

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—214

Subtitle H—Improved Coordination for Dual Eligible Beneficiaries

SEC. 2601. 5-YEAR PERIOD FOR DEMONSTRATION PROJECTS.

(a) IN GENERAL.—Section 1915(h) of the Social Security Act (42 U.S.C. 1396n(h)) is amended—

- (1) by inserting “(1)” after “(h)”;
- (2) by inserting “, or a waiver described in paragraph (2)” after “(e)”;
- (3) by adding at the end the following new paragraph:

“(2)(A) Notwithstanding subsections (c)(3) and (d) (3), any waiver under subsection (b), (c), or (d), or a waiver under section 1115, that provides medical assistance for dual eligible individuals (including any such waivers under which non dual eligible individuals may be enrolled in addition to dual eligible individuals) may be conducted for a period of 5 years and, upon the request of the State, may be extended for additional 5-year periods unless the Secretary determines that for the previous waiver period the conditions for the waiver have not been met or it would no longer be cost-effective and efficient, or consistent with the purposes of this title, to extend the waiver.

“(B) In this paragraph, the term ‘dual eligible individual’ means an individual who is entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and is eligible for medical assistance under the State plan under this title or under a waiver of such plan.”

(b) CONFORMING AMENDMENTS.—

(1) Section 1915 of such Act (42 U.S.C. 1396n) is amended—

(A) in subsection (b), by adding at the end the following new sentence: “Subsection (h)(2) shall apply to a waiver under this subsection.”;

(B) in subsection (c)(3), in the second sentence, by inserting “(other than a waiver described in subsection (h)(2))” after “A waiver under this subsection”;

(C) in subsection (d)(3), in the second sentence, by inserting “(other than a waiver described in subsection (h)(2))” after “A waiver under this subsection”.

(2) Section 1115 of such Act (42 U.S.C. 1315) is amended—

(A) in subsection (e)(2), by inserting “(5 years, in the case of a waiver described in section 1915(h)(2))” after “3 years”; and

(B) in subsection (f)(6), by inserting “(5 years, in the case of a waiver described in section 1915(h)(2))” after “3 years”.

SEC. 2602. PROVIDING FEDERAL COVERAGE AND PAYMENT COORDINATION FOR DUAL ELIGIBLE BENEFICIARIES.

(a) ESTABLISHMENT OF FEDERAL COORDINATED HEALTH CARE OFFICE.—

(1) IN GENERAL.—Not later than March 1, 2010, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a Federal Coordinated Health Care Office.

(2) ESTABLISHMENT AND REPORTING TO CMS ADMINISTRATOR.—The Federal Coordinated Health Care Office—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—215

(A) shall be established within the Centers for Medicare & Medicaid Services; and

(B) have as the Office a Director who shall be appointed by, and be in direct line of authority to, the Administrator of the Centers for Medicare & Medicaid Services.

(b) PURPOSE.—The purpose of the Federal Coordinated Health Care Office is to bring together officers and employees of the Medicare and Medicaid programs at the Centers for Medicare & Medicaid Services in order to—

(1) more effectively integrate benefits under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act; and

(2) improve the coordination between the Federal Government and States for individuals eligible for benefits under both such programs in order to ensure that such individuals get full access to the items and services to which they are entitled under titles XVIII and XIX of the Social Security Act.

(c) GOALS.—The goals of the Federal Coordinated Health Care Office are as follows:

(1) Providing dual eligible individuals full access to the benefits to which such individuals are entitled under the Medicare and Medicaid programs.

(2) Simplifying the processes for dual eligible individuals to access the items and services they are entitled to under the Medicare and Medicaid programs.

(3) Improving the quality of health care and long-term services for dual eligible individuals.

(4) Increasing dual eligible individuals' understanding of and satisfaction with coverage under the Medicare and Medicaid programs.

(5) Eliminating regulatory conflicts between rules under the Medicare and Medicaid programs.

(6) Improving care continuity and ensuring safe and effective care transitions for dual eligible individuals.

(7) Eliminating cost-shifting between the Medicare and Medicaid program and among related health care providers.

(8) Improving the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs.

(d) SPECIFIC RESPONSIBILITIES.—The specific responsibilities of the Federal Coordinated Health Care Office are as follows:

(1) Providing States, specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Social Security Act (42 U.S.C. 1395w–28(b)(6))), physicians and other relevant entities or individuals with the education and tools necessary for developing programs that align benefits under the Medicare and Medicaid programs for dual eligible individuals.

(2) Supporting State efforts to coordinate and align acute care and long-term care services for dual eligible individuals with other items and services furnished under the Medicare program.

(3) Providing support for coordination of contracting and oversight by States and the Centers for Medicare & Medicaid Services with respect to the integration of the Medicare and Medicaid programs in a manner that is supportive of the goals described in paragraph (3).

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—216

(4) To consult and coordinate with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) and the Medicaid and CHIP Payment and Access Commission established under section 1900 of such Act (42 U.S.C. 1396) with respect to policies relating to the enrollment in, and provision of, benefits to dual eligible individuals under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act.

(5) To study the provision of drug coverage for new full-benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act (42 U.S.C. 1396u–5(c)(6))), as well as to monitor and report annual total expenditures, health outcomes, and access to benefits for all dual eligible individuals.

(e) REPORT.—The Secretary shall, as part of the budget transmitted under section 1105(a) of title 31, United States Code, submit to Congress an annual report containing recommendations for legislation that would improve care coordination and benefits for dual eligible individuals.

(f) DUAL ELIGIBLE DEFINED.—In this section, the term “dual eligible individual” means an individual who is entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act, or enrolled for benefits under part B of title XVIII of such Act, and is eligible for medical assistance under a State plan under title XIX of such Act or under a waiver of such plan.

Subtitle I—Improving the Quality of Medicaid for Patients and Providers

SEC. 2701. ADULT HEALTH QUALITY MEASURES.

Title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 401 of the Children’s Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), is amended by inserting after section 1139A the following new section:

“SEC. 1139B. ADULT HEALTH QUALITY MEASURES.

“(a) DEVELOPMENT OF CORE SET OF HEALTH CARE QUALITY MEASURES FOR ADULTS ELIGIBLE FOR BENEFITS UNDER MEDICAID.—The Secretary shall identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults in the same manner as the Secretary identifies and publishes a core set of child health quality measures under section 1139A, including with respect to identifying and publishing existing adult health quality measures that are in use under public and privately sponsored health care coverage arrangements, or that are part of reporting systems that measure both the presence and duration of health insurance coverage over time, that may be applicable to Medicaid eligible adults.

“(b) DEADLINES.—

“(1) RECOMMENDED MEASURES.—Not later than January 1, 2011, the Secretary shall identify and publish for comment a recommended core set of adult health quality measures for Medicaid eligible adults.

“(2) DISSEMINATION.—Not later than January 1, 2012, the Secretary shall publish an initial core set of adult health quality measures that are applicable to Medicaid eligible adults.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—218

“(e) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated for each of fiscal years 2010 through 2014, \$60,000,000 for the purpose of carrying out this section. Funds appropriated under this subsection shall remain available until expended.”.

SEC. 2702. PAYMENT ADJUSTMENT FOR HEALTH CARE-ACQUIRED CONDITIONS.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall identify current State practices that prohibit payment for health care-acquired conditions and shall incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program in regulations. Such regulations shall be effective as of July 1, 2011, and shall prohibit payments to States under section 1903 of the Social Security Act for any amounts expended for providing medical assistance for health care-acquired conditions specified in the regulations. The regulations shall ensure that the prohibition on payment for health care-acquired conditions shall not result in a loss of access to care or services for Medicaid beneficiaries.

(b) HEALTH CARE-ACQUIRED CONDITION.—In this section, the term “health care-acquired condition” means a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code described in section 1886(d)(4)(D)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(4)(D)(iv)).

(c) MEDICARE PROVISIONS.—In carrying out this section, the Secretary shall apply to State plans (or waivers) under title XIX of the Social Security Act the regulations promulgated pursuant to section 1886(d)(4)(D) of such Act (42 U.S.C. 1395ww(d)(4)(D)) relating to the prohibition of payments based on the presence of a secondary diagnosis code specified by the Secretary in such regulations, as appropriate for the Medicaid program. The Secretary may exclude certain conditions identified under title XVIII of the Social Security Act for non-payment under title XIX of such Act when the Secretary finds the inclusion of such conditions to be inapplicable to beneficiaries under title XIX.

SEC. 2703. STATE OPTION TO PROVIDE HEALTH HOMES FOR ENROLLEES WITH CHRONIC CONDITIONS.

(a) STATE PLAN AMENDMENT.—Title XIX of the Social Security Act (42 U.S.C. 1396a et seq.), as amended by sections 2201 and 2305, is amended by adding at the end the following new section:

“SEC. 1945. STATE OPTION TO PROVIDE COORDINATED CARE THROUGH A HEALTH HOME FOR INDIVIDUALS WITH CHRONIC CONDITIONS.—

“(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and any other provision of this title for which the Secretary determines it is necessary to waive in order to implement this section, beginning January 1, 2011, a State, at its option as a State plan amendment, may provide for medical assistance under this title to eligible individuals with chronic conditions who select a designated provider (as described under subsection (h)(5)), a team of health care professionals (as described under subsection (h)(6)) operating with such a provider, or a health team (as described under subsection (h)(7)) as the individual’s health home for purposes of providing the individual with health home services.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—219

“(b) HEALTH HOME QUALIFICATION STANDARDS.—The Secretary shall establish standards for qualification as a designated provider for the purpose of being eligible to be a health home for purposes of this section.

“(c) PAYMENTS.—

“(1) IN GENERAL.—A State shall provide a designated provider, a team of health care professionals operating with such a provider, or a health team with payments for the provision of health home services to each eligible individual with chronic conditions that selects such provider, team of health care professionals, or health team as the individual’s health home. Payments made to a designated provider, a team of health care professionals operating with such a provider, or a health team for such services shall be treated as medical assistance for purposes of section 1903(a), except that, during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 90 percent.

“(2) METHODOLOGY.—

“(A) IN GENERAL.—The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of health home services. Such methodology for determining payment—

“(i) may be tiered to reflect, with respect to each eligible individual with chronic conditions provided such services by a designated provider, a team of health care professionals operating with such a provider, or a health team, as well as the severity or number of each such individual’s chronic conditions or the specific capabilities of the provider, team of health care professionals, or health team; and

“(ii) shall be established consistent with section 1902(a)(30)(A).

“(B) ALTERNATE MODELS OF PAYMENT.—The methodology for determining payment for provision of health home services under this section shall not be limited to a per-member per-month basis and may provide (as proposed by the State and subject to approval by the Secretary) for alternate models of payment.

“(3) PLANNING GRANTS.—

“(A) IN GENERAL.—Beginning January 1, 2011, the Secretary may award planning grants to States for purposes of developing a State plan amendment under this section. A planning grant awarded to a State under this paragraph shall remain available until expended.

“(B) STATE CONTRIBUTION.—A State awarded a planning grant shall contribute an amount equal to the State percentage determined under section 1905(b) (without regard to section 5001 of Public Law 111–5) for each fiscal year for which the grant is awarded.

“(C) LIMITATION.—The total amount of payments made to States under this paragraph shall not exceed \$25,000,000.

“(d) HOSPITAL REFERRALS.—A State shall include in the State plan amendment a requirement for hospitals that are participating providers under the State plan or a waiver of such plan to establish

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—220

procedures for referring any eligible individuals with chronic conditions who seek or need treatment in a hospital emergency department to designated providers.

“(e) COORDINATION.—A State shall consult and coordinate, as appropriate, with the Substance Abuse and Mental Health Services Administration in addressing issues regarding the prevention and treatment of mental illness and substance abuse among eligible individuals with chronic conditions.

“(f) MONITORING.—A State shall include in the State plan amendment—

“(1) a methodology for tracking avoidable hospital readmissions and calculating savings that result from improved chronic care coordination and management under this section; and

“(2) a proposal for use of health information technology in providing health home services under this section and improving service delivery and coordination across the care continuum (including the use of wireless patient technology to improve coordination and management of care and patient adherence to recommendations made by their provider).

“(g) REPORT ON QUALITY MEASURES.—As a condition for receiving payment for health home services provided to an eligible individual with chronic conditions, a designated provider shall report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services. When appropriate and feasible, a designated provider shall use health information technology in providing the State with such information.

“(h) DEFINITIONS.—In this section:

“(1) ELIGIBLE INDIVIDUAL WITH CHRONIC CONDITIONS.—

“(A) IN GENERAL.—Subject to subparagraph (B), the term ‘eligible individual with chronic conditions’ means an individual who—

“(i) is eligible for medical assistance under the State plan or under a waiver of such plan; and

“(ii) has at least—

“(I) 2 chronic conditions;

“(II) 1 chronic condition and is at risk of having a second chronic condition; or

“(III) 1 serious and persistent mental health condition.

“(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall prevent the Secretary from establishing higher levels as to the number or severity of chronic or mental health conditions for purposes of determining eligibility for receipt of health home services under this section.

“(2) CHRONIC CONDITION.—The term ‘chronic condition’ has the meaning given that term by the Secretary and shall include, but is not limited to, the following:

“(A) A mental health condition.

“(B) Substance use disorder.

“(C) Asthma.

“(D) Diabetes.

“(E) Heart disease.

“(F) Being overweight, as evidenced by having a Body Mass Index (BMI) over 25.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—221

“(3) HEALTH HOME.—The term ‘health home’ means a designated provider (including a provider that operates in coordination with a team of health care professionals) or a health team selected by an eligible individual with chronic conditions to provide health home services.

“(4) HEALTH HOME SERVICES.—

“(A) IN GENERAL.—The term ‘health home services’ means comprehensive and timely high-quality services described in subparagraph (B) that are provided by a designated provider, a team of health care professionals operating with such a provider, or a health team.

“(B) SERVICES DESCRIBED.—The services described in this subparagraph are—

“(i) comprehensive care management;

“(ii) care coordination and health promotion;

“(iii) comprehensive transitional care, including appropriate follow-up, from inpatient to other settings;

“(iv) patient and family support (including authorized representatives);

“(v) referral to community and social support services, if relevant; and

“(vi) use of health information technology to link services, as feasible and appropriate.

“(5) DESIGNATED PROVIDER.—The term ‘designated provider’ means a physician, clinical practice or clinical group practice, rural clinic, community health center, community mental health center, home health agency, or any other entity or provider (including pediatricians, gynecologists, and obstetricians) that is determined by the State and approved by the Secretary to be qualified to be a health home for eligible individuals with chronic conditions on the basis of documentation evidencing that the physician, practice, or clinic—

“(A) has the systems and infrastructure in place to provide health home services; and

“(B) satisfies the qualification standards established by the Secretary under subsection (b).

“(6) TEAM OF HEALTH CARE PROFESSIONALS.—The term ‘team of health care professionals’ means a team of health professionals (as described in the State plan amendment) that may—

“(A) include physicians and other professionals, such as a nurse care coordinator, nutritionist, social worker, behavioral health professional, or any professionals deemed appropriate by the State; and

“(B) be free standing, virtual, or based at a hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity deemed appropriate by the State and approved by the Secretary.

“(7) HEALTH TEAM.—The term ‘health team’ has the meaning given such term for purposes of section 3502 of the Patient Protection and Affordable Care Act.”.

