SEC. 1201. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), as amended by section 1001, is further amended—

(1) by striking the heading for subpart 1 and inserting the following:

"Subpart I—General Reform";

(2)(A) in section 2701 (42 U.S.C. 300gg), by striking the section heading and subsection (a) and inserting the following:

"SEC. 2704 [42 U.S.C. 300gg-3]. PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS OR OTHER DISCRIMINATION BASED ON HEALTH STATUS.

- "(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage."; and
 - (B) by transferring such section (as amended by subparagraph (A)) so as to appear after the section 2703 added by paragraph (4);
 - (3)(Å) in section 2702 (42 U.S.C. 300gg–1)—
 - (i) by striking the section heading and all that follows through subsection (a);
 - (ii) in subsection (b)—
 - (I) by striking "health insurance issuer offering health insurance coverage in connection with a group health plan" each place that such appears and inserting "health insurance issuer offering group or individual health insurance coverage"; and
 - (II) in paragraph (2)(A)—
 - (aa) by inserting "or individual" after "employer"; and
 - (bb) by inserting "or individual health coverage, as the case may be" before the semicolon; and
 - (iii) in subsection (e)—
 - (I) by striking "(a)(1)(F)" and inserting "(a)(6)";
 - (II) by striking "2701" and inserting "2704"; and (III) by striking "2721(a)" and inserting "2735(a)";

and

- (B) by transferring such section (as amended by subparagraph (A)) to appear after section 2705(a) as added by paragraph (4); and
- (4) by inserting after the subpart heading (as added by paragraph (1)) the following:

"SEC. 2701 [42 U.S.C. 300gg]. FAIR HEALTH INSURANCE PREMIUMS.

"(a) Prohibiting Discriminatory Premium Rates.—

"(1) IN GENERAL.—With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

"(A) such rate shall vary with respect to the particular

plan or coverage involved only by-

"(i) whether such plan or coverage covers an indi-

vidual or family;

"(ii) rating area, as established in accordance with

paragraph (2);

"(iii) age, except that such rate shall not vary by more than 3 to 1 for adults (consistent with section 2707(c)); and

"(iv) tobacco use, except that such rate shall not

vary by more than 1.5 to 1; and

"(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A).

"(2) RATING AREA.—

"(A) IN GENERAL.—Each State shall establish 1 or more rating areas within that State for purposes of apply-

ing the requirements of this title.

"(B) SECRETARIAL REVIEW.—The Secretary shall review the rating areas established by each State under subparagraph (A) to ensure the adequacy of such areas for purposes of carrying out the requirements of this title. If the Secretary determines a State's rating areas are not adequate, or that a State does not establish such areas, the Secretary may establish rating areas for that State.

"(3) PERMISSIBLE AGE BANDS.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall define the permissible age bands for rating pur-

poses under paragraph (1)(A)(iii).

- "(4) APPLICATION OF VARIATIONS BASED ON AGE OR TO-BACCO USE.—With respect to family coverage under a group health plan or health insurance coverage, the rating variations permitted under clauses (iii) and (iv) of paragraph (1)(A) shall be applied based on the portion of the premium that is attributable to each family member covered under the plan or coverage.
- "(5) Special rule for large group market.—[As revised by section 10103(a)] If a State permits health insurance issuers that offer coverage in the large group market in the State to offer such coverage through the State Exchange (as provided for under section 1312(f)(2)(B) of the Patient Protection and Affordable Care Act), the provisions of this subsection shall apply to all coverage offered in such market (other than self-insured group health plans offered in such market) in the State.

"SEC. 2702 [42 U.S.C. 300gg-1]. GUARANTEED AVAILABILITY OF COVERAGE

"(a) GUARANTEED ISSUANCE OF COVERAGE IN THE INDIVIDUAL AND GROUP MARKET.—Subject to subsections (b) through (e), each

health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

"(b) Enrollment.—

"(1) RESTRICTION.—A health insurance issuer described in subsection (a) may restrict enrollment in coverage described in

such subsection to open or special enrollment periods.

"(2) ESTABLISHMENT.—Â health insurance issuer described in subsection (a) shall, in accordance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 603 of the Employee Retirement Income Security Act of 1974).

"(3) REGULATIONS.—The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs

(1) and (2).

"SEC. 2703 [42 U.S.C. 300gg-2]. GUARANTEED RENEWABILITY OF COVERAGE.

"(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.

"SEC. 2705 [42 U.S.C. 300gg-4]. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

- "(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:
 - "(1) Health status.
 - "(2) Medical condition (including both physical and mental illnesses).
 - "(3) Claims experience.
 - "(4) Receipt of health care.
 - "(5) Medical history.
 - "(6) Genetic information.
 - "(7) Evidence of insurability (including conditions arising out of acts of domestic violence).
 - "(8) Disability.
 - "(9) Any other health status-related factor determined appropriate by the Secretary.
- "(j) Programs of Health Promotion or Disease Prevention.—
 - "(1) GENERAL PROVISIONS.—
 - "(A) GENERAL RULE.—For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a 'wellness program') shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.
 - "(B) NO CONDITIONS BASED ON HEALTH STATUS FAC-TOR.—If none of the conditions for obtaining a premium

discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

^{*(}C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—
If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of

paragraph (3) are complied with.

"(2) Wellness programs not subject to requirements.—If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

"(A) A program that reimburses all or part of the cost

for memberships in a fitness center.

"(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

"(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

"(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to

whether the individual quits smoking.

"(E) A program that provides a reward to individuals

for attending a periodic health education seminar.

