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1. Health Insurance Exchanges and Quality Health Plans

Sec. 1311 Affordable Choices for Health Benefit Plan

- *Overview.* States must establish American Health Benefit Exchanges through which insurers will offer "qualified health plans" and implement a Small Business Health Options Program (SHOP Exchange) that will assist small business owners in providing health insurance for their employees.[1]
- *Criteria.* Issuers may list plans on the Exchange by meeting the Secretary of Health and Human Services' criteria for designation as a "qualified health plan."[2] At minimum, the Secretary must require plans to meet nine criteria identified by the ACA. These criteria address issues such as marketing requirements, choice of provider, and include the following health information requirements:
    - Plans must be accredited, or obtain accreditation within a time period established by the Secretary, "with respect to local performance on clinical quality measures" (e.g. Healthcare Effectiveness Data and Information Set), "consumer access, utilization management, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs."[3] The Secretary will recognize entities that may provide such accreditation.
    - Plans must "report to the Secretary at least annually and in such manner as the Secretary shall require, pediatric quality reporting measures consistent with the pediatric quality reporting measures established under section 1139A of the Social Security Act."[4]
- *Internet Portal.* The Secretary must maintain an Internet portal, assist states in maintaining an Internet portal and create a template for State Internet portals that will assist consumers in purchasing plans on the Exchanges.[5]
- *Rating System.* The Secretary must establish "a rating system that would rate qualified health plans offered through an Exchange in each benefits level on the basis of relative quality and price.[6] Exchange Internet portals must make these ratings available to employers and individuals.[7]
- *Transparency.* The ACA requires transparency in coverage. To that end, plans must submit data regarding enrollment, disenrollment, claims denials, and any other such information as the Secretary may require to the Secretary, the State Exchange, and the State Insurance Commissioner.[8]

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1311(b)(1)(A)-(B) (2010); The Health Care and Education Affordability Reconciliation Act, Pub. L. 111-152, 111th Congress, 2nd sess. (2010).
[2] Affordable Care Act §1311(c)(1).
[3] Affordable Care Act §1311(c)(1)(D).
[4] Affordable Care Act §1311(c)(1)(I).
[5] Affordable Care Act §1311(c)(5).
[6] Affordable Care Act §1311(c)(4).
[7] Affordable Care Act §1311(c)(4).
[8] Affordable Care Act §1311(e)(3).

- *Quality Incentives.* The Secretary will develop a quality improvement incentive program to reward plans that take actions such as implementing patient safety and care improvement activities that include the use of health information technology.[9]

Sec. 6005 Pharmacy Benefit Managers Transparency Requirements

- *Reporting.* Health benefits plans and entities that administer "pharmacy benefits management services" (PBMs) pursuant to contracts with "a PDP sponsor of a prescription drug plan or an MA organization offering an MA-PD plan under Part D of title XVIII" or "a qualified health benefits plan offered through an exchange established by a state under Section 1311 of the [ACA]" must report to the Secretary of Health and Human Services the following prescription information:
    - The percentage of prescriptions filled through retail pharmacies in comparison to mail order pharmacies.[10]
    - The percentage of prescriptions filled with a generic drug, when available. This data must be broken down into pharmacy type (e.g. supermarket pharmacy, independent pharmacy). [11]
    - The aggregate difference between the amount paid by health plans to PBMs and the amount paid by PBMs to retail and mail order pharmacies. This data must include the total number of filled prescriptions. [12]
- *Disclosure.* The information is confidential, but the Secretary may disclose it for limited purposes so long any information identifying a PBM, plan, or prices is withheld. These purposes include: (1) use of the information for the purposes of this section or part D of XVIII; (2) review by the Comptroller General; (3) review by the Director of the Congressional Budget Office; and (4) use by the States in carrying out ACA Section 1311.[13]

2. Private Insurance

Sec. 1001 Amendments to the Public Health Service Act

- *Quality Reporting.* The Secretary of Health and Human Services must, after consultation with health care quality experts and other stakeholders, establish requirements for quality reporting by health insurance issuers and group plans in regards to coverage benefits or reimbursement structures that improve outcomes (e.g. case management, care coordination) prevent hospital readmissions (e.g. patient-centered education, discharge planning), improve patient safety (e.g. evidence based medicine), and promote health and wellness.[14] Health and wellness activities "include personalized wellness and prevention services" provided by a wellness manager, wellness

[9] Affordable Care Act §133(g)(1)(C).
[10] Affordable Care Act §6005; 42 U.S.C. 1320b-23(b)(1).
[11] Affordable Care Act §6005; 42 U.S.C. 1320b-23(b)(2).
[12] Affordable Care Act §6005; 42 U.S.C. 1320b-23(b)(3).
[13] Affordable Care Act §6005; 42 U.S.C. 1320b-23(c).
[14] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(a)(1)(A)-(D).

organization, or health care provider and that focus on issues such as smoking, nutrition, and physical fitness.[15]

- *Requirements.*
  - Issuers and plans must submit annual reports to the Secretary and enrollees pertaining to the ability of the plan or coverage benefits to improve outcomes, prevent hospital readmissions, improve patient safety, and promote health and wellness. [16]
  - Enrollees must have access to the reports during the open enrollment period.[17]
  - The Secretary must publish the reports on the Internet for public consumption.[18]
  - The Secretary may establish penalties for noncompliance with the reporting requirements as well as exceptions for certain requirements for issuers and plans "that substantially meet the goals of this section."[19]
- *Limitations.* The ACA places limitations on the collection, dissemination and use, by the Secretary, health plans and issuers, of information regarding an individual's lawful ownership, possession, or use of a firearm or ammunition.[20] In particular, wellness and prevention programs may not require disclosure of such information, the Secretary may not collect or store such information in a database, and such information cannot be used to affect premium rates, discounts, or rewards.[21]
- *Regulations.* The Secretary must establish, within two years of the ACA's enactment, regulations containing criteria for "determining whether a reimbursement structure is" subject to the quality reporting requirements.[22] Within 180 days of the Secretary's promulgation of these regulations, the GAO must conduct a review of the regulations and submit a report to Congress describing their impact on the quality and cost of health care.[23]

Sec. 1201 Amendment to the Public Health Service Act

Health Insurers and employee sponsored wellness programs –that meet certain requirements–may not discriminate against participants and beneficiaries based on their health status.[24] The Secretary of Health and Human Services must submit a report to Congress three years after passage of the ACA that details the efficacy of employer sponsored wellness programs in preventing disease and promoting health, the impact on access to care, and the impact of cost-sharing and premium based incentives on participants' behavior.[25]

3. Medicare, Medicaid, and Value-Based Purchasing

[15] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(b).
[16] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(a)(2)(A).
[17] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(a)(2)(B).
[18] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(a)(2)(C).
[19] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(a)(2)(D)-(E).
[20] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(c).
[21] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(c).
[22] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(d).
[23] Affordable Care Act §1001(1); 42 U.S.C. 300gg-17(e).
[24] Affordable Care Act §1201(1); 42 U.S.C. 300gg-4(a), (j).
[25] Affordable Care Act §1201(1); 42 U.S.C. 300gg-4 (m).

a. The Role of Public Programs

Sec. 2402 Removal of Barriers to Providing Home and Community-Based Services

The Secretary of Health and Human Services must establish regulations "to ensure that all states develop service systems…." These systems must (1) allocate resources in a way that accounts for "the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and supports" and maximizes beneficiary independence;" (2) support beneficiaries in designing "an individualized, self-directed, community-supported life;" and (3) improve coordination among providers in order to "achieve more consistent administration" of federal and state programs and monitor the service system functions. Such monitoring must assure (1) the "coordination of, and effectiveness of, eligibility determinations and individual assessments;" (2) that a complaint system, management system, provider monitoring system, and role-setting and budget determination system are developed; and (3) that there are an "adequate number of qualified direct care workers to provide self-directed personal assistance services."[26]

Sec. 2703 State Option to Provide Health Homes for Enrollees with Chronic Conditions

The ACA establishes "Health Homes" for the care of Medicaid eligible individuals with chronic conditions.[27] In order to receive payment for health home care, providers must submit quality information to the Secretary of Health and Human Services. Providers must utilize Health Information Technology, to the extent feasible, when submitting such information.[28] Please see the Medicaid section for more information.

Sec. 2801 MACPAC Assessment of Policies affecting all Medicaid Beneficiaries

The Social Security Act defines the qualifications for members of Medicaid and CHIP Advisory Commission (MACPAC).[29] Experience with Health Information Technology is one of the listed criteria.[30] Please see the section on Medicaid for more information.

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

The Secretary of Health and Human Services will provide funds to States and eligible entities to conduct activities aimed at improving and increasing the support provided to families living in at risk communities. Entities that receive funding for early childhood home visitation programs must demonstrate "quantifiable, measurable improvement in benchmark areas." These areas include

[26] Affordable Care Act § 2402(a).
[27] Affordable Care Act §2703(a); 42 U.S.C.S. 1396w-4.
[28] Affordable Care Act §2703(a); 42 U.S.C.S. 1396w-4(g).
[29] Affordable Care Act §2801(a)(2)(A); 42 U.S.C. 1396(c)(2)(A)-(B).
[30] Affordable Care Act §2801(a)(2)(A); 42 U.S.C. 1396(c)(2)(B).

improved health and reduced rates of domestic violence.[31] Please see the Medicaid section for more information.

b. Linking Payment to Quality Outcomes Under the Medicare Program

Sec. 3001 Hospital Value-Based Purchasing Program

The Secretary of Health and Human Services must establish a hospital value-based purchasing program.[32] Please see the section on Medicare for more information.

Sec. 3002 Improvements to the Physician Quality Reporting System

The ACA integrates the Physician Quality Reporting System with Electronic Health Records reporting.[33] Please see the Medicare section for more information.

Sec. 3003 Improvements to the Physician Feedback Program

The Secretary of Health and Human Services must assess claims data in order to provide physicians with reports on their resource utilization.[34] Please see the Medicare section for more information.

Sec. 3004 Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Hospitals, and Hospice Programs

Long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs must annually report quality data to the Center for Medicare and Medicaid Services. Failure to comply with the quality reporting requirements will result in financial penalties.[35] Please see the Medicare section for more information.

Sec. 3005 Quality Reporting for PPS-Exempt Cancer Hospitals

PPS-exempt cancer hospitals must annually report quality data to the Center for Medicare and Medicaid Services.[36] Please see the Medicare section for more information.

Sec. 3006 Plans for a Value-Based Purchasing Program for Skilled Nursing Facilities and Home Health Agencies

[31] Affordable Care Act §2951; 42 U.S.C. 711.
[32] Affordable Care Act §3001; 42 U.S.C. 1395ww(o).
[33] Affordable Care Act §3002(d); 42 U.S.C. 1395w-4(m)(7).
[34] Affordable Care Act §3003(a); 42 U.S.C. 1395w-4(n).
[35] Affordable Care Act §3004(a); 42 U.S.C. 1395ww(m); 3004(b); 42 U.S.C. 1395ww(j); 3004(c); 42 U.S.C. 1395f(i).
[36] Affordable Care Act §3005; 42 U.S.C 1395cc.

The Secretary of Health and Human Services must create plans for value-based purchasing programs for use by skilled nursing facilities and home health agencies.[37] Please see the Medicare section for more information.

Sec. 3007 Value-Based Payment Modifier under the Physician Fee Schedule

The Secretary of Health and Human Services must create a payment modifier that will adjust physician payments under the physician fee schedule according to the quality of care rendered during a performance period.[38] Please see the Medicare section for more information.

Sec. 3008 Payment Adjustment for Conditions Acquired in Hospitals

Beginning in the fiscal year of 2015, or later, payments to hospitals for discharges will be reduced to account for hospital-acquired conditions.[39] Please see the Medicare section for more information.

c. Encouraging Development of New Patient Care Models

Sec. 3021 Establishment of Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid

The Center for Medicare and Medicaid Innovation will test the ability of payment and delivery models to decrease costs and improve or maintain the quality of care.[40] The ACA identifies potential test models including one that coordinates care for "chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home tele-health technology."[41] Please see the Medicare section for more information.

Sec. 3023 National Pilot Program on Payment Bundling

The Secretary of Health and Human Services must create a pilot program to test the impact of bundled payments on the quality and efficiency of care.[42] Please see the Medicare section for more information.

Sec. 3024 Independence at Home Demonstration Program

The Secretary of Health and Human Services must implement the Independence at Home Demonstration Program to test the ability of Independence at Home Medical Practices to improve

[37] Affordable Care Act §3006.
[38] Affordable Care Act §3007; 42 U.S.C. 1395w-4.
[39] Affordable Care Act §3008(a); 42 U.S.C. 1395ww(p).
[40] Affordable Care Act §3021(a); 42 U.S.C. 1315a(a).
[41] Affordable Care Act §3021(a); 42 U.S.C. 1315a(b)(2)(B).
[42] Affordable Care Act §3023; 42 U.S.C. 1395cc-4.

outcomes and reduce costs.[43] The ACA defines Independence at Home Medical Practices as entities that, among other attributes, use health information technology and electronic health records.[44] Participating entities will have to submit data pertaining to quality measures.[45] Please see the Medicare section for more information.

Sec. 3025 Hospital Readmissions Reduction Program

The Secretary of Health and Human Services must create the Hospital Readmissions Reduction Program. This program will reduce hospital payments based upon the readmission rate of Medicare patients.[46] Please see the Medicare section for more information.