(b) EVALUATION.—

(1) INDEPENDENT EVALUATION.—

(A) IN GENERAL.—The Secretary shall enter into a contract with an independent entity or organization to conduct an evaluation and assessment of the States that have

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—222

elected the option to provide coordinated care through a health home for Medicaid beneficiaries with chronic conditions under section 1945 of the Social Security Act (as added by subsection (a)) for the purpose of determining the effect of such option on reducing hospital admissions, emergency room visits, and admissions to skilled nursing facilities.

(B) EVALUATION REPORT.—Not later than January 1, 2017, the Secretary shall report to Congress on the evaluation and assessment conducted under subparagraph (A).

(2) SURVEY AND INTERIM REPORT.—

(A) IN GENERAL.—Not later than January 1, 2014, the Secretary of Health and Human Services shall survey States that have elected the option under section 1945 of the Social Security Act (as added by subsection (a)) and report to Congress on the nature, extent, and use of such option, particularly as it pertains to—

- (i) hospital admission rates;
- (ii) chronic disease management;
- (iii) coordination of care for individuals with chronic conditions;
- (iv) assessment of program implementation;
- (v) processes and lessons learned (as described in subparagraph (B));
- (vi) assessment of quality improvements and clinical outcomes under such option; and
- (vii) estimates of cost savings.

(B) IMPLEMENTATION REPORTING.—A State that has elected the option under section 1945 of the Social Security Act (as added by subsection (a)) shall report to the Secretary, as necessary, on processes that have been developed and lessons learned regarding provision of coordinated care through a health home for Medicaid beneficiaries with chronic conditions under such option.

SEC. 2704. DEMONSTRATION PROJECT TO EVALUATE INTEGRATED CARE AROUND A HOSPITALIZATION.

(a) AUTHORITY TO CONDUCT PROJECT.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a demonstration project under title XIX of the Social Security Act to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary—

(A) with respect to an episode of care that includes a hospitalization; and

(B) for concurrent physicians services provided during a hospitalization.

(2) DURATION.—The demonstration project shall begin on January 1, 2012, and shall end on December 31, 2016.

(b) REQUIREMENTS.—The demonstration project shall be conducted in accordance with the following:

(1) The demonstration project shall be conducted in up to 8 States, determined by the Secretary based on consideration of the potential to lower costs under the Medicaid program while improving care for Medicaid beneficiaries. A State selected to participate in the demonstration project may target

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—223

the demonstration project to particular categories of beneficiaries, beneficiaries with particular diagnoses, or particular geographic regions of the State, but the Secretary shall insure that, as a whole, the demonstration project is, to the greatest extent possible, representative of the demographic and geographic composition of Medicaid beneficiaries nationally.

(2) The demonstration project shall focus on conditions where there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished to Medicaid beneficiaries while reducing total expenditures under the State Medicaid programs selected to participate, as determined by the Secretary.

(3) A State selected to participate in the demonstration project shall specify the 1 or more episodes of care the State proposes to address in the project, the services to be included in the bundled payments, and the rationale for the selection of such episodes of care and services. The Secretary may modify the episodes of care as well as the services to be included in the bundled payments prior to or after approving the project. The Secretary may also vary such factors among the different States participating in the demonstration project.

(4) The Secretary shall ensure that payments made under the demonstration project are adjusted for severity of illness and other characteristics of Medicaid beneficiaries within a category or having a diagnosis targeted as part of the demonstration project. States shall ensure that Medicaid beneficiaries are not liable for any additional cost sharing than if their care had not been subject to payment under the demonstration project.

(5) Hospitals participating in the demonstration project shall have or establish robust discharge planning programs to ensure that Medicaid beneficiaries requiring post-acute care are appropriately placed in, or have ready access to, post-acute care settings.

(6) The Secretary and each State selected to participate in the demonstration project shall ensure that the demonstration project does not result in the Medicaid beneficiaries whose care is subject to payment under the demonstration project being provided with less items and services for which medical assistance is provided under the State Medicaid program than the items and services for which medical assistance would have been provided to such beneficiaries under the State Medicaid program in the absence of the demonstration project.

(c) WAIVER OF PROVISIONS.—Notwithstanding section 1115(a) of the Social Security Act (42 U.S.C. 1315(a)), the Secretary may waive such provisions of titles XIX, XVIII, and XI of that Act as may be necessary to accomplish the goals of the demonstration, ensure beneficiary access to acute and post-acute care, and maintain quality of care.

(d) EVALUATION AND REPORT.—

(1) DATA.—Each State selected to participate in the demonstration project under this section shall provide to the Secretary, in such form and manner as the Secretary shall specify, relevant data necessary to monitor outcomes, costs, and quality, and evaluate the rationales for selection of the episodes of care and services specified by States under subsection (b)(3).

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—224

(2) REPORT.—Not later than 1 year after the conclusion of the demonstration project, the Secretary shall submit a report to Congress on the results of the demonstration project.

SEC. 2705. MEDICAID GLOBAL PAYMENT SYSTEM DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall, in coordination with the Center for Medicare and Medicaid Innovation (as established under section 1115A of the Social Security Act, as added by section 3021 of this Act), establish the Medicaid Global Payment System Demonstration Project under which a participating State shall adjust the payments made to an eligible safety net hospital system or network from a fee-for-service payment structure to a global capitated payment model.

(b) DURATION AND SCOPE.—The demonstration project conducted under this section shall operate during a period of fiscal years 2010 through 2012. The Secretary shall select not more than 5 States to participate in the demonstration project.

(c) ELIGIBLE SAFETY NET HOSPITAL SYSTEM OR NETWORK.—For purposes of this section, the term “eligible safety net hospital system or network” means a large, safety net hospital system or network (as defined by the Secretary) that operates within a State selected by the Secretary under subsection (b).

(d) EVALUATION.—

(1) TESTING.—The Innovation Center shall test and evaluate the demonstration project conducted under this section to examine any changes in health care quality outcomes and spending by the eligible safety net hospital systems or networks.

(2) BUDGET NEUTRALITY.—During the testing period under paragraph (1), any budget neutrality requirements under section 1115A(b)(3) of the Social Security Act (as so added) shall not be applicable.

(3) MODIFICATION.—During the testing period under paragraph (1), the Secretary may, in the Secretary’s discretion, modify or terminate the demonstration project conducted under this section.

(e) REPORT.—Not later than 12 months after the date of completion of the demonstration project under this section, the Secretary shall submit to Congress a report containing the results of the evaluation and testing conducted under subsection (d), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

SEC. 2706. PEDIATRIC ACCOUNTABLE CARE ORGANIZATION DEMONSTRATION PROJECT.

(a) AUTHORITY TO CONDUCT DEMONSTRATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating State to allow pediatric medical providers that meet specified requirements to be recognized as an accountable care organization for purposes of receiving incentive payments (as described under subsection (d)), in the same manner as an accountable care

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—225

organization is recognized and provided with incentive payments under section 1899 of the Social Security Act (as added by section 3022).

(2) DURATION.—The demonstration project shall begin on January 1, 2012, and shall end on December 31, 2016.

(b) APPLICATION.—A State that desires to participate in the demonstration project under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) REQUIREMENTS.—

(1) PERFORMANCE GUIDELINES.—The Secretary, in consultation with the States and pediatric providers, shall establish guidelines to ensure that the quality of care delivered to individuals by a provider recognized as an accountable care organization under this section is not less than the quality of care that would have otherwise been provided to such individuals.

(2) SAVINGS REQUIREMENT.—A participating State, in consultation with the Secretary, shall establish an annual minimal level of savings in expenditures for items and services covered under the Medicaid program under title XIX of the Social Security Act and the CHIP program under title XXI of such Act that must be reached by an accountable care organization in order for such organization to receive an incentive payment under subsection (d).

(3) MINIMUM PARTICIPATION PERIOD.—A provider desiring to be recognized as an accountable care organization under the demonstration project shall enter into an agreement with the State to participate in the project for not less than a 3-year period.

(d) INCENTIVE PAYMENT.—An accountable care organization that meets the performance guidelines established by the Secretary under subsection (c)(1) and achieves savings greater than the annual minimal savings level established by the State under subsection (c)(2) shall receive an incentive payment for such year equal to a portion (as determined appropriate by the Secretary) of the amount of such excess savings. The Secretary may establish an annual cap on incentive payments for an accountable care organization.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

SEC. 2707. MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION PROJECT.

(a) AUTHORITY TO CONDUCT DEMONSTRATION PROJECT.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a demonstration project under which an eligible State (as described in subsection (c)) shall provide payment under the State Medicaid plan under title XIX of the Social Security Act to an institution for mental diseases that is not publicly owned or operated and that is subject to the requirements of section 1867 of the Social Security Act (42 U.S.C. 1395dd) for the provision of medical assistance available under such plan to individuals who—

(1) have attained age 21, but have not attained age 65;

(2) are eligible for medical assistance under such plan;

and

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—226

(3) require such medical assistance to stabilize an emergency medical condition.

(b) **STABILIZATION REVIEW.**—A State shall specify in its application described in subsection (c)(1) establish a mechanism for how it will ensure that institutions participating in the demonstration will determine whether or not such individuals have been stabilized (as defined in subsection (h)(5)). This mechanism shall commence before the third day of the inpatient stay. States participating in the demonstration project may manage the provision of services for the stabilization of medical emergency conditions through utilization review, authorization, or management practices, or the application of medical necessity and appropriateness criteria applicable to behavioral health.

(c) **ELIGIBLE STATE DEFINED.**—

(1) **IN GENERAL.**—An eligible State is a State that has made an application and has been selected pursuant to paragraphs (2) and (3).

(2) **APPLICATION.**—A State seeking to participate in the demonstration project under this section shall submit to the Secretary, at such time and in such format as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require.

(3) **SELECTION.**—A State shall be determined eligible for the demonstration by the Secretary on a competitive basis among States with applications meeting the requirements of paragraph (1). In selecting State applications for the demonstration project, the Secretary shall seek to achieve an appropriate national balance in the geographic distribution of such projects.

(d) **LENGTH OF DEMONSTRATION PROJECT.**—The demonstration project established under this section shall be conducted for a period of 3 consecutive years.

(e) **LIMITATIONS ON FEDERAL FUNDING.**—

(1) **APPROPRIATION.**—

(A) **IN GENERAL.**—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to carry out this section, \$75,000,000 for fiscal year 2011.

(B) **BUDGET AUTHORITY.**—Subparagraph (A) constitutes budget authority in advance of appropriations Act and represents the obligation of the Federal Government to provide for the payment of the amounts appropriated under that subparagraph.

(2) **5-YEAR AVAILABILITY.**—Funds appropriated under paragraph (1) shall remain available for obligation through December 31, 2015.

(3) **LIMITATION ON PAYMENTS.**—In no case may—

(A) the aggregate amount of payments made by the Secretary to eligible States under this section exceed \$75,000,000; or

(B) payments be provided by the Secretary under this section after December 31, 2015.

(4) **FUNDS ALLOCATED TO STATES.**—Funds shall be allocated to eligible States on the basis of criteria, including a State's application and the availability of funds, as determined by the Secretary.

(5) **PAYMENTS TO STATES.**—The Secretary shall pay to each eligible State, from its allocation under paragraph (4), an amount each quarter equal to the Federal medical assistance

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—227

percentage of expenditures in the quarter for medical assistance described in subsection (a). As a condition of receiving payment, a State shall collect and report information, as determined necessary by the Secretary, for the purposes of providing Federal oversight and conducting an evaluation under subsection (f)(1).

(f) EVALUATION AND REPORT TO CONGRESS.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the demonstration project in order to determine the impact on the functioning of the health and mental health service system and on individuals enrolled in the Medicaid program and shall include the following:

(A) An assessment of access to inpatient mental health services under the Medicaid program; average lengths of inpatient stays; and emergency room visits.

(B) An assessment of discharge planning by participating hospitals.

(C) An assessment of the impact of the demonstration project on the costs of the full range of mental health services (including inpatient, emergency and ambulatory care).

(D) An analysis of the percentage of consumers with Medicaid coverage who are admitted to inpatient facilities as a result of the demonstration project as compared to those admitted to these same facilities through other means.

(E) A recommendation regarding whether the demonstration project should be continued after December 31, 2013, and expanded on a national basis.

(2) REPORT.—Not later than December 31, 2013, the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation under paragraph (1).

(g) WAIVER AUTHORITY.—

(1) IN GENERAL.—The Secretary shall waive the limitation of subdivision (B) following paragraph (28) of section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) (relating to limitations on payments for care or services for individuals under 65 years of age who are patients in an institution for mental diseases) for purposes of carrying out the demonstration project under this section.

(2) LIMITED OTHER WAIVER AUTHORITY.—The Secretary may waive other requirements of titles XI and XIX of the Social Security Act (including the requirements of sections 1902(a)(1) (relating to statewideness) and 1902(1)(10)(B) (relating to comparability)) only to extent necessary to carry out the demonstration project under this section.

(h) DEFINITIONS.—In this section:

(1) EMERGENCY MEDICAL CONDITION.—The term “emergency medical condition” means, with respect to an individual, an individual who expresses suicidal or homicidal thoughts or gestures, if determined dangerous to self or others.

(2) FEDERAL MEDICAL ASSISTANCE PERCENTAGE.—The term “Federal medical assistance percentage” has the meaning given that term with respect to a State under section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)).

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—228

(3) INSTITUTION FOR MENTAL DISEASES.—The term “institution for mental diseases” has the meaning given to that term in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i)).

(4) MEDICAL ASSISTANCE.—The term “medical assistance” has the meaning given that term in section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)).

(5) STABILIZED.—The term “stabilized” means, with respect to an individual, that the emergency medical condition no longer exists with respect to the individual and the individual is no longer dangerous to self or others.

(6) STATE.—The term “State” has the meaning given that term for purposes of title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

Subtitle II—Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC)

SEC. 2801. MACPAC ASSESSMENT OF POLICIES AFFECTING ALL MEDICAID BENEFICIARIES.

(a) IN GENERAL.—Section 1900 of the Social Security Act (42 U.S.C. 1396) is amended—

(1) in subsection (b)—

(A) in paragraph (1)—

(i) in the paragraph heading, by inserting “FOR ALL STATES” before “AND ANNUAL”; and

(ii) in subparagraph (A), by striking “children’s”;

(iii) in subparagraph (B), by inserting “, the Secretary, and States” after “Congress”;

(iv) in subparagraph (C), by striking “March 1” and inserting “March 15”; and

(v) in subparagraph (D), by striking “June 1” and inserting “June 15”;

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (i)—

(aa) by inserting “the efficient provision of” after “expenditures for”; and

(bb) by striking “hospital, skilled nursing facility, physician, Federally-qualified health center, rural health center, and other fees” and inserting “payments to medical, dental, and health professionals, hospitals, residential and long-term care providers, providers of home and community based services, Federally-qualified health centers and rural health clinics, managed care entities, and providers of other covered items and services”; and

(II) in clause (iii), by inserting “(including how such factors and methodologies enable such beneficiaries to obtain the services for which they are eligible, affect provider supply, and affect providers that serve a disproportionate share of low-income and other vulnerable populations)” after “beneficiaries”;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—290

websites, performance information summarizing data on quality measures. Such information shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.

“(b) INFORMATION ON CONDITIONS.—The performance information made publicly available on an Internet website, as described in subsection (a), shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

“(c) CONSULTATION.—

“(1) IN GENERAL.—In carrying out this section, the Secretary shall consult with the entity with a contract under section 1890(a) of the Social Security Act, and other entities, as appropriate, to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites.

