodic basis
3507	**FDA Requirements for Medical Products**: Presentation of Prescription Drug Benefit and Risk Information	Requires the Secretary to report to Congress about whether adding quantitative summaries of health benefit and risk information in a standardized format to prescription drug labeling and advertising would help clinicians, patients, and consumers make health care decisions.	3/23/2011		
3507	**FDA Requirements for Medical Products**: Presentation of Prescription Drug Benefit and Risk Information	Requires the Secretary to promulgate regulations if the Secretary determines that adding quantitative summaries of health benefit and risk information in a standardized format to prescription drug labeling and advertising would help clinicians, patients, and consumers make health care decisions.	Three years after publication of report on health benefit and risk information		
10907	**Revenue Provisions Related to FDA-Regulated Products**: Excise Tax on Indoor Tanning Services	Effective date for 10% excise tax on indoor tanning services.	7/1/2010		
HCERA 1405	**Revenue Provisions Related to FDA-Regulated Products**: Medical Device Tax	Requires certain manufacturers and importers to pay to the Secretary of the Treasury a 2.3% excise tax on the sale of certain medical devices.	1/1/2013		
9008 (amended by HCERA 1404)	**Revenue Provisions Related to FDA-Regulated Products**: Annual Fee for Brand Name Pharmaceuticals	Requires the Secretaries of HHS, Veterans Affairs, and Defense to report to the Secretary of Treasury specified information on prescription drug sales.	Date as determined by Treasury Secretary		Annually
9008 (amended by HCERA 1404)	**Revenue Provisions Related to FDA-Regulated Products**: Annual Fee for Brand Name Pharmaceuticals	Requires the Secretary of the Treasury to calculate fees, according to specified criteria, to be paid by each covered entity (branded prescription pharmaceutical manufacturers and importers).			Annually

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
ELDER JUSTICE					
6703(a)	**Elder Justice**: Option for State Plan under TANF Program	Effective date for a state's TANF state plan to indicate whether the state intends to assist individuals to train for, seek, and maintain employment providing direct care in a LTC facility or in other related elder care occupations.	1/1/2011		
6703(a)[a]	**Elder Justice**: Advisory Board on Elder Abuse, Neglect, and Exploitation	Requires the Advisory Board on Elder Abuse, Neglect, and Exploitation to prepare and submit a report to the Elder Justice Coordinating Council and to Congress containing a report on the status of federal, state, and local elder justice activities and recommendations.	9/23/2011		Annually thereafter
6703(c)[a]	**Elder Justice**: National Nurse Aide Registry	Requires the Secretary to submit to the Elder Justice Coordinating Council and to Congress a report containing the findings and recommendations of a study on establishing a national nurse aide registry.	9/23/2011		
6703(a)[a]	**Elder Justice**: Coordinating Council	Requires the Elder Justice Coordinating Council to submit a report to Congress on the Council's activities and recommendations for legislation or other action.	3/23/2012		Every two years thereafter
6703(a)	**Elder Justice**: Report	Requires the Secretary to submit to the Elder Justice Coordinating Council and to Congress a report containing specified information and recommendations regarding state APS grantee activities.	10/1/2014		
6703(a)[a]	**Elder Justice**: Adoption of Standards for Transactions Involving Clinical Data by LTC Facilities	Requires the Secretary to have procedures in place to accept the electronic submission of clinical data by LTC facilities pursuant to specified standards.	3/23/2020		
6703(a)[a]	**Elder Justice**: Evaluation Reports	Requires an eligible entity receiving assistance to conduct evaluations of funded Elder Justice activities to submit to the Secretary and to Congress a report containing the results of the evaluation and recommendations.	Not later than date specified by the Secretary		
EMERGENCY CARE					
3505[a]	**Trauma Care Centers**: Grant Programs	Requires the Secretary to submit to Congress a report on the status of grant programs for trauma centers.	3/23/2012		Every two years thereafter