Sec. 3026 Community-Based Care Transitions Program

The Secretary of Health and Human Services must create a "Community-Based Care Transitions Program." The program will provide community-based organizations with funding to implement interventions designed to aid high-risk Medicare patients as they transition from hospitalization to community care.[47] Please see the Medicare section for more information.

d. Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans

Sec. 3311 Improved Medicare Prescription Drug Plan and Medicare Advantage-Prescription Drug (MA-PD) Plan Complaint System

- *Overview.* The Secretary of Health and Human Services shall develop and maintain a well known and user friendly complaint system to collect and maintain information on MA-PD plan and prescription drug plan complaints that are received by the Secretary.[48] The Secretary should also develop a model electronic complaint form to be used for reporting plan complaints under the system which shall be prominently displayed on the front page on the Medicare.gov website.[49]
- *Reports.* The Secretary must submit annual reports in the system to Congress, including an analysis of the number and types of complaints reported in the system, geographic variations in such complaints, the timelines of agency or plan responses to such complaints, and the resolution of such complaints.[50]

e. Ensuring Medicare Sustainability

[43] Affordable Care Act §3024; 42 U.S.C. 1395cc-5(a).
[44] Affordable Care Act §3024; 42 U.S.C. 1395cc-5(b)(1)(A)(vi).
[45] Affordable Care Act §3024; 42 U.S.C. 1395cc-5(b)(1).
[46] Affordable Care Act §3025; 42 U.S.C. 1395ww(q).
[47] Affordable Care Act §3026; 42 U.S.C. 1395b-1.
[48] Affordable Care Act §42 USC 7, §1395w-154(a).
[49] Affordable Care Act §42 USC 7, §1395w-154(b).
[50] Affordable Care Act §42 USC 7, §1395w-154(c).

Sec. 3401 Revision of Certain Market Basket Updates and Incorporation of Productivity Improvements into Market Basket Updates that do not Already Incorporate such Improvements

Psychiatric Hospitals must annually submit quality data to the Secretary of Health and Human Services.[51] Please see the Medicare section for more information.

Sec. 3403 Independent [Medicare] [Payment] Advisory Board[52]

The ACA creates the Independent Payment Advisory Board ("IPAB") for the purpose of "reduc[ing] the per capita rate of growth in Medicare spending." The IPAB must issue proposals for reducing the Medicare growth rate if the Chief Actuary of the Centers for Medicare & Medicaid Services determines that the projected growth rate will exceed the target growth rate. The IPAB must include, to the extent possible, recommendations in the proposals regarding quality and care coordination.[53] Please see the Medicare section for more information.

f. Prevention of Chronic Diseases and Improving Public Health

Sec. 4103 Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan

The ACA makes "health risk assessments" available to Medicare beneficiaries as part of their annual wellness visit. The Secretary is to encourage Health Information Technology use during these health risk assessments.[54] Please see the Medicare section for more information.

Sec. 4202 Healthy Aging, Living Well; Evaluation of Community-Based Prevention and Wellness Programs for Medicare Beneficiaries

- *Overview.* The Secretary of Health and Human Services must evaluate community-based prevention and wellness programs that: (1) "are sponsored by the Administration on Aging;" (2) "are evidence based;" and (3) "have demonstrated potential to help Medicare beneficiaries…reduce their risk of disease, disability, and injury" through various lifestyle changes (e.g. diet and exercise).[55]

[51] Affordable Care Act §3401(f); 1395ww(s).
[52] The House of Representatives passed a bill to repeal the IPAB on March 22, 2012. However, the White House has indicated that Obama will likely veto the bill if it passes the Senate. H.R. 5, 112th Cong. (2012); EXECUTIVE OFFICE OF THE PRESIDENT, STATEMENT OF ADMINISTRATION POLICY: H.R. 5- PROTECTING ACCESS TO HEALTHCARE ACT (2012), http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/112/saphr305r_20120320.pdf.
[53] Affordable Care Act §3403; 42 U.S.C. 1395kkk.
[54] Affordable Care Act §4103(b); 42 U.S.C. 1395x(hhh).
[55] Affordable Care Act §4202(b)(2)(A); 42 U.S.C. 300u-14(b)(2)(A).

- *Evidence Review.* The Secretary will review evidence with a focus on "available evidence, literature, best practices, and resources that are relevant to programs that promote healthy lifestyles and reduce risk factors for the Medicare population." The Secretary, at minimum, must review information on "physical activity, nutrition and obesity," falls, chronic disease self-management, and mental health," but may review additional information at their discretion. [56]
- *Program Evaluation.* The Centers for Medicare & Medicaid Services (CMS), with help from the Assistant Secretary for Aging, will conduct a program evaluation. The evaluation will explore whether Medicare beneficiary participation in a community prevention and wellness program: (1) improves health, reduces risk, and leads to a healthy lifestyle; (2) improves the ability of beneficiaries to manage chronic conditions; and (3) reduces utilization of service and Medicare costs. [57]
- *Reporting and Funding.* The Secretary must provide Congress with a report containing recommendations and findings by September 30, 2013. [58] Congress authorized funding to implement this section in the amount of 50 million dollars. The Secretary must obtain such funds from the Federal Hospital Insurance Trust Fund and the Federal Supplemental Insurance Trust Fund. [59]

Sec. 4302 Understanding Health Disparities: Data Collection and Analysis

While administering their Medicaid and CHIP programs, States must collect and evaluate data regarding "disparities in health care services and performance on the basis of race, ethnicity, sex, primary language, and disability status."[60] Please see the Medicaid section for more information.

g. Transparency and Program Integrity

Sec. 6103 Nursing Home Compare Medicare Website

The Secretary of Health and Human Services must establish a Nursing Home Compare website that will contain information on staffing, quality, and criminal violations.[61] Please see the Medicare section for more information.

[56] Affordable Care Act §4202(b)(2)(B)(i); 42 U.S.C. 300u-14(b)(2)(B)(i).
[57] Affordable Care Act §4202(b)(2)(B)(ii); 42 U.S.C. 300u-14(b)(2)(B)(ii).
[58] Affordable Care Act § 4202(b)(3); 42 U.S.C. 300u-14(b)(3).
[59] Affordable Care Act §4202(b)(4); 42 U.S.C. 300u-14(b)(4).
[60] Affordable Care Act §4302(b); 42 U.S.C. 1396w-5.
[61] Affordable Care Act § 6103(a)(B); 42 U.S.C. 1395i-3(h)(i).

Sec. 6301 Patient-Centered Outcomes Research

The ACA establishes the 'Patient-Centered Outcomes Research Institute.'[62] Please see the Social Security Act Administrative Provisions Section for more information.

Sec. 6402 Enhanced Medicare and Medicaid Program Integrity Provisions

The Center for Medicare and Medicaid Services must keep an Integrated Data Repository that includes information obtained pursuant to the Social Security Act, by the Secretaries of Veteran Affairs and Defense, and by the Indian Health Service.[63] Please see the Social Security Act Administrative Provisions Section for more information.

Sec. 6403 Elimination of Duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank

The Secretary of Health and Human Services will "maintain a national health care fraud and abuse data collection program…for the reporting of final adverse actions…"[64] Please see the Social Security Act Administrative Provisions Section for more information.

Sec. 6703 Elder Justice

The ACA establishes an Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation for the purpose of improving the quality of long term elder care and protecting such individuals from abuse.[65] The Secretary of Health and Human Services will make grants available to create programs such as the Long-Term Care Ombudsman Program and Adult Protective Services Program(s).[66] Entities that receive a grant pursuant to this section must comply with information sharing and Electronic Health Records requirements. Please see Social Security Act Administrative Provisions Section for more information. [67]

h. Provisions Relating to Title II: The Role of Public Programs and Title III: Improving the Quality and Efficiency of Health Care

Sec. 10202 Incentives for States to Offer Home and Community-Based Services as a Long-Term Care Alternative to Nursing Homes.

[62] Affordable Care Act §6301(a); 42 U.S.C. 1320e(b).
[63] Affordable Care Act §6402(a); 42 U.S.C. 1320a-7k(a)(1).
[64] Affordable Care Act §6403(a); 42 U.S.C. 1320a-7e(a).
[65] Affordable Care Act §6703(a)(1)(C); 42 U.S.C. 1397k; 42 U.S.C. 1397k-1.
[66] Affordable Care Act §6703(a)(1)(C); 42 U.S.C. 1397m; 42 U.S.C. 1397m-2.
[67] Affordable Care Act §6703(a)(1)(C); 42 U.S.C. 1397m(b); 42 U.S.C. 1397m-2(b).

The Secretary of Health and Human Services will provide "balancing incentive payments" to states that qualify as a "balancing incentive payment state."[68] States that expend "less than 50 percent of [their] total expenditures for medical assistance under the State Medicaid program for a fiscal year for long-term services and supports…are for non-institutionally-based long-term services and supports…" qualify if they meet certain conditions and the Secretary selects them for participation.[69] The necessary conditions include: (1) an application containing a budget and plans for the State's expansion of "medical assistance for non-institutionally-based long-term services and supports;" (2) a target spending percentage; (3) the maintenance of eligibility requirements for "medical assistance for non-institutionally-based long-term services and supports;" (4) an agreement to use the funds provided pursuant to this section to expand non-institutionally-based long term services and supports; (5) an agreement to make structural changes (e.g. single point entry system, conflict free case management services); and (6) an agreement to collect services data, quality data, and outcome measures data.[70]

Sec. 10322 Quality Reporting for Psychiatric Hospitals

Psychiatric hospitals must submit quality measure data to Secretary of Health and Human Services on an annual basis beginning with the rate year of 2014. [71] Please see the Medicare section for more information.

Sec. 10327 Improvements to the Physician Quality Reporting System

Eligible professionals that submit quality data will receive an additional incentive payment via the physician quality reporting system.[72] Please see the Medicare section for more information.

Sec. 10331 Physician Compare Website; Public Reporting of Performance Information

- *Overview.* "Not later than January 1, 2011, the Secretary of Health and Human Services shall develop a Physician Compare Internet website with information on physicians enrolled in the Medicare program under section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) and other eligible professionals who participate in the Physician Quality Reporting Initiative under section 1848 of such Act (42 U.S.C. 1395w-4)."[73] The Secretary must also implement a plan for making comparable information on physician performance, specifically quality and patient experience measures, available to the public on the Physician Compare website. This plan should be in place

[68] Affordable Care Act §10202(a); 42 U.S.C. 1396d(a).
[69] Affordable Care Act §10202(b); 42 U.S.C. 1396d(b).
[70] Affordable Care Act §10202(c); 42 U.S.C. 1396d(c).
[71] Affordable Care Act §10322; 42 U.S.C. 1886(s)(4).
[72] Affordable Care Act §10327; 42 U.S.C. 1395w-4(m)(7).
[73] Affordable Care Act §10331; 42 USC 7, §1395w-5(a)(1).

no later than January 1, 2013, with respect to reporting periods that begin no earlier than January 1, 2012.[74]

- *Information Criteria.* The information should include: "(1) measures collected under the Physician Quality Reporting Initiative; (2) an assessment of patient health outcomes and the functional status of patients; (3) an assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use; (4) an assessment of efficiency; (5) an assessment of patient experience and patient, caregiver, and family engagement; (6) an assessment of the safety, effectiveness, and timeliness of care; and (7) other information as determined appropriate by the Secretary."[75]
- *Safeguards.* The Secretary should include processes to ensure that data being made public is statistically valid and reliable, that a physician or other professional whose performance is being publicly reported has a reasonable opportunity to review his or her individual results before they are made public, that the data available provide a robust and accurate portrayal of a physician's performance, the data reflects care provided to all patients, not just those under the Medicare program, that appropriate attribution of care is given when multiple providers are involved in the care of a patient, that timely statistical performance feedback is provided to physicians, and computer and data systems that support valid, reliable, and accurate public reporting activities are implemented by the Centers for Medicare & Medicaid Services (CMS).[76]
- *Privacy.* Information on physician performance and patient experience should not be disclosed in a manner that violates the privacy of individually identifiable health information.[77]

Sec. 10332 Availability of Medicare Data for Performance Measurement

The Secretary of Health and Human Services must "develop a prospective payment system for payment for federally qualified health center services."[78] The Secretary will collect data from federally qualified health centers in order to develop the program.[79] Please see the Medicare section for more information.