“(2) CONSULTATION WITH STAKEHOLDERS.—The entity with a contract under section 1890(a) of the Social Security Act shall convene multi-stakeholder groups, as described in such section, to review the design and format of each Internet website made available under subsection (a) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

“(d) COORDINATION.—Where appropriate, the Secretary shall coordinate the manner in which data are presented through Internet websites described in subsection (a) and for public reporting of other quality measures by the Secretary, including such quality measures under title XVIII of the Social Security Act.

“(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.”.

PART 3—ENCOURAGING DEVELOPMENT OF NEW PATIENT CARE MODELS

SEC. 3021. ESTABLISHMENT OF CENTER FOR MEDICARE AND MEDICAID INNOVATION WITHIN CMS.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1115 the following new section:

“CENTER FOR MEDICARE AND MEDICAID INNOVATION

“SEC. 1115A. (a) CENTER FOR MEDICARE AND MEDICAID INNOVATION ESTABLISHED.—

“(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the ‘CMI’) to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—291

also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).

“(2) DEADLINE.—The Secretary shall ensure that the CMI is carrying out the duties described in this section by not later than January 1, 2011.

“(3) CONSULTATION.—In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties.

“(4) DEFINITIONS.—In this section:

“(A) APPLICABLE INDIVIDUAL.—The term ‘applicable individual’ means—

“(i) an individual who is entitled to, or enrolled for, benefits under part A of title XVIII or enrolled for benefits under part B of such title;

“(ii) an individual who is eligible for medical assistance under title XIX, under a State plan or waiver; or

“(iii) an individual who meets the criteria of both clauses (i) and (ii).

“(B) APPLICABLE TITLE.—The term ‘applicable title’ means title XVIII, title XIX, or both.

“(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas. *[As added by section 10306(1)]*

“(b) TESTING OF MODELS (PHASE I).—

“(1) IN GENERAL.—The CMI shall test payment and service delivery models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models under the applicable title (as defined in subsection (a)(4)(B)) on program expenditures under such titles and the quality of care received by individuals receiving benefits under such title.

“(2) SELECTION OF MODELS TO BE TESTED.—

“(A) IN GENERAL.—*[As revised by section 10306(a)(2)(A)]* The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

“(B) OPPORTUNITIES.—The models described in this subparagraph are the following models:

“(i) Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, medical homes that address women’s unique health care

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—292

needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.

“(ii) Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.

“(iii) Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following:

“(I) An inability to perform 2 or more activities of daily living.

“(II) Cognitive impairment, including dementia.

“(iv) Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.

“(v) Supporting care coordination 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.

“(vi) Varying payment to physicians who order advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) according to the physician’s adherence to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders.

“(vii) Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act.

“(viii) Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.

“(ix) Assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.

“(x) Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State, including the management and oversight of all funds under the applicable titles with respect to such individuals.

“(xi) Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—293

“(xii) Aligning nationally recognized, evidence-based guidelines of cancer care with payment incentives under title XVIII in the areas of treatment planning and follow-up care planning for applicable individuals described in clause (i) or (iii) of subsection (a)(4)(A) with cancer, including the identification of gaps in applicable quality measures.

“(xiii) Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge.

“(xiv) Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.

“(xv) Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for—

“(I) developing, documenting, and disseminating best practices and proven care methods;

“(II) implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and

“(III) providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.

“(xvi) Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.

“(xvii) Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.

“(xviii) Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.

【Clauses (xix) and (xx) added by section 10306(2)(B)】

“(xix) Utilizing, in particular in entities located in medically underserved areas and facilities of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), telehealth services—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—294

“(I) in treating behavioral health issues (such as post-traumatic stress disorder) and stroke; and

“(II) to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex conditions.

“(xx) Utilizing a diverse network of providers of services and suppliers to improve care coordination for applicable individuals described in subsection (a)(4)(A)(i) with 2 or more chronic conditions and a history of prior-year hospitalization through interventions developed under the Medicare Coordinated Care Demonstration Project under section 4016 of the Balanced Budget Act of 1997 (42 U.S.C. 1395b–1 note).

“(C) ADDITIONAL FACTORS FOR CONSIDERATION.—In selecting models for testing under subparagraph (A), the CMI may consider the following additional factors:

“(i) Whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of applicable individuals.

“(ii) Whether the model places the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the care team of the applicable individual.

“(iii) Whether the model provides for in-person contact with applicable individuals.

“(iv) Whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.

“(v) Whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers.

“(vi) Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching.

“(vii) Whether, under the model, providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real time basis.

“(viii) *【As added by section 10306(2)(C)】* Whether the model demonstrates effective linkage with other public sector or private sector payers.

“(3) BUDGET NEUTRALITY.—

“(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.

“(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services,

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—295

with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—

“(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;

“(ii) reduce spending under the applicable title without reducing the quality of care; or

“(iii) improve the quality of care and reduce spending.

Such termination may occur at any time after such testing has begun and before completion of the testing.

“(4) EVALUATION.—

“(A) IN GENERAL.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—

“(i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and

“(ii) the changes in spending under the applicable titles by reason of the model.

“(B) INFORMATION.—The Secretary shall make the results of each evaluation under this paragraph available to the public in a timely fashion and may establish requirements for States and other entities participating in the testing of models under this section to collect and report information that the Secretary determines is necessary to monitor and evaluate such models.

“(C) MEASURE SELECTION.—*[As added by section 10306(3)]* To the extent feasible, the Secretary shall select measures under this paragraph that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in 1890(b)(7)(B).

“(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—*[As revised by section 10306(4)]*

“(1) the Secretary determines that such expansion is expected to—

“(A) reduce spending under applicable title without reducing the quality of care; or

“(B) improve the quality of patient care without increasing spending;

“(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

[Paragraph (3) and succeeding sentence added by section 10306(4)]

“(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—296

In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

“(d) IMPLEMENTATION.—

“(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).

“(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

“(A) the selection of models for testing or expansion under this section;

“(B) the selection of organizations, sites, or participants to test those models selected;

“(C) the elements, parameters, scope, and duration of such models for testing or dissemination;

“(D) determinations regarding budget neutrality under subsection (b)(3);

“(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

“(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

“(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models or expansion of such models under this section.

“(e) APPLICATION TO CHIP.—The Center may carry out activities under this section with respect to title XXI in the same manner as provided under this section with respect to the program under the applicable titles.

“(f) FUNDING.—

“(1) IN GENERAL.—There are appropriated, from amounts in the Treasury not otherwise appropriated—

“(A) \$5,000,000 for the design, implementation, and evaluation of models under subsection (b) for fiscal year 2010;

“(B) \$10,000,000,000 for the activities initiated under this section for the period of fiscal years 2011 through 2019; and

“(C) the amount described in subparagraph (B) for the activities initiated under this section for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period beginning with fiscal year 2020).

Amounts appropriated under the preceding sentence shall remain available until expended.

“(2) USE OF CERTAIN FUNDS.—Out of amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not less than \$25,000,000 shall be made available each such fiscal year to design, implement, and evaluate models under subsection (b).

“(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—297

report shall describe the models tested under subsection (b), including the number of individuals described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.”

(b) **MEDICAID CONFORMING AMENDMENT.**—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 8002(b), is amended—

- (1) in paragraph (81), by striking “and” at the end;
- (2) in paragraph (82), by striking the period at the end and inserting “; and”; and
- (3) by inserting after paragraph (82) the following new paragraph:

“(83) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State.”

(c) **REVISIONS TO HEALTH CARE QUALITY DEMONSTRATION PROGRAM.**—Subsections (b) and (f) of section 1866C of the Social Security Act (42 U.S.C. 1395cc–3) are amended by striking “5-year” each place it appears.

SEC. 3022. MEDICARE SHARED SAVINGS PROGRAM.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

“SHARED SAVINGS PROGRAM

“SEC. 1899. (a) **ESTABLISHMENT.**—

“(1) **IN GENERAL.**—Not later than January 1, 2012, the Secretary shall establish a shared savings program (in this section referred to as the ‘program’) that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under such program—

“(A) groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to in this section as an ‘ACO’); and

“(B) ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings under subsection (d)(2).

“(b) **ELIGIBLE ACOS.**—

“(1) **IN GENERAL.**—Subject to the succeeding provisions of this subsection, as determined appropriate by the Secretary, the following groups of providers of services and suppliers which have established a mechanism for shared governance are eligible to participate as ACOs under the program under this section:

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—298

“(A) ACO professionals in group practice arrangements.

“(B) Networks of individual practices of ACO professionals.

“(C) Partnerships or joint venture arrangements between hospitals and ACO professionals.

“(D) Hospitals employing ACO professionals.

“(E) Such other groups of providers of services and suppliers as the Secretary determines appropriate.

“(2) REQUIREMENTS.—An ACO shall meet the following requirements:

“(A) The ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.

“(B) The ACO shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period (referred to in this section as the ‘agreement period’).

“(C) The ACO shall have a formal legal structure that would allow the organization to receive and distribute payments for shared savings under subsection (d)(2) to participating providers of services and suppliers.

“(D) The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subsection (c). At a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it under subsection (c) in order to be eligible to participate in the ACO program.

“(E) The ACO shall provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements under paragraph (3), and the determination of payments for shared savings under subsection (d)(2).

“(F) The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.

“(G) The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

“(H) The ACO shall demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

“(3) QUALITY AND OTHER REPORTING REQUIREMENTS.—

“(A) IN GENERAL.—The Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of—

“(i) clinical processes and outcomes;

“(ii) patient and, where practicable, caregiver experience of care; and

“(iii) utilization (such as rates of hospital admissions for ambulatory care sensitive conditions).

“(B) REPORTING REQUIREMENTS.—An ACO shall submit data in a form and manner specified by the Secretary

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—299

on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. Such data may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up by ACO professionals, as the Secretary determines appropriate.

“(C) QUALITY PERFORMANCE STANDARDS.—The Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs. The Secretary shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.

“(D) OTHER REPORTING REQUIREMENTS.—The Secretary may, as the Secretary determines appropriate, incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI) under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. The incentive payments described in the preceding sentence shall not be taken into consideration when calculating any payments otherwise made under subsection (d).

“(4) NO DUPLICATION IN PARTICIPATION IN SHARED SAVINGS PROGRAMS.—A provider of services or supplier that participates in any of the following shall not be eligible to participate in an ACO under this section:

“(A) A model tested or expanded under section 1115A that involves shared savings under this title, or any other program or demonstration project that involves such shared savings.

“(B) The independence at home medical practice pilot program under section 1866E.

“(c) ASSIGNMENT OF MEDICARE FEE-FOR-SERVICE BENEFICIARIES TO ACOS.—The Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A).

“(d) PAYMENTS AND TREATMENT OF SAVINGS.—

“(1) PAYMENTS.—

“(A) IN GENERAL.—Under the program, subject to paragraph (3), payments shall continue to be made to providers of services and suppliers participating in an ACO under the original Medicare fee-for-service program under parts A and B in the same manner as they would otherwise be made except that a participating ACO is eligible to receive payment for shared savings under paragraph (2) if—

“(i) the ACO meets quality performance standards established by the Secretary under subsection (b)(3); and

“(ii) the ACO meets the requirement under subparagraph (B)(i).

“(B) SAVINGS REQUIREMENT AND BENCHMARK.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—300

“(i) DETERMINING SAVINGS.—In each year of the agreement period, an ACO shall be eligible to receive payment for shared savings under paragraph (2) only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under clause (ii). The Secretary shall determine the appropriate percent described in the preceding sentence to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.

“(ii) ESTABLISH AND UPDATE BENCHMARK.—The Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary. Such benchmark shall be reset at the start of each agreement period.

“(2) PAYMENTS FOR SHARED SAVINGS.—Subject to performance with respect to the quality performance standards established by the Secretary under subsection (b)(3), if an ACO meets the requirements under paragraph (1), a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title. The Secretary shall establish limits on the total amount of shared savings that may be paid to an ACO under this paragraph.

“(3) MONITORING AVOIDANCE OF AT-RISK PATIENTS.—If the Secretary determines that an ACO has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO the Secretary may impose an appropriate sanction on the ACO, including termination from the program.

“(4) TERMINATION.—The Secretary may terminate an agreement with an ACO if it does not meet the quality performance standards established by the Secretary under subsection (b)(3).

“(e) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program.

“(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of this Act as may be necessary to carry out the provisions of this section.

“(g) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

“(1) the specification of criteria under subsection (a)(1)(B);

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—301

“(2) the assessment of the quality of care furnished by an ACO and the establishment of performance standards under subsection (b)(3);

“(3) the assignment of Medicare fee-for-service beneficiaries to an ACO under subsection (c);

“(4) the determination of whether an ACO is eligible for shared savings under subsection (d)(2) and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under subsection (d)(1)(B);

“(5) the percent of shared savings specified by the Secretary under subsection (d)(2) and any limit on the total amount of shared savings established by the Secretary under such subsection; and

“(6) the termination of an ACO under subsection (d)(4).

“(h) DEFINITIONS.—In this section:

“(1) ACO PROFESSIONAL.—The term ‘ACO professional’ means—

“(A) a physician (as defined in section 1861(r)(1)); and

“(B) a practitioner described in section 1842(b)(18)(C)(i).

“(2) HOSPITAL.—The term ‘hospital’ means a subsection (d) hospital (as defined in section 1886(d)(1)(B)).

“(3) MEDICARE FEE-FOR-SERVICE BENEFICIARY.—The term ‘Medicare fee-for-service beneficiary’ means an individual who is enrolled in the original Medicare fee-for-service program under parts A and B and is not enrolled in an MA plan under part C, an eligible organization under section 1876, or a PACE program under section 1894.

【Subsections (i)-(k) added by section 10307】

“(i) OPTION TO USE OTHER PAYMENT MODELS.—

“(1) IN GENERAL.—If the Secretary determines appropriate, the Secretary may use any of the payment models described in paragraph (2) or (3) for making payments under the program rather than the payment model described in subsection (d).

“(2) PARTIAL CAPITATION MODEL.—

“(A) IN GENERAL.—Subject to subparagraph (B), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians’ services or all items and services under part B. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary.

“(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Payments to an ACO for items and services under this title for beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary.

“(3) OTHER PAYMENT MODELS.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—302

“(A) IN GENERAL.—Subject to subparagraph (B), a model described in this paragraph is any payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under this title.

“(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Subparagraph (B) of paragraph (2) shall apply to a payment model under subparagraph (A) in a similar manner as such subparagraph (B) applies to the payment model under paragraph (2).

“(j) INVOLVEMENT IN PRIVATE PAYER AND OTHER THIRD PARTY ARRANGEMENTS.—The Secretary may give preference to ACOs who are participating in similar arrangements with other payers.

“(k) TREATMENT OF PHYSICIAN GROUP PRACTICE DEMONSTRATION.—During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary.”

SEC. 3023. NATIONAL PILOT PROGRAM ON PAYMENT BUNDLING.

Title XVIII of the Social Security Act, as amended by section 3021, is amended by inserting after section 1866C the following new section: **[As revised by section 10308(b)(1)]**

“NATIONAL PILOT PROGRAM ON PAYMENT BUNDLING

“SEC. 1866D. (a) IMPLEMENTATION.—

“(1) IN GENERAL.—The Secretary shall establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services under this title.