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
HEALTH CARE CENTERS AND CLINICS					
10504[a]	**Health Care and the Uninsured**: Access to Affordable Care Demonstration	Requires the Secretary to establish a 3-year demonstration project in up to 10 states to provide access to comprehensive health care services to the uninsured at reduced fees.	9/23/2010		
HEALTH DATA COLLECTION					
4302[a]	**Health Disparities Data Collection and Analysis**: Data Collection	Requires the Secretary to submit to Congress a report on a specified evaluation of approaches to health care disparities data collection.	9/23/2011		
4302[a]	**Health Disparities Data Collection and Analysis**: Reporting Requirements	Requires the Secretary to ensure that any federally conducted or supported health care or public health program, activity or survey collects and reports data as specified regarding race, ethnicity, sex, primary language, and disability status.	3/23/2012		
4302[a]	**Health Disparities Data Collection and Analysis**: Improving Disparities in Medicaid and CHIP	Requires the Secretary to submit to Congress a report with recommendations for improving the identification of health care disparities for beneficiaries of Medicaid and CHIP.	3/23/2014		
5605[a]	**Key National Indicators**: Commission Appointment	Requires the appointment of members to the Commission on Key National Indicators by the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives.	4/22/2010		
5605[a]	**Key National Indicators**: Schedule for Review and Reports	Requires the Commission on Key National Indicators to develop and implement a schedule for completion of (1) a certain review and (2) reports required under this act.	5/22/2010		
5605[a]	**Key National Indicators**: National Academy of Sciences Report	Requires the National Academy of Sciences to submit annually to the Commission a report with its findings and recommendations.	12/18/2010		Every year thereafter
5605[a]	**Key National Indicators**: Review and Establishment	Requires the co-chairpersons of the Committee on Key National Indicators to enter into an arrangement with the National Academy of Sciences under which the Academy must review and recommend approaches to selecting and establishing a key set of national indicators, and enable the establishment of the Key National Indicator System.	As soon as practicable after the selection of the two co-chairpersons		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
5605[a]	**Key National Indicators**: Report to Congress	Requires the Commission to submit annually to Congress and to the President a report with its findings and recommendations.	Not later than six months after the selection of the two co-chairpersons		Every year thereafter
5605[a]	**Key National Indicators**: Commission Report	Requires the Commission to submit annually to the National Academy of Sciences a report with its findings and recommendations.	Not later than one year after the selection of the two co-chairpersons		Every year thereafter
HEALTH INFORMATION TECHNOLOGY					
1561	**Standards**: Enrollment Standards for Health and Human Services Programs	Requires the Secretary to develop interoperable and secure standards to facilitate enrollment of individuals in federal and state health and human services programs.	9/19/2010		
10109	**HIPAA Administrative Simplification**: ICD-10 Codes	Deadline for the Secretary to convene a meeting of the ICD-9-CM Coordination and Maintenance Committee to make recommendations about revisions to the crosswalk between the ICD-9 and ICD-10 codes.	1/1/2011		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to adopt operating rules for the following electronic transactions: plan eligibility and health claims status.	7/1/2011		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to adopt a standard for EFT.	1/1/2012		
10109	**HIPAA Administrative Simplification**: Additional Standards and Operating Rules	Deadline for the Secretary to solicit input from NCVHS, the HIT Policy Committee and other stakeholders on whether to develop standards and operating rules for other administrative and financial transactions.	1/1/2012		Every three years thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to adopt operating rules for the following electronic transactions: health claims payment/remittance and EFT.	7/1/2012		
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for the unique health plan identifier.	10/1/2012		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for operating rules for the following electronic transactions: plan eligibility and health claims status.	1/1/2013		
1104	**HIPAA Administrative Simplification**: Operating Rules	Deadline for health plans to certify their compliance with the standards and operating rules for the following electronic transactions: plan eligibility, health claims status, claims payment/remittance, and EFT.	12/31/2013		
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for operating rules for the following electronic transactions: health claims payment/remittance and EFT.	1/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to establish a committee to review, and provide recommendations for updating and improving electronic transactions standards and operating rules.	1/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for the EFT standard.	1/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to adopt a standard and associated operating rules for health claims attachments.	1/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires that Medicare pay for Part A and Part B benefits by EFT or in a HIPAA-compliant electronic remittance.	1/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to assess a penalty fee against a health plan that has failed to certify its compliance with any applicable electronic transactions standards and associated operating rules.	4/1/2014		Annually thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the electronic transactions review committee to conduct hearings to evaluate and review the adopted standards and operating rules.	4/1/2014		No less than biennially thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the HHS Secretary to provide the Treasury Secretary with a list of health plans that have been assessed a penalty fee for noncompliance with the electronic transactions standards and associated operating rules.	5/1/2014		Annually thereafter