4. Grants

[74] Affordable Care Act §10331; 42 USC 7, §1395w-5(a)(2).
[75] Affordable Care Act § 10331; 42 USC 7, §1395w-5(a)(2)(A)-(G).
[76] Affordable Care Act §10331; 42 USC 7, §1395w-5(b)(1)-(7).
[77] Affordable Care Act §10331; 42 USC 7, §1395w-5(c).
[78] Affordable Care Act §10501(i)(3)(A); 42 U.S.C. 1395m(o).
[79] Affordable Care Act §10501(i)(3)(A); 42 U.S.C. 1395m(o).

a. Immediate Improvements to the Public Health Services Act

Sec. 1002 Health Insurance Consumer Information

The Secretary of Health and Human Services must award grants to assist states in establishing health insurance consumer assistance and ombudsman programs.[80] States must designate a health insurance consumer assistance or ombudsman office to work with State regulators and consumer organization programs to respond to complaints about health insurance.[81] The office or ombudsman will collect data regarding consumer problems and must report such data to the Secretary.[82]

b. Health Care Quality Improvements

Sec. 3502 Establishing Community Health Teams to Support the Patient-Centered Medical Home

- *Creation.* The Secretary of Health and Human Services must enter into contracts or award grants to eligible entities in order to create "health teams" that will support primary care providers.[83] States, entities designated by states, and Indian tribes or organizations are eligible for funding. Interested entities must submit an application to the Secretary that includes plans for reaching financial stability within three years and delivery of prevention initiatives, patient education, and care management. Entities must build their health teams so that they meet the standards established by the Secretary pertaining to "interdisciplinary, interprofessional" providers (e.g. medical specialists, nutritionists, social workers). Finally, entities must agree to comply with the provisions of section 1945 of the Security Act pertaining to the care of patients with "chronic conditions" and payments for such care.[84] Section 1945 defines "chronic conditions" as including mental health conditions, substance use disorders, asthma, diabetes, heart disease, overweight, and any other condition specified by the Secretary.[85] States will specify the method of payment for health home services (e.g. tiering based on chronic conditions) and may obtain Secretary approval to use alternative payment models.[86]
- *Health Team Requirements.* Health Teams must (1) provide support to primary care providers; (2) provide support to patient centered medical homes; (3) Coordinate prevention, chronic disease management, case management, and care transitions by working with local primary care providers and other state or local resources; (4) Work with local providers to create and implement "interprofessional care plans;" (5) Develop and oversee program in a way that includes providers, patients, and other caregivers; (6) Support providers' capacity to provide access to quality care, prevention and promotion services, specialty care and inpatient services, culturally appropriate and patient centered care, medication delivery and management, complementary and alternative

[80] Affordable Care Act §1002; 42 U.S.C. 300gg-93(a).
[81] Affordable Care Act §1002; 42 U.S.C. 300gg-93 (b)(1).
[82] Affordable Care Act §1002; 42 U.S.C. 300gg-93 (d).
[83] Affordable Care Act §3502; 42 U.S.C. 256a-1(a).
[84] Affordable Care Act §3502; 42 U.S.C. 256a-1(b).
[85] Affordable Care Act §3505; 42 U.S.C. 1396w-4(h)(2).
[86] Affordable Care Act § 3505; 42 U.S.C. 1396w-4(c).

services, support provider's capacity to "collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement;" and "establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;" (7) Provide support for management and transitions on a 24 hour basis; (8) Facilitate communication between local prevention and treatment programs; (9) Have, or exhibit an ability to implement, health information technology capable of certification as Electronic Health Records technology; (10) Report quality measures to the Secretary as required pursuant to 399JJ of he PHSA. [87]

- *Provider Requirements.* Primary care providers that enter into a contract with a health team formed pursuant to this section must: (1) Share with the heath team their plan of care for each patient; (2) grant the health team with access to patient health records; (3) conduct regular meeting with the care team.[88]
- *Reporting Requirements.* Entitles that receive funds must comply with any reporting requirements established by the Secretary. [89]

Sec. 3504 Design and Implementation of Regionalized Systems for Emergency Care

- *Overview.* The Secretary of Health and Human Services, through the Assistant Secretary for Preparedness and Response, must award a minimum of 4 "multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems."[90]
- *Eligible Entity. The* ACA defines, for the purposes of this section, "eligible entity" as states, partnerships among states and local governments, Indian tribes, and partnerships among Indian tribes, "region" as areas within a state or multiple states "as determined by the Secretary, and "emergency services" as inclusive of "acute, pre-hospital, and trauma care." [91]
- *Project Selection.* The Secretary must award grants or contracts to entities that propose a pilot project that: (1) coordinates the development of "an approach to emergency medical and trauma system access. . . , including 9-1-1- Public Safety Answering Points and emergency medical dispatch" among regional emergency, public health and safety, and medical entities; (2) has a means of ensuring that a patient "is taken to [a] medically appropriate facility…in a timely fashion;" (3) has the ability to track "pre-hospital and hospital resources" as well as "coordinat[e]…such tracking with regional communications and hospital destination decisions;" and (4) has "a consistent region-wide pre-hospital, hospital, and inter-facility data management system" that (a) is capable of submitting data to, among others, the National EMS Information System and National Trauma Data Bank; (b) is capable of reporting data to Federal and State

[87] Affordable Care Act §3502; 42 U.S.C. 256a-1(c).
[88] Affordable Care Act §3502; 42 U.S.C. 256a-1(d).
[89] Affordable Care Act §3502; 42 U.S.C. 256a-1(e).
[90] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(a); 3504(a)(3)(B), 42 U.S.C. 300d-6(1232(c)).
[91] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(b).

registries; and (c) has sufficient information for purposes of evaluating "key elements pre-hospital care, hospital destination decisions, including initial hospital and inter-facility decisions, and relevant health outcomes of hospital care."[92] The Secretary will give preference in awarding grants to entities that provide service to medically underserved areas.[93]

- *Application.* Entities must apply for emergency care and trauma system grants pursuant to guidelines established within the Secretary's discretion.[94] The application must, however, contain assurances from entity applicants that their system (1) is "coordinated with the applicable State Office of Emergency Medical Services;" (2) has consistent medical oversight of transport within the applicable region; (3) "coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;" (4) has a means of integrating a "categorization or designation system for special medical facilities" with "transport and destination protocols;" (5) has "a regional medical direction, patient tracking, and resource allocation system that supports day-to-day emergency care and surge capacity and is integrated with other components of the national and State emergency preparedness system;" and (6) "addresses pediatric concerns related to integration, planning, preparedness, and coordination of emergency medical services for infants, children, and adolescents."[95]
- *Grantee Requirements.* Entities that receive grants pursuant to this section must match 1 dollar of funding for each 3 dollars of federal funding.[96] Entities may match funds in cash or in kind and obtain such funds from private or public sources.[97] Entities that receive funds must submit a report to the Secretary, ninety days after completion of the project, that details the impact of the project on patient outcomes in critical care categories (e.g. stroke, cardiac emergencies), the project characteristics that contributed or inhibited project's "effectiveness and efficiency," the means to assure financial sustainability of the project in the long-term, barriers to developing the project and the means to overcome such barriers, and recommendations on the use of funds for additional "regionalization efforts."[98] The Secretary must disseminate the findings from these reports to Congress and the public, as appropriate.[99]

Sec. 3505 Trauma Care Centers and Service Availability

- *Grant Programs.* The Secretary of Health and Human Services must establish three programs to award grants to qualified trauma centers for the purpose of: (1) defraying costs of uncompensated care; (2) "futher[ing] the core missions of …trauma centers" by defraying costs such as those associated with stabilizing and transferring patients and personnel costs; and (3) providing emergency relief funds so that trauma centers remain available.[100] Costs of uncompensated care

[92] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(c).
[93] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(f).
[94] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(d).
[95] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(d).
[96] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(e).
[97] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(e).
[98] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(g).
[99] Affordable Care Act §3504(a), 42 U.S.C. 300d-6(h).
[100] Affordable Care Act §3505(a), 42 U.S.C. 300d-41(a).

"means unreimbursed costs from serving self-pay, charity, or Medicaid patients…attributable to emergency care and trauma care, including costs related to subsequent inpatient admissions to the hospital."[101]

- *Qualification.* In order to qualify for a grant, trauma centers must
  - Comply with the professional guidelines established in section 1213, unless they are located in a state that lacks a trauma care system;[102] and, if seeking a grant for the costs of uncompensated care, meet at least one of the criteria identified pertaining to the percentage of patients the trauma center serves that self-pay, receive Medicaid benefits, and etc; or qualify for "a Low Income Pool or Safety Net Care Pool."[103]
  - Receive verification by the American College of Surgeons or a comparable state or local agency;
  - Demonstrate to the Secretary their "commitment to serving trauma patients regardless of their ability to pay;"
  - Have policies, such as a sliding scale, that help patients that cannot afford the total cost of their care to pay at least a portion and that "ensure fair billing and collection practices;" and
  - Comply with the application process as specified by the Secretary.[104]
  - The Secretary has discretion to require grantees "maintain access to trauma services at comparable levels to the prior year during the grant period and "provide data to a national and centralized registry of trauma cases, in accordance with guidelines developed by the American College of Surgeons, and as the Secretary may otherwise require."[105]
- *Amount and Duration.* The Secretary may award 100% of uncompensated costs of care to trauma centers within Category A, 75% to those in Category B, and 50% to those in Category C.[106]
  - The Secretary must award 25% of the funds allocated for "Core Mission" grants to Level III and Level IV trauma centers and 25% to "large urban Level I and II trauma centers" that: (1) have a trauma related graduate medical fellowship "for which demand is exceeding supply;" or (2) incur at least 10 million dollars in uncompensated costs of care on an annual basis, but do not otherwise qualify for uncompensated care grants.[107] The Secretary must give preference when awarding "Emergency" grants to trauma centers in locations where "the availability of trauma care has significantly decreased or will significantly decrease if the center is forced to close or downgrade service or growth in demand for trauma services exceeds capacity."[108] The Secretary must divert any unused funds allocated for Emergency grants to grants for uncompensated costs of care.[109]

[101] Affordable Care Act §3505(6); 42 U.S.C. 300d-46
[102] Affordable Care Act §3505(a), 42 U.S.C. 300d-41(a)(3).
[103] Affordable Care Act §3505(a), 42 U.S.C. 300d-41(a)(4).
[104] Affordable Care Act §3505(a), 42 U.S.C. 300d-41(a)(5); 3505(a), 42 U.S.C. 300d-41(c); 3504(a)(4), 42 U.S.C. 300d-44(a).
[105] Affordable Care Act §3505(a)(3), 42 U.S.C. 300d-44(a)-(b).
[106] Affordable Care Act §3505(a)(2), 42 U.S.C. 300d-42(a).
[107] Affordable Care Act §3505(a)(2), 42 U.S.C. 300d-42(b).
[108] Affordable Care Act §3505(a)(2), 42 U.S.C. 300d-42(c).
[109] Affordable Care Act §3505(a)(2), 42 U.S.C. 300d-42(c).

  - The Secretary must limit payments to trauma centers to a period of three fiscal years, but may such limit for an additional fiscal year.[110] Further, such grants cannot exceed 2 million dollars per fiscal year.[111] The Secretary must use 70% of the appropriations for uncompensated costs of care grants, 20% for Core Mission grants, and 10% for Emergency grants.[112] If, however, Congress appropriates less than 25 million dollars for grants under this subsection, then the Secretary must use all the funds for uncompensated costs of care grants.[113] Further, the Secretary must award 50% of allocations for uncompensated costs of care grants to Category A trauma centers, 35% to Category B, and 15% to Category C.[114]
- *Reporting.* The Secretary must report the status of grants to Congress on a biannual basis beginning two years after enactment.[115]

Sec. 3509 Improving Women's Health

Health and Human Services Office on Women's Health
The ACA establishes an Office on Women's Health within the Department of Health and Human Services. The Secretary of Health and Human Services will act through the office to (1) establish long and short term goals and objectives for prevention, promotion, delivery of care, research and education regarding women's health issues; (2) provide advice regarding women's health legal, ethical, scientific and policy issues; (3) Identify women's health activities within HHS offices and agencies whereby coordination is feasible; (4) create the HHS Coordinating Committee on Women's Health, comprised of senior level representatives from HHS and chaired by the Deputy Assistant Secretary for Women's Health; (5) create the National Women's Health Information Center in order to "facilitate the exchange," access, and analysis, "of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care" and "provide technical assistance with respect to the exchange of such information;" (6) coordinate women's health promotion activities with the private sector; and (7) exchange information between the Office and grantees, contractors, health professionals, and the public via publication "and any other means appropriate."[116]

The Secretary has authority to issue grants and enter into contracts or interagency agreements with public and private entities in order to carry out the [above] mandates.[117] The Secretary must evaluate the activities carried out pursuant to such grants or contracts and disseminate the information generated by the activities.[118] The Secretary must report to Congress regarding the activities of the office every

[110] Affordable Care Act § 3505; 42 U.S.C. 300d-44(b).
[111] Affordable Care Act § 3505; 42 U.S.C. 300d-44(c).
[112] Affordable Care Act § 3505; 42 U.S.C. 300d-44(e).
[113] Affordable Care Act § 3505; 42 U.S.C. 300d-44(f).
[114] Affordable Care Act §; 3505; 42 U.S.C. 300d-44(g).
[115] Affordable Care Act § 3505; 42 U.S.C. 300d-44(h).
[116] Affordable Care Act §3509(a); 42 U.S.C. 237(a).
[117] Affordable Care Act §3509(a); 42 U.S.C. 237(b).
[118] Affordable Care Act §3509(a); 42 U.S.C. 237(c).

two years beginning no later than a year following enactment. Congress appropriated funds "as necessary" for the fiscal years between 2010 and 2014.[119]

Food and Drug Administration (FDA) Office of Women's Health

The ACA establishes the Office of Women's Health within the FDA.[120] The Office must (1) provide information regarding women's participation in clinical trials of medical devices, drugs, and biological products and information regarding the sex based data analysis in these trials to the Commissioner; (2) identify goals and objectives related to women's health that are within the FDA's jurisdiction; (3) disseminate information to providers and women regarding differences between men and women; (4) consult with private entities, such as drug manufacturers, health professionals, and consumer organizations on women's policy; (5) annually estimate the funds necessary "to monitor clinical trials and analysis of data in accordance with needs that are identified;" and (6) sit on Coordinating Committee on Women's Health.[121] The ACA appropriated funds "as necessary" for the fiscal years between 2010 and 2014. [122]

c. Creating Healthier Communities

Sec. 4201 Community Transformation Grants

- *Purpose.* The Secretary of Health and Human Services, through the Centers for Disease Control and Prevention (CDC), must award grants, on a competitive basis, to eligible entities for the purpose of designing and implementing "evidence-based community preventive health activities" that address issues such as chronic disease prevalence and *health disparities* while developing "a stronger evidence-base of effective prevention programming."[123] A minimum of 20% of these grants must go to "rural and frontier areas."[124]
- *Eligibility.* State and local agencies, community-based organization networks, state and local non-profit organizations, and Indian tribes are eligible for grants.[125] These entities must submit an application to the Director of the CDC and demonstrate their ability to engage with diverse stakeholders in their community.[126]
- *Community Transformation Plan.* Upon receipt of funds, grantees must submit a Community Transformation Plan to the Director for their approval. This plan must describe changes necessary, in areas such as policy and infrastructure, "to promote healthy living and reduce disparities."[127] The ACA does not place a limit on the possible focus on Community Transformation Plans, but