“(2) DEFINITIONS.—In this section:

“(A) APPLICABLE BENEFICIARY.—The term ‘applicable beneficiary’ means an individual who—

“(i) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B of such title, but not enrolled under part C or a PACE program under section 1894; and

“(ii) is admitted to a hospital for an applicable condition.

“(B) APPLICABLE CONDITION.—The term ‘applicable condition’ means 1 or more of 10 conditions selected by the Secretary. In selecting conditions under the preceding sentence, the Secretary shall take into consideration the following factors: **[As revised by section 10308(a)(1)]**

“(i) Whether the conditions selected include a mix of chronic and acute conditions.

“(ii) Whether the conditions selected include a mix of surgical and medical conditions.

“(iii) Whether a condition is one for which there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished while reducing total expenditures under this title.

“(iv) Whether a condition has significant variation in—

“(I) the number of readmissions; and

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—303

“(II) the amount of expenditures for post-acute care spending under this title.

“(v) Whether a condition is high-volume and has high post-acute care expenditures under this title.

“(vi) Which conditions the Secretary determines are most amenable to bundling across the spectrum of care given practice patterns under this title.

“(C) APPLICABLE SERVICES.—The term ‘applicable services’ means the following:

“(i) Acute care inpatient services.

“(ii) Physicians’ services delivered in and outside of an acute care hospital setting.

“(iii) Outpatient hospital services, including emergency department services.

“(iv) Post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital.

“(v) Other services the Secretary determines appropriate.

“(D) EPISODE OF CARE.—

“(i) IN GENERAL.—Subject to clause (ii), the term ‘episode of care’ means, with respect to an applicable condition and an applicable beneficiary, the period that includes—

“(I) the 3 days prior to the admission of the applicable beneficiary to a hospital for the applicable condition;

“(II) the length of stay of the applicable beneficiary in such hospital; and

“(III) the 30 days following the discharge of the applicable beneficiary from such hospital.

“(ii) ESTABLISHMENT OF PERIOD BY THE SECRETARY.—The Secretary, as appropriate, may establish a period (other than the period described in clause (i)) for an episode of care under the pilot program.

“(E) PHYSICIANS’ SERVICES.—The term ‘physicians’ services’ has the meaning given such term in section 1861(q).

“(F) PILOT PROGRAM.—The term ‘pilot program’ means the pilot program under this section.

“(G) PROVIDER OF SERVICES.—The term ‘provider of services’ has the meaning given such term in section 1861(u).

“(H) READMISSION.—The term ‘readmission’ has the meaning given such term in section 1886(q)(5)(E).

“(I) SUPPLIER.—The term ‘supplier’ has the meaning given such term in section 1861(d).

“(3) DEADLINE FOR IMPLEMENTATION.—The Secretary shall establish the pilot program not later than January 1, 2013.

“(b) DEVELOPMENTAL PHASE.—

“(1) DETERMINATION OF PATIENT ASSESSMENT INSTRUMENT.—The Secretary shall determine which patient assessment instrument (such as the Continuity Assessment Record and Evaluation (CARE) tool) shall be used under the pilot program to evaluate the applicable condition of an applicable beneficiary for purposes of determining the most

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—304

clinically appropriate site for the provision of post-acute care to the applicable beneficiary.

“(2) DEVELOPMENT OF QUALITY MEASURES FOR AN EPISODE OF CARE AND FOR POST-ACUTE CARE.—

“(A) IN GENERAL.—The Secretary, in consultation with the Agency for Healthcare Research and Quality and the entity with a contract under section 1890(a) of the Social Security Act, shall develop quality measures for use in the pilot program—

“(i) for episodes of care; and

“(ii) for post-acute care.

“(B) SITE-NEUTRAL POST-ACUTE CARE QUALITY MEASURES.—Any quality measures developed under subparagraph (A)(ii) shall be site-neutral.

“(C) COORDINATION WITH QUALITY MEASURE DEVELOPMENT AND ENDORSEMENT PROCEDURES.—The Secretary shall ensure that the development of quality measures under subparagraph (A) is done in a manner that is consistent with the measures developed and endorsed under section 1890 and 1890A that are applicable to all post-acute care settings.

“(c) DETAILS.—

“(1) DURATION.—

“(A) IN GENERAL.—Subject to subparagraph (B), the pilot program shall be conducted for a period of 5 years.

“(B) EXPANSION.—~~【Replaced by section 10308(a)(2)】~~ The Secretary may, at any point after January 1, 2016, expand the duration and scope of the pilot program, to the extent determined appropriate by the Secretary, if—

“(i) the Secretary determines that such expansion is expected to—

“(I) reduce spending under title XVIII of the Social Security Act without reducing the quality of care; or

“(II) improve the quality of care and reduce spending;

“(ii) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under such title XVIII; and

“(iii) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under this title for individuals.

“(2) PARTICIPATING PROVIDERS OF SERVICES AND SUPPLIERS.—

“(A) IN GENERAL.—An entity comprised of providers of services and suppliers, including a hospital, a physician group, a skilled nursing facility, and a home health agency, who are otherwise participating under this title, may submit an application to the Secretary to provide applicable services to applicable individuals under this section.

“(B) REQUIREMENTS.—The Secretary shall develop requirements for entities to participate in the pilot program under this section. Such requirements shall ensure that applicable beneficiaries have an adequate choice of providers of services and suppliers under the pilot program.

“(3) PAYMENT METHODOLOGY.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—305

“(A) IN GENERAL.—

“(i) ESTABLISHMENT OF PAYMENT METHODS.—The Secretary shall develop payment methods for the pilot program for entities participating in the pilot program. Such payment methods may include bundled payments and bids from entities for episodes of care. The Secretary shall make payments to the entity for services covered under this section.

“(ii) NO ADDITIONAL PROGRAM EXPENDITURES.—

Payments under this section for applicable items and services under this title (including payment for services described in subparagraph (B)) for applicable beneficiaries for a year shall be established in a manner that does not result in spending more for such entity for such beneficiaries than would otherwise be expended for such entity for such beneficiaries for such year if the pilot program were not implemented, as estimated by the Secretary.

“(B) INCLUSION OF CERTAIN SERVICES.—A payment methodology tested under the pilot program shall include payment for the furnishing of applicable services and other appropriate services, such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities as determined appropriate by the Secretary.

“(C) BUNDLED PAYMENTS.—

“(i) IN GENERAL.—A bundled payment under the pilot program shall—

“(I) be comprehensive, covering the costs of applicable services and other appropriate services furnished to an individual during an episode of care (as determined by the Secretary); and

“(II) be made to the entity which is participating in the pilot program.

“(ii) REQUIREMENT FOR PROVISION OF APPLICABLE SERVICES AND OTHER APPROPRIATE SERVICES.—Applicable services and other appropriate services for which payment is made under this subparagraph shall be furnished or directed by the entity which is participating in the pilot program.

“(D) PAYMENT FOR POST-ACUTE CARE SERVICES AFTER THE EPISODE OF CARE.—The Secretary shall establish procedures, in the case where an applicable beneficiary requires continued post-acute care services after the last day of the episode of care, under which payment for such services shall be made.

“(4) QUALITY MEASURES.—

“(A) IN GENERAL.—The Secretary shall establish quality measures (including quality measures of process, outcome, and structure) related to care provided by entities participating in the pilot program. Quality measures established under the preceding sentence shall include measures of the following:

“(i) Functional status improvement.

“(ii) Reducing rates of avoidable hospital readmissions.

“(iii) Rates of discharge to the community.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—306

“(iv) Rates of admission to an emergency room after a hospitalization.

“(v) Incidence of health care acquired infections.

“(vi) Efficiency measures.

“(vii) Measures of patient-centeredness of care.

“(viii) Measures of patient perception of care.

“(ix) Other measures, including measures of patient outcomes, determined appropriate by the Secretary.

“(B) REPORTING ON QUALITY MEASURES.—

“(i) IN GENERAL.—A entity shall submit data to the Secretary on quality measures established under subparagraph (A) during each year of the pilot program (in a form and manner, subject to clause (iii), specified by the Secretary).

“(ii) SUBMISSION OF DATA THROUGH ELECTRONIC HEALTH RECORD.—To the extent practicable, the Secretary shall specify that data on measures be submitted under clause (i) through the use of an qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act (42 U.S.C. 300jj–11(13)) in a manner specified by the Secretary.

“(d) WAIVER.—The Secretary may waive such provisions of this title and title XI as may be necessary to carry out the pilot program.

“(e) INDEPENDENT EVALUATION AND REPORTS ON PILOT PROGRAM.—

“(1) INDEPENDENT EVALUATION.—The Secretary shall conduct an independent evaluation of the pilot program, including the extent to which the pilot program has—

“(A) improved quality measures established under subsection (c)(4)(A);

“(B) improved health outcomes;

“(C) improved applicable beneficiary access to care; and

“(D) reduced spending under this title.

“(2) REPORTS.—

“(A) INTERIM REPORT.—Not later than 2 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the initial results of the independent evaluation conducted under paragraph (1).

“(B) FINAL REPORT.—Not later than 3 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the final results of the independent evaluation conducted under paragraph (1).

“(f) CONSULTATION.—The Secretary shall consult with representatives of small rural hospitals, including critical access hospitals (as defined in section 1861(mm)(1)), regarding their participation in the pilot program. Such consultation shall include consideration of innovative methods of implementing bundled payments in hospitals described in the preceding sentence, taking into consideration any difficulties in doing so as a result of the low volume of services provided by such hospitals.

“(g) APPLICATION OF PILOT PROGRAM TO CONTINUING CARE HOSPITALS.—**[Replaced by section 10308(a)(3)]**

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—307

“(1) IN GENERAL.—In conducting the pilot program, the Secretary shall apply the provisions of the program so as to separately pilot test the continuing care hospital model.

“(2) SPECIAL RULES.—In pilot testing the continuing care hospital model under paragraph (1), the following rules shall apply:

“(A) Such model shall be tested without the limitation to the conditions selected under subsection (a)(2)(B).

“(B) Notwithstanding subsection (a)(2)(D), an episode of care shall be defined as the full period that a patient stays in the continuing care hospital plus the first 30 days following discharge from such hospital.

“(3) CONTINUING CARE HOSPITAL DEFINED.—In this subsection, the term ‘continuing care hospital’ means an entity that has demonstrated the ability to meet patient care and patient safety standards and that provides under common management the medical and rehabilitation services provided in inpatient rehabilitation hospitals and units (as defined in section 1886(d)(1)(B)(ii)), long term care hospitals (as defined in section 1886(d)(1)(B)(iv)(I)), and skilled nursing facilities (as defined in section 1819(a)) that are located in a hospital described in section 1886(d).

“(h) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the selection, testing, and evaluation of models or the expansion of such models under this section.”

SEC. 3024. INDEPENDENCE AT HOME DEMONSTRATION PROGRAM.

Title XVIII of the Social Security Act is amended by inserting after section 1866D, as inserted by section 3023, the following new section: **[As revised by section 10308(b)(2)]**

“INDEPENDENCE AT HOME MEDICAL PRACTICE DEMONSTRATION PROGRAM

“SEC. 1866E. (a) ESTABLISHMENT.—

“(1) IN GENERAL.—The Secretary shall conduct a demonstration program (in this section referred to as the ‘demonstration program’) to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries (as defined in subsection (d)).

“(2) REQUIREMENT.—The demonstration program shall test whether a model described in paragraph (1), which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, results in—

“(A) reducing preventable hospitalizations;

“(B) preventing hospital readmissions;

“(C) reducing emergency room visits;

“(D) improving health outcomes commensurate with the beneficiaries’ stage of chronic illness;

“(E) improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;

“(F) reducing the cost of health care services covered under this title; and

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—308

“(G) achieving beneficiary and family caregiver satisfaction.

“(b) INDEPENDENCE AT HOME MEDICAL PRACTICE.—

“(1) INDEPENDENCE AT HOME MEDICAL PRACTICE DEFINED.—

In this section:

“(A) IN GENERAL.—The term ‘independence at home medical practice’ means a legal entity that—

“(i) is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who have experience providing home-based primary care to applicable beneficiaries, make in-home visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary’s chronic conditions and designed to achieve the results in subsection (a);

“(ii) is organized at least in part for the purpose of providing physicians’ services;

“(iii) has documented experience in providing home-based primary care services to high-cost chronically ill beneficiaries, as determined appropriate by the Secretary;

“(iv) furnishes services to at least 200 applicable beneficiaries (as defined in subsection (d)) during each year of the demonstration program;

“(v) has entered into an agreement with the Secretary;

“(vi) uses electronic health information systems, remote monitoring, and mobile diagnostic technology; and

“(vii) meets such other criteria as the Secretary determines to be appropriate to participate in the demonstration program.

The entity shall report on quality measures (in such form, manner, and frequency as specified by the Secretary, which may be for the group, for providers of services and suppliers, or both) and report to the Secretary (in a form, manner, and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the demonstration program.

“(B) PHYSICIAN.—The term ‘physician’ includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians’ services and has the medical training or experience to fulfill the physician’s role described in subparagraph (A)(i).

“(2) PARTICIPATION OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS.—Nothing in this section shall be construed to prevent a nurse practitioner or physician assistant from participating in, or leading, a home-based primary care team as part of an independence at home medical practice if—

“(A) all the requirements of this section are met;

“(B) the nurse practitioner or physician assistant, as the case may be, is acting consistent with State law; and

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—309

“(C) the nurse practitioner or physician assistant has the medical training or experience to fulfill the nurse practitioner or physician assistant role described in paragraph (1)(A)(i).

“(3) INCLUSION OF PROVIDERS AND PRACTITIONERS.—Nothing in this subsection shall be construed as preventing an independence at home medical practice from including a provider of services or a participating practitioner described in section 1842(b)(18)(C) that is affiliated with the practice under an arrangement structured so that such provider of services or practitioner participates in the demonstration program and shares in any savings under the demonstration program.

“(4) QUALITY AND PERFORMANCE STANDARDS.—The Secretary shall develop quality performance standards for independence at home medical practices participating in the demonstration program.

“(c) PAYMENT METHODOLOGY.—

“(1) ESTABLISHMENT OF TARGET SPENDING LEVEL.—The Secretary shall establish an estimated annual spending target, for the amount the Secretary estimates would have been spent in the absence of the demonstration, for items and services covered under parts A and B furnished to applicable beneficiaries for each qualifying independence at home medical practice under this section. Such spending targets shall be determined on a per capita basis. Such spending targets shall include a risk corridor that takes into account normal variation in expenditures for items and services covered under parts A and B furnished to such beneficiaries with the size of the corridor being related to the number of applicable beneficiaries furnished services by each independence at home medical practice. The spending targets may also be adjusted for other factors as the Secretary determines appropriate.

“(2) INCENTIVE PAYMENTS.—Subject to performance on quality measures, a qualifying independence at home medical practice is eligible to receive an incentive payment under this section if actual expenditures for a year for the applicable beneficiaries it enrolls are less than the estimated spending target established under paragraph (1) for such year. An incentive payment for such year shall be equal to a portion (as determined by the Secretary) of the amount by which actual expenditures (including incentive payments under this paragraph) for applicable beneficiaries under parts A and B for such year are estimated to be less than 5 percent less than the estimated spending target for such year, as determined under paragraph (1).