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Secretary to adopt operating rules for the following electronic transactions: health claims, plan enrollment/disenrollment, premium payments, and prior authorization and referral.	7/1/2014		
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the electronic transactions review committee to provide recommendations for updating and improving the adopted standards and associated operating rules.	7/1/2014		Not less than biennially thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Requires the Treasury Secretary to provide notice to each health plan that has been assessed a penalty fee for noncompliance with the electronic transactions standards and associated operating rules.	8/1/2014		Annually thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Deadline for health plans to pay penalty fees for noncompliance with the electronic transactions standards and associated operating rules.	11/1/2014		Annually thereafter
1104	**HIPAA Administrative Simplification**: Operating Rules	Deadline for health plans to certify their compliance with the standards and operating rules for the following electronic transactions: health claims, plan enrollment/disenrollment, premium payments, and prior authorization and referral.	12/31/2015		
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for operating rules for the following electronic transactions: health claims, plan enrollment/disenrollment, premium payments, and prior authorization and referral.	1/1/2016		
1104	**HIPAA Administrative Simplification**: Operating Rules	Effective date for the health claims attachment standard and associated operating rules.	1/1/2016		
HEALTH WORKFORCE					
5304[a]	**Dental Workforce**: Alternative Dental Health Care Provider Demonstration	Requires alternative dental health care providers demonstration projects funded under the section to begin and end according to specified dates.	3/23/2012	3/23/2017	
5507[b]	**Geriatric and LTC Workforce**: Health Workforce Demonstrations	Requires the Secretary to award grants to eligible states to conduct demonstration projects related to personal or home care aides.	9/23/2011		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
5507[b]	**Geriatric and LTC Workforce**: Health Workforce Demonstrations	Requires the Secretary to submit to Congress a report on the initial implementation of activities conducted under the home care aide demonstration project.	3/23/2012		
5103[a]	**Health Workforce Evaluation and Assessment**: Health Care Workforce Program Assessment	Transfers the responsibilities and resources of the National Center for Health Workforce Analysis to the National Center for Health Care Workforce Analysis.	9/19/2010		
5104 [added by ACA 10501(b)]	**Health Workforce Evaluation and Assessment**: Task Force on Alaska Health Care	Requires the Interagency Access to Health Care in Alaska Task Force to submit to Congress a report on improving the delivery of care to federal health care systems beneficiaries in Alaska.	9/19/2010		
5101[a]	**Health Workforce Evaluation and Assessment**: National Health Care Workforce Commission	Requires the Comptroller General to make initial appointments of members to the NHCWC.	9/30/2010		
5101[a]	**Health Workforce Evaluation and Assessment**: National Health Care Workforce Commission	Requires the NHCWC to make the first of 2 annual reports to Congress and to the Administration with recommendations for meeting the need for health care workers.	4/1/2011		Annually thereafter
5101[a]	**Health Workforce Evaluation and Assessment**: National Health Care Workforce Commission	Requires the NHCWC to make the second of 2 annual reports to Congress and to the Administration on meeting the need for health care workers.	10/1/2011		Annually thereafter
5102[a]	**Health Workforce Evaluation and Assessment**: State Health Workforce Development Grants	Requires entities receiving a grant to report on their grant activities within 1 year of receiving a grant. The administration will use these reports to develop a report to Congress on the program.	One year after grants are awarded		Annually thereafter
5701	**Health Workforce Evaluation and Assessment**: Reports	Requires the Secretary to submit an annual report to Congress on the activities carried out under Title V of ACA, as amended.			Annually