[119] Affordable Care Act §3509(a); 42 U.S.C. 237(d)-(e).
[120] Affordable Care Act §3509(g); 21 U.S.C. 399b(a).
[121] Affordable Care Act §3509(g); 21 U.S.C. 399b(b).
[122] Affordable Care Act §3509(g); 21 U.S.C. 399b(c).
[123] Affordable Care Act §4201(a); 42 U.S.C. 300u-13(a)
[124] Affordable Care Act §4201(b); 42 U.S.C. 300u-13(b)
[125] Affordable Care Act §4201(b)(1); 42 U.S.C. 300u-13(b)(1).
[126] Affordable Care Act §4201(b)(2)-(3); 42 U.S.C. 300u-13(b)(2)-(3).
[127] Affordable Care Act §4201(c)(2)(A); 42 U.S.C. 300u-13(c)(2)(A).

does provide potential areas for grantees to focus upon such as healthy school initiatives, worksite wellness initiatives, and initiatives aimed at reducing racial and ethnic disparities.[128]

- *Evaluation.* Grantees that receive approval of their Community Transformation Plan must subsequently use the funds to implement and evaluate their plan. The evaluation must measure the effect of participation in the prevention activities on the prevalence of chronic disease.[129] This will require entities to measure changes in weight, nutrition, physical activity, tobacco use, emotional well-being and mental health, "other factors using community-specific data from the Behavioral Risk Factor Surveillance Survey, and other measures specified by the Secretary." [130] Entities must report the results of their evaluation to the Director on an annual basis, attend annual meetings to share the knowledge gained from their activities, and develop models that facilitate replication of their activities.[131]
- *Training.* The Director must (1) establish a program to train eligible entities on chronic disease prevention and control activities as well as "the link between physical, emotional, and social well-being:" (2) give grantees feedback and technical assistance regarding their Community Transformation Plan; and (3) establish "a literature review and framework for the evaluation of programs" and partner with "academic institutions or other entities with expertise in outcome evaluation." [132]
- *Limitations.* Grantees may not use funds to create video games or develop other programs that can increase obesity or inactivity.[133]

Sec. 4202 Healthy Aging, Living Well; Evaluation of Community-Based Prevention and Wellness Programs for Medicare Beneficiaries

- *Grants.* The Secretary of Health and Human Services, through the CDC, will award five year grants to state or local health departments and Indian tribes for the purpose of conducting five year community health pilot projects for the benefit of individuals between the ages of 55 and 64.[134] Health departments or Indian tribes interested in receiving a grant must (1) develop a community based intervention focused on the specified age group; (2) have the capacity to work with providers, community organizations, and insurers; and (3) submit an application to the Secretary.[135]
    - *Public health interventions.* Grantees must work with the CDC to design and implement activities aimed at issues such as nutrition, substance abuse, and physical activity.[136]
    - *Community Prevention Screenings*. Grantees must screen for cancer, stroke, diabetes, and cardiovascular disease risk factors. Such screening may entail screening for mental and behavioral health issues, substance abuse, smoking, nutrition, physical activity, and other

[128] Affordable Care Act §4201(c)(2)(B); 42 U.S.C. 300u-13(c)(2)(B).
[129] Affordable Care Act §4201(c)(4)(A); 42 U.S.C. 300u-13(c)(4)(A).
[130] Affordable Care Act §4201(c)(4)(B); 42 U.S.C. 300u-13(c)(4)(B).
[131] Affordable Care Act §4201(c)(4)(C)-(5); 42 U.S.C. 300u-13(c)(4)(C)-(5).
[132] Affordable Care Act §4201(d); 42 U.S.C. 300u-13(d).
[133] Affordable Care Act §4201(e); 42 U.S.C. 300u-13(e).
[134] Affordable Care Act §4202(a)(1); 42 U.S.C. 300u-14(a)(1).
[135] Affordable Care Act §4202(a)(2); 42 U.S.C. 300u-14(a)(2).
[136] Affordable Care Act §4202(a)(3)(B); 42 U.S.C. 300u-14(a)(3)(B).

criteria determined by the Secretary. Grantees must "maintain records of screening results…to establish the baseline data for monitoring the target population**.**"[137]

- *Clinical Referral and Treatment for Chronic Diseases*. Grantees must refer individuals identified through screening as at risk for chronic disease for treatment. Grantees must enter into contracts with "community health centers or rural health clinics and mental health and substance use disorder service providers" to facilitate referral of at risk individuals to resources that provide clinical follow-up and can "help determine eligibility for other public programs." Grantees should refer insured individuals to their current provider or an in-network provider and should refer uninsured individuals to the "grantee's community based clinical partner."[138]

- *Evaluation*.
  - Grantees must use awards funds to evaluate the impact of their program on the "prevalence of chronic disease risk factors among participants."[139]
  - The Secretary must evaluate the effectiveness of the programs on an annual basis. [140] The evaluation must "consider changes in the prevalence of uncontrolled chronic disease risk factors among new Medicare enrollees" that reside in areas receiving funds "as compared with national and historical data for those States and localities for the same population."[141]

Sec. 4204 Immunizations

Demonstration Program to Improve Immunization Coverage

- *Grants.* The Secretary of Health and Human Services, through the CDC, must award grants to States to increase immunizations "for children, adolescents, and adults through the use of evidence-based population-based interventions for high-risk populations."[142]
- *Application.* States may obtain funds by submitting a plan to the Secretary that details their proposed interventions and describes how the interventions meet the needs and capacity of the targeted area.[143] The Secretary will award grants to States after considering recommendations from the Task Force on Community Prevention Planning Services.[144]
- *Interventions.* States must use the funds to "implement interventions that are recommended by the Task Force on Community Preventive Planning Services…or other evidence-based interventions. These interventions include sending targeted immunization reminders, providing education, lowering out-of-pocket expenses, and use of "immunization information systems to allow all States to have electronic databases for immunization records."[145]

[137] Affordable Care Act §4202(a)(3)(C); 42 U.S.C. 300u-14(a)(3)(C).
[138] Affordable Care Act §4202(a)(3)(D); 42 U.S.C. 300u-14(a)(3)(D).
[139] Affordable Care Act §4202(a)(3)(E); 42 U.S.C. 300u-14(a)(3)(E).
[140] Affordable Care Act § 4202(a)(4); 42 U.S.C. 300u-14(a)(4).
[141] Affordable Care Act §4202(a)(4); 42 U.S.C. 300u-14(a)(4).
[142] Affordable Care Act §4204(b); 42 U.S.C. 247b(m)(1).
[143] Affordable Care Act §4204(b); 42 U.S.C. 247b(m)(2).
[144] Affordable Care Act § 4204(b); 42 U.S.C. 247b(m)(4).
[145] Affordable Care Act §4204(b); 42 U.S.C. 247b(m)(3).

- *Evaluation and Reporting.* States must conduct an evaluation of their progress within three years of receiving funds and submit the results of this evaluation to the Secretary.[146] The Secretary must submit a report to Congress, within 4 years of enactment of the Affordable Health Choices Act, containing project findings and recommendations on the future of the program.[147]

GAO Study and Report on Medicare Beneficiary Access to Vaccines

- *Overview.* The Comptroller General must study "the ability of Medicare beneficiaries who were 65 years of age or older to access routinely recommended vaccines covered under the [Medicare prescription drug program] over the period since the establishment of such program."[148] The study must contain information on: (1) the number of beneficiaries eligible for a "routinely recommended vaccine…covered under part D;" (2) the number of beneficiaries receiving such vaccine; (3) access barriers to covered vaccines; and (4) "a summary of the findings and recommendations" by government entities and professional organizations "on the impact of including "routinely recommended vaccines" in the Medicare prescription drug benefit on Medicare beneficiary access to such vaccines.[149]
- *Report and Funding.* The Comptroller General must provide Congress with the report and recommendations by June 1, 2011.[150] Congress appropriated 1 million dollars "out of any funds in the Treasury not otherwise appropriated" to carry out the study during 2010. [151]

d. Support for Prevention and Public Health Innovation

Sec. 4304 Epidemiology-Laboratory Capacity Grants

- *Grants.* The Secretary of Health and Human Services must, pending appropriation availability, create an Epidemiology and Laboratory Capacity Grant Program. Grants under this program will be available to State and local health departments and tribal organizations, subject to criteria established by the Secretary. Additionally, the Secretary has discretion to award grants to academic centers that provide support to any of the eligible entities.[152]
- *Requirements.* Grantees must use the funds to improve the surveillance of and response to infectious diseases and other public health concerns by: (1) improving the "epidemiologic capacity to identify and monitor the occurrence of" diseases; (2) "enhancing laboratory practice as well as systems to report test orders and results electronically;" (3) "Improving information systems including developing and maintaining an information exchange using national guidelines and complying with capacities and functions determined by an advisory council established and

[146]Affordable Care Act § 4204(b); 42 U.S.C. 247b(m)(5).
[147]Affordable Care Act § 4204(b); 42 U.S.C. 247b(m)(6).
[148] Affordable Care Act §4204(e)(1).
[149] Affordable Care Act §4204(e)(1)(A)-(B).
[150] Affordable Care Act §4204(e)(2).
[151] Affordable Care Act §4204(e)(3).
[152]Affordable Care Act § 4304; 42 U.S.C. 300hh-31(a).

appointed by the Director;" and (4) "developing and implementing prevention and control strategies."[153]

- *Funding.* Congress appropriated 190 million for the fiscal years 2010-2013. The Secretary must allocate a minimum of 95 million to all of the identified activities, a minimum of 60 million each year for information systems improvement, and a minimum of 32 million each year improving electronic reporting systems.[154]

e. Enhancing Health Care Workforce Education and Training

Sec. 5304 Alternative Dental Health Care Providers Demonstration Project

- *Grants.* The Secretary of Health and Human Services has authority to award grants to fifteen eligible entities for the purpose of increasing access to dental care in rural and underserved areas by training or employing "alternative dental health care providers."[155] The ACA defines "alternative health care providers" as inclusive of "community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and" other professionals within the Secretary's discretion.[156]
- *Eligible Entities.* The Secretary may award the grants to higher education institutions, partnerships between public and private entities, federally qualified health centers, Indian Health Service facilities or tribal organizations, State and county public health clinics, Indian tribe health facilities, and public hospitals that are accredited by the Commission on Dental Accreditation (or operate "within a dental education program in an accredited institution), comply with the Secretary's application requirements, and certify their compliance with State licensing requirements.[157]
- *Funding.* Congress appropriated funds "as necessary" to conduct the demonstration projects.[158] The Secretary must provide a minimum of 4 million dollars to grantees for use over a five year testing period.[159] The Secretary may disburse a maximum of 20% of funding to grantees for the purpose of planning the demonstration project and may disburse a minimum of 15% during each subsequent grant year.[160] The demonstration projects must occur within two years and conclude within 7 years of enactment.[161]
- *Evaluation.* The Secretary, through contract with the Director of the Institute of Medicine, must evaluate the programs. The evaluation must "provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States."[162]

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[153] Affordable Care Act §4304; 42 U.S.C. 300hh-31(a).
[154] Affordable Care Act § 4304; 42 U.S.C. 300hh-31(b).
[155] Affordable Care Act §5304; 42 U.S.C. 256g-1(a)(1).
[156] Affordable Care Act §5304; 42 U.S.C. 256g-1(a)(2).
[157] Affordable Care Act §5304; 42 U.S.C. 256g-1(c).
[158] Affordable Care Act §5304; 42 U.S.C. 256g-1(h).
[159] Affordable Care Act §5304; 42 U.S.C. 256g-1(d)(1).
[160] Affordable Care Act §5304; 42 U.S.C. 256g-1(d)(2).
[161] Affordable Care Act §5304; 42 U.S.C. 256g-1(b).
[162] Affordable Care Act §5304; 42 U.S.C. 256g-1(f).

f. Supporting the Existing Health Care Workforce

Sec. 5405 Primary Care Extension Program (PCEP)

- *Overview.* The Secretary of Health and Human Services, via the Director of the AHRQ, will establish the Primary Care Extension Program (PCEP) as a means to support, assist, and educate providers regarding prevention, management, behavioral and mental health services, and other such items that will improve community health upon incorporation into their practice.[163] The PCEP will carry out this purpose through the use of "Health Extension Agents;" defined as health workers, on the local or community level, that support primary care providers as they change their practices to include quality improvement measures and provide patient centered care.[164]
- *Grants.* The Secretary will award grants to States for the purpose of planning and establishing Primary Care Extension Program State Hubs ("Hubs") and "Local Primary Extension Agencies" (LPEAs).[165] States may obtain either two year planning grants or six year implementation grants by submitting an application to the Secretary and agreeing to undergo evaluation of their efforts.[166] The Secretary may extend funding beyond six years in the even of a satisfactory evaluation.[167] States may not allocate more than 10% of funds to the administration of the program. [168]
- *Hub Composition and Function.* States must compose their hub to include, at minimum, their state health department, the entity administering the state Medicaid program, and the professional school departments that train providers within the state.[169] Other entities, such as hospital associations and consumer groups may also participate in the Hub.[170] Hubs will function as the state level administrator of the PCEP by contracting with and providing funding to LPEAs, organizing LPEAs into networks whereby knowledge exchange is feasible, and establishing a plan for coordinating with quality improvement organizations.[171]
- *LPEA Functions.*
    - LPEAs must (1) assist primary care providers in establishing patient centered medical homes, making their practices more accessible and offering better quality and more efficient care; (2) develop "learning communities" to facilitate the exercise of evidence-based practice and the exchange of knowledge and best practices among community providers; (3) "participate in a national network of Primary Care Extension Hubs and propose how the [PCEA] will share and disseminate lesson learned and best practices;" and

[163] Affordable Care Act §5405; 42 U.S.C. 280g-12(a)(1)-(2).
[164] Affordable Care Act §5405; 42 U.S.C. 280g-12(a)(3)(A).
[165] Affordable Care Act §5405; 42 U.S.C. 280g-12(b)(1).
[166] Affordable Care Act §5405; 42 U.S.C. 280g-12(d)(1)-(3).
[167] Affordable Care Act §5405; 42 U.S.C. 280g-12(d)(4).
[168] Affordable Care Act §5405; 42 U.S.C. 280g-12(d)(5).
[169] Affordable Care Act §5405; 42 U.S.C. 280g-12(b)(2)(A).
[170] Affordable Care Act §5405; 42 U.S.C. 280g-12(b)(2)(B).
[171] Affordable Care Act §5405; 42 U.S.C. 280g-12(c)(1).