“(d) APPLICABLE BENEFICIARIES.—

“(1) DEFINITION.—In this section, the term ‘applicable beneficiary’ means, with respect to a qualifying independence at home medical practice, an individual who the practice has determined—

“(A) is entitled to benefits under part A and enrolled for benefits under part B;

“(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1894;

“(C) has 2 or more chronic illnesses, such as congestive heart failure, diabetes, other dementias designated by the

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—310

Secretary, chronic obstructive pulmonary disease, ischemic heart disease, stroke, Alzheimer's Disease and neurodegenerative diseases, and other diseases and conditions designated by the Secretary which result in high costs under this title;

“(D) within the past 12 months has had a nonelective hospital admission;

“(E) within the past 12 months has received acute or subacute rehabilitation services;

“(F) has 2 or more functional dependencies requiring the assistance of another person (such as bathing, dressing, toileting, walking, or feeding); and

“(G) meets such other criteria as the Secretary determines appropriate.

“(2) PATIENT ELECTION TO PARTICIPATE.—The Secretary shall determine an appropriate method of ensuring that applicable beneficiaries have agreed to enroll in an independence at home medical practice under the demonstration program. Enrollment in the demonstration program shall be voluntary.

“(3) BENEFICIARY ACCESS TO SERVICES.—Nothing in this section shall be construed as encouraging physicians or nurse practitioners to limit applicable beneficiary access to services covered under this title and applicable beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from an independence at home medical practice.

“(e) IMPLEMENTATION.—

“(1) STARTING DATE.—The demonstration program shall begin no later than January 1, 2012. An agreement with an independence at home medical practice under the demonstration program may cover not more than a 3-year period.

“(2) NO PHYSICIAN DUPLICATION IN DEMONSTRATION PARTICIPATION.—The Secretary shall not pay an independence at home medical practice under this section that participates in section 1899.

“(3) NO BENEFICIARY DUPLICATION IN DEMONSTRATION PARTICIPATION.—The Secretary shall ensure that no applicable beneficiary enrolled in an independence at home medical practice under this section is participating in the programs under section 1899.

“(4) PREFERENCE.—In approving an independence at home medical practice, the Secretary shall give preference to practices that are—

“(A) located in high-cost areas of the country;

“(B) have experience in furnishing health care services to applicable beneficiaries in the home; and

“(C) use electronic medical records, health information technology, and individualized plans of care.

“(5) LIMITATION ON NUMBER OF PRACTICES.—In selecting qualified independence at home medical practices to participate under the demonstration program, the Secretary shall limit the number of such practices so that the number of applicable beneficiaries that may participate in the demonstration program does not exceed 10,000.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—311

“(6) WAIVER.—The Secretary may waive such provisions of this title and title XI as the Secretary determines necessary in order to implement the demonstration program.

“(7) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to this section.

“(f) EVALUATION AND MONITORING.—

“(1) IN GENERAL.—The Secretary shall evaluate each independence at home medical practice under the demonstration program to assess whether the practice achieved the results described in subsection (a).

“(2) MONITORING APPLICABLE BENEFICIARIES.—The Secretary may monitor data on expenditures and quality of services under this title after an applicable beneficiary discontinues receiving services under this title through a qualifying independence at home medical practice.

“(g) REPORTS TO CONGRESS.—The Secretary shall conduct an independent evaluation of the demonstration program and submit to Congress a final report, including best practices under the demonstration program. Such report shall include an analysis of the demonstration program on coordination of care, expenditures under this title, applicable beneficiary access to services, and the quality of health care services provided to applicable beneficiaries.

“(h) FUNDING.—For purposes of administering and carrying out the demonstration program, other than for payments for items and services furnished under this title and incentive payments under subsection (c), in addition to funds otherwise appropriated, there shall be transferred to the Secretary for the Center for Medicare & Medicaid Services Program Management Account from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in proportions determined appropriate by the Secretary) \$5,000,000 for each of fiscal years 2010 through 2015. Amounts transferred under this subsection for a fiscal year shall be available until expended.

“(i) TERMINATION.—

“(1) MANDATORY TERMINATION.—The Secretary shall terminate an agreement with an independence at home medical practice if—

“(A) the Secretary estimates or determines that such practice will not receive an incentive payment for the second of 2 consecutive years under the demonstration program; or

“(B) such practice fails to meet quality standards during any year of the demonstration program.

“(2) PERMISSIVE TERMINATION.—The Secretary may terminate an agreement with an independence at home medical practice for such other reasons determined appropriate by the Secretary.”.

SEC. 3025. HOSPITAL READMISSIONS REDUCTION PROGRAM.

(a) IN GENERAL.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww), as amended by sections 3001 and 3008, is amended by adding at the end the following new subsection:

“(q) HOSPITAL READMISSIONS REDUCTION PROGRAM.—

“(1) IN GENERAL.—With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—316

feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.”.

(b) **QUALITY IMPROVEMENT.**—Part S of title III of the Public Health Service Act, as amended by section 3015, is further amended by adding at the end the following:

“SEC. 399KK. QUALITY IMPROVEMENT PROGRAM FOR HOSPITALS WITH A HIGH SEVERITY ADJUSTED READMISSION RATE.

“(a) **ESTABLISHMENT.**—

“(1) **IN GENERAL.**—Not later than 2 years after the date of enactment of this section, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 921(4)).

“(2) **ELIGIBLE HOSPITAL DEFINED.**—In this subsection, the term ‘eligible hospital’ means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the conditions described in section 1886(q)(8)(A) of the Social Security Act and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

“(3) **RISK ADJUSTMENT.**—The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

“(b) **REPORT TO THE SECRETARY.**—As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.”.

SEC. 3026. COMMUNITY-BASED CARE TRANSITIONS PROGRAM.

(a) **IN GENERAL.**—The Secretary shall establish a Community-Based Care Transitions Program under which the Secretary provides funding to eligible entities that furnish improved care transition services to high-risk Medicare beneficiaries.

(b) **DEFINITIONS.**—In this section:

(1) **ELIGIBLE ENTITY.**—The term “eligible entity” means the following:

(A) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) identified by the Secretary as having a high readmission rate, such as under section 1886(q) of the Social Security Act, as added by section 3025.

(B) An appropriate community-based organization that provides care transition services under this section across a continuum of care through arrangements with subsection (d) hospitals (as so defined) to furnish the services described in subsection (c)(2)(B)(i) and whose governing body includes sufficient representation of multiple health care stakeholders (including consumers).

(2) **HIGH-RISK MEDICARE BENEFICIARY.**—The term “high-risk Medicare beneficiary” means a Medicare beneficiary who has attained a minimum hierarchical condition category score, as determined by the Secretary, based on a diagnosis of multiple chronic conditions or other risk factors associated with a hospital readmission or substandard transition into post-hospitalization care, which may include 1 or more of the following:

(A) Cognitive impairment.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—317

(B) Depression.

(C) A history of multiple readmissions.

(D) Any other chronic disease or risk factor as determined by the Secretary.

(3) **MEDICARE BENEFICIARY.**—The term “Medicare beneficiary” means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and enrolled under part B of such title, but not enrolled under part C of such title.

(4) **PROGRAM.**—The term “program” means the program conducted under this section.

(5) **READMISSION.**—The term “readmission” has the meaning given such term in section 1886(q)(5)(E) of the Social Security Act, as added by section 3025.

(6) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Human Services.

(c) **REQUIREMENTS.**—

(1) **DURATION.**—

(A) **IN GENERAL.**—The program shall be conducted for a 5-year period, beginning January 1, 2011.

(B) **EXPANSION.**—The Secretary may expand the duration and the scope of the program, to the extent determined appropriate by the Secretary, if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to spending under this title, certifies) that such expansion would reduce spending under this title without reducing quality.

(2) **APPLICATION; PARTICIPATION.**—

(A) **IN GENERAL.**—

(i) **APPLICATION.**—An eligible entity seeking to participate in the program shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(ii) **PARTNERSHIP.**—If an eligible entity is a hospital, such hospital shall enter into a partnership with a community-based organization to participate in the program.

(B) **INTERVENTION PROPOSAL.**—Subject to subparagraph (C), an application submitted under subparagraph (A)(i) shall include a detailed proposal for at least 1 care transition intervention, which may include the following:

(i) Initiating care transition services for a high-risk Medicare beneficiary not later than 24 hours prior to the discharge of the beneficiary from the eligible entity.

(ii) Arranging timely post-discharge follow-up services to the high-risk Medicare beneficiary to provide the beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with information regarding responding to symptoms that may indicate additional health problems or a deteriorating condition.

(iii) Providing the high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with assistance to ensure productive and timely interactions between patients and post-acute and outpatient providers.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—318

(iv) Assessing and actively engaging with a high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) through the provision of self-management support and relevant information that is specific to the beneficiary's condition.

(v) Conducting comprehensive medication review and management (including, if appropriate, counseling and self-management support).

(C) LIMITATION.—A care transition intervention proposed under subparagraph (B) may not include payment for services required under the discharge planning process described in section 1861(ee) of the Social Security Act (42 U.S.C. 1395x(ee)).

(3) SELECTION.—In selecting eligible entities to participate in the program, the Secretary shall give priority to eligible entities that—

(A) participate in a program administered by the Administration on Aging to provide concurrent care transitions interventions with multiple hospitals and practitioners; or

(B) provide services to medically underserved populations, small communities, and rural areas.

(d) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the provisions of this section by program instruction or otherwise.

(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act as may be necessary to carry out the program.

(f) FUNDING.—For purposes of carrying out this section, the Secretary of Health and Human Services shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines appropriate, of \$500,000,000, to the Centers for Medicare & Medicaid Services Program Management Account for the period of fiscal years 2011 through 2015. Amounts transferred under the preceding sentence shall remain available until expended.

SEC. 3027. EXTENSION OF GAINSHARING DEMONSTRATION.

(a) IN GENERAL.—Subsection (d)(3) of section 5007 of the Deficit Reduction Act of 2005 (Public Law 109–171) is amended by inserting “(or September 30, 2011, in the case of a demonstration project in operation as of October 1, 2008)” after “December 31, 2009”.

(b) FUNDING.—

(1) IN GENERAL.—Subsection (f)(1) of such section is amended by inserting “and for fiscal year 2010, \$1,600,000,” after “\$6,000,000.”

(2) AVAILABILITY.—Subsection (f)(2) of such section is amended by striking “2010” and inserting “2014 or until expended”.

(c) REPORTS.—

(1) QUALITY IMPROVEMENT AND SAVINGS.—Subsection (e)(3) of such section is amended by striking “December 1, 2008” and inserting “March 31, 2011”.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—327

is amended by inserting “or during the 1-year period beginning on July 1, 2010” before the period at the end.

SEC. 3123. EXTENSION OF THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) ONE-YEAR EXTENSION.—Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272) is amended by adding at the end the following new subsection:

“(g) FIVE-YEAR EXTENSION OF DEMONSTRATION PROGRAM.—
[Replaced by section 10313(a)]

“(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall conduct the demonstration program under this section for an additional 5-year period (in this section referred to as the ‘5-year extension period’) that begins on the date immediately following the last day of the initial 5-year period under subsection (a)(5).

“(2) EXPANSION OF DEMONSTRATION STATES.—Notwithstanding subsection (a)(2), during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary under such subsection to 20. In determining which States to include in such expansion, the Secretary shall use the same criteria and data that the Secretary used to determine the States under such subsection for purposes of the initial 5-year period.

“(3) INCREASE IN MAXIMUM NUMBER OF HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROGRAM.—Notwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section.

“(4) HOSPITALS IN DEMONSTRATION PROGRAM ON DATE OF ENACTMENT.—In the case of a rural community hospital that is participating in the demonstration program under this section as of the last day of the initial 5-year period, the Secretary—

“(A) shall provide for the continued participation of such rural community hospital in the demonstration program during the 5-year extension period unless the rural community hospital makes an election, in such form and manner as the Secretary may specify, to discontinue such participation; and

“(B) in calculating the amount of payment under subsection (b) to the rural community hospital for covered inpatient hospital services furnished by the hospital during such 5-year extension period, shall substitute, under paragraph (1)(A) of such subsection—

“(i) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period, for

“(ii) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program.”

(b) CONFORMING AMENDMENTS.—Subsection (a)(5) of section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272) is

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—328

amended by inserting “(in this section referred to as the ‘initial 5-year period’) and, as provided in subsection (g), for the 5-year extension period” after “5-year period”. **[As revised by section 10313(b)]**

(c) TECHNICAL AMENDMENTS.—

(1) Subsection (b) of section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272) is amended—

(A) in paragraph (1)(B)(ii), by striking “2)” and inserting “2))”; and

(B) in paragraph (2), by inserting “cost” before “reporting period” the first place such term appears in each of subparagraphs (A) and (B).

(2) Subsection (f)(1) of section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272) is amended—

(A) in subparagraph (A)(ii), by striking “paragraph (2)” and inserting “subparagraph (B)”; and

(B) in subparagraph (B), by striking “paragraph (1)(B)” and inserting “subparagraph (A)(ii)”.

SEC. 3124. EXTENSION OF THE MEDICARE-DEPENDENT HOSPITAL (MDH) PROGRAM.

(a) EXTENSION OF PAYMENT METHODOLOGY.—Section 1886(d)(5)(G) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—

(1) in clause (i), by striking “October 1, 2011” and inserting “October 1, 2012”; and

(2) in clause (ii)(II), by striking “October 1, 2011” and inserting “October 1, 2012”.

(b) CONFORMING AMENDMENTS.—

(1) EXTENSION OF TARGET AMOUNT.—Section 1886(b)(3)(D) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(D)) is amended—

(A) in the matter preceding clause (i), by striking “October 1, 2011” and inserting “October 1, 2012”; and

(B) in clause (iv), by striking “through fiscal year 2011” and inserting “through fiscal year 2012”.

(2) PERMITTING HOSPITALS TO DECLINE RECLASSIFICATION.—Section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1395ww note) is amended by striking “through fiscal year 2011” and inserting “through fiscal year 2012”.

SEC. 3125. TEMPORARY IMPROVEMENTS TO THE MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.

Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (A), by inserting “or (D)” after “subparagraph (B)”; and

(2) in subparagraph (B), in the matter preceding clause (i), by striking “The Secretary” and inserting “For discharges occurring in fiscal years 2005 through 2010 and for discharges occurring in fiscal year 2013 and subsequent fiscal years, the Secretary”;

(3) in subparagraph (C)(i)—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—329

(A) by inserting “(or, with respect to fiscal years 2011 and 2012, 15 road miles)” after “25 road miles”; and

(B) by inserting “(or, with respect to fiscal years 2011 and 2012, 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A)” after “800 discharges”; and **[As revised by section 10314(1)]**

(4) by adding at the end the following new subparagraph:

“(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 and 2012, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. **[As revised by section 10314(2)]**”.

SEC. 3126. IMPROVEMENTS TO THE DEMONSTRATION PROJECT ON COMMUNITY HEALTH INTEGRATION MODELS IN CERTAIN RURAL COUNTIES.

(a) REMOVAL OF LIMITATION ON NUMBER OF ELIGIBLE COUNTIES SELECTED.—Subsection (d)(3) of section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395i–4 note) is amended by striking “not more than 6”.