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
5503(a)	**Medicare GME Payments**: Distribution of Additional Residency Positions	Requires the Secretary to permanently reduce the residency caps of hospitals with unused residency slots. Further requires the Secretary to redistribute these unused positions, based on a specified formula, to increase a hospital's resident limit, provided that the hospital uses a specified percentage of these residency positions in primary care and general surgery.	7/1/2011		
5503(b)	**Medicare GME Payments**: Distribution of Additional Residency Positions	Requires that the redistributed residency positions be counted when determining a hospital's IME payments.	7/1/2011		
5602	**NHSC**: Designating Medically Underserved Populations and HPSAs	Requires the negotiated rulemaking committee for designating medically underserved populations and HPSAs to deliver a specified progress report to the Secretary.	4/1/2010		
5602	**NHSC**: Designating Medically Underserved Populations and HPSAs	Requires the Secretary to publish a required notice of proposed negotiated rulemaking for designating medically underserved populations and HPSAs.	5/7/2010		
5602	**NHSC**: Designating Medically Underserved Populations and HPSAs	Requires the Secretary to publish an interim final rule, subject to revision after public comment, for designating medically underserved populations and HPSAs.	7/1/2010		
5602	**NHSC**: Designating Medically Underserved Populations and HPSAs	Requires the Secretary to publish the final rule, after the public comment period.	7/1/2011		
5309(b)[a]	**Nursing Workforce**: Nurse Retention Grants	Requires the Secretary to submit a report to Congress, before the end of each fiscal year, containing information about the nurse retention grants and contracts awarded in this section.	Before 9/30/2010		Annually thereafter
5509[b]	**Nursing Workforce**: Medicare Graduate Nurse Education Demonstration Program	Requires the Secretary to submit to Congress a report on the graduate nurse education demonstration program.	10/17/2017		
10501(l)[a]	**Physician Workforce**: Rural Physician Training Grants	Requires the Secretary to define by regulation "underserved rural community" for purposes of the section.	5/22/2010		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
5508(c)[b]	**Physician Workforce**: Teaching Health Centers	Requires qualified teaching health centers receiving GME payments under this section to submit a report to the Secretary that contains certain specified information about the residents trained by the teaching health center.	One year after GME funds are awarded		
MATERNAL AND CHILD HEALTH					
2951(b)[b]	**Early Childhood Home Visitations Programs**: Needs Assessment	Requires states receiving FY2011 funding under the Maternal and Child Health (MCH) Block Grant to conduct a statewide needs assessment as specified.	9/23/2010		
2951(g)[b]	**Early Childhood Home Visitations Programs**: Advisory Panel	Requires the Secretary to appoint an independent advisory panel of experts to advise the Secretary on evaluation of the early childhood home visiting program.	3/23/2011		
2951(g)[b]	**Early Childhood Home Visitations Programs**: Evaluation	Requires the Secretary to submit to Congress a report on its evaluation of the early childhood home visitation program.	3/31/2015		
2951(c)[b]	**Early Childhood Home Visitations Programs**: State Report on Benchmark Area Improvements	Requires a state (or other grantee) receiving early childhood home visitation funds to submit a final report on any improvements in each of the six specified benchmark areas.	12/31/2015		
2951(h)[b]	**Early Childhood Home Visitations Programs**: Report to Congress	Requires the Secretary to submit a report to Congress regarding the early childhood home visitation programs.	12/31/2015		
2951(c)[b]	**Early Childhood Home Visitations Programs**: State Report Demonstrating Benchmark Area Improvements	Requires states conducting early childhood home visitation programs to submit a report to the Secretary demonstrating improvements in at least 4 of 6 benchmark areas.	30 days after the end of the third year in which state conducts program		
2952(b)[a]	**Support, Education, and Research for Postpartum Depression**: Study Results	Requires the Secretary to submit to Congress the results of a study on the benefits of screening for postpartum conditions.	3/23/2012		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
2952(a)[a]	**Support, Education, and Research for Postpartum Depression**: Report to Congress	Authorizes the Director of the National Institute of Mental Health to submit to Congress the first periodic report on the findings of an authorized study on the relative mental health consequences for women of resolving a pregnancy in various ways.	3/23/2015		
MEDICAL MALPRACTICE AND LIABILITY REFORM					
10608	**Medical Malpractice Coverage**: Liability Protection for Free Clinics	Extends malpractice coverage to certain persons providing services for free clinics.	3/23/2010		
10607[a]	**Medical Liability Reform**: State Demonstration Programs to Evaluate Alternatives to Tort Litigation	Requires MedPAC and the Medicaid and CHIP Payment and Access Commission to report to Congress on the impact of medical liability alternatives and provide recommendations.	12/31/2016		
NURSING HOMES AND OTHER LTC FACILITIES AND PROVIDERS[c]					
6201[b]	**LTC Background Checks**: Nationwide Program on Criminal Background Checks for Employees of LTC Facilities and Providers	Requires Inspector General to submit a report to Congress containing results of evaluation of the nationwide program for background checks to employees of LTC facilities.	180 days after program's completion		