(4) have a plan for maintaining financial stability that includes a reduction in federal funding following a six year period. [172]

- LPEAs may (1) "provide technical assistance, training, and organizational support for community health teams…;" (2) "collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvements;" (3) work with local and community health departments and organizations to identify and address issues health priorities, workforce needs, and health disparities; (4) "develop measures to monitor the impact of the proposed program on the health of practice enrollees and the wider community served;" and (5) conduct any other activities specified by the Secretary.[173]

- *Consultation.* The Secretary must administer the PCEP after consultation with various federal agencies including the CDC and Office of the National Coordinator for Health Information Technology. [174]

g. Patient-Centered Outcomes Research

Sec. 6301 Patient-Centered Outcomes Research

- *Office Functions.*
  - The Office of Communication and Knowledge Transfer ("Office"), housed in the AHRQ, must disseminate the information produced by the Patient Centered Outcomes Research Institute after consulting with the NIH. The Office must develop tools to facilitate dissemination to physicians, health care providers, patients, payers, and policymakers and establish a public database of government-funded research.[175]
  - The Office must disseminate the Institute's research regarding comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans."[176] The means used to disseminate the research findings must describe "considerations for specific subpopulations, the research methodology" and limitations, and the entities that conducted the research.[177] The Office must ensure that the information disseminated is not "construed as mandates, guidelines, or recommendations for payment, coverage, or treatment."[178]

[172] Affordable Care Act §5405; 42 U.S.C. 280g-12(c)(2)(A).
[173] Affordable Care Act §5405; 42 U.S.C. 280g-12(c)(2)(B).
[174] Affordable Care Act §5405; 42 U.S.C. 280g-12(e).
[175] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(a)(1).
[176] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(a)(2).
[177] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(a)(2)(A).
[178] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(a)(2)(B).

  - The Office must help "users of health information technology focused on clinical decision support to promote the timely incorporation of research findings…into clinical practices and to promote the ease of use of such incorporation."[179]
- *Grants.* The AHRQ, after consulting with the NIH, must create a grant program in order to train researchers. The training, at minimum, must "be in methods that meet the methodological standards adopted in section 1181(d)(9) of the [Social Security Act]."[180]
- *Data Registries.* The Secretary of Health and Human Services must build data capacity research by developing "clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records."[181]
- *Contracts.* Federal agencies and instrumentalities may contract for the Institute's services in conducting clinical effectiveness research so long as the agencies or entities have authority derived from their governing statutes.[182]

h. Provisions Relating to Title VI: Transparency and Program Integrity

Sec. 10607 State Demonstration Programs to Evaluate Alternatives to Current Medical Tort Litigation

- *Grants.* The Secretary of Health and Human Services has authority to award states with grants, for a maximum of five years, to develop and test "alternatives to current tort litigation for resolving disputes over injuries allegedly caused" by health care professionals.[183] States interested in receiving a grant must develop an alternative to litigation and submit an application to the Secretary.
- *Alternative Requirements*
  - The alternative to litigation must: (1) facilitate dispute resolution; and (2) "promote a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes…by organizations that engage in efforts to improve patient safety and the quality of health care." [184]
  - States must show that their alternative: (1) increases the "availability of prompt and fair resolution of disputes" thereby resulting in a more reliable medical liability system; (2)

[179] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(b).
[180] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(e).
[181] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(f).
[182] Affordable Care Act §6301(b); 42 U.S.C. 299b-37(g).
[183] Affordable Care Act §10607; 42 U.S.C. 280g-15(a)-(c).
[184] Affordable Care Act §10607; 42 U.S.C. 280g-15(c)(1).

encourages dispute resolution efficiency; (3) "encourages the disclosure of health care errors;" (3) improves patient safety through the detection and analysis of medical errors; (4) "improves access to liability insurance;" (5) educates patients regarding the difference between tort litigation and the alternative; (6) permits patients to withdraw or opt out of participating in the alternative and permits them to pursue litigation or other options; (7) not conflict with state law in a way that would prohibit adoption of the alternative; and (8) not place any limits on patient's legal rights or access to the legal system. [185]

- States must detail the sources of compensation for their alternative. States may permissibly fund the alternative with private funds, public funds, or a combination of public and private funds. If possible, the funding method should incentivize patient safety activities.[186]
- States must identify the scope of jurisdiction for their demonstration project. This may be statewide, within certain a geographic area, or within a group of health care providers or organizations. States must notify patients that receive care within the relevant scope of their ability to opt out or withdraw from participation.[187]

- *Award Process*.
  - The Secretary will review the applications along with a review panel comprised by 9-13 individuals appointed by the Comptroller general. These individuals must be "highly qualified and knowledgeable" and chosen to fairly represent patient advocates, health care providers, health care organizations, plaintiff's and defendant's attorneys, medical malpractice insurers, state officials, and patient safety experts.[188] The Comptroller General, or their designee, will serve as chair of the panel and ensure that the panel has access to "such information, personnel, and administrative services and assistance as the review panel may reasonably require."[189] The review panel may also request information from any federal agency or office that is necessary to perform their duties.
  - The Secretary must give preference to States that: (1) consulted with relevant stakeholders (e.g. providers, patient safety advocates) when created their proposal; (2) have proposed a method that is "likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and (3) have proposed a method that is "likely to improve access to liability insurance."[190]
- *Reports*. States grantees must provide the Secretary with annual reports that evaluate the alternative's effectiveness. At minimum, these reports must evaluate the impact on patient safety and the price and availability of medical liability insurance. The Secretary must submit an annual report to Congress containing a compilation of state reports and an analysis that discusses the differences in state activities. [191]
- *Technical Assistance.* The Secretary must provide states with technical assistance. Such assistance include "guidance on non-economic damages" and "the development, in consultation with States,

[185] Affordable Care Act §10607; 42 U.S.C. 280g-15(c)(2).
[186] Affordable Care Act §10607; 42 U.S.C. 280g-15(c)(3).
[187] Affordable Care Act §10607; 42 U.S.C. 280g-15(c)(4).
[188] Affordable Care Act §10607; 42 U.S.C. 280g-15(d)(2)(B)(ii).
[189] Affordable Care Act §10607; 42 U.S.C. 280g-15(d)(2)(D).
[190] Affordable Care Act §10607; 42 U.S.C. 280g-15(c)(5).
[191] Affordable Care Act §10607; 42 U.S.C. 280g-15(e).

of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States. These common definitions may also be used by states that do not receive funding. [192]

- *Evaluation.* The Secretary, after consulting with the review panel, will contract with a research organization to provide an annual evaluation of the granting program as well as an annual report to submit to Congress. This evaluation must occur within 18 months of awarding the first grant. The evaluation must: (1) analyze the effects of the program using specific measures; (3) analyze the effectiveness of each state at meeting the alternative's criteria; (3) compare the effectiveness of state alternatives at meeting the criteria; (4) compare performance on specific measures between states that receive and do not receive grants; (5) compare performance on specific measures between states receiving grants, states that did not have damage caps prior to 2010, and states that had certificate of merit requirements prior to 2010.[193]
- *Evaluation Measures.* The ACA defines the specific "measures" as including: (1) the "nature and number of disputes over injuries allegedly caused by the health care providers or health care organizations;" (2) "the nature and number of claims in which tort litigation was pursued despite the existence of an alternative;" (3) the outcome of all disputes and claims including information on the expended time and money by each party; (4) "the medical liability environment;" (5) "health care quality;" (6) "patients and health care provider satisfaction with the alternative…and with the medical liability environment;" and (7) the "impact on utilization of medical services, appropriately adjusted for risk."[194]
- *MedPac and MACPAC.* The Medicare Payment Advisory Commission ("MedPAC") and Medicaid and CHIP Payment and Access Commission ("MACPAC") must independently review the alternatives tested through grants to determine their effect, respectively, on the Medicare program and Medicare beneficiaries and the Medicaid and CHIP programs and Medicaid and CHIP beneficiaries. MedPAC and MACPAC must subsequently provide Congress with reports that contain an analysis of the impact and effectiveness of the alternatives as well as other findings and recommendations. MedPAC and MACPAC must submit this report by December 31, 2016.[195]

5. Quality Improvement Initiatives

a. National Strategy to Improve Health Care Quality

Sec. 3011 National Strategy

[192] Affordable Care Act §10607; 42 U.S.C. 280g-15(f).
[193] Affordable Care Act §10607; 42 U.S.C. 280g-15(g).
[194] Affordable Care Act §10607; 42 U.S.C. 280g-15(g)(3).
[195] Affordable Care Act §10607; 42 U.S.C. 280g-15(h).

- *Overview.* The Secretary of Health and Human Services must formulate a "National Strategy for Quality in Health Care" to "improve the delivery of health care services, patient health outcomes, and population health."[196]
- *National Priorities.* The Secretary must identify national priorities that will (1) improve outcomes and efficiency; (2) "identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;" (3) address information gaps pertaining to "quality, efficiency, and comparative effectiveness" as well as gaps in "health outcome measures and data aggregation techniques;" (4) emphasize quality and efficiency through Federal payment policy; (5) "enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;" (6) address the care of patients with costly chronic diseases; (7) improve patient safety and readmissions through better research and dissemination; (8) address health disparities; and (9) take other actions as specified by the Secretary.[197]
- *National Strategy.* The Secretary will subsequently develop a strategic plan to address the priorities.[198] At minimum, the plan must provide for coordination of agency action, agency specific plans, benchmarks for success, reporting requirements, and must "incorporat[e] quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009."[199]
- *Website.* The Secretary must establish a "Health Care Quality Internet Website" by January 1, 2011 that provides information regarding the national priorities for quality improvement and the agency plans for quality improvement for public consumption.[200] The Secretary has discretion to require additional information that they deem "appropriate."[201]

Sec. 3012 Interagency Working Group on Health Care Quality

The President must convene an "Interagency Working Group on Health Care Quality" for the purpose of developing and implementing the National Quality Strategy, streamlining quality reporting and compliance requirements so as to avoid inefficient duplication of actions, and to evaluate alignment of public and private quality initiatives.[202] Senior level representatives of numerous federal agencies, including the Office of the National Coordinator for Health Information Technology, will comprise the working group's membership with the HHS representative as chair.[203] The working group must submit, and make public, an annual report to Congress beginning no later than December 31, 2010.[204]

[196] Affordable Care Act §3011; 42 U.S.C. 280j(a).
[197] Affordable Care Act §3011; 42 U.S.C. 280j(a)(2)(B)(i)-(ix).
[198] Affordable Care Act § 3011; 42 U.S.C. 280j(b)(1).
[199] Affordable Care Act §3011; 42 U.S.C.S. 280j(b)(2)(A)-(F).
[200] Affordable Care Act §3011; 42 U.S.C. 280j(e)(1)-(2).
[201] Affordable Care Act §3011; 42 U.S.C. 280j(e)(3).
[202] Affordable Care Act §3012(b)(1)-(3).
[203] Affordable Care Act §3012(b)(1)-(2).
[204] Affordable Care Act §3012(d).

Sec. 3013 Quality Measure Development

- *Measure Identification.* The Secretary of Health and Human Services must consult with the directors of the Agency for Healthcare Research and Quality (AHRQ) and Centers for Medicare & Medicaid Services (CMS) to identify gaps in quality measure development. This consultation must occur at least three times a year and the National Strategy should guide its focus. The Secretary must also consider gaps identified by the National Quality Forum, the Pediatric Quality Measures Program, and the Medicaid Quality Measurement Program.[205]
- *Grants.* The Secretary must award grants and contracts for the development of quality measures.[206] The Secretary must give priority to measures that allow assessment of: (1) patient outcomes; (2) care management and coordination; (3) "the experience, quality, and use of information" by individuals making care decisions; (4) "the meaningful use of health information technology;" (5) "the safety, effectiveness, patient-centeredness, appropriateness, and timeliness of care;" (6) "the efficiency of care;" (7) health equity and health disparities; (8) "patient experience and satisfaction;" (9) the National Strategy for Quality in Health Care; and (9) other areas as specified by the Secretary.[207]
- *Grantees.* Entities that have experience with developing measures, consider the views of various stakeholders while developing measures, can collaborate with the National Quality Forum, and maintain transparent policies are eligible for grants.[208] Entities that receive grants must use the funds to develop measures for use in Medicare and Medicaid quality programs, support quality measure programs run through Medicare and Medicaid that allow for data collection through health information technology, that are free for users, and that are publically available on the internet.[209]

Sec. 3015 Data Collection; Public Reporting

- *Strategic Framework.* The Secretary of Health and Human Services must establish a strategic framework for reporting performance information to the public.[210]
- *Data Collection and Aggregation.* The Secretary must "collect and aggregate consistent data on quality and resource use measures from information systems used to support health care

[205] Affordable Care Act §3013(a)(4); 42 U.S.C. 299b-31(b)(1)(A)-(C).
[206] Affordable Care Act §3013(a)(4); 42 U.S.C. 299b-31(c)(1).
[207] Affordable Care Act §3013(a)(4); 42 U.S.C. 299b-31(c)(2)(A)-(J).
[208] Affordable Care Act §3013(a)(4); 42 U.S.C. 299b-31(c)(3)(A)-(D).
[209] Affordable Care Act §3013(a)(4); 42 U.S.C. 299b-31(c)(4)(A)-(E).
[210] Affordable Care Act §3015; 42 U.S.C. 280-1(a)(1).

delivery."[211] The Secretary must align these efforts with requirements and standards regarding the expansion and interoperability of health information technology systems.[212]