(b) REMOVAL OF REFERENCES TO RURAL HEALTH CLINIC SERVICES AND INCLUSION OF PHYSICIANS’ SERVICES IN SCOPE OF DEMONSTRATION PROJECT.—Such section 123 is amended—

(1) in subsection (d)(4)(B)(i)(3), by striking subclause (III); and

(2) in subsection (j)—

(A) in paragraph (8), by striking subparagraph (B) and inserting the following:

“(B) Physicians’ services (as defined in section 1861(q) of the Social Security Act (42 U.S.C. 1395x(q)).”;

(B) by striking paragraph (9); and

(C) by redesignating paragraph (10) as paragraph (9).

SEC. 3127. MEDPAC STUDY ON ADEQUACY OF MEDICARE PAYMENTS FOR HEALTH CARE PROVIDERS SERVING IN RURAL AREAS.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the adequacy of payments for items and services furnished by providers of services and suppliers in rural areas under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.). Such study shall include an analysis of—

(1) any adjustments in payments to providers of services and suppliers that furnish items and services in rural areas;

(2) access by Medicare beneficiaries to items and services in rural areas;

(3) the adequacy of payments to providers of services and suppliers that furnish items and services in rural areas; and

(4) the quality of care furnished in rural areas.

(b) REPORT.—Not later than January 1, 2011, the Medicare Payment Advisory Commission shall submit to Congress a report containing the results of the study conducted under subsection

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—345

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to payments for biosimilar biological products beginning with the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary).

SEC. 3140. MEDICARE HOSPICE CONCURRENT CARE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall establish a Medicare Hospice Concurrent Care demonstration program at participating hospice programs under which Medicare beneficiaries are furnished, during the same period, hospice care and any other items or services covered under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) from funds otherwise paid under such title to such hospice programs.

(2) DURATION.—The demonstration program under this section shall be conducted for a 3-year period.

(3) SITES.—The Secretary shall select not more than 15 hospice programs at which the demonstration program under this section shall be conducted. Such hospice programs shall be located in urban and rural areas.

(b) INDEPENDENT EVALUATION AND REPORTS.—

(1) INDEPENDENT EVALUATION.—The Secretary shall provide for the conduct of an independent evaluation of the demonstration program under this section. Such independent evaluation shall determine whether the demonstration program has improved patient care, quality of life, and cost-effectiveness for Medicare beneficiaries participating in the demonstration program.

(2) REPORTS.—The Secretary shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with such recommendations as the Secretary determines appropriate.

(c) BUDGET NEUTRALITY.—With respect to the 3-year period of the demonstration program under this section, the Secretary shall ensure that the aggregate expenditures under title XVIII for such period shall not exceed the aggregate expenditures that would have been expended under such title if the demonstration program under this section had not been implemented.

SEC. 3141. APPLICATION OF BUDGET NEUTRALITY ON A NATIONAL BASIS IN THE CALCULATION OF THE MEDICARE HOSPITAL WAGE INDEX FLOOR.

In the case of discharges occurring on or after October 1, 2010, for purposes of applying section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note) and paragraph (h)(4) of section 412.64 of title 42, Code of Federal Regulations, the Secretary of Health and Human Services shall administer subsection (b) of such section 4410 and paragraph (e) of such section 412.64 in the same manner as the Secretary administered such subsection (b) and paragraph (e) for discharges occurring during fiscal year 2008 (through a uniform, national adjustment to the area wage index).

SEC. 3142. HHS STUDY ON URBAN MEDICARE-DEPENDENT HOSPITALS.

(a) STUDY.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—413

may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

“(e) EVALUATION.—

“(1) IN GENERAL.—The Director shall evaluate the performance of each entity that receives a grant or contract under this section. The evaluation of an entity shall include a study of—

“(A) the success of such entity in achieving the implementation, by the health care institutions and providers assisted by such entity, of the models and practices identified in the research conducted by the Center under section 933;

“(B) the perception of the health care institutions and providers assisted by such entity regarding the value of the entity; and

“(C) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity.

“(2) EFFECT OF EVALUATION.—Based on the outcome of the evaluation of the entity under paragraph (1), the Director shall determine whether to renew a grant or contract with such entity under this section.

“(f) COORDINATION.—The entities that receive a grant or contract under this section shall coordinate with health information technology regional extension centers under section 3012(c) and the primary care extension program established under section 399V–1 regarding the dissemination of quality improvement, system delivery reform, and best practices information. *[As revised by section 10501(f)(2)]*”.

SEC. 3502. ESTABLISHING COMMUNITY HEALTH TEAMS TO SUPPORT THE PATIENT-CENTERED MEDICAL HOME.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (referred to in this section as “health teams”) to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants or contracts shall be used to—

(1) establish health teams to provide support services to primary care providers; and

(2) provide capitated payments to primary care providers as determined by the Secretary.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1)(A) be a State or State-designated entity; or

(B) be an Indian tribe or tribal organization, as defined in section 4 of the Indian Health Care Improvement Act;

(2) submit a plan for achieving long-term financial sustainability within 3 years;

(3) submit a plan for incorporating prevention initiatives and patient education and care management resources into the delivery of health care that is integrated with community-based prevention and treatment resources, where available;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—414

(4) ensure that the health team established by the entity includes an interdisciplinary, interprofessional team of health care providers, as determined by the Secretary; such team may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers (including substance use disorder prevention and treatment providers), doctors of chiropractic, licensed complementary and alternative medicine practitioners, and physicians' assistants;

(5) agree to provide services to eligible individuals with chronic conditions, as described in section 1945 of the Social Security Act (as added by section 2703), in accordance with the payment methodology established under subsection (c) of such section; and

(6) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) REQUIREMENTS FOR HEALTH TEAMS.—A health team established pursuant to a grant or contract under subsection (a) shall—

(1) establish contractual agreements with primary care providers to provide support services;

(2) support patient-centered medical homes, defined as a mode of care that includes—

(A) personal physicians or other primary care providers; **[As revised by section 10321]**

(B) whole person orientation;

(C) coordinated and integrated care;

(D) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements;

(E) expanded access to care; and

(F) payment that recognizes added value from additional components of patient-centered care;

(3) collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(4) in collaboration with local health care providers, develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(5) incorporate health care providers, patients, caregivers, and authorized representatives in program design and oversight;

(6) provide support necessary for local primary care providers to—

(A) coordinate and provide access to high-quality health care services;

(B) coordinate and provide access to preventive and health promotion services;

(C) provide access to appropriate specialty care and inpatient services;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—415

(D) provide quality-driven, cost-effective, culturally appropriate, and patient- and family-centered health care;

(E) provide access to pharmacist-delivered medication management services, including medication reconciliation;

(F) provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services;

(G) promote effective strategies for treatment planning, monitoring health outcomes and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) 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

(J) 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 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator, assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals, nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 3000 of the Public Health Service Act (42 U.S.C. 300jj)) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 399JJ of the Public Health Service Act.

(d) REQUIREMENT FOR PRIMARY CARE PROVIDERS.—A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—416

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

(e) REPORTING TO SECRETARY.—An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out by the entity under subsection (c).

(f) DEFINITION OF PRIMARY CARE.—In this section, the term “primary care” means the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

SEC. 3503. MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASE.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3501, is further amended by inserting after section 934 the following:

“SEC. 935. GRANTS OR CONTRACTS TO IMPLEMENT MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASES.

“(a) IN GENERAL.—The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the ‘Center’), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as ‘MTM’) services provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

“(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant or contract under subsection (a), an entity shall—

“(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

“(2) submit to the Secretary a plan for achieving long-term financial sustainability;

“(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 3502 of the Patient Protection and Affordable Care Act or in collaboration with primary care extension programs established in section 399V–1; *【As revised by section 10501(f)(3)】*

“(4) submit a plan for meeting the requirements under subsection (c); and

“(5) submit to the Secretary such other information as the Secretary may require.

“(c) MTM SERVICES TO TARGETED INDIVIDUALS.—The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

“(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—417

“(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

“(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

“(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

“(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

“(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

“(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

“(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

“(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

“(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

“(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

“(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

“(2) take any ‘high risk’ medications;

“(3) have 2 or more chronic diseases, as identified by the Secretary; or

“(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

“(e) CONSULTATION WITH EXPERTS.—In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—418

“(f) REPORTING TO THE SECRETARY.—An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.

“(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

“(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

“(2) assess changes in overall health care resource use by targeted individuals;

“(3) assess patient and prescriber satisfaction with MTM services;

“(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

“(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

“(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

“(h) GRANTS OR CONTRACTS TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.”

SEC. 3504. DESIGN AND IMPLEMENTATION OF REGIONALIZED SYSTEMS FOR EMERGENCY CARE.

(a) IN GENERAL.—Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.) is amended—

(1) in section 1203—

(A) in the section heading, by inserting “**FOR TRAUMA SYSTEMS**” after “**GRANTS**”; and

(B) in subsection (a), by striking “Administrator of the Health Resources and Services Administration” and inserting “Assistant Secretary for Preparedness and Response”;

(2) by inserting after section 1203 the following:

“SEC. 1204. COMPETITIVE GRANTS FOR REGIONALIZED SYSTEMS FOR EMERGENCY CARE RESPONSE.

“(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—427

“(6) Making capital improvements to enhance access and expedite trauma care, including providing helipads and associated safety infrastructure.

“(7) Enhancing trauma surge capacity at specific trauma centers.

“(8) Ensuring expedient receipt of trauma patients transported by ground or air to the appropriate trauma center.

“(9) Enhancing interstate trauma center collaboration.

“(e) LIMITATION.—

“(1) IN GENERAL.—A State may use not more than 20 percent of the amount available to the State under this part for a fiscal year for administrative costs associated with awarding grants and related costs.

“(2) MAINTENANCE OF EFFORT.—The Secretary may not provide funding to a State under this part unless the State agrees that such funds will be used to supplement and not supplant State funding otherwise available for the activities and costs described in this part.

“(f) DISTRIBUTION OF FUNDS.—The following shall apply with respect to grants provided in this part:

“(1) LESS THAN \$10,000,000.—If the amount of appropriations for this part in a fiscal year is less than \$10,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3)(A).

“(2) LESS THAN \$20,000,000.—If the amount of appropriations in a fiscal year is less than \$20,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under subparagraphs (A) and (B) of section 1241(b)(3).

“(3) LESS THAN \$30,000,000.—If the amount of appropriations for this part in a fiscal year is less than \$30,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3).

“(4) \$30,000,000 OR MORE.—If the amount of appropriations for this part in a fiscal year is \$30,000,000 or more, the Secretary shall divide such funding evenly among all States.

“SEC. 1282. AUTHORIZATION OF APPROPRIATIONS.

“For the purpose of carrying out this part, there is authorized to be appropriated \$100,000,000 for each of fiscal years 2010 through 2015.”.

SEC. 3506. PROGRAM TO FACILITATE SHARED DECISIONMAKING.

Part D of title IX of the Public Health Service Act, as amended by section 3503, is further amended by adding at the end the following:

“SEC. 936. PROGRAM TO FACILITATE SHARED DECISIONMAKING.

“(a) PURPOSE.—The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decisionmaking, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

“(b) DEFINITIONS.—In this section:

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—428

“(1) PATIENT DECISION AID.—The term ‘patient decision aid’ means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

“(2) PREFERENCE SENSITIVE CARE.—The term ‘preference sensitive care’ means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

“(c) ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS FOR PREFERENCE SENSITIVE CARE.—

“(1) CONTRACT WITH ENTITY TO ESTABLISH STANDARDS AND CERTIFY PATIENT DECISION AIDS.—

“(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the entity with a contract under section 1890 of the Social Security Act. Such contract shall provide that the entity perform the duties described in paragraph (2).

“(B) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contract under subparagraph (A).

“(C) PERIOD OF CONTRACT.—A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

“(2) DUTIES.—The following duties are described in this paragraph:

“(A) DEVELOP AND IDENTIFY STANDARDS FOR PATIENT DECISION AIDS.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

“(B) ENDORSE PATIENT DECISION AIDS.—The entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference sensitive care.

“(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS.—

“(1) IN GENERAL.—The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—429

of Health, shall establish a program to award grants or contracts—

“(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

“(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make informed decisions about patient care and can be easily incorporated into a broad array of practice settings; and

“(C) to educate providers on the use of such materials, including through academic curricula.

“(2) REQUIREMENTS FOR PATIENT DECISION AIDS.—Patient decision aids developed and produced pursuant to a grant or contract under paragraph (1)—

“(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decisionmaking with health care providers;

“(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

“(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

“(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

“(3) DISTRIBUTION.—The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

“(4) NONDUPLICATION OF EFFORTS.—The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

“(e) GRANTS TO SUPPORT SHARED DECISIONMAKING IMPLEMENTATION.—

“(1) IN GENERAL.—The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

“(2) SHARED DECISIONMAKING RESOURCE CENTERS.—

“(A) IN GENERAL.—The Secretary shall provide grants for the establishment and support of Shared Decision-making Resource Centers (referred to in this subsection as ‘Centers’) to provide technical assistance to providers and to develop and disseminate best practices and other

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—430

information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers.

“(B) OBJECTIVES.—The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decisionmaking through—

“(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

“(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

“(3) SHARED DECISIONMAKING PARTICIPATION GRANTS.—

“(A) IN GENERAL.—The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques and to assess the use of such techniques.

“(B) PREFERENCE.—In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care providers who participate in training by Shared Decisionmaking Resource Centers or comparable training.

“(C) LIMITATION.—Funds under this paragraph shall not be used to purchase or implement use of patient decision aids other than those certified under the process identified in subsection (c).

“(4) GUIDANCE.—The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

“(f) FUNDING.—For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.”.

SEC. 3507. PRESENTATION OF PRESCRIPTION DRUG BENEFIT AND RISK INFORMATION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

(b) REVIEW AND CONSULTATION.—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women’s and pediatric health.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides—

(1) the determination by the Secretary under subsection (a); and

(2) the reasoning and analysis underlying that determination.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—581

SEC. 5603. REAUTHORIZATION OF THE WAKEFIELD EMERGENCY MEDICAL SERVICES FOR CHILDREN PROGRAM.

Section 1910 of the Public Health Service Act (42 U.S.C. 300w-9) is amended—

(1) in subsection (a), by striking “3-year period (with an optional 4th year” and inserting “4-year period (with an optional 5th year”;

(2) in subsection (d)—

(A) by striking “and such sums” and inserting “such sums”; and

(B) by inserting before the period the following: “, \$25,000,000 for fiscal year 2010, \$26,250,000 for fiscal year 2011, \$27,562,500 for fiscal year 2012, \$28,940,625 for fiscal year 2013, and \$30,387,656 for fiscal year 2014”.

SEC. 5604. CO-LOCATING PRIMARY AND SPECIALTY CARE IN COMMUNITY-BASED MENTAL HEALTH SETTINGS.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by adding at the end the following:

“SEC. 520K. AWARDS FOR CO-LOCATING PRIMARY AND SPECIALTY CARE IN COMMUNITY-BASED MENTAL HEALTH SETTINGS.

“(a) DEFINITIONS.—In this section:

“(1) ELIGIBLE ENTITY.—The term ‘eligible entity’ means a qualified community mental health program defined under section 1913(b)(1).

“(2) SPECIAL POPULATIONS.—The term ‘special populations’ means adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

“(b) PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator shall award grants and cooperative agreements to eligible entities to establish demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

“(c) APPLICATION.—To be eligible to receive a grant or cooperative agreement under this section, an eligible entity shall submit an application to the Administrator at such time, in such manner, and accompanied by such information as the Administrator may require, including a description of partnerships, or other arrangements with local primary care providers, including community health centers, to provide services to special populations.