NUTRITION LABELING					
4205	**Chain Restaurant Menus and Vending Machines**: Nutrition Information	Requires the Secretary to publish a Federal Register notice with information for retail food establishments seeking to voluntarily provide nutrition information to consumers.	7/21/2010		
4205	**Chain Restaurant Menus and Vending Machines**: Nutrition Labeling Recommendations	Requires the Secretary to promulgate proposed nutrition labeling regulations.	3/23/2011		
PAIN CARE MANAGEMENT					
4305(a)[a]	**IOM Conference on Pain**: Report	Requires a report to Congress summarizing the Conference on Pain's findings and recommendations.	6/30/2011		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
4305(a)[a]	**IOM Conference on Pain**: Conference Agreement	Requires Secretary to seek an agreement with IOM (or another appropriate entity if the IOM declines) to convene a Conference on Pain.	One year after funds appropriated		
4305(b)	**Pain Research**: Interagency Pain Research Coordinating Committee	Requires the Secretary to establish, and as necessary maintain, the Interagency Pain Research Coordinating Committee.	3/23/2011		Review necessity every two years thereafter
4305(b)	**Pain Research**: Recommendations	Requires the Pain Consortium to develop and submit to the NIH Director recommendations on pain research initiatives.			Not less than annually thereafter
PREVENTION AND WELLNESS					
10413[a]	**Community-Based Prevention Programs**: Young Women's Breast Health Awareness	Requires the Secretary to establish an advisory committee to assist in creating and conducting required education campaigns regarding young women's breast health.	5/22/2010		
4001 [amended by ACA 10401(a)]	**Community-Based Prevention Programs**: National Prevention, Health Promotion and Public Health Council	Requires the National Prevention, Health Promotion and Public Health Council to submit to the President and the relevant committees of Congress, an annual report on prevention, health promotion, and public health activities, goals, and progress.	7/1/2010	1/1/2015	Annually thereafter
Sec. 4004 [amended by ACA 10401(c)] [a]	**Community-Based Prevention Programs:** Education and Outreach Regarding Preventive Benefits	Requires the Secretary to report to Congress on outreach efforts for states and providers regarding obesity-related services for Medicaid beneficiaries	1/1/2011	1/1/2017	Triennially
3509[a]	**Community-Based Prevention Programs**: Offices on Women's Health	Requires the Secretary to submit a report to Congress describing projects related to improving women's health.	3/23/2011		Biennially thereafter
4001 [amended by ACA 10401(a)]	**Community-Based Prevention Programs**: National Prevention, Health Promotion and Public Health Council	Requires the Secretary to publish a national prevention, health promotion and public health strategy.	3/23/2011		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
4004 [amended by ACA 10401(c)][a]	**Community-Based Prevention Programs**: Education and Outreach Campaign Regarding Preventive Benefits	Requires the Secretary to establish a national media campaign on health promotion and disease prevention.	3/23/2011		
10334[a]	**Community-Based Prevention Programs**: Offices of Minority Health	Requires the Secretary to submit to Congress reports describing the activities of the Office of Minority Health and agencies regarding minority health.	3/23/2011		Biennially thereafter
4204[b]	**Community-Based Prevention Programs**: Immunizations	Requires GAO to submit a report to Congress on Medicare beneficiary access to vaccines.	6/1/2011		
4102[a]	**Community-Based Prevention Programs**: Oral Health Activities	Requires the Secretary to implement a 5-year oral health care prevention and education campaign.	3/23/2012		
4203	**Community-Based Prevention Programs**: Wellness for Individuals with Disabilities	Requires the Architectural and Transportation Barriers Compliance Board to issue regulatory standards for medical diagnostic equipment, to improve disabled access.	3/23/2012		
10407(d)[a]	**Community-Based Prevention Programs**: Better Diabetes Care	Requires the Secretary to submit to Congress a report on a required study on the appropriate level of diabetes medical education.	3/23/2012		
4202[b]	**Community-Based Prevention Programs**: Community Wellness Pilot; Medicare Wellness Evaluation	Requires the Secretary to submit a report to Congress on programs that promote healthy lifestyles and reduce risk factors for the Medicare population based on an evidence review and evaluation of programs.	9/30/2013		
4204[a]	**Community-Based Prevention Programs**: Immunizations	Requires the Secretary to submit a report to Congress on the demonstration program to improve the provision of recommended immunizations.	3/23/2014		
1302 [amended by HCERA 1004]	**Prevention in Private Health Insurance**: Essential Health Benefits Requirement	Effective date for inclusion of the "essential health benefits package," including preventive and wellness services, in plans offered by qualified health plans that participate in insurance exchanges.	Plan years beginning on or after 1/1/2014		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
4107 [amended by ACA 10201(c)]	**Prevention Under Medicaid**: Medicaid Tobacco Cessation Services for Pregnant Women	Requires states to provide Medicaid coverage to pregnant women for counseling and drug therapy for tobacco cessation.	10/1/2010		