- *Data Collection Grants.* The Secretary may award grants to support data collection activities.
  - Entities are eligible for grants if they: (1) are "multi-stakeholder entities specializing in development of quality and cost reporting methods," capable of population or provider specific reporting, or are an IHS or Indian Tribe program (2) promote the use of data systems in care coordination and improvement efforts; (3) support the appropriate exchange of quality and resource use information to health care providers and other organizations; and (4) support the ability of providers to correct errors in measurements, and agree to publically report quality and resource use measures.[213] Grantees must also agree to match every $5 dollars of federal funding with $1 of non-federal funding.[214]
- *Data Aggregation Grants.* The Secretary may award grants for data aggregation "only to entities that enable summary data that can be integrated and compared across multiple sources."[215]
- *Public Reporting.* The Secretary must develop websites that contain quality measure data tailored to particular audiences such as consumers, hospitals, and policymakers.
  - The Secretary should provide, as feasible, provider specific information on specific conditions so as to meet the needs of consumers.[216] The National Quality Forum (NQF) will convene interested stakeholders in order to assess their views on the development of these reporting websites. The NQF will pass on these views to the Secretary and act as a consultant during the development process.[217] Congress grants the Secretary the authority to coordinate the data collection and reporting established in Section 3015 with the public reporting requirements for quality measures under Title XVIII of the Social Security Act [See Medicare section for more information on these reporting requirements].[218]

b. Establishment of Center to Research Health Care Quality Practices

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

Health Care Delivery System Research

- *Function.* The Center for Health Care Quality Improvement and Patient Safety ("Center") will

[211] Affordable Care Act §3015; 42 U.S.C. 280-1(a)(2).
[212] Affordable Care Act §3015; 42 U.S.C. 280-1(a)(2).
[213] Affordable Care Act §3015; 42 U.S.C. 280-1(b)(2)(A).
[214] Affordable Care Act §3015; 42 U.S.C. 280-1(d).
[215] Affordable Care Act §3015; 42 U.S.C. 280-1(c).
[216] Affordable Care Act §3015: 42 U.S.C. 280j-2(a)-(b).
[217] Affordable Care Act §3015: 42 U.S.C. 280j-2(c).
[218] Affordable Care Act §3015: 42 U.S.C. 280j-2(d).

facilitate the development and implementation of quality improvement practices.[219] The Center must:

- Use "a variety of disciplines" to "carry out its functions;"
- Focus on improved delivery practices regarding "processes of care," patient safety, reduction of medical errors, and workflow;
- Identify providers that delivery high quality care using "best practices that are adaptable" throughout the health care system;
- Evaluate research regarding most effective methods to improve the delivery of health care;
- Identify means to quickly and effectively implement methods into practice;
- Generate quality improvement strategies;
- "Identify, measure, and improve organizational, human or other causative factors, including those related to the culture and system design of a health care organization, that contribute to the success and sustainability of specific quality improvement and patient safety strategies;
- Facilitate development of best practices of the delivery of care that are, based on empirical evidence, likely to succeed, have sufficient detail regarding processes, training, and required knowledge for implementation into the health care system, can be readily adapted by providers, and help providers to work with other providers to engage patients and their families in an effort to improve outcomes;
- Allocate funding for organizations that have experience in improving the delivery of health care services, including children's care, by utilizing numerous disciplines, health care manages, development and training, patients, etc.; and
- Build state and community level capacity to advance quality and safety efforts through means such as education and training.[220]

- *Research.* The Center must undertake specific research tasks and may establish a Quality Improvement Network Research Program in order to conduct testing and development of quality and efficiency interventions.[221]
  - The Center must conduct research consistent with the National Strategic Action Plan, identify knowledge gaps, respond to concerns of health care institutions, and build the capacity of patient safety research in order to reduce associated deaths, injuries, and costs. The Center must develop practice recommendations for dissemination pertaining to the improvement of Intensive Care Units, antibiotic resistant infections, and hospital readmissions.[222]
  - The Center must expand children's health and HIT demonstration projects. The Center must develop means to mitigate hazards by collecting and analyzing data from patient safety organizations and reporting systems. The Center must "conduct systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery" and "include the examination of how to measure and evaluate the progress of quality and

[219] Affordable Care Act §3501; 42 U.S.C. 299b-33(a)-(b).
[220] Affordable Care Act §3501; 42 U.S.C. 299b-33(b)(1)-(10).
[221] Affordable Care Act §3501; 42 U.S.C. 299b-33(c).
[222] Affordable Care Act §3501; 42 U.S.C. 299b-33(c)(2).

patient safety activities."[223]

- *Dissemination.* The Director of the Center must make the research findings publicly available in a way that facilitates access by individuals with varying health literacy capacity. The director must also disseminate the Center's research to the Office of the National Coordinator of Health Information Technology for the Office's use in carrying out the tasks mandated by Section 3012.[224]
- *Priorities.* The Director must establish and continually update a lost of research priorities based on the following criteria: (1) "cost to Federal health programs;" (2) "consumer assessment of health care experience;" (3) provider assessment; (4) The impact of identified processes and systems on patient health; (5) knowledge gaps; (6) "the evolution of meaningful use of health information technology, as defined in section 3000."[225]

Quality Improvement Technical Assistance and Implementation

- *Grants.* The Director has authority to award grants and contracts for technical support and implementation of quality improvement actions.[226]
    - Entities eligible for "technical assistance awards" are those that fall into a specified category (e.g. providers, patient safety organizations) and have knowledge and experience with providing technical support to providers regarding quality improvement. Hospitals and other providers, as determined by the Secretary, that have knowledge and experience with providing technical support to health care providers pertaining to quality improvement efforts may obtain "implementation awards."[227]
    - Entities must apply to the director to receive either a technical assistance or implementation award. The application for a technical assistance award must include a "sustainable business mode" that has a system for charging provider and institutions for the receipt of technical assistance, a means of reducing such fees for providers with low-income clientele, and any other requirements that the Director specifies.[228] The application for an implementation award must contain "a plan for implementation of a model or practice identified by the Center."[229] This plan must identify items such as cost, staffing needs, implementation timelines, estimated quality measure performance both before and after implementation, and any other requirements that the Director may specify.[230]
    - Entities that receive either technical assistance or implementation awards must agree to match every $5 of federal funding with $1 of non-federal funding.[231] The Director will assess the progress of each grantee focusing, in particular, on the implementation success rate, perceived value of the grantee from the perspective of institutions and providers receiving assistance, and whether implementation generated cost savings or improved

[223] Affordable Care Act §3501; 42 U.S.C. 299b-33(c)(2).
[224] Affordable Care Act §3501; 42 U.S.C. 299b-33(d).
[225] Affordable Care Act §3501; 42 U.S.C. 299b-33(e).
[226] Affordable Care Act §3501; 42 U.S.C. 299b-34(a).
[227] Affordable Care Act §3501; 42 U.S.C. 299b-34(b)(1).
[228] Affordable Care Act §3501; 42 U.S.C. 299b-34(c)(1).
[229] Affordable Care Act §3501; 42 U.S.C. 299b-34(c)(2).
[230] Affordable Care Act §3501; 42 U.S.C. 299b-34(c)(2).
[231] Affordable Care Act §3501; 42 U.S.C. 299b-34(d).

health outcomes. The Director will condition grant renewal upon the results of this evaluation.[232] Grantees must coordinate their efforts with HIT regional extension centers and the primary care extension program.[233]

c. Improving Access to Health Care Services

Sec. 5605 Key National Indicators

Commission on Key National Indicators

- *Composition.* The Senate majority and minority together with the House speaker and minority leader will appoint, no later than thirty days following enactment of the ACA, eight members to sit on the Commission for terms of 2 years, except for initial members who may receive appointments for 3 year terms.[234] These Congressional leaders should seek appointees that "have shown a dedication to improving civic dialogue and decision-making through the wide use of scientific evidence and factual information."[235] Congressional members and elected government officials at all levels of government cannot receive an appointment.[236] Within 60 days following enactment, the Commission members must develop a plan for carrying out their tasks.[237] The Commission members must also select two co-chairs.[238]
- *Commission Functions.* The ACA tasks the Commission with: (1) overseeing the national indicators system; (2) recommending system improvements; (3) "coordinat[ing] with Federal Government users and information providers to assure access to relevant and quality data;" and (4) contracting with the National Academy of Sciences ("Academy"). The Commission must provide Congress and the President with annual reports containing the Commission's recommendations, findings, and conclusions.[239] The Commission must provide annual reports "to the Academy and a designated Institute" that makes "recommendations concerning potential issue areas and key indicators to be included in the Key National Indicators."[240]
- *Academy Functions.* The contract between the Commission and the Academy must require the Academy to: (1) "review available public and private sector research on the selection of a set of key national indicators;" (2) determine whether the Academy is the best entity to create the system or whether it is best to designate a "private nonprofit organization as an institute" for the purpose of establishing the system; (3) if designating an institute to establish the system, "provide scientific and technical advice to the Institute and create an appropriate governance mechanism that balances Academy involvement and the Independence of the Institute;" and (4) report to the Commission annually regarding "scientific and technical issues" and, if using an Institute, information regarding

[232] Affordable Care Act § 3501; 42 U.S.C. 299b-34(e).
[233] Affordable Care Act §3501; 42 U.S.C. 299b-34(f).
[234] Affordable Care Act §5605(b)(2)(A),(D); 36 U.S.C. 150303(b)(2)(A),(D).
[235] Affordable Care Act §5605(b)(2)(C); 36 U.S.C. 150303(b)(2)(C).
[236] Affordable Care Act §5605(b)(2)(B); 36 U.S.C. 150303(b)(2)(B).
[237] Affordable Care Act §5605(b)(2)(F); 36 U.S.C. 150303(b)(2)(F).
[238] Affordable Care Act §5605(b)(2)(G); 36 U.S.C. 150303(b)(2)(G).
[239] Affordable Care Act §5605(c)(1)(A)-(D); 36 U.S.C. 150303(c)(1)(A)-(D).
[240] Affordable Care Act §5605(c)(2)(A)-(B); 36 U.S.C. 150303(c)(2)(A)-(B).

the Institute's operation, governance, and budget.[241] The Academy, in carrying out these duties, must "convene a multi-sector, multi-disciplinary process to define major scientific and technical issues associated with developing, maintaining, and evolving [the System] and, if an Institute is established, to provide it with scientific and technical advice."[242]

National Key Indicator System

- *Overview.* The National Academy of Sciences must either establish the System pursuant to their institutional capacity or partner with a private Institute to establish the system.[243] A private Institute is eligible for such partnership if they are a non-profit and have "an educational mission, a governance structure that emphasizes independence, and characteristics that make such an entity appropriate for establishing" the System.[244]
- *Requirements.* The Academy or an Institute, in creating the System, must: (1) identify and select the key national indicator issues; (2) identify and select indicator measures; (3) identify and select population data for the indicators; (4) establish a public website to house a database of indicator information for public access; (5) "develop[] a quality assurance framework to ensure rigorous and independent processes and the selection of quality data;" (6) create a budget for developing and managing the System that contains all Academy funding and Institute information, if applicable; (7) submit annual progress reports to the Commission; and (8) respond to Commission recommendations and Academy inquiries.[245]
- *Governance.* The Academy must create a means of governing the system "that incorporates advisory and control functions" and, if applicable, balances an Institute's independence with Academy involvement in the system.[246] The Academy has discretion to change the approach in establishing the System and alter their relationship with an Institute.[247] The ACA does not prohibit the Academy or Institute from using private funds to create the System.[248] The Academy must submit, within 270 days of enactment, a report to the Commission regarding their "findings and recommendations."[249]
- *Evaluation.* The Government Accountability Office (GAO) must (1) study the use of key indicator systems by "public agencies, private organizations, or foreign countries;" (2) conduct an annual financial audit of any Institute designated pursuant to this section and report the findings to the Commission and Congress; and (3) conduct a "programmatic assessment," at the direction of the Comptroller General, of any Institute designated pursuant to this section and report the findings to the Commission and Congress.[250]

[241] Affordable Care Act §5605(c)(3)(A)(i)-(iv); 36 U.S.C. 150303(c)(3)(A)(i)-(iv).
[242] Affordable Care Act §5605(c)(3)(B); 36 U.S.C. 150303(c)(3)(B).
[243] Affordable Care Act §5605(c)(3)(C)(i)(I)-(II); 36 U.S.C. 150303(c)(3)(C)(i)(I)-(II).
[244] Affordable Care Act §5605(c)(3)(C)(ii); 36 U.S.C. 150303(c)(3)(C)(ii).
[245] Affordable Care Act §5605(c)(3)(C)(iii)(I)-(VIII); 36 U.S.C. 150303(c)(3)(C)(iii)(I)-(VIII).
[246] Affordable Care Act §5605(c)(3)(C)(iv); 36 U.S.C. 150303(c)(3)(C)(iv).
[247] Affordable Care Act §5605(c)(3)(C)(v); 36 U.S.C. 150303(c)(3)(C)(v).
[248] Affordable Care Act §5605(c)(3)(C)(vi); 36 U.S.C. 150303(c)(3)(C)(vi).
[249] Affordable Care Act §5605(c)(3)(D); 36 U.S.C. 150303(c)(3)(D).
[250] Affordable Care Act §5605(d)(1)-(3); 36 U.S.C. 150303(d)(1)-(3).