“(d) USE OF FUNDS.—

“(1) IN GENERAL.—For the benefit of special populations, an eligible entity shall use funds awarded under this section for—

“(A) the provision, by qualified primary care professionals, of on site primary care services;

“(B) reasonable costs associated with medically necessary referrals to qualified specialty care professionals, other coordinators of care or, if permitted by the terms of the grant or cooperative agreement, by qualified specialty care professionals on a reasonable cost basis on site at the eligible entity;

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—582

“(C) information technology required to accommodate the clinical needs of primary and specialty care professionals; or

“(D) facility modifications needed to bring primary and specialty care professionals on site at the eligible entity.

“(2) LIMITATION.—Not to exceed 15 percent of grant or cooperative agreement funds may be used for activities described in subparagraphs (C) and (D) of paragraph (1).

“(e) EVALUATION.—Not later than 90 days after a grant or cooperative agreement awarded under this section expires, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

“(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$50,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2014.”.

SEC. 5605. KEY NATIONAL INDICATORS.

(a) DEFINITIONS.—In this section:

(1) ACADEMY.—The term “Academy” means the National Academy of Sciences.

(2) COMMISSION.—The term “Commission” means the Commission on Key National Indicators established under subsection (b).

(3) INSTITUTE.—The term “Institute” means a Key National Indicators Institute as designated under subsection (c)(3).

(b) COMMISSION ON KEY NATIONAL INDICATORS.—

(1) ESTABLISHMENT.—There is established a “Commission on Key National Indicators”.

(2) MEMBERSHIP.—

(A) NUMBER AND APPOINTMENT.—The Commission shall be composed of 8 members, to be appointed equally by the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives.

(B) PROHIBITED APPOINTMENTS.—Members of the Commission shall not include Members of Congress or other elected Federal, State, or local government officials.

(C) QUALIFICATIONS.—In making appointments under subparagraph (A), the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives shall appoint individuals who have shown a dedication to improving civic dialogue and decision-making through the wide use of scientific evidence and factual information.

(D) PERIOD OF APPOINTMENT.—Each member of the Commission shall be appointed for a 2-year term, except that 1 initial appointment shall be for 3 years. Any vacancies shall not affect the power and duties of the Commission but shall be filled in the same manner as the original appointment and shall last only for the remainder of that term.

(E) DATE.—Members of the Commission shall be appointed by not later than 30 days after the date of enactment of this Act.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—622

transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

“(2) RELOCATION.—

“(A) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

“(B) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under paragraph (1) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.

“(3) SANCTIONS.—Any individual who is the administrator of a facility that fails to comply with the requirements of paragraph (1)—

“(A) shall be subject to a civil monetary penalty of up to \$100,000;

“(B) may be subject to exclusion from participation in any Federal health care program (as defined in section 1128B(f)); and

“(C) shall be subject to any other penalties that may be prescribed by law.

“(4) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty or exclusion under paragraph (3) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).”

(b) CONFORMING AMENDMENTS.—Section 1819(h)(4) of the Social Security Act (42 U.S.C. 1395i–3(h)(4)) is amended—

(1) in the first sentence, by striking “the Secretary shall terminate” and inserting “the Secretary, subject to section 1128I(h), shall terminate”; and

(2) in the second sentence, by striking “subsection (c)(2)” and inserting “subsection (c)(2) and section 1128I(h)”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 6114. NATIONAL DEMONSTRATION PROJECTS ON CULTURE CHANGE AND USE OF INFORMATION TECHNOLOGY IN NURSING HOMES.

(a) IN GENERAL.—The Secretary shall conduct 2 demonstration projects, 1 for the development of best practices in skilled nursing facilities and nursing facilities that are involved in the culture change movement (including the development of resources for facilities to find and access funding in order to undertake culture change) and 1 for the development of best practices in skilled nursing facilities and nursing facilities for the use of information technology to improve resident care.

(b) CONDUCT OF DEMONSTRATION PROJECTS.—

(1) GRANT AWARD.—Under each demonstration project conducted under this section, the Secretary shall award 1 or more

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—623

grants to facility-based settings for the development of best practices described in subsection (a) with respect to the demonstration project involved. Such award shall be made on a competitive basis and may be allocated in 1 lump-sum payment.

(2) CONSIDERATION OF SPECIAL NEEDS OF RESIDENTS.—Each demonstration project conducted under this section shall take into consideration the special needs of residents of skilled nursing facilities and nursing facilities who have cognitive impairment, including dementia.

(c) DURATION AND IMPLEMENTATION.—

(1) DURATION.—The demonstration projects shall each be conducted for a period not to exceed 3 years.

(2) IMPLEMENTATION.—The demonstration projects shall each be implemented not later than 1 year after the date of the enactment of this Act.

(d) DEFINITIONS.—In this section:

(1) NURSING FACILITY.—The term “nursing facility” has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(2) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(3) SKILLED NURSING FACILITY.—The term “skilled nursing facility” has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a)).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(f) REPORT.—Not later than 9 months after the completion of the demonstration project, the Secretary shall submit to Congress a report on such project, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

PART 3—IMPROVING STAFF TRAINING

SEC. 6121. DEMENTIA AND ABUSE PREVENTION TRAINING.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(A)(i)(I)) is amended by inserting “(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training, and patient abuse prevention training” before “, (II)”.

(2) CLARIFICATION OF DEFINITION OF NURSE AIDE.—Section 1819(b)(5)(F) of the Social Security Act (42 U.S.C. 1395i–3(b)(5)(F)) is amended by adding at the end the following flush sentence:

“Such term includes an individual who provides such services through an agency or under a contract with the facility.”

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1396r(f)(2)(A)(i)(I)) is amended by inserting “(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training, and patient abuse prevention training” before “, (II)”.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—707

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary for the purpose of carrying out this subsection.

(d) CONFORMING AMENDMENTS.—

(1) TITLE XX.—Title XX of the Social Security Act (42 U.S.C. 1397 et seq.), as amended by section 6703(a), is amended—

(A) in the heading of section 2001, by striking “TITLE” and inserting “SUBTITLE”; and

(B) in subtitle 1, by striking “this title” each place it appears and inserting “this subtitle”.

(2) TITLE IV.—Title IV of the Social Security Act (42 U.S.C. 601 et seq.) is amended—

(A) in section 404(d)—

(i) in paragraphs (1)(A), (2)(A), and (3)(B), by inserting “subtitle 1 of” before “title XX” each place it appears;

(ii) in the heading of paragraph (2), by inserting “SUBTITLE 1 OF” before “TITLE XX”; and

(iii) in the heading of paragraph (3)(B), by inserting “SUBTITLE 1 OF” before “TITLE XX”; and

(B) in sections 422(b), 471(a)(4), 472(h)(1), and 473(b)(2), by inserting “subtitle 1 of” before “title XX” each place it appears.

(3) TITLE XI.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended—

(A) in section 1128(h)(3)—

(i) by inserting “subtitle 1 of” before “title XX”; and

(ii) by striking “such title” and inserting “such subtitle”; and

(B) in section 1128A(i)(1), by inserting “subtitle 1 of” before “title XX”.

Subtitle I—Sense of the Senate Regarding Medical Malpractice

SEC. 6801. SENSE OF THE SENATE REGARDING MEDICAL MALPRACTICE.

It is the sense of the Senate that—

(1) health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance;

(2) States should be encouraged to develop and test alternatives to the existing civil litigation system as a way of improving patient safety, reducing medical errors, encouraging the efficient resolution of disputes, increasing the availability of prompt and fair resolution of disputes, and improving access to liability insurance, while preserving an individual’s right to seek redress in court; and

(3) Congress should consider establishing a State demonstration program to evaluate alternatives to the existing civil litigation system with respect to the resolution of medical malpractice claims.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—818

“(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a psychiatric hospital and a psychiatric unit has the opportunity to review the data that is to be made public with respect to the hospital or unit prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in psychiatric hospitals and psychiatric units on the Internet website of the Centers for Medicare & Medicaid Services.”.

(b) *[Amended section 1890(b)(7)(B)(i)(I) of the Social Security Act, as added by section 3014]*

SEC. 10323. MEDICARE COVERAGE FOR INDIVIDUALS EXPOSED TO ENVIRONMENTAL HEALTH HAZARDS.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1881 the following new section:

“SEC. 1881A. MEDICARE COVERAGE FOR INDIVIDUALS EXPOSED TO ENVIRONMENTAL HEALTH HAZARDS.

“(a) DEEMING OF INDIVIDUALS AS ELIGIBLE FOR MEDICARE BENEFITS.—

“(1) IN GENERAL.—For purposes of eligibility for benefits under this title, an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(2) shall be deemed to meet the conditions specified in section 226(a).

“(2) DISCRETIONARY DEEMING.—For purposes of eligibility for benefits under this title, the Secretary may deem an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(3) to meet the conditions specified in section 226(a).

“(3) EFFECTIVE DATE OF COVERAGE.—An Individual who is deemed eligible for benefits under this title under paragraph (1) or (2) shall be—

“(A) entitled to benefits under the program under Part A as of the date of such deeming; and

“(B) eligible to enroll in the program under Part B beginning with the month in which such deeming occurs.

“(b) PILOT PROGRAM FOR CARE OF CERTAIN INDIVIDUALS RESIDING IN EMERGENCY DECLARATION AREAS.—

“(1) PROGRAM; PURPOSE.—

“(A) PRIMARY PILOT PROGRAM.—The Secretary shall establish a pilot program in accordance with this subsection to provide innovative approaches to furnishing comprehensive, coordinated, and cost-effective care under this title to individuals described in paragraph (2)(A).

“(B) OPTIONAL PILOT PROGRAMS.—The Secretary may establish a separate pilot program, in accordance with this subsection, with respect to each geographic area subject to an emergency declaration (other than the declaration of June 17, 2009), in order to furnish such comprehensive, coordinated and cost-effective care to individuals described in subparagraph (2)(B) who reside in each such area.

“(2) INDIVIDUAL DESCRIBED.—For purposes of paragraph (1), an individual described in this paragraph is an individual

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—819

who enrolls in part B, submits to the Secretary an application to participate in the applicable pilot program under this subsection, and—

“(A) is an environmental exposure affected individual described in subsection (e)(2) who resides in or around the geographic area subject to an emergency declaration made as of June 17, 2009; or

“(B) is an environmental exposure affected individual described in subsection (e)(3) who—

“(i) is deemed under subsection (a)(2); and

“(ii) meets such other criteria or conditions for participation in a pilot program under paragraph (1)(B) as the Secretary specifies.

“(3) FLEXIBLE BENEFITS AND SERVICES.—A pilot program under this subsection may provide for the furnishing of benefits, items, or services not otherwise covered or authorized under this title, if the Secretary determines that furnishing such benefits, items, or services will further the purposes of such pilot program (as described in paragraph (1)).

“(4) INNOVATIVE REIMBURSEMENT METHODOLOGIES.—For purposes of the pilot program under this subsection, the Secretary—

“(A) shall develop and implement appropriate methodologies to reimburse providers for furnishing benefits, items, or services for which payment is not otherwise covered or authorized under this title, if such benefits, items, or services are furnished pursuant to paragraph (3); and

“(B) may develop and implement innovative approaches to reimbursing providers for any benefits, items, or services furnished under this subsection.

“(5) LIMITATION.—Consistent with section 1862(b), no payment shall be made under the pilot program under this subsection with respect to benefits, items, or services furnished to an environmental exposure affected individual (as defined in subsection (e)) to the extent that such individual is eligible to receive such benefits, items, or services through any other public or private benefits plan or legal agreement.

“(6) WAIVER AUTHORITY.—The Secretary may waive such provisions of this title and title XI as are necessary to carry out pilot programs under this subsection.

“(7) FUNDING.—For purposes of carrying out pilot programs under this subsection, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in such proportion as the Secretary determines appropriate, of such sums as the Secretary determines necessary, to the Centers for Medicare & Medicaid Services Program Management Account.

“(8) WAIVER OF BUDGET NEUTRALITY.—The Secretary shall not require that pilot programs under this subsection be budget neutral with respect to expenditures under this title.

“(c) DETERMINATIONS.—

“(1) BY THE COMMISSIONER OF SOCIAL SECURITY.—For purposes of this section, the Commissioner of Social Security, in consultation with the Secretary, and using the cost allocation method prescribed in section 201(g), shall determine whether individuals are environmental exposure affected individuals.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—820

“(2) BY THE SECRETARY.—The Secretary shall determine eligibility for pilot programs under subsection (b).

“(d) EMERGENCY DECLARATION DEFINED.—For purposes of this section, the term ‘emergency declaration’ means a declaration of a public health emergency under section 104(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.

“(e) ENVIRONMENTAL EXPOSURE AFFECTED INDIVIDUAL DEFINED.—

“(1) IN GENERAL.—For purposes of this section, the term ‘environmental exposure affected individual’ means—

“(A) an individual described in paragraph (2); and

“(B) an individual described in paragraph (3).

“(2) INDIVIDUAL DESCRIBED.—

“(A) IN GENERAL.—An individual described in this paragraph is any individual who—

“(i) is diagnosed with 1 or more conditions described in subparagraph (B);

“(ii) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to an emergency declaration specified in subsection (b)(2)(A), during a period ending—

“(I) not less than 10 years prior to such diagnosis; and

“(II) prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7;

“(iii) files an application for benefits under this title (or has an application filed on behalf of the individual), including pursuant to this section; and

“(iv) is determined under this section to meet the criteria in this subparagraph.

“(B) CONDITIONS DESCRIBED.—For purposes of subparagraph (A), the following conditions are described in this subparagraph:

“(i) Asbestosis, pleural thickening, or pleural plaques as established by—

“(I) interpretation by a ‘B Reader’ qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or

“(II) such other diagnostic standards as the Secretary specifies,

except that this clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses.

“(ii) Mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by—

“(I) pathologic examination of biopsy tissue;

“(II) cytology from bronchioalveolar lavage; or

“(III) such other diagnostic standards as the Secretary specifies.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—821

“(iii) Any other diagnosis which the Secretary, in consultation with the Commissioner of Social Security, determines is an asbestos-related medical condition, as established by such diagnostic standards as the Secretary specifies.

“(3) OTHER INDIVIDUAL DESCRIBED.—An individual described in this paragraph is any individual who—

“(A) is not an individual described in paragraph (2);

“(B) is diagnosed with a medical condition caused by the exposure of the individual to a public health hazard to which an emergency declaration applies, based on such medical conditions, diagnostic standards, and other criteria as the Secretary specifies;

“(C) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to the emergency declaration involved, during a period determined appropriate by the Secretary;

“(D) files an application for benefits under this title (or has an application filed on behalf of the individual), including pursuant to this section; and

“(E) is determined under this section to meet the criteria in this paragraph.”.

(b) PROGRAM FOR EARLY DETECTION OF CERTAIN MEDICAL CONDITIONS RELATED TO ENVIRONMENTAL HEALTH HAZARDS.—Title XX of the Social Security Act (42 U.S.C. 1397 et seq.), as amended by section 5507, is amended by adding at the end the following:

“SEC. 2009. PROGRAM FOR EARLY DETECTION OF CERTAIN MEDICAL CONDITIONS RELATED TO ENVIRONMENTAL HEALTH HAZARDS.