4108[b]	**Prevention Under Medicaid**: Incentives for Chronic Disease Prevention Under Medicaid	Requires the Secretary to award grants to states to provide incentives to Medicaid beneficiaries to participate in healthy lifestyle programs.	1/1/2011	1/1/2016	
4106	**Prevention Under Medicaid**: Medicaid Preventive Services for Adults	Provides states an enhanced federal match if they provide Medicaid coverage of recommended preventive services for eligible adults.	1/1/2013		
4108[b]	**Prevention Under Medicaid**: Incentives for Chronic Disease Prevention Under Medicaid	Requires the Secretary to submit an initial report and a final report to Congress on the Medicaid healthy lifestyle initiatives implemented through the state grant program.	1/1/2014	1/1/2016	
4103 [amended by ACA 10402(b)]	**Prevention Under Medicare**: Medicare Annual Visit and Personalized Prevention Plan	Effective date of coverage of Medicare personalized prevention plan services.	1/1/2011		
4104 [amended by ACA 10406]	**Prevention Under Medicare**: Removal of Cost-Sharing for Medicare Preventive Services	Effective date of waiver of cost-sharing for Medicare covered preventive services.	1/1/2011		
10501(i)	**Prevention Under Medicare**: Preventive Services Furnished at FQHCs	Effective date for FQHCs to receive reimbursement for Medicare covered preventive services.	1/1/2011		
4103(b) [amended by ACA 10402(b)]	**Prevention Under Medicare**: Medicare Annual Visit and Personalized Prevention Plan	Requires the Secretary to publish guidelines for health risk assessments, to support Medicare coverage of personalized prevention plan services.	3/23/2011		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
4103(b) [amended by ACA 10402(b)]	**Prevention Under Medicare**: Medicare Annual Visit and Personalized Prevention Plan	Requires the Secretary to establish standards for interactive telephonic or web-based programs used to furnish health risk assessments.	3/23/2011		
4103 [amended by ACA 10402(b)]	**Prevention Under Medicare**: Medicare Annual Visit and Personalized Prevention Plan	Requires the Secretary to publish a health risk assessment model, to support Medicare coverage of personalized prevention plan services.	9/23/2011		
1001	**Wellness Programs**: Reporting Requirements for Group Health Plans	Requires the Secretary to develop reporting requirements for group health plans and health insurance issuers related to benefits and reimbursement that implement, among other things, "wellness and health promotion activities."	3/23/2012		
1001	**Wellness Programs**: Reporting Requirements for Group Health Plans	Requires the Secretary to promulgate regulations providing criteria for determining whether a reimbursement structure meets specified reporting elements for, among other things, "wellness and health promotion activities."	3/23/2012		
4303	**Wellness Programs**: CDC Grants for Employer Based Wellness Programs	Requires the CDC Director to conduct a national survey of employer-based health policies and programs.	3/23/2012		Regular intervals
1201	**Wellness Programs**: Regarding Prohibiting Discrimination Based on Health Status	Requires the Secretary to submit a report to Congress regarding the impact and effectiveness of wellness programs and incentives.	3/23/2013		
1201	**Wellness Programs**: Regarding Prohibiting Discrimination Based on Health Status	Requires the Secretary to establish a 10-state pilot program in which participating states are required to apply the wellness program provisions to health insurers in the individual market.	7/1/2014		
1001	**Wellness Programs**: Reporting Requirements for Group Health Plans	Requires GAO to submit a report to Congress regarding the impact of the reporting requirement for group health plans have had on the quality and cost of health care.	180 days after regulations published		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
4303	**Wellness Programs**: CDC Grants for Employer Based Wellness Programs	Requires the CDC Director to submit a report to Congress with recommendations for the implementation of effective employer-based health policies and programs.	Upon completion of the employer-based health policies survey		
QUALITY					
3503[a]	**Care Coordination**: Medication Management Services in Treatment of Chronic Disease	Requires the Secretary to commence as specified a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists.	5/1/2010		
10410(b)[a]	**Care Coordination**: Centers of Excellence for Depression	Requires the Secretary to establish no more than 20 depression centers of excellence.	3/23/2011		
10410(b)[a]	**Care Coordination**: Centers of Excellence for Depression	Requires the Secretary to make recommendations to: (1) depression centers of excellence regarding improvements, and (2) Congress regarding expanding the centers to serve individuals with other types of mental disorders.	9/30/2015		
10410(b)[a]	**Care Coordination**: Centers of Excellence for Depression	Requires the Secretary to establish no more than 30 depression centers of excellence.	9/30/2016		
3012	**National Strategy to Improve Health Care Quality and Quality Measurement**: Interagency Working Group on Health Care Quality	Requires the Interagency Working Group on Health Care Quality to submit to Congress and make public on an Internet website a report on its progress and recommendations.	12/31/2010		
3011	**National Strategy to Improve Health Care Quality and Quality Measurement**: National Strategy	Requires the Secretary to submit to Congress the first annual report on the national strategy to improve the delivery of health care services, patient health outcomes, and population health.	1/1/2011		Annually updated thereafter

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
3011	**National Strategy to Improve Health Care Quality and Quality Measurement**: National Strategy	Requires the Secretary to create an Internet website to make public information regarding the national priorities, agency-specific strategic plans for quality, and other information.	1/1/2011		
3014(b) [amended by ACA 10304][b]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measurement	Requires the Secretary, as part of a required pre-rulemaking process, to make publicly available a list of quality and efficiency measures being considered for use in health care programs or in reporting performance information to the public.	12/1/2011		Annually thereafter
3014(a) [amended by ACA 10304][b]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measurement	Requires the entity with a contract with the Secretary under SSA Sec. 1890 to transmit to the Secretary the input of multi-stakeholder groups on the selection of quality measures and the national priorities (identified under ACA Sec. 3011).	2/1/2012		
3014(b) [amended by ACA 10304][b]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measurement	Requires, as part of a required pre-rulemaking process, the consensus-based entity with a contract with the Secretary under SSA Sec. 1890 to transmit to the Secretary the input of multi-stakeholder groups on the selection of quality and efficiency measures.	2/1/2012		Annually thereafter
3014(b) [amended by ACA 10304][b]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measurement	Requires the Secretary to conduct and make public, as part of a required pre-rulemaking process, an assessment of the quality and efficiency impact of using endorsed measures.	3/1/2012		Every three years thereafter
3013(a) [amended by ACA 10303(a)][a]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measure Development	Requires the Secretary to develop at least 10 outcome quality measures on acute and chronic diseases.	3/23/2012		
3013(a) [amended by ACA 10303(a)][a]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measure Development	Requires the Secretary to develop at least 10 outcome quality measures for primary and preventive care.	3/23/2013		

ACA Section	Title	Description	Start or Effective Date or Deadline	End Date	Frequency or Duration
3014(b) [amended by ACA 10304][b]	**National Strategy to Improve Health Care Quality and Quality Measurement**: Quality Measurement	Requires the Secretary to periodically review quality and efficiency measures to determine whether to phase out or maintain the use of the measures.			In no case less often than once every three years
3508[a]	**Quality Improvement and Patient Safety**: Quality and Patient Safety Training in Clinical Education	Requires the Secretary to submit to specified committees of Congress a report on demonstration projects to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals.	3/23/2012		Annually thereafter

Source: Prepared by the Congressional Research Service based on a review of the Patient Protection and Affordable Care Act (ACA), P.L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152.

a. For the specified new and/or existing program or activity, ACA authorizes appropriations. For further information on ACA's discretionary provisions for which appropriations are authorized, see CRS Report R41390, *Discretionary Spending in the Patient Protection and Affordable Care Act (ACA)*, coordinated by C. Stephen Redhead.

b. For the specified new and/or existing program or activity, ACA mandates an appropriation or requires the Secretary to transfers funds. For further information on ACA's mandated appropriations and fund transfers, see CRS Report R41301, *Appropriations and Fund Transfers in the Patient Protection and Affordable Care Act (ACA)*, by C. Stephen Redhead.

c. For a timeline of information associated with ACA Secs. 6101-6107, 6111-6114, and 6121, regarding Nursing Homes and Other Long-Term Care Facilities and Providers, see CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al.

Appendix C. Acronyms Used in the Report

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
AFL	Adolescent Family Life
AHEC	Area Health Education Center
AHRQ	Agency for Healthcare Research and Quality
AMP	average manufacturer price
APS	adult protective services
ARRA	American Recovery and Reinvestment Act
CAN	Cures Acceleration Network
CBO	Congressional Budget Office
CCN	collaborative care networks
CDC	Centers for Disease Control and Prevention
CFCIP	Chafee Foster Care Independence Program
CHC	Community Health Center
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
CHW	community health worker
CMP	civil monetary penalty
CMS	Centers for Medicare and Medicaid Services
COE	Center of Excellence
DOJ	Department of Justice
EFT	electronic funds transfer
EIS	Epidemic Intelligence Service
EHR	electronic health record
ERISA	Employee Retirement Income Security Act
FACA	Federal Advisory Committee Act
FCCCER	Federal Coordinating Council for Comparative Effectiveness Research
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FLSA	Fair Labor Standards Act
FQHC	Federally Qualified Health Center
FTCA	Federal Tort Claims Act
GAO	Government Accountability Office
GEC	Geriatric Education Center
HCERA	Health Care and Education Reconciliation Act
HELP	Senate Committee on Health, Education, Labor, and Pensions
HHS	Health and Human Services

HIT	Health Information Technology
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
HRSA	Health Resources and Services Administration
HPSA	Health Professional Shortage Area
IHS	Indian Health Service
IOM	Institute of Medicine
IPPE	initial preventive physical examination (Medicare)
IRC	Internal Revenue Code
LTC	long term care
MA	Medicare Advantage
MCH	Maternal and Child Health
MACPAC	Medicaid and CHIP Payment Access Commission
MedPAC	Medicare Payment Advisory Commission
MEPS	Medical Expenditure Panel Survey
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MTM	medication therapy management
NCHS	National Center for Health Statistics
NCHWA	National Center for Health Workforce Analysis
NCVHS	National Committee on Vital and Health Statistics
NF	nursing facility
NHSC	National Health Service Corps
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NHANES	National Health and Nutrition Examination Survey
NMHC	Nurse-Managed Health Clinic
NOHSS	National Oral Health Surveillance System
OAA	Older Americans Act
OIG	Office of Inspector General
OMB	Office of Management and Budget
ONCHIT	Office of the National Coordinator for Health Information Technology
PCORTF	Patient-Centered Outcomes Research Trust Fund
PDP	prescription drug plan
PHSA	Public Health Service Act
PQRI	Physician Quality Reporting Initiative
PRAMS	Pregnancy Risk Assessment Monitoring System
QHBP	Qualified Health Benefits Plan
RHQDAPU	Reporting Hospital Quality Data for Annual Payment Update
SAMHSA	Substance Abuse and Mental Health Services Administration
SBHC	School-Based Health Clinic

SG	U.S. Surgeon General
SNF	skilled nursing facility
SSA	Social Security Act
SSAN	such sums as may be necessary
TANF	Temporary Assistance for Needy Families
TFCPS	Task Force on Community Preventive Services
USPHS	U.S. Public Health Service
USPSTF	U.S. Preventive Services Task Force

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