6. Health Information Technology

Sec. 1561 Health Information Technology Enrollment Standards and Protocols

- *Overview.* The Secretary of Health and Human Services must consult with the HIT Policy and Standards Committees to develop standards and protocols that will "facilitate enrollment of individuals in Federal and State health and human services programs."[251] The Secretary has discretion to determine the methods for enrollment, but must "include providing individuals and third parties authorized by such individuals and their designees notification of eligibility and verification of eligibility required under such programs."[252]
- *Standards and Protocols.* The ACA mandates that the standards and protocols contain the following parameters: (1) the ability to electronically match federal and state data as a means of determining eligibility; (2) permit "simplification and submission of electronic digitization of documents, and systems verification of eligibility;" (3) permit the "[r]euse of stored eligibility information (including documentation) to assist with retention of eligible individuals;" (4) provide individuals with a mechanism for online application, recertification, and management of their information at various locations such as their homes and the point of service; (5) have capacity to expand the system to include new programs, operations, and a higher volume "and to apply streamlined verification and eligibility processes to other Federal and State programs, as appropriate;" (6) the ability to notify individuals regarding issues such as their eligibility or recertification via email or cell phone; and (7) include any other "functionalities necessary to provide eligibles with streamlined enrollment process."[253]
- *Notification.* The Secretary must notify states upon the approval of standards and protocols by the HIT Policy and Standards Committees and may condition state receipt of funds upon their compliance with such standards and protocols.[254]
- *Grants.* The Secretary must award grants to "eligible entities" for the purposes of developing and updating technology capable of adhering to the HIT enrollment standards and protocols.[255] States, their political subdivisions, and entities of government subdivisions are eligible to receive these grants.[256] Interested entities must submit an application to the Secretary that identifies their plans to create and implement HIT enrollment technology and their agreement to adhere to sharing requirements.[257]

[251] Affordable Care Act §1561; 42 U.S.C. 300jj-51(a)(1).
[252] Affordable Care Act §1561; 42 U.S.C. 300jj-51(a)(2).
[253] Affordable Care Act §1561; 42 U.S.C. 300jj-51(b).
[254] Affordable Care Act §1561; 42 U.S.C. 300jj-51(c).
[255] Affordable Care Act §1561; 42 U.S.C. 300jj-51(d)(1).
[256] Affordable Care Act §1561; 42 U.S.C. 300jj-51(d)(2)(A).
[257] Affordable Care Act §1561; 42 U.S.C. 300jj-51(d)(2)(B).

- *Sharing.* The Secretary must facilitate the sharing of HIT technology created pursuant to grants with other qualified entities.[258] The Secretary will define "qualified entity" after considering the HIT Policy Committee and Standards Committee's recommendations. [259]

Sec. 6114 National Demonstration Projects on Culture Change and the Use of Information Technology in Nursing Homes

The Secretary of Health and Human Services must administer two demonstration projects to develop best practices for use in skilled nursing facilities and nursing facilities. One project must focus on culture change while the other must focus on using Health Information Technology to improve care. The Secretary must submit a report to Congress containing legislative and administrative recommendations within 9 months of completing the projects.[260]

7. Public Health Initiatives

a. Modernizing Disease Prevention and Public Health Systems

Sec. 4004 Education and Outreach Campaign Regarding Preventive Benefits

- *Overview.* The Secretary of Health and Human Services must facilitate the creation of a "national public-private partnership for a prevention and health promotion and outreach campaign to raise public awareness of health improvement across the life span."[261]
- *Information.* The campaign must release information regarding (1) the ability of preventive services to "promote wellness, reduce health disparities, and mitigate chronic disease;" (2) the recommendations created by the United States Preventive Services Task Force and the Community Preventive Services Task Force; (3) the link between health behavior and chronic disease prevention; (4) "the preventive services covered under health plans offered through an Exchange;" (5) the preventive care services supported by federal agencies such as the Centers for Disease Control (CDC) and the Health Resources and Services Administration; and (6) general information on health promotion.[262]
- *Media Campaign.* The Director of the CDC, on behalf of the Secretary, must create a "national science-based media campaign on health promotion and disease prevention." The Director must solicit bids from entities to design a campaign that will focus on promoting "proper nutrition, regular exercise, smoking cessation, obesity reduction," and disease screening. The winning bidders may use various media channels such as television and Internet, may target age groups, and

[258] Affordable Care Act §1561; 42 U.S.C. 300jj-51(d)(3)(A).
[259] Affordable Care Act § 1561; 42 U.S.C. 300jj-51(d)(3)(B).
[260] Affordable Care Act §6114; 42 U.S.C. 1395i-3.
[261] Affordable Care Act §4004(a); 42 U.S.C. 300u-12(a).
[262] Affordable Care Act §4004(a); 42 U.S.C. 300u-12(a).

may use humor and positive role models. The campaign messages must be distinct from existing health promotion efforts.[263]

- *Website.* The Secretary must create a website that will contain nutrition, exercise, smoking cessation, and obesity reduction guidelines.[264]
- *Providers.* The Secretary must create a plan to facilitate the dissemination of health promotion information by providers that participate in federal health care programs.[265]
- *Personalized Prevention Plans.* The Director of the CDC, on the Secretary's behalf, must contract for the creation of an Internet based "personalized prevention plan tool." This tool must allow individuals to input information such as their BMI and health history in order to generate the individual's risk for obtaining "the 5 leading diseases in the United States" and suggestions on how the individual may alleviate their risk.[266]

b. Increasing Access to Clinical Preventative Services

Sec. 4102 Oral Healthcare Prevention Activities

- *Oral Health Infrastructure.* The Secretary of Health and Human Services must "enter into cooperative agreements with State, territorial, and Indian tribes or tribal organizations…to establish oral health leadership and program guidance, oral health data collection and interpretation (including determinants of poor oral health among vulnerable populations), a multi dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health."[267]
- *Oral Health Surveillance Activities.* The Secretary must "update and improve the Pregnancy Risk Assessment Monitoring System (PRAMS) as it relates to oral healthcare." Such improvements include developing oral healthcare quality measures for use in PRAMS and requiring states to submit reports on their PRAMS activities every five years beginning no later than 2015.[268] The Secretary must also "develop [and update every six years] oral healthcare components that shall include tooth-level surveillance for inclusion in the National Health and Nutrition Examination Survey."[269]

c. Support for Prevention and Public Health Innovation

Sec. 4302 Understanding Health Disparities: Data Collection and Analysis

[263] Affordable Care Act §4004(c); 42 U.S.C. 300u-12(c).
[264] Affordable Care Act § 4004(d); 42 U.S.C. 300u-12(d).
[265] Affordable Care Act §4004(e); 42 U.S.C. 300u-12(e).
[266] Affordable Care Act §4004(f); 42 U.S.C. 300u-12(f).
[267] Affordable Care Act §4102(c); 42 U.S.C. 247b-14(d).
[268] Affordable Care Act §4102(d)(1); 42 U.S.C. 280k-3.
[269] Affordable Care Act §4102(d)(2); 42 U.S.C. 280k-3.

- *Data Collection.* The Secretary of Health and Human Services must facilitate the collection of demographic data by any health care or public health program supported by the federal government within two years of the ACA's enactment.[270] Data collected must include (1) the "race, ethnicity, sex, primary language, and disability status" of individuals that apply, participate in, or receive benefits from an applicable program; (2) "data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;" (3) data that is sufficient to provide "statistically reliable estimates by racial, ethic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and" (4) data identified by the Secretary.[271] Data collected pertaining to racial and ethnic minorities must also include data on underserved rural and frontier populations.[272]
- *Collection Standards.* The Secretary will establish data collection standards pursuant to the following criteria: (1) use the standards of the Office of Management and Budget as the minimum measure for race and ethnicity; (2) create standard measures for sex, primary language, and disability status; (3) create standards for the collection or demographic data that allows for self reporting by participants and collection from parents or legal guardians; (4) conduct a survey of providers regarding the amount of access that individuals with disabilities have to care and treatment; focusing on the types of facilities available (e.g. primary care, long-term care), quantity of providers with sufficient treatment facilities and the amount of providers "trained in disability awareness and patient care of individuals with disabilities;" and (5) mandate that reports made pursuant to the quality reporting requirements of health care and public health programs include data regarding the race, ethnicity, sex, primary language, and disability status of participants.[273]
- *Data Management.* The Secretary, through the National Coordinator for Health Information Technology, must develop standards for managing collected data and "interoperability and security systems for data management."[274]
- *Data Analysis and Reporting.* The Secretary must analyze the data collected in order to "detect and monitor trends in health disparities…at the Federal and State levels."[275] The Secretary has discretion to share the results of the analysis with appropriate entities, but must share the results with the Office of Minority Health, National Center on Minority Health and Health Disparities,[276] AHRQ, CDC, CMS, IHS, Office of Rural Health, and other HHS agencies.[277] The Secretary must report disparity data and analysis on the HHS website and through any other appropriate means.[278] The Secretary has discretion to provide the disparity data and analysis to additional federal agencies, private entities, and the public for the purpose of research, analysis, or dissemination.

[270] Affordable Care Act §4302(a); 42 U.S.C. 300k(a)(1).
[271] Affordable Care Act §4302(a); 42 U.S.C. 300k(a)(1)(A)-(D).
[272] Affordable Care Act §4302(a); 42 U.S.C. 300k(f).
[273] Affordable Care Act §4302(a); 42 U.S.C. 300k(a)(2)(A)-(E).
[274] Affordable Care Act §4302(a); 42 U.S.C. 300k(a)(3).
[275] Affordable Care Act §4302(a); 42 U.S.C. 300k(b)(1).
[276] Affordable Care Act §4302(a); 42 U.S.C. 300k(c)(1).
[277] Affordable Care Act §4302(a); 42 U.S.C. 300k(c)(2).
[278] Affordable Care Act §4302(a); 42 U.S.C. 300k(c)(2).

However, such data sharing may occur "in accordance with any Federal agency's data user agreements."[279]

- *Limitations and Protections.* The Secretary cannot use the data collected "in a manner that would adversely affect any individual" and must protect the data.[280] In particular, the Secretary must ensure (1) that data collection occurs with privacy protections greater than or equal to those established pursuant to HIPPA; and (2) that data is protected from inappropriate use by entities that receive, collect, or store the data. The Secretary must also make sure that "all appropriate information security safeguards are used" during data collection, analysis, and sharing.[281] The Secretary must create procedures for sharing data.[282]

Sec. 4303 CDC and Employer-Based Wellness Programs

- *Technical Assistance.* The Secretary of Health and Human Services must provide technical assistance for the expansion of employer-based wellness programs.[283] In particular, the Secretary must provide assistance in: (1) measuring participation and the means of increasing participation in wellness programs; (2) "developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employee's health behaviors, health outcomes, and health care expenditures;" and (3) evaluate the effect of the wellness program on the health status, absenteeism, productive, injury rate, and medical costs of employees.[284] The Secretary must also assist employers in the evaluation of their wellness programs by providing training and other resources.[285]
- *Worksite Wellness Study*, The Director of the CDC must conduct, no later 2012, a survey of workplace wellness policies and programs in order to obtain data for use in assessing and developing instruments to evaluate these policies and programs.[286] The Director must subsequently use the results to provide Congress with recommendations for implementing "effective employer-based health policies and programs."[287]

d. Provisions Relating to Title IV: Prevention of Chronic Diseases and Improving Public Health

Sec. 10407 Better Diabetes Care

- *Reports Cards.* The Secretary of Health and Human Services, along with the CDC, must prepare a national diabetes report card on a biannual basis. If feasible, the Secretary must also prepare state

[279] Affordable Care Act § 4302(a); 42 U.S.C. 300k(c)(3).
[280] Affordable Care Act §4302(a); 42 U.S.C. 300k(d).
[281] Affordable Care Act §4302(a); 42 U.S.C. 300k(e)(1).
[282] Affordable Care Act §4302(a); 42 U.S.C. 300k(e)(2).
[283] Affordable Care Act §4303; 42 U.S.C. 280l
[284] Affordable Care Act § 4303; 42 U.S.C. 280l(1)
[285] Affordable Care Act §4303; 42 U.S.C. 280l(2)
[286] Affordable Care Act §4303; 42 U.S.C. 280l-1(a).
[287] Affordable Care Act §4303; 42 U.S.C. 280l-1(b).

diabetes report cards. [288] The report cards will contain "aggregate health outcomes related to individuals diagnosed with diabetes and pre-diabetes" and all subsequent report cards must contain trend analysis.[289] The Secretary must release the report cards to the public through the internet. [290]

- *Data Collection.* The Secretary and CDC must work with federal and state agencies to improve the collection of vital statistics. This includes "training physicians on the importance of birth and death certificate data" and how to properly complete the documents, promoting the adoption by states "of the latest standard revisions of birth and death certificates," and helping states to "re-engineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data."[291] The Secretary has discretion to also "promote improvements to the collection of diabetes mortality data."[292]
- *Study.* The Secretary, along with the Institute of Medicine and other "appropriate associations," must study "the impact of diabetes on the practice of medicine...and the appropriateness of the level of diabetes medical education that should be required prior to licensure" and certification.[293] The Secretary must report the results of this study to Congress within 2 years of enactment.[294]

Sec. 10410 Centers of Excellence for Depression

- *Grants.* The Secretary of Health and Human Services must provide grants for the purpose of establishing National Centers of Excellence for Depression.[295] Public or private nonprofit research institutions and academic institutions may apply for such grants by submitting an application to the Secretary that contains evidence of the institution's ability to provide mental health service, coordinate with additional mental health providers, and provide professionals with training on mental health.[296] Entities that receive grants must match every five dollars of federal funding with 1 dollar of non-federal funding. [297]
- *Priority.* The Secretary will give priority to applicants that: (1) have the "capacity and expertise to serve the targeted population;" (2) have an infrastructure to provide "evidence-based and culturally, and linguistically competent services;" (3) are located in an area with "disproportionate numbers of underserved and at-risk populations in medically underserved areas and health professional shortage areas;" (4) have "innovative approaches" to increasing services; (5) use the latest practices and interventions; (6) have the capacity to work with community entities (e.g. health centers) "to provide mental health, social, and human services to individuals with depressive disorders."[298]

[288] Affordable Care Act §10407(b)(1); 42 U.S.C. 247b-9a(b)(1).
[289] Affordable Care Act §10407(b)(2); 42 U.S.C. 247b-9a(b)(2).
[290] Affordable Care Act §10407(b)(3); 42 U.S.C. 247b-9a(b)(3).
[291] Affordable Care Act §10407(c)(1); 42 U.S.C. 247b-9a(c)(1).
[292] Affordable Care Act §10407(c)(2); 42 U.S.C. 247b-9a(c)(2).
[293] Affordable Care Act §10407(d)(1); 42 U.S.C. 247b-9a(d)(1).
[294] Affordable Care Act §10407(d)(2); 42 U.S.C. 247b-9a(d)(2).
[295] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b).
[296] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b)(5).
[297] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b)(7).
[298] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b)(5)(C).