“(a) PROGRAM ESTABLISHMENT.—The Secretary shall establish a program in accordance with this section to make competitive grants to eligible entities specified in subsection (b) for the purpose of—

“(1) screening at-risk individuals (as defined in subsection (c)(1)) for environmental health conditions (as defined in subsection (c)(3)); and

“(2) developing and disseminating public information and education concerning—

“(A) the availability of screening under the program under this section;

“(B) the detection, prevention, and treatment of environmental health conditions; and

“(C) the availability of Medicare benefits for certain individuals diagnosed with environmental health conditions under section 1881A.

“(b) ELIGIBLE ENTITIES.—

“(1) IN GENERAL.—For purposes of this section, an eligible entity is an entity described in paragraph (2) which submits an application to the Secretary in such form and manner, and containing such information and assurances, as the Secretary determines appropriate.

“(2) TYPES OF ELIGIBLE ENTITIES.—The entities described in this paragraph are the following:

“(A) A hospital or community health center.

“(B) A Federally qualified health center.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—822

“(C) A facility of the Indian Health Service.

“(D) A National Cancer Institute-designated cancer center.

“(E) An agency of any State or local government.

“(F) A nonprofit organization.

“(G) Any other entity the Secretary determines appropriate.

“(c) DEFINITIONS.—In this section:

“(1) AT-RISK INDIVIDUAL.—The term ‘at-risk individual’ means an individual who—

“(A)(i) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to an emergency declaration specified under paragraph (2), during a period ending—

“(I) not less than 10 years prior to the date of such individual’s application under subparagraph (B); and

“(II) prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7; or

“(ii) meets such other criteria as the Secretary determines appropriate considering the type of environmental health condition at issue; and

“(B) has submitted an application (or has an application submitted on the individual’s behalf), to an eligible entity receiving a grant under this section, for screening under the program under this section.

“(2) EMERGENCY DECLARATION.—The term ‘emergency declaration’ means a declaration of a public health emergency under section 104(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.

“(3) ENVIRONMENTAL HEALTH CONDITION.—The term ‘environmental health condition’ means—

“(A) asbestosis, pleural thickening, or pleural plaques, as established by—

“(i) interpretation by a ‘B Reader’ qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or

“(ii) such other diagnostic standards as the Secretary specifies;

“(B) mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by—

“(i) pathologic examination of biopsy tissue;

“(ii) cytology from bronchioalveolar lavage; or

“(iii) such other diagnostic standards as the Secretary specifies; and

“(C) any other medical condition which the Secretary determines is caused by exposure to a hazardous substance or pollutant or contaminant at a Superfund site to which an emergency declaration applies, based on such criteria and as established by such diagnostic standards as the Secretary specifies.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—823

“(4) HAZARDOUS SUBSTANCE; POLLUTANT; CONTAMINANT.—The terms ‘hazardous substance’, ‘pollutant’, and ‘contaminant’ have the meanings given those terms in section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601).

“(5) SUPERFUND SITE.—The term ‘Superfund site’ means a site included on the National Priorities List developed by the President in accordance with section 105(a)(8)(B) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9605(a)(8)(B)).

“(d) HEALTH COVERAGE UNAFFECTED.—Nothing in this section shall be construed to affect any coverage obligation of a governmental or private health plan or program relating to an at-risk individual.

“(e) FUNDING.—

“(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary, to carry out the program under this section—

“(A) \$23,000,000 for the period of fiscal years 2010 through 2014; and

“(B) \$20,000,000 for each 5-fiscal year period thereafter.

“(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available until expended.

“(f) NONAPPLICATION.—

“(1) IN GENERAL.—Except as provided in paragraph (2), the preceding sections of this title shall not apply to grants awarded under this section.

“(2) LIMITATIONS ON USE OF GRANTS.—Section 2005(a) shall apply to a grant awarded under this section to the same extent and in the same manner as such section applies to payments to States under this title, except that paragraph (4) of such section shall not be construed to prohibit grantees from conducting screening for environmental health conditions as authorized under this section.”.

SEC. 10324. PROTECTIONS FOR FRONTIER STATES.

(a) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

(1) IN GENERAL.—Section 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(A) in clause (i), by striking “clause (ii)” and inserting “clause (ii) or (iii)”; and

(B) by adding at the end the following new clause:

“(iii) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

“(I) IN GENERAL.—Subject to subclause (IV), for discharges occurring on or after October 1, 2010, the area wage index applicable under this subparagraph to any hospital which is located in a frontier State (as defined in subclause (II)) may not be less than 1.00.

“(II) FRONTIER STATE DEFINED.—In this clause, the term ‘frontier State’ means a State in which at least 50 percent of the counties in the State are frontier counties.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—828

(1) IN GENERAL.—Section 1858 of the Social Security Act (42 U.S.C. 1395w–27a) is amended by striking subsection (e).

(2) TRANSITION.—Any amount contained in the MA Regional Plan Stabilization Fund as of the date of the enactment of this Act shall be transferred to the Federal Supplementary Medical Insurance Trust Fund.

SEC. 10328. IMPROVEMENT IN PART D MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS.

(a) IN GENERAL.—Section 1860D–4(c)(2) of the Social Security Act (42 U.S.C. 1395w–104(c)(2)) is amended—

(1) by redesignating subparagraphs (C), (D), and (E) as subparagraphs (E), (F), and (G), respectively; and

(2) by inserting after subparagraph (B) the following new subparagraphs:

“(C) REQUIRED INTERVENTIONS.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Patient Protection and Affordable Care Act, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

“(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

“(I) shall include a review of the individual’s medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

“(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

“(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

“(D) ASSESSMENT.—The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

“(E) AUTOMATIC ENROLLMENT WITH ABILITY TO OPT-OUT.—The prescription drug plan sponsor shall have in place a process to—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—829

“(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

“(ii) permit such beneficiaries to opt-out of enrollment in such program.”.

(b) **RULE OF CONSTRUCTION.**—Nothing in this section shall limit the authority of the Secretary of Health and Human Services to modify or broaden requirements for a medication therapy management program under part D of title XVIII of the Social Security Act or to study new models for medication therapy management through the Center for Medicare and Medicaid Innovation under section 1115A of such Act, as added by section 3021.

SEC. 10329. DEVELOPING METHODOLOGY TO ASSESS HEALTH PLAN VALUE.

(a) **DEVELOPMENT.**—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), in consultation with relevant stakeholders including health insurance issuers, health care consumers, employers, health care providers, and other entities determined appropriate by the Secretary, shall develop a methodology to measure health plan value. Such methodology shall take into consideration, where applicable—

- (1) the overall cost to enrollees under the plan;
- (2) the quality of the care provided for under the plan;
- (3) the efficiency of the plan in providing care;
- (4) the relative risk of the plan’s enrollees as compared to other plans;
- (5) the actuarial value or other comparative measure of the benefits covered under the plan; and
- (6) other factors determined relevant by the Secretary.

(b) **REPORT.**—Not later than 18 months after the date of enactment of this Act, the Secretary shall submit to Congress a report concerning the methodology developed under subsection (a).

SEC. 10330. MODERNIZING COMPUTER AND DATA SYSTEMS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES TO SUPPORT IMPROVEMENTS IN CARE DELIVERY.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall develop a plan (and detailed budget for the resources needed to implement such plan) to modernize the computer and data systems of the Centers for Medicare & Medicaid Services (in this section referred to as “CMS”).

(b) **CONSIDERATIONS.**—In developing the plan, the Secretary shall consider how such modernized computer system could—

- (1) in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, make available data in a reliable and timely manner to providers of services and suppliers to support their efforts to better manage and coordinate care furnished to beneficiaries of CMS programs; and
- (2) support consistent evaluations of payment and delivery system reforms under CMS programs.

(c) **POSTING OF PLAN.**—By not later than 9 months after the date of the enactment of this Act, the Secretary shall post on

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—867

(2) SUBPOENAS UNDER THE CIVIL RIGHTS OF INSTITUTIONALIZED PERSONS ACT.—The Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997 et seq.) is amended by inserting after section 3 the following:

“SEC. 3A. SUBPOENA AUTHORITY.

“(a) AUTHORITY.—The Attorney General, or at the direction of the Attorney General, any officer or employee of the Department of Justice may require by subpoena access to any institution that is the subject of an investigation under this Act and to any document, record, material, file, report, memorandum, policy, procedure, investigation, video or audio recording, or quality assurance report relating to any institution that is the subject of an investigation under this Act to determine whether there are conditions which deprive persons residing in or confined to the institution of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States.

“(b) ISSUANCE AND ENFORCEMENT OF SUBPOENAS.—

“(1) ISSUANCE.—Subpoenas issued under this section—

“(A) shall bear the signature of the Attorney General or any officer or employee of the Department of Justice as designated by the Attorney General; and

“(B) shall be served by any person or class of persons designated by the Attorney General or a designated officer or employee for that purpose.

“(2) ENFORCEMENT.—In the case of contumacy or failure to obey a subpoena issued under this section, the United States district court for the judicial district in which the institution is located may issue an order requiring compliance. Any failure to obey the order of the court may be punished by the court as a contempt that court.

“(c) PROTECTION OF SUBPOENAED RECORDS AND INFORMATION.—Any document, record, material, file, report, memorandum, policy, procedure, investigation, video or audio recording, or quality assurance report or other information obtained under a subpoena issued under this section—

“(1) may not be used for any purpose other than to protect the rights, privileges, or immunities secured or protected by the Constitution or laws of the United States of persons who reside, have resided, or will reside in an institution;

“(2) may not be transmitted by or within the Department of Justice for any purpose other than to protect the rights, privileges, or immunities secured or protected by the Constitution or laws of the United States of persons who reside, have resided, or will reside in an institution; and

“(3) shall be redacted, obscured, or otherwise altered if used in any publicly available manner so as to prevent the disclosure of any personally identifiable information.”.

SEC. 10607. STATE DEMONSTRATION PROGRAMS TO EVALUATE ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by this Act, is further amended by adding at the end the following:

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—868

“SEC. 399V-4. STATE DEMONSTRATION PROGRAMS TO EVALUATE ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.

“(a) IN GENERAL.—The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

“(b) DURATION.—The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

“(c) CONDITIONS FOR DEMONSTRATION GRANTS.—

“(1) REQUIREMENTS.—Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

“(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

“(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

“(2) ALTERNATIVE TO CURRENT TORT LITIGATION.—Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

“(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

“(B) encourages the efficient resolution of disputes;

“(C) encourages the disclosure of health care errors;

“(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

“(E) improves access to liability insurance;

“(F) fully informs patients about the differences in the alternative and current tort litigation;

“(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

“(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

“(I) would not limit or curtail a patient’s existing legal rights, ability to file a claim in or access a State’s legal system, or otherwise abrogate a patient’s ability to file a medical malpractice claim.

“(3) SOURCES OF COMPENSATION.—Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

“(4) SCOPE.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—869

“(A) IN GENERAL.—Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

“(B) NOTIFICATION OF PATIENTS.—A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

“(5) PREFERENCE IN AWARDING DEMONSTRATION GRANTS.—In awarding grants under subsection (a), the Secretary shall give preference to States—

“(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in representing patients and health care providers, medical malpractice insurers, and patient safety experts;

“(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

“(C) that make proposals that are likely to improve access to liability insurance.

“(d) APPLICATION.—

“(1) IN GENERAL.—Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

“(2) REVIEW PANEL.—

“(A) IN GENERAL.—In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

“(B) COMPOSITION.—

“(i) NOMINATIONS.—The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

“(ii) APPOINTMENT.—The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

“(I) Patient advocates.

“(II) Health care providers and health care organizations.

“(III) Attorneys with expertise in representing patients and health care providers.

“(IV) Medical malpractice insurers.

“(V) State officials.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—870

“(VI) Patient safety experts.

“(C) CHAIRPERSON.—The Comptroller General, or an individual within the Government Accountability Office designated by the Comptroller General, shall be the chairperson of the review panel.

“(D) AVAILABILITY OF INFORMATION.—The Comptroller General shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

“(E) INFORMATION FROM AGENCIES.—The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

“(e) REPORTS.—

“(1) BY STATE.—Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

“(2) BY SECRETARY.—The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

“(f) TECHNICAL ASSISTANCE.—

“(1) IN GENERAL.—The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

“(2) REQUIREMENTS.—Technical assistance under paragraph (1) shall include—

“(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

“(B) the development, in consultation with States, 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.

“(3) USE OF COMMON DEFINITIONS, FORMATS, AND DATA COLLECTION INFRASTRUCTURE.—States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

“(g) EVALUATION.—

“(1) IN GENERAL.—The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—871

into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

“(2) CONTENTS.—The evaluation under paragraph (1) shall include—

“(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

“(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

“(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

“(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

“(E) a comparison, with regard to the measures described in paragraph (3), of—

“(i) States receiving grants under subsection (a);

“(ii) States that enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, any cap on non-economic damages; and

“(iii) States that have enacted, prior to the date of enactment of the Patient Protection and Affordable Care Act, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bearing on whether the complainant may proceed with a case.

“(3) MEASURES.—The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

“(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

“(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

“(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

“(D) the medical liability environment;

“(E) health care quality;

“(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

“(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

“(H) impact on utilization of medical services, appropriately adjusted for risk.

“(4) FUNDING.—The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

“(h) MEDPAC AND MACPAC REPORTS.—

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—872

“(1) MEDPAC.—The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act, and its beneficiaries.

“(2) MACPAC.—The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act, and their beneficiaries.

“(3) REPORTS.—Not later than December 31, 2016, the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommendations of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

“(i) OPTION TO PROVIDE FOR INITIAL PLANNING GRANTS.—Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed \$500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

“(j) DEFINITIONS.—In this section:

“(1) HEALTH CARE SERVICES.—The term ‘health care services’ means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

“(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

“(B) the assessment of the health of human beings.

“(2) HEALTH CARE ORGANIZATION.—The term ‘health care organization’ means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

“(3) HEALTH CARE PROVIDER.—The term ‘health care provider’ means any individual or entity—

“(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

“(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

“(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

“(l) CURRENT STATE EFFORTS TO ESTABLISH ALTERNATIVE TO TORT LITIGATION.—Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

Ppaca & Hcera; Public Laws 111-148 & 111-152: Consolidated Print—873

“(m) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as limiting states’ authority over or responsibility for their state justice systems.”.

SEC. 10608. EXTENSION OF MEDICAL MALPRACTICE COVERAGE TO FREE CLINICS.

(a) **IN GENERAL.**—Section 224(o)(1) of the Public Health Service Act (42 U.S.C. 233(o)(1)) is amended by inserting after “to an individual” the following: “, or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic.”.

(b) **EFFECTIVE DATE.**—The amendment made by this section shall take effect on the date of enactment of this Act and apply to any act or omission which occurs on or after that date.

SEC. 10609. LABELING CHANGES.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

“(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

“(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

“(ii) the labeling revision described under clause (i) does not include a change to the ‘Warnings’ section of the labeling;

“(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

“(iv) such application otherwise meets the applicable requirements for approval under this subsection.

“(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.”.

Subtitle G—Provisions Relating to Title VIII

SEC. 10801. PROVISIONS RELATING TO TITLE VIII [AMENDMENTS FULLY INCORPORATED ABOVE].

(a) **[Amended sections 3203 and 3204 of the Public Health Service Act, as added by section 8002(a)(1)]**

(b) **[Amended heading for subsection (d) of section 8002]**

(c) **[Amended section 6021(d)(2)(A)(iv) of the Deficit Reduction Act of 2005, as added by section 8002(d)]**