"(3) Wellness programs subject to requirements.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

"(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may

participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

"(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.

"(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under

the program at least once each year.

"(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

"(i) The reward is not available to all similarly situated individuals for a period unless the wellness pro-

gram allows—

"(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

"(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

"(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

"(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

"(k) EXISTING PROGRAMS.—Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to the date of enactment of this section and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.

"(1) Wellness Program Demonstration Project.—

"(1) IN GENERAL.—Not later than July 1, 2014, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall establish a 10-State demonstration project under which participating States shall apply the provisions of subsection (j) to programs of health promotion offered by a health insurance issuer that offers health insurance coverage in the individual market in such State.

"(2) EXPANSION OF DEMONSTRATION PROJECT.—If the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, determines that the demonstration project described in paragraph (1) is effective, such Secretaries may, beginning on July 1, 2017 expand such demonstration

project to include additional participating States.

"(3) REQUIREMENTS.—

"(A) MAINTENANCE OF COVERAGE.—The Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall not approve the participation of a State in the demonstration project under this section unless the Secretaries determine that the State's project is designed in a manner that—

"(i) will not result in any decrease in coverage;

and

- "(ii) will not increase the cost to the Federal Government in providing credits under section 36B of the Internal Revenue Code of 1986 or cost-sharing assistance under section 1402 of the Patient Protection and Affordable Care Act.
- "(B) OTHER REQUIREMENTS.—States that participate in the demonstration project under this subsection—
 - "(i) may permit premium discounts or rebates or the modification of otherwise applicable copayments or deductibles for adherence to, or participation in, a reasonably designed program of health promotion and disease prevention;

"(ii) shall ensure that requirements of consumer protection are met in programs of health promotion in

the individual market;

"(iii) shall require verification from health insurance issuers that offer health insurance coverage in the individual market of such State that premium discounts—

"(I) do not create undue burdens for individuals insured in the individual market;

(II) do not lead to cost shifting; and

"(III) are not a subterfuge for discrimination; "(iv) shall ensure that consumer data is protected in accordance with the requirements of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note); and

"(v) shall ensure and demonstrate to the satisfaction of the Secretary that the discounts or other rewards provided under the project reflect the expected level of participation in the wellness program involved and the anticipated effect the program will have on utilization or medical claim costs.

"(m) Report.—

'(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall submit a report to the appropriate committees of Congress concerning-

"(A) the effectiveness of wellness programs (as defined in subsection (j)) in promoting health and preventing dis-

"(B) the impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs;

(C) the impact of premium-based and cost-sharing incentives on participant behavior and the role of such pro-

grams in changing behavior; and "(D) the effectiveness of different types of rewards.

"(2) Data collection.—In preparing the report described in paragraph (1), the Secretaries shall gather relevant information from employers who provide employees with access to wellness programs, including State and Federal agencies.

"(n) REGULATIONS.—Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.

"SEC. 2706 [42 U.S.C. 300gg-5]. NON-DISCRIMINATION IN HEALTH CARE.

"(a) Providers.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

"(b) Individuals.—The provisions of section 1558 of the Patient Protection and Affordable Care Act (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

"SEC. 2707 [42 U.S.C. 300gg-6]. COMPREHENSIVE HEALTH INSURANCE COVERAGE.

"(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS PACKAGE.—A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Patient Protection and Affordable Care Act.

"(b) COST-SHARING UNDER GROUP HEALTH PLANS.—A group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under

paragraphs (1) and (2) of section 1302(c).

"(c) CHILD-ONLY PLANS.—If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d) of the Patient Protection and Affordable Care Act, the issuer shall also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

"(d) DENTAL ONLY.—This section shall not apply to a plan de-

scribed in section 1302(d)(2)(B)(ii)(I).

"SEC. 2708 [42 U.S.C. 300gg-7]. PROHIBITION ON EXCESSIVE WAITING PERIODS.

"[As revised by section 10103(b)] A group health plan and a health insurance issuer offering group health insurance coverage shall not apply any waiting period (as defined in section 2704(b)(4)) that exceeds 90 days.

"SEC. 2709 [42 U.S.C. 300gg-8]. COVERAGE FOR INDIVIDUALS PARTICI-PATING IN APPROVED CLINICAL TRIALS.

[Section added by section 10103(c)]

"(a) COVERAGE —

- "(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—
 - "(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);
 - "(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

"(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

"(2) ROUTINE PATIENT COSTS.—

"(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

"(B) EXCLUSION.—For purposes of paragraph (1)(B),

routine patient costs does not include—

"(i) the investigational item, device, or service, itself;

"(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the pa-

"(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

"(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

outside the State in which the qualified individual resides.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

"(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

"(2) Either—

"(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

"(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1)

paragraph (1).

"(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

"(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding

through in-kind contributions) by one or more of the following:

"(i) The National Institutes of Health.

``(ii) The Centers for Disease Control and Prevention.

"(iii) The Agency for Health Care Research and $\operatorname{Quality}$.

"(iv) The Centers for Medicare & Medicaid Services.

"(v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

"(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

"(vii) Any of the following if the conditions described in paragraph (2) are met:

"(I) The Department of Veterans Affairs.

"(II) The Department of Defense. "(III) The Department of Energy.

"(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

"(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug ap-

²(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

"(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

"(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

"(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term 'life-threatening condition' means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

"(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

"(g) APPLICATION TO FEHBP.—Notwithstanding any provision of chapter 89 of title 5, United States Code, this section shall apply to health plans offered under the program under such chapter.

"(h) PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section."

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PART 2—OTHER PROVISIONS