- *National Coordinating Center.* The Secretary will select one grantee to function as the National Coordinating Center.[299] The Coordinating Center's duties will include coordinating a network of Centers, coordinating a national database, disseminating information, and acting a liaison to other government agencies or initiatives."[300]
- *Center Functions.* Centers will conduct research in order to develop evidence-based interventions, develop a research agenda after consulting with "a broad cross-section of stakeholders," train mental health professionals, and educate the public, policy makers, community leaders, and employers about depressive disorders in an effort to reduce the stigma associated with treatment.[301] Centers must collaborate with other Centers to create treatment guidelines and protocols, facilitate communication with providers regarding "co-occurring physical health conditions" (e.g. cancer, diabetes), develop "self-management" plans," and "use electronic health records and telehealth technology to better coordinate and manage, and improve access to, care, as determined by the coordinating center."[302] Finally, Centers must collaborate with community-based organizations to (1) "demonstrate the effective use of public-private partnership to foster collaborations among networks and community-based organizations;" (2) increase "interdisciplinary, translational, and patient-oriented research and treatment;" and (3) work with academic programs to provide continual education for mental health providers.[303]
- *National Database.* The Coordinating Center must create, and make public, a national database that will house data collected by each Center.[304] Such data includes: (1) "prevalence and incidence of depressive disorders;" (2) "health and social outcomes of individuals with depressive disorders;" (3) intervention effectiveness; and (4) any other information as specified by the Secretary. Centers must submit data to the Coordinating Center prior to publishing their findings. [305]
- *Evaluation.* The Secretary must create a report card for each Center that evaluates their performance. This report card must be issued within 3 years of the Secretary awarding the Center a grant. The Secretary must also submit a report card to Congress within three years of awarding the first Center grant that rates the network's performance.[306] The Secretary will use these report cards to provide Centers with recommended improvements and Congress with recommendations on how to expand the program to serve other mental disorders.[307] Finally, the Secretary must contract, within three years of awarding a grant, for review of the Centers by an independent third party.[308]

Sec. 10411 Programs Relating to Congenital Heart Disease

[299] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b)(6).
[300] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(b)(6)(C).
[301] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(c)(1).
[302] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(c)(2).
[303] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(c)(3).
[304] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(d)(1).
[305] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(d)(2).
[306] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(e)(2).
[307] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(e)(3).
[308] Affordable Care Act §10410(b); 42 U.S.C. 290bb-33(e)(4).

- *Surveillance.* The Secretary of Health and Human Services must establish a National Congenital Heart Disease Surveillance System through the Centers for Disease Control and Prevention ("CDC") or a contract with a "public or private nonprofit entity with specialized experience in congenital heart disease."[309]
- *Data Collection.* The System may collect and organize data on (1) the incidence of congenital heart disease in the United States; (2) the demographics, risk factors, and causes associated with congenital heart disease; (3) treatments for congenital heart disease and outcome measures that will allow for development of "evidence-based best practices and guidelines;" and (4) the "longitudinal data related to individuals of all ages with congenital heart disease…"[310] The Secretary must provide the public, and heart disease researches in particular, with appropriate access to the System's data.[311] However, the Secretary must protect patient privacy by maintaining the System in compliance with HIPPA regulations.[312]
- *Research.* The Director may expand congenital heart disease research. Permissible areas of research include studies on the cause, long term outcomes, diagnosis, treatment, and prevention of congenital heart disease, "studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes," and studies on the barriers to "life-long care" for persons with congenital heart disease.[313] The Director has authority to coordinate congenital heart disease research, conducted pursuant to this section, among institutions and to establish research networks.[314] The Director must conduct congenital heart disease research after consideration of the application of such research to "minority and medically underserved communities."[315]

8. Care Coordination and Access to Care

Sec. 1554 Access to Therapies

The Secretary of Health and Human Services may not, unless expressly authorized in the ACA, establish regulations that (1) unreasonably inhibit access to "appropriate Medical care;" (2) prevent "timely" access to care; (3) prevent providers and patients from discussing all relevant treatment options; (4) prevent providers from disclosing information to their patients that is relevant to making a treatment decision, (5) "violates the principles of informed consent and ethical standards of health care professionals;" or (6) would prevent a patient from obtaining treatment "for the full duration of [their] medical needs."[316]

Sec. 2402 Removal of Barriers to Providing Home and Community-Based Services

[309] Affordable Care Act §10411(b)(1); 42 U.S.C. 280g-13(a).
[310] Affordable Care Act §10411(b)(1); 42 U.S.C. 280g-13(c).
[311] Affordable Care Act §10411(b)(1); 42 U.S.C. 280g-13(d).
[312] Affordable Care Act §10411(b)(1); 42 U.S.C. 280g-13(e).
[313] Affordable Care Act §10411(b)(2); 42 U.S.C. 285b-8(a).
[314] Affordable Care Act §10411(b)(2); 42 U.S.C. 285b-8(b).
[315] Affordable Care Act §10411(b)(2); 42 U.S.C. 285b-8(c).
[316] Affordable Care Act §1554; 42 U.S.C. 18114.

The Secretary of Health and Human Services must establish regulations to guide states in developing "service systems" capable of (1) "allocat[ing] resources" in response to beneficiary needs; (2) Maximizing beneficiary independence; (3) Aiding beneficiaries in the "design [of] an individualized, self-directed, community-supported life;" and (4) Improving provider coordination and regulation in an effort to consistently administer programs and facilitate oversight and monitoring of the service system functions.[317]

Sec. 3503 Medication Management Services in Treatment of Chronic Disease

- *Overview.* The Secretary of Health and Human Services must, through the Patient Safety Research Center, award grants to entities for the purpose of providing medication management (MTM) services to "targeted individuals" with chronic diseases.[318]
- *Eligible Entities.* Entities are eligible for grants if they have the capacity to provide MTM services and submit an application to the Secretary that contains their plan for long-term financial sustainability, their plan, if applicable, for coordinating MTM services with community health teams or a primary care extension program, and any other information specified by the Secretary.[319]
- *MTM Services.* Entities must use grant funds to (1) assess the health status of patients; (2) create a "medication treatment plan" that reflects the treatment decisions made by the prescribing provider and the patient; (3) "selecting, initiating, modifying, recommending changes to, or administering medication therapy;" (4) monitor and evaluate the patient's response to medication; (5) conduct "an initial comprehensive medication review to identify, resolve, and prevent medication-related problems" and follow up reviews on a quarterly basis and as scheduled by the prescribing provider; (6) keep documentation regarding the care provided; (7) share pharmacist recommendations and summaries of medication reviews with other appropriate health care providers; (8) provide patients with information, strategies, and support in an effort to increase patient adherence to medication regimens; (9) provide patients and their caregivers with information and training about the appropriate use of their medications; (10) coordinate "MTM services within the broader health care management services provided to the patient;" and (11) provide patients with any other MTM services that are used in other federal programs and within the professional scope of pharmacy practice.[320]
- *Targeted Individuals.* MTM services will be available to individuals that take at least 4 prescription medications, take "high risk" medications, have at least 2 chronic diseases, or have a high risk of experiencing problems with their medications.[321]
- *Reporting.* Grantees must submit reports to the Secretary that information specified by the Secretary. The Secretary must then provide Congress with a report that assesses and evaluates the

[317] Affordable Care Act §2402(a).
[318] Affordable Care Act §3503; 42 U.S.C. 299b-35(a).
[319] Affordable Care Act §3503; 42 U.S.C. 299b-35(b).
[320] Affordable Care Act §3503; 42 U.S.C. 299b-35(c).
[321] Affordable Care Act §3503; 42 U.S.C. 299b-35(d).

effectiveness of the MTM services program and its impact on issues such as health care resource utilization.[322]

- *Performance Measures.* The Secretary may award grants to entities in order to develop MTM services performance measures.[323]

Sec. 3506 Program to Facilitate Shared Decision-making

- *Overview.* The "Program to Facilitate Shared Decision-making" will establish standards and create educational tools in an effort to make treatment decisions the result of an open communication between patients, patient representatives, and providers regarding available treatment options and the patient's preferences and values.[324]
- *Standards.* The Secretary of Health and Human Services must contract with the National Quality Forum for the creation and endorsement of educational tools, termed "patient decision aids," that will help patients discuss their beliefs and treatment options and with their provider so that the treatment decision is a reflection of the "treatment options, scientific evidence, circumstances, beliefs, and preferences."[325]
- *Programs.* The Secretary, in coordination with relevant federal agencies, must create a program to develop and test patient decision aids and educate providers on use of such aids. The Secretary will carry out this program through grants or contracts.[326]
- *Decision aid criteria.* The decision aids created by grants must (1) have the capacity to engage patients and providers in informed decision-making; (2) contain current clinical evidence regarding treatment decisions; (3) present information in a form that is understandable by individuals regardless of their age, culture, educational background, and health literacy status; (4) provide an explanation in the event that evidence does not support a certain treatment over another treatment; and (5) address "decisions across the age span, including those affecting vulnerable populations including children." [327]
- *Grants.* The Secretary must award grants to create "Shared Decision-making Resource Centers." These centers will help providers implement patient decision aids and will disseminate patient decision aid research and best practices. The Secretary must also award grants to providers to support their development and implementation of patient decision aids.[328]

Sec. 4003 Clinical and Community Preventive Services

- *Overview.* The Director of the Centers for Disease Control and Prevention (CDC) must create a "Community Preventive Services Task Force" that will review scientific evidence and create

[322] Affordable Care Act §3503; 42 U.S.C. 299b-35(f).
[323] Affordable Care Act §3503; 42 U.S.C. 299b-35(g).
[324] Affordable Care Act §3506; 42 U.S.C. 299b-36(a).
[325] Affordable Care Act §3506; 42 U.S.C. 299b-36(c).
[326] Affordable Care Act §3506; 42 U.S.C. 299b-36(d).
[327] Affordable Care Act §3506; 42 U.S.C. 299b-36(d)(2).
[328] Affordable Care Act §3506; 42 U.S.C. 299b-36(e).

recommendations regarding the delivery of community preventive services that will be utilized by "individuals and organizations delivering population-based services" and policymakers.[329]

- *Task Force Duties.* The Task Force must: (1) identify topics for recommendations and interventions, including topics that address specific populations, social determinant of health, and health disparities; (2) Review and revise the recommendations and interventions at least once every five years; (3) Integrate their activities with the federal health objectives and health improvement targets; (4) improve the dissemination of their recommendations; (5) provide professionals, agencies, and organizations with technical assistance as they implement the recommendations; and (6) submit annual reports to Congress and relevant agencies regarding research gaps and priorities.[330]
- *CDC Duties.* The Director must provide the Task Force with "administrative, research, and technical support."[331]

9. Equity and Disparities

Sec. 1001 Amendments to the Public Health Service Act

- *Overview.* The Secretary of Health and Human Services must consult with the National Association of Insurance Commissioners to develop standards for use by group health plans and issuers as they create benefit and coverage summaries.[332]
- *Standards.* The standards must establish a uniform format, "ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee," and identify specific coverage and benefits information that plans and issuers must include in the summaries (e,g. standard definitions, cost-sharing, coverage exceptions).[333]

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

The Secretary of Health and Human Services may, in collaboration with various entities, organizations, and experts, award grants for developing and conducting research, demonstration projects, and model curricula regarding "cultural competency, prevention, public health proficiency, reduc[tion] [of] health disparities" and the training of professionals to work with persons with disabilities. Curricula generated by these grants must be disseminated through an Internet Clearinghouse. The Secretary must conduct an evaluation of any entities that adopt and implement curricula created by these grants and must, if appropriate, "facilitate inclusion of these competency measures in quality measurement systems."[334]

[329] Affordable Care Act § 4003(b); 42 U.S.C. 280g-10(a).
[330] Affordable Care Act §4003(b); 42 U.S.C. 280g-10(b).
[331] Affordable Care Act §4003(b); 42 U.S.C. 280g-10(c).
[332] Affordable Care Act §1001; 42 U.S.C. 300hh-15(a).
[333] Affordable Care Act §1001; 42 U.S.C. 300hh-15(b).
[334] Affordable Care Act §5307; 42 U.S.C. 293e.

Sec. 10334 Minority Health

Office of Minority Health
The ACA transfers the Office of Minority Health from the Office of Public Health and Science to the Department of Health and Human Services and establishes the Deputy Assistant Secretary of Minority Health to lead the office and report directly to the Secretary of Health and Human Services. The office will continue to work toward reducing health disparities while improving the quality of care received by minorities as well as their overall health status. The office will achieve these goals by executing contracts and agreements for minority health initiatives with other government agencies and public and private entities. Such initiatives must include the development of measures to evaluate "community outreach activities, language services, [and] work force cultural competence."[335]

Individual Offices of Minority Health Within the Department
The head officials of the Centers for Disease Control and Prevention, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Agency for Healthcare Research and Quality, Food and Drug Administration, and Centers for Medicare & Medicaid Services must create an "Office of Minority Health" within their agencies and appoint a director of this office.[336]

[335] Affordable Care Act §10334(a); 42 U.S.C. 300u-6.
[336] Affordable Care Act §10334(b); 42 U.S.C. 300u-